NICE National Institute for Health and Care Excellence

Medical technologies advisory committee (MTAC)

14th July 2023

Information pack for draft guidance considerations on

GID-HTE10007 Digitally enabled weight management programmes to support treatment with weight management medication

This product was selected for early value assessment in 2022. Clinical and economic evidence has been submitted to NICE by the company, and an external assessment centre report has been completed.

This pack presents the information required for the MTAC to make draft recommendations on this topic. The consultation period on these draft recommendations is scheduled to take place between 02 August 2023 and 16 August 2023.

Guidance lead team

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Papers included in pack:

1. Front sheet
2. Scope
3. Updated EAG assessment report (post fact check)
4. Assessment Report Overview (ARO
5. Register of interest
6. Company fact check comments with EAG responses
7. SCM fact check comments with EAG responses
8. Patient organisation submission from Diabetes UK

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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Digitally enabled weight management programmes to support treatment with weight management medication: early value assessment

Final scope

July 2023

1 Introduction

The topic has been identified by NICE for early value assessment (EVA). The objective of EVA is to identify promising technologies in health and social care where there is greatest need and enable earlier conditional access while informing further evidence generation. The evidence developed will demonstrate if the expected benefits of the technologies are realised and inform a final NICE evaluation and decision on the routine use of the technology in the NHS.

The final scope was informed by discussions at the scoping workshop held on 10th May 2023.

2 Description of the technologies

This section describes the properties of digitally enabled weight management programmes based on information provided to NICE by companies and experts, and information available in the public domain. NICE has not carried out an independent evaluation of this description.

2.1 Purpose of the medical technology

Approximately 63% of adults in England are classified as overweight or obese. The NHS has committed to improving access to weight management services to reduce health inequalities and the economic burden of obesity (NHS Long Term Plan). Specialist weight management services, such as tier 3 and tier 4 services, support the management and maintenance of weight loss through behavioural and lifestyle changes. Services provide access to a

clinician led multidisciplinary team that can include doctors, GPs with a special interest, specialist nurses, dietitians, psychologists, psychiatrists, physiotherapists and specialist exercise therapists.

The provision of specialist weight management services varies across England and Wales, and many people who are eligible do not have any access to these services (NICE's technology appraisal guidance for semaglutide for managing overweight and obesity). Unequal distribution of specialist weight management services produces a postcode lottery. In areas with established specialist weight management services, there is an increasing number of people on waiting lists due to limited resources and funding.

Weight management medication, such as semaglutide and liraglutide, can only be accessed with specialist weight management services, leading to unequal access to treatment. Support from a multidisciplinary team (MDT) using digitally enabled weight management programmes is a treatment option for people who are eligible for weight management medication. Providing specialist weight management services using digitally enabled programmes can potentially improve access to weight management treatment. These technologies could also reduce the number of in person appointments and increase the capacity of service delivery in areas that have established services.

2.2 Product properties

This scope focuses on digitally enabled weight management programmes to support treatment with weight management medication. Following referral, digitally enabled programmes can be used to facilitate access to specialist weight management programmes. They can be accessed online or via an app with in-programme support from a multidisciplinary team of healthcare professionals. NICE's clinical guideline for the identification, assessment and management of obesity recommends that weight management programmes should include behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake. Behavioural interventions should be delivered with the support of an appropriately trained healthcare professional.

Information, support and counselling on additional diet, physical activity and behavioural strategies should be given when weight management medication is prescribed. The effect of weight management medication should be monitored, and lifestyle advice and adherence reinforced through regular reviews whilst treatment is ongoing. Some digitally enabled weight

management programmes may offer in-programme medication reviews with a prescribing clinician alongside regular reviews with health coaches such a nutritionists or dieticians. Other digitally enabled programmes may be used to support weight management medication prescribing by sharing medication adherence data with local healthcare professionals as well as delivering lifestyle and behavioural support. The frequency of reviews may vary depending on the technology and the stage of the programme. NICE's technology appraisal guidance for semaglutide states that semaglutide has a 16-week dose escalation period and reassessment at 6 months should be done to see if treatment should be continued.

For this EVA, NICE will consider digitally enabled weight management programmes that:

- are intended for use by adults
- deliver a specialist weight management programme that includes behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake in line with tier 3 or tier 4 services
- facilitate weight management medication monitoring or prescribing
- facilitate communication with an MDT of healthcare professionals which could include dieticians, nutritionists, specialist nurses, psychologists, psychiatrists, physiotherapists, pharmacists and obesity physicians
- meet the standards within the digital technology assessment criteria (DTAC), have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC
- are available for use in the NHS.

Eight digitally enabled weight management programmes designed to support treatment with weight management medication are included in the scope[1].

ChecUp

CheqUp (CheqUp Health) is a weight management app that provides a multidisciplinary weight management programme alongside prescription of

[1] This information has been provided by a company or through review of publicly available information. The list and descriptions may be subject to change following provision of additional information.

weight management medication. The CheqUp app includes 3 packages (achieve, transform and empower) that vary in the level of support from healthcare professionals and the inclusion of fitness technologies such as digital scales and fitness trackers. The 'achieve' weight management programme begins with an initial prescription meeting with a doctor and a 30-minute session with a weight loss coach and dietician. The programme includes weekly dose increase meetings with a health coach, personalised progress meetings with a weight loss coach every 2 weeks, support with medication side effects, specific lifestyle advice (sleep and stress management), progress reviews by an MDT, access to obesity specialists for nutrition and physical activity, and access to psychological support delivered by weight management experts.

Gro Health W8Buddy

Gro Health W8Buddy (DDM Health Ltd) is a digital online platform that delivers tier 3 and tier 4 specialist weight management programmes. It provides personalised information on nutrition, mental wellbeing, activity and exercise and sleep from an MDT including dieticians, psychologists, personal trainers and doctors. The platform can be linked with local systems and can be customised by a person's clinician using the GroCARE clinical dashboard. The GroCARE dashboard can also be used to communicate with users and monitor health outcomes and engagement with the programme. Weight management medication adherence can be tracked and managed using the app. This data is provided to a person's clinician via the clinician dashboard, and remote medication reviews can take place with this data available. Gro Health W8Buddy is available in 11 different languages.

Juniper

Juniper (Juniper Technologies UK Ltd) is a weight management app that provides a weight management programme alongside prescription of weight management medication. The 12-month 'weight reset' programme includes educational advice on nutrition, movement, stress and sleep and users can connect with UK based health coaches, clinicians and other users via the app. Juniper also provides scales and a digital weight tracker to monitor weight loss.

Liva

Liva (Liva Health) is a digital online platform consisting of an app and an online dashboard for clinicians that delivers a personalised weight management programme. Programmes are tailored depending on user eligibility and can last up to 9 months. All programmes include an initial 45

minute live video session between the user and a health coach. Health coaches can communicate with users through messages and videos in the app, and will send resources, recipes and provide tailored advice throughout the programme. Health coaches are UK based and include physiologists, nutritionists & dietitians, sports & exercise specialists, nurses and physiotherapists. Weight management medication adherence can be tracked in the app using the goal tracking feature and the company says that it has a comprehensive process for flagging adverse events and side effects and reporting these back to the user's clinician. The Liva online dashboard can be used by healthcare professionals to track user adherence and communicate with users via video or message.

Oviva

Oviva (Oviva) is a digital health app that delivers a tier 3 specialist weight management programme alongside prescription of weight management medication. Users receive personalised support from an MDT of healthcare professionals, which may include a specialist weight management dietician, a health coach, clinical psychologists or psychological wellbeing practitioners and weight management doctors. Users have the choice of one-to-one or group support and can be contacted via the Oviva app, by phone or by video call. The app provides information on how to manage diet and lifestyle changes, and new learning modules and resources unlock as users interact with the content. Users can track weight loss, activity and mood, and log food diaries in the app. People referred for weight management medication can have prescribing, titration and monitoring appointments through the app alongside a 24 month weight management programme.

Roczen

Roczen (Reset Health) delivers a tier 3 specialist weight management programme through a patient facing web and mobile app. The mobile app is used by the user to communicate with clinicians and mentors, track their health data and progress, and access educational resources. Clinicians manage care, track health data and contact users through the clinician web app. Prescriptions are provided using an ePrescribing platform and only following eligibility checks and health assessment. Ongoing follow up is provided by the clinical team every 4 weeks for the length of the programme.

Second Nature

Second Nature delivers a tier 3 specialist weight management programme through a web and mobile app, Users can access instant messaging with

health coaches and their peers, educational resources, goal setting and health tracking. Video calls can be arranged with members of the MDT. Prescribing and medication monitoring are available through independent prescribing pharmacists who are part of the MDT.

Wellbeing way

Wellbeing way (Xyla Health and Wellbeing) provides a tier 3 specialist weight management service for adults. This is delivered by a multi-disciplinary team that includes a clinical lead endocrinologist, specialised dietician, registered nurse, clinical psychologist and exercise therapist. The service includes a personalised treatment plan, motivational group and one-to-one sessions facilitated by the MDT focused on diet, physical activity, and psychological and behavioural support, pharmacotherapies and low-calorie diets may be prescribed where appropriate. There is also a maintenance support phase that includes a self-management plan, drop-ins, phone support and weight loss champions.

3 Target conditions

Obesity is a chronic condition characterised by excess body fat. People living with obesity are at an increased risk of developing other health conditions such as cardiovascular disease, type 2 diabetes, atherosclerosis (the presence of fatty deposits in the arteries), hypertension, dyslipidaemia (abnormal levels of fats in the blood), stroke and some types of cancer (for example, breast cancer and bowel cancer). Other conditions associated with obesity are non-alcoholic fatty liver disease, non-diabetic hyperglycaemia, subfertility, osteoarthritis, dyslipidaemia, obstructive sleep apnoea and idiopathic intracranial hypertension.

Obesity is typically measured by calculating a person's body mass index (BMI). Obesity is defined as 30.0 kg/m^2 and above and severe obesity is defined as 40.0 kg/m^2 and above (NHS England, 2023). Slightly lower thresholds for obesity (usually reduced by 2.5 kg/m^2) are used for people with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background.

The Health Survey for England 2021 estimated that 25.9% of adults (25.4% of men and 26.5% of women) are living with obesity in England. The same survey found that people aged 45 to 74 and those living in the most deprived areas are more likely to have obesity. In 2019 to 2020, 10,780 hospital admissions were directly attributed to obesity, and obesity was a factor in over 1 million admissions (NHS Digital, 2021). In the same year, it was reported that there were 6,740 hospital admissions with a primary diagnosis of obesity and a procedure for bariatric surgery.

4 Care pathway

This assessment will focus on the use of digital weight management technologies to support treatment with weight management medication. NICE's technology appraisal guidance for semaglutide recommends that it is used as an option for weight management only if it is used within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4). NICE's technology appraisal guidance for liraglutide recommends it as an option for managing overweight and obesity only if it is prescribed in secondary care by a specialist multidisciplinary tier 3 weight management service.

Tier 3 and 4 specialist weight management services for people with overweight and obesity as defined in the guidance for Clinical

Commissioning Groups (CCGs): Service Specification Guidance for Obesity Surgery (2016) could include:

- Tier 3 specialist care: One to one management by a medically qualified specialist in obesity. This may be community or hospital base, with or without outreach and delivered by a team led by a specialist obesity physician. Patient management will also include specialist dietetic, psychological and physical activity input. This will include group work and access to leisure services. There will be access to a full range of medical specialists as required for co-morbidity management.

- Tier 4 specialist care: One to one management provided by specialist obesity medical and surgical MDTs with full access to a full range of medical specialists as required. All patients will be referred to Tier 4 by a Tier 3 service. The difference between the medical speciality in tier 3 and 4 will be qualitative level of experience in complex patient management. All surgical procedures will take place in tier 4.

The intensity, frequency and variety of support from an MDT of healthcare professionals varies between specialist weight management programmes. They may be offered in person, remotely via telephone or video call, or a combination of in person and remote support. Programmes can last between 6 and 24 months and eligibility to access these services may vary depending on area and local funding.

Potential place of digital weight management support in the care pathway

Digitally enabled weight management programmes would be offered as an option to adults with obesity that are referred for weight management medications.

Specialist weight management services are typically hospital based. However, some services may be offered remotely, or in a range of accessible locations such as local health centres or in people's homes. Assessments are done by a member of a clinician led specialist MDT, such as a psychologist. Weight management medication is prescribed by a qualified member of the clinician led MDT with input from the pharmacy team.

Digitally enabled weight management programmes can be offered to facilitate treatment with weight management medication and provide support from a MDT of healthcare professionals to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the

person's diet, and reduce energy intake.Patient preference and engagement should be considered when helping people make decisions about the care that they want to receive. Weight management medication adherence and effectiveness is typically monitored by a clinician led MDT between initial prescription and the 16-week titration period of the medication. After this time, the medication may be prescribed on an ongoing basis by a primary care healthcare professional if requested by a specialist at a local level. Digitally enabled weight management programmes should be accessible to a range of clinicians and care settings to allow for this transfer of care.

5 Patient issues and preferences

Digitally enabled weight management programmes can be run via mobile phones, tablets or computers and can be accessed remotely. In areas without specialist weight management services, digitally enabled programmes could improve access to services and weight management medication, reducing health inequalities. In areas with established specialist weight management services, digitally enabled programmes could improve access to services and weight management medication by, increasing convenience, and giving more flexible access to people who are eligible. Expansion of current specialist weight management services may give people faster access to weight management medication than current standard care.

NHS England's enhanced service specification for weight management says that assessment of a person's willingness to engage with weight management services is an integral part of the referral process. Access to digitally enabled weight management programmes could improve engagement and appeal to regular users of digital technologies, people who prefer to access healthcare remotely or people who are housebound due to illness.

Some people may not choose to use digitally enabled weight management programmes and may prefer in person clinician led treatment if this is available to them. There may be some concerns about the level of support provided by digitally enabled programmes and concerns around data security and quality control. There may also be concerns about medication management and how side effects may be monitored and reported. People should be supported by healthcare professionals to make informed decisions about their care, including the use of digitally enabled weight management programmes. Shared decision making should be supported so that people are fully involved throughout their care (NICE's guideline for shared decision making).

6 Comparator

The comparator for this assessment is standard care for adults with obesity alongside weight management medication. Standard care includes specialist weight management programmes (including tier 3 and 4); delivered face-to-face, remotely or hybrid).

Access to specialist weight management services varies across the country and some people are on waiting lists to access services or have no access at all. So, no or delayed treatment is also a relevant comparator.

7 Scope of the assessment

Table 1 Scope of the assessment

Populations	Adults with obesity referred for treatment with weight management medication in line with NICE's guidance including but not limited to: • NICE's technology appraisal guidance for semaglutide for managing overweight and obesity • NICE's technology appraisal guidance for liraglutide for managing overweight and obesity
Interventions (proposed technologies)	Digitally enabled weight management programmes providing specialist weight management services (such as tier 3 or tier 4) for adults to support treatment with weight management medication. This includes: • CheqUp (CheqUp) • Gro Health W8Buddy (DDM Health Ltd) • Juniper (Juniper Technologies UK Ltd) • Liva UK (Liva UK) • Oviva (Oviva) • Wellbeing way (Xyla Health and Wellbeing) • Roczen (Reset Health) • Second Nature (Second Nature)
Comparator	Standard care which could include: • specialist weight management services (including tier 3 and 4; face-to-face, remote or hybrid) alongside treatment with weight management medication • no treatment or waiting list
Healthcare setting	Specialist weight management services (including but not limited to tier 3 and tier 4)

Outcomes	Intermediate measures for consideration may include: • Treatment satisfaction and engagement • Intervention adherence, rates of attrition (dropouts) and completion • Intervention-related adverse events • Weight management medication adherence and medication-related adverse events • Inaccessibility to intervention (digital inequalities)
	Clinical outcomes for consideration may include: • BMI • Weight loss • Body fat • Waist circumference • Waist-to-height ratio • Hip circumference • HbA_{1c} level • Cardiovascular events • Mortality • Physical activity • Rate of referral for bariatric surgery • Eating habits
	Patient reported outcomes for consideration may include: • Health-related quality of life • Patient experience and acceptability • Psychological outcomes

	Costs will be considered from and NHS and Person Social Services perspective. Costs for consideration may include:
	• Cost of the technologies
	• Cost of other resource use (e.g. associated with managing obesity, adverse events, or complications):
	  ○ GP or secondary care appointments
	  ○ Medication use and adverse events
	  ○ Healthcare professional grade and time

Time horizon	The time horizon for estimating the clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

	Semaglutide and liraglutide are recommended for use for a maximum of 2 years.

8 Other issues for consideration

Characteristics of digitally enabled programmes

The digitally enabled weight management programmes included in the scope may have differences in terms of mode of delivery (computer, app), length of programme, and the frequency and intensity of support from a range of healthcare professionals. Some technologies include in-programme weight management medication prescribing and monitoring. Others can track medication adherence and side effects but do not have in-programme prescribers.

Risk of disordered eating

Digitally enabled weight management programmes used tomonitor eating behaviours may increase the risk of developing an eating disorder. Education about nutrition is important whilst using these technologies alongside treatment with weight management medication to avoid developing disordered eating behaviours. Patient and clinical experts also noted the importance of digitally enabled weight management programmes including appropriate monitoring and safeguarding features to ensure risks and potential harms are monitored whilst using the technologies.

9 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Obesity rates increase with age and people aged 45 and over have an increased risk of obesity. Obesity rates differ between socio-economic groups. People living in the most deprived areas are more likely to be living with obesity than those in the least deprived areas.

People with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background are prone to central adiposity and have an increased risk of chronic health conditions at a lower BMI.

Digitally enabled weight management programmes are accessed via a mobile phone, tablet, or computer. People will need regular access to a device with internet access to use the technologies. Additional support and resources

may therefore be needed for people who are unfamiliar with digital technologies or people who do not have access to smart devices or the internet. People with visual, hearing, or cognitive impairment; problems with manual dexterity; a learning disability; or who are unable to read or understand health-related information (including people who cannot read English) or neurodivergent people may need additional support to use digitally enabled programmes. Some people would benefit from digitally enabled weight management programmes in languages other than English. People's ethnic, religious, and cultural background may affect their views of digitally enabled weight management interventions. Healthcare professionals should discuss the language and cultural content of digitally enabled programmes with patients before use.

Age, disability, race, and religion or belief are protected characteristics under the Equality Act 2010.

10 Potential implementation issues

Variations and uncertainties in the care pathway

Access to specialist weight management services varies across England and Wales. In areas with established services the referral criteria, programme length and programme content also vary depending on resources and available funding. Implementation of digitally enabled weight management programmes could vary depending on the technology and how services are currently delivered and funded.

Costs

Costs of technologies may differ. Implementation of digitally enabled weight management programmes may initially increase staff workload and costs to set up new pathways and change service delivery. Smaller service areas may have higher costs per user due to not needing as many licences for the technology. Digitally enabled programmes may be chosen based on the balance between costs and expected outcomes.

11 Authors

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July 2023

Document cover sheet

Assessment report: GID-HTE10007 Diet and activity apps

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EAG sign-off: Luke Vale, Andrew Sims

Version number	Brief description of changes	Author/reviewer (for example J Smith)	Date	Date sent to NICE (if applicable)
0.01	Report template Adding content to clinical context section	K Keltie H Dervin	25/04/2023 26/04/2023	
	Adding technologies, identifies studies, PICO tables	K Keltie	12/05/2023	
	Adding final scope	K Keltie	17/05/2023	
	Adding content to included studies, PICO tables and clinical context section	H Dervin	17/05/2023	
	Review of statistical analysis	R Kenny	22/05/2023	
	Adding additional identified studies	P Leslie, K Keltie	23/05/2023	
0.02	Adding additional identified studies	K Keltie	24/05/2023	
	QA of PICO, identified studies and results table	H Dervin	25/05/2023	
	Adding literature search write up	A Inskip	31/05/2023	
	Review	S Wallace	02/06/2023	
0.03	Adding additional identified studies	K Keltie	04/06/2023 08/06/2023	
	QA of results	R Kenny	05/06/2023 08/06/2023	

Version number	Brief description of changes	Author/reviewer (for example J Smith)	Date	Date sent to NICE (if applicable)
	QA of excluded technologies, QA of excluded studies	D Muir	08/06/2023	
	Adding content to literature sift; Completing PRISMA diagram	R Parker	07/06/2023 12/06/2023	
	Adding narrative of outcomes	K Keltie	09/06/2023	
	Review	S Wallace	12/06/2023	
	Adding summary of published economic evidence, adding to early economic modelling section	T Robinson, C Fernandez-Garcia	12/06/2023	
0.04	Completing write up of clinical outcomes, formatting	K Keltie, R Parker	13/06/2023	
	Adding to technology section	H Dervin	13/06/2023	
	Senior review	L Vale	13/06/2023	
	Adding reviewer comments	K Keltie, R Parker	14/06/2023	
	QA	P Leslie	14/06/2023	
	Senior review	AJ Sims	14/06/2023	
0.05	Addressing reviewer comments,	K Keltie, R Parker, T Robinson, C Fernandez-Garcia, A Inskip	14/06/2023	
	Adding content to sections 2 and 9, addressing comments	R Parker, H Dervin	15/06/2023	
	Review	G Sagoo, S Wallace K Keltie	15/06/2023 19/06/2023	
	Addressing reviewer comments, adding content to evidence generation section, QA of outcomes section	K Keltie, R Parker	16/06/2023	
	Review of sections 9, 10, 11 and exec summary	R Kenny	19/06/2023	
	Review of economics section	T Robinson, C Fernandez-Garcia	19/06/2023	
	Pre-submission checklists	H Dervin, R Parker, K Keltie	19/06/2023	
1.00	Clean version for NICE	R Parker	19/06/2023	19/06/2023
1.01	Addressing internal comments on economics section	T Robinson	19/06/2023	
	Adding 2 additional technologies	R Parker, H Dervin, P Leslie	20/06/2023	
	Adding AiC and CiC content from companies	K Keltie	21/06/2023	
1.02	Updating report based on feedback received by NICE	K Keltie	21/06/2023	

Version number	Brief description of changes	Author/reviewer (for example J Smith)	Date	Date sent to NICE (if applicable)
	Adding to economic section	C Fernandez-Garcia, T Robinson	21/06/2023	
	Review PRISMA based on new evidence	R Parker	21/06/2023	
1.03	Merging of changes, updating report based on feedback received by NICE	R Parker, C Fernandez-Garcia, K Keltie	22/06/2023	
	Adding sensitivity analyses to economics	C Fernandez-Garcia	22/06/2023	
	Adding to evidence gap tables	R Parker, K Keltie	22/06/2023	
1.04	Updates based on NICE comments	K Keltie, R Parker, T Robinson, C Fernandez-Garcia,	23/06/2023	
	Reviewing technology section	H Dervin	23/06/2023	
1.05	Adding results from abstracts, unpublished studies	K Keltie	26/06/2023	
	Adding latest Clinical Expert responses	P Leslie	26/06/2023	
	Updating technology and integration into NHS sections	R Parker	26/06/2023	
1.06	Updating ongoing studies and evidence generation gap tables	K Keltie, R Parker, T Robinson	27/06/2023	
	Updating summary, conclusions and executive summary	R Parker, K Keltie	27/06/2023	
	Updating economic analysis, adding summary to economic sections	T Robinson, C Fernandez-Garcia, G Sagoo	27/06/2023	
	Senior review	L Vale	27/06/2023	
	Addressing review comments	K Keltie, T Robinson, C Fernandez-Garcia, G Sagoo, R Parker	28/06/2023	
1.07	Review	K Keltie, T Robinson, G Sagoo, R Kenny, R Parker	28/06/2023	28/06/2023
	Senior review	L Vale	28/06/2023	
1.08	Addressing review comments	K Keltie, R Parker	29/06/2023	
	Review	K Keltie, T Robinson, G Sagoo, R Parker	29/06/2023	
	Updating executive summary and conclusions	K Keltie, R Parker, T Robinson, G Sagoo,	29/06/2023	
	Senior review	L Vale	29/06/2023	
1.09	Addressing review comments	K Keltie, T Robinson, G Sagoo, R Parker	30/06/2023	
	QA and formatting	K Keltie, R Parker	30/06/2023	
1.10	Combining report and appendix	K Keltie	30/06/2023	

Version number	Brief description of changes	Author/reviewer (for example J Smith)	Date	Date sent to NICE (if applicable)
	Pre-submission checklist	K Keltie, E Belilios	30/06/2023	
	Review	K Keltie	01/07/2023	
1.11	Review	R Parker, K Keltie, P Leslie, T Robinson, A Inskip, E Belilios	03/07/2023	
2.00	Clean version	K Keltie, R Parker	03/07/2023	
2.01	Addressing fact check	R Parker, K Keltie, T Robinson, C Fernandez-Garcia	06/07/2023	
3.00	Clean version	K Keltie, R Parker	10/07/2023	11/07/2023

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

GID-HTE10007 Digitally enabled weight management programmes to support treatment with weight management medication

External Assessment Group report

Produced by: Newcastle External Assessment Group (EAG)

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Date completed: 11 July 2023

Contains confidential information: Yes

Number of attached appendices: 6 (Appendix A – F)

Purpose of the assessment report

The purpose of this External assessment group (EAG) report is to review the evidence currently available for included technologies and advise what further evidence should be collected to help inform decisions on whether the technologies should be widely adopted in the NHS. The report may also include additional analysis of the submitted evidence or new clinical or economic evidence. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Medical Technologies Advisory Committee when it is making decisions about the early value assessment.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

None.

Acknowledgements

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Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Any 'commercial in confidence' information in the submission document (or corresponding appendices) are highlighted in turquoise.

Any 'academic in confidence' information in the submission document (or corresponding appendices) are highlighted in yellow.

Contents

Abbreviations

Term	Definition
AfC	Agenda for Change
AI	Artificial intelligence
AiC	Academic in confidence
ARB	Angiotensin receptor blocker
ACE	Angiotensin-converting-enzyme inhibitor
BED	Binge eating disorder scale
BMI	Body mass index
BP	Blood pressure
CCEMG	Campbell and Cochrane Economic Methods Group
CI	Confidence interval
CiC	Commercial in confidence
CKD	Chronic Kidney Disease
DPP4	Dipeptidyl peptidase-4 inhibitors
DTAC	Digital Technology Assessment Criteria
EAG	External assessment group
EVA	Early Value Assessment
F2F	Face-to-face
GPhC	General Pharmaceutical Council
GLP-1	Glucagon-like peptide-1
GPAQ	Global Physical Activity Questionnaire
HbA1c	Glycated haemoglobin
HCP	Healthcare professional
HDL	High-density lipoprotein
HRQoL	Health-related quality of life
IQR	Interquartile range
ITT	Intention-to-treat
LDL	Low-density lipoprotein
MAUDE	Manufacturer and User Facility Device Experience
MCS	Mental component summary
MES	Medication effect score
MET-min	Metabolic equivalent minutes per week
MDT	Multidisciplinary team
MHRA	Medicines and Healthcare products Regulatory Agency
MTEP	Medical Technologies Evaluation Programme
NB	Net Benefit
NHS EED	NHS Economic Evaluation Database
NICE	National Institute for Health and Care Excellence
NICE CG	NICE clinical guideline
NHS DPP	National Health Service Diabetes Prevention Programme
NICE QS	NICE quality standard
NR	Not Reported
PCS	Physical component summary
PHQ-9	Patient Health Questionnaire
PROMs	Patient Reported Outcome Measures

Term	Definition
PSSRU	Personal social services research unit
QALY	Quality Adjusted Life Year
QoL	Quality of life
RCT	Randomised controlled trial
SD	Standard deviation
SF-12	12-item Short Form Health Survey
SGLT2	Sodium-glucose co-transporter-2 inhibitors
SWEMWBS	Short Warwick-Edinburgh Mental Wellbeing Scale
TA	Technology Assessment
T1DM	Type 2 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TFEQ	3-factor eating questionnaire
VAS	Visual analogue scale
Vs	Versus

Executive summary

Clinical evidence relevant to the decision problem was identified for 4 of the 8 technologies included in this EVA (Gro Health, Liva, Oviva, Roczen). Evidence comprised 27 publications from 22 studies, including 7 abstracts and 8 in confidence reports from 3 Companies. The digitally enabled weight loss programme duration ranged between 14 days and 24 months, 2 studies (including 1 abstract) reported patients taking weight loss medication, 5 studies reported combination with specified diets. All studies reporting on weight stated a reduction when compared with baseline. The clinical significance and duration of this weight loss, beyond 1 year is uncertain due to limited comparative and longitudinal evidence. Initial uptake and adherence to the intervention was generally comparable to standard care, however the definitions varied. Only 1 study (shared in confidence) reported on weight management medication adherence. No evidence was identified for cardiovascular events, mortality, rate of referral for bariatric surgery, or intervention-related adverse events. No ongoing studies were identified that would address these evidence gaps.

No economic evidence directly relevant to the decision problem was identified. Early economic modelling undertaken by the EAG has shown that there is a prima facie case for the digitally enabled specialist weight management programme being cost-effective (plausibly being dominant) compared with current Tier 3 specialist weight management services. However, this analysis is highly uncertain and subject to a number of strong assumptions included within the model. The results appear most sensitive to the cost of the Tier 3 specialist service. Provision of a robust cost estimate should be prioritised alongside development of a more complex model to capture the full range of costs and benefits of such services over a more appropriate time horizon which takes into account the complex nature of obesity.

Use of digitally enabled programmes may increase patient access to specialist weight management services across the NHS. However, patient safety should be considered when monitoring medications remotely. Future evidence generation should refer to the technology used, reach consensus on definitions of key outcome measures, and focus on a subset of outcomes that will inform a future health technology assessment such as: proportion initiating digitally enabled weight management programmes, attendance at follow-up, weight loss over time, and health related quality of life.

1 Decision problem

The EAG has provided minor clarifications to the decision problem specified in the Final Scope, Table 1.

Table 1: Scope of the decision problem

Decision problem	Scope	Variation
Population	Adults with obesity referred for treatment with weight management medication in line with NICE's guidance including but not limited to: • NICE's technology appraisal guidance for semaglutide for managing overweight and obesity (TA875) • NICE's technology appraisal guidance for liraglutide for managing overweight and obesity (TA664)	None.
Intervention	Digitally enabled weight management programmes providing specialist weight management services (such as Tier 3 or Tier 4) for adults to support treatment with weight management medication. This includes: • CheqUp (CheqUp) • Gro Health W8Buddy (DDM Health Ltd) • Juniper (Juniper Technologies UK Ltd) • Liva (Liva UK) • Oviva (Oviva) • Xyla Health and Wellbeing (Xyla Health and Wellbeing)	The EAG have only considered those digital technologies listed within the Final Scope as determined by NICE as meeting eligibility criteria. On 12 June 2023 NICE were informed by NHS England (NHSE) that there were additional technologies within the Scope of the decision problem to be included within this EVA: • Roczen (Reset Health) • Second Nature (Second Nature). DDM Health Ltd confirmed that W8Buddy is a bespoke pathway that uses existing NHS MDT specialist weight management services and W8Buddy+ has a fully in-house MDT and prescriber, both use the Gro Health technology. The EAG has considered all evidence relating to Gro Health, W8Buddy and W8Buddy+ as relevant to the Scope.

Decision problem	Scope	Variation
Comparator(s)	Standard care which could include: • specialist weight management services (including Tier 3 and 4; face-to-face, remote or hybrid) alongside treatment with weight management medication • no treatment or waiting list	None.
Healthcare setting	Specialist weight management services (including but not limited to Tier 3 and Tier 4)	Limited to Tier 3 and Tier 4 specialist weight management services delivered in any setting.
Outcomes	Intermediate measures for consideration may include: • Treatment satisfaction and engagement • Intervention adherence, rates of attrition (dropouts) and completion • Intervention-related adverse events • Weight management medication adherence and medication-related adverse events • Inaccessibility to intervention (digital inequalities) Clinical outcomes for consideration may include: • Measures of adiposity: ○ BMI ○ Weight loss ○ Waist circumference ○ Waist-to-height ratio ○ Hip circumference • HbA1c level • Cardiovascular events • Mortality • Physical activity • Rate of referral for bariatric surgery • Eating habits Patient reported outcomes for consideration may include: • Health-related quality of life • Patient experience and acceptability • Psychological outcomes Costs for consideration may include: • Costs of the technologies • Costs of other resource use (for example, associated with managing obesity, adverse events, or complications): • GP or secondary care appointments	Other measures of adiposity such as waist-to-hip ratio are also reported in the literature. The EAG note the acknowledged difficulty in measuring these (WHO, 2008). The EAG acknowledge that bariatric surgery may also be known as metabolic surgery, so have used the term 'weight loss surgery' as per UK NHS definition.

Decision problem	Scope	Variation
	• Medication use and adverse events • Healthcare professional grade and time	
Cost analysis	Costs considered from an NHS and Personal Social Services perspective.	None.
Time horizon	The time horizon for estimating the clinical and cost-effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Semaglutide and liraglutide are recommended for use for a maximum of 2 years due to the limited length of Tier 3 specialist weight management services.	None.
Abbreviations: BMI, body mass index; EAG, External Assessment Group; EVA, early value assessment; NHSE, NHS England		

The EAG has adopted the following terminology throughout this EVA report for consistency:

- 'specialist weight management services' refers to Tier 3 and Tier 4 weight management services.
- 'technologies' refers to the technologies that provide a digitally enabled specialist weight management programme of care included within the NICE Final Scope.
- Body mass index (BMI) is a metric based on a person's weight and height and is measured in kg/m2 (NHS, 2023), the EAG have removed this unit value from the report for readability.

2 Overview of the technology

2.1 Purpose of the medical technology

Digitally enabled specialist weight management programmes for patients living with obesity or are overweight may provide a more accessible method for managing weight for those people living in England and Wales who are eligible, but may not

have access to these services. Unequal distribution of specialist weight management services produces a postcode lottery. In areas with established specialist weight management services, there is an increasing number of people on waiting lists because of limited resources and funding.

Weight management medication, such as semaglutide and liraglutide, can only be accessed with specialist weight management services, potentially leading to unequal access to treatment (TA664, 2020; TA875, 2023). Support from a multidisciplinary team (MDT) using digitally enabled weight management programmes may be a treatment option for people who are eligible for weight management medication. Providing specialist weight management services using digitally enabled programmes can potentially improve access to weight management treatment, including medication. These technologies could also reduce the number of in-person appointments and increase the capacity of service delivery in areas that have established services.

Approximately 63% of adults in England and Wales are classified as overweight or obese (NHS Digital, 2020). The NHS has committed to improving access to weight management services to reduce health inequalities and the economic burden of obesity (NHS Long Term Plan, 2019). Specialist weight management services support the management and maintenance of weight loss through behavioural and lifestyle changes for people with severe or complex obesity and supported with medication where appropriate. Services provide access to a clinician-led MDT that can include doctors, GPs with a special interest, specialist nurses, dietitians, psychologists, psychiatrists, physiotherapists and specialist exercise therapists.

Digitally enabled specialist weight management programmes in healthcare are typically delivered through downloadable applications (that can be installed on a smartphone or other smart device) or online platforms and need internet access. The programmes tend to span several months with the aim of making life-long changes to habits, diet, and activity. Access to the programmes needs a referral from a primary or secondary care service provider, involve support from an MDT and may involve prescription or monitoring of weight management medication; for example

glucagon-like peptide-1 (GLP-1) receptor agonists. Patients that are eligible for weight loss management, are typically overweight or obese, but may also include the presence of other comorbidities such as Type I or II diabetes (T1DM or T2DM) or high blood pressure (hypertension).

2.2 Product properties

The Scope of this EVA focuses on technologies that deliver digitally enabled specialist weight management programmes that meet the following criteria:

- Are intended for use by adults.
- Deliver a specialist weight management programme that includes behaviour change strategies to increase people's physical activity levels, improve eating behaviour and the quality of the person's diet in line with Tier 3 or Tier 4 specialist weight management services.
- Facilitate weight management medication monitoring or prescribing.
- Facilitate communication with an MDT of healthcare professionals, which could include dietitians, nutritionists, specialist nurses, psychologists, psychiatrists, physiotherapists, pharmacists, and obesity physicians.
- Meet the standards within the Digital Technology Assessment Criteria (DTAC), have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC.
- Are available for use in the NHS.

A total of 8 technologies providing digitally enabled specialist weight management programmes are included within this Early Value Assessment (EVA), Table 2. The EAG did not receive any communication from Juniper, therefore information relating to this technology was identified from the public domain only and has not been verified by the Company. Two Companies stated that their technology is CE marked as a medical device: Gro Health (Class I) and Oviva (Class IIa), Appendix E. Five

Companies stated that their technology has been assessed and approved by DTAC (Gro Health, Liva, Oviva, Second Nature, Wellbeing Way) and 2 are working towards DTAC assessment (CheqUp, Roczen).

Referrals

Five technologies accept self-referral to programmes (CheqUp, Gro Health, Oviva, Roczen, SecondNature), 5 technologies can be accessed through GPs (Wellbeing Way, Second Nature, Liva, Oviva, Gro Health) with the latter 3 also accepting referrals from secondary care providers. CheqUp also accepts referrals from private doctors. Second Nature also accepts referrals from other healthcare professionals (nurses, dietitians).

MDT staff and frequency of reviews

The level of support or provision of Tier 3 specialist weight management services differed across the included technologies. The healthcare professionals involved and the frequency of reviews varied, for example reviews with a dietitian occur between every 2 to 12 weeks and MDT meetings also range from occurring daily to monthly. Some technologies also include non-healthcare professionals, such as nutritionists, health coaches, or physical activity advisers. All 7 of 8 Companies confirmed that some members of the care team are employed within the NHS (Appendix E). DDM Health Ltd offer Tier 3 specialist weight management services using Gro Health through 2 different programmes: W8Buddy, which uses the existing NHS MDT for clinical oversight, or W8Buddy+, which uses the Company in-house MDT and prescribing team. One Company (Liva) without an in-house prescriber notes that responsibility for medicines management and principal care remains with the referring clinician. None of the included technologies included a surgeon within their MDT and no published data was identified for any technology that reported progression to weight loss surgery.

Adherence monitoring

All technologies provide the ability to record or monitor medication adherence. Medication reviews, where appropriate, occur weekly to monthly and may take place with a health professional, nurse, or doctor depending on the technology and the

participant's needs. Six technologies include methods for recording and reporting adverse events (Gro Health, Liva, Oviva, Roczen, Second Nature, Wellbeing Way). CheqUp did not define how adverse events were captured (Appendix E). For further details on adverse events and risk management, see Section 6.

Programme adherence is measured in several ways across the technologies, including through the number of consultations attended, communication with a healthcare professional, time spent on the app or programme platform, activity (such as, goal setting, meal tracking, or inputting of measurement data including weight or physical activity), and last log-in time (for example, within the last 7 days).

Table 2: Summary of included technologies including summary of functionality (Note: information for Juniper and Wellbeing obtained from public domain only)

			Eligibility criteria		Technology components				Review features								Staff included within MDT									
Technology name [Manufacturer]	Duration	In-house prescribing (medication)	Inclusion criteria	Exclusion criteria	Wearable	App (smart phone, web-based)	Software (laptop, PC)	Other (for example, phone)	Medication review	Physical activity	Weight	Food intake	Education	1:1 appointments	Online group support	Other	GP,Specialist doctor,consultant	Dietitian	Nurse	Physiotherapist	Psychologist	Pharmacist	Nutritionist	Health Coach	Physical Activity Adviser	Other
CheqUp Virtual Health Platform [CheqUp]	≥24 months	✓ (liraglutide, semaglutide, dulaglutide)	≥18 years old In line with the medication's licence within the general population or within the NICE TAs if prescribed within the NHS	History of eating disorders including anorexia nervosa and bulimia, failure to complete identification process, pregnant or planning pregnancy, other GLP-1 medication, contraindications to medication in accordance with SmPC.	✓*		✓	✓	✓	✓	✓	✓	✓		✓		✓				✓ †			✓	✓	
GroHealth Tier 3 and 4 Weight management programme (including bespoke version W8Buddy) [DDM Health Ltd]	**Tier 3**: 12 to 15 months **Tier 4:** 6 to 24 months	✓ (liraglutide semaglutide, orlistat, dulaglutide)	≥18 years old BMI ≥40 or BMI ≥35 and living with a long term health condition (T2DM) or BMI ≥33 and of South Asian descent such as Bangladeshi, Indian or Pakistani and a long term health condition (T2DM)	NR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓ (Sleep, Mental wellbeing, Menopause, Health tracking, symptom tracking)	✓	✓	✓	✓	✓	✓	✓	✓	✓	Psychotherapist
Juniper [Juniper Technologies UK Ltd]	≥8 weeks	✓ (semaglutide)	≥18 years old BMI ≥30 or BMI ≥27 with a comorbidity (caused or worsened by excess body weight)	NR		✓	✓		✓		✓		✓		✓		✓	✓			✓	✓		✓		
Liva [Liva]	6 to 24 months	× Not currently available but is being explored	≥18 years old BMI>35 or BMI>33 with long-term conditions or comorbidities or those from ethnic minority backgrounds	Pregnant or breastfeeding Active eating disorder Serious mental illnesses		✓			✓	✓	✓	✓	✓	✓	✓	✓ (Mood tracking, blood pressure, blood glucose, blood pressure, HbA1c, alcohol consumption, smoking status, and pain)	✓	✓						✓		
Oviva Tier 3 Digital-enabled Weight Management programme [Oviva]	**Tier 3:** 12 months **On GLP-1:** 24 months	✓ (All licensed and NICE approved GLP-1 and Orlistat)	≥18 years old BMI>40 or BMI>35 and long term health conditions (T2DM) or BMI>33 and South Asian descent with long term health conditions (T2DM)	Pregnant or breastfeeding Criteria can vary based on the local NHS commissioning region requirements		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓ (Mood, blood pressure, blood glucose, psychological wellbeing, symptoms)	✓	✓	✓	✓	✓		✓		✓	Psychological Wellbeing Practitioner.

			Eligibility criteria		Technology components				Review features								Staff included within MDT										
Technology name [Manufacturer]	Duration	In-house prescribing (medication)	Inclusion criteria	Exclusion criteria	Wearable	App (smart phone, web-based)	Software (laptop, PC)	Other (for example, phone)	Medication review	Physical activity	Weight	Food intake	Education	1:1 appointments	Online group support	Other	GP,Specialist doctor,consultant	Dietitian	Nurse	Physiotherapist	Psychologist	Pharmacist	Nutritionist	Health Coach	Physical Activity Adviser	Other
Roczen [Reset Health Ltd]	Rolling monthly subscription for >1 year	✓ (liraglutide, semaglutide)	≥18 years old Overweight or obese, patients may have T2DM or be pre-diabetic. Patients with BMI >50 will be eligible for Roczen Plus.	Major adverse cardiovascular <6 months, uncontrolled heart arrhythmia or thyroid disease, cancer or other malignancy that is undergoing active treatment, T1DM, previously diagnosed or active eating disorder (bulimia, anorexia, BED), liver cirrhosis, CKD stage IV or V, uncontrolled psychiatric disorder, suicidal ideation, BMI >50^, previous bariatric surgery (not including endoscopic procedures where gastric band or balloon has been removed), Ileostomy, active inflammatory bowel disease (ulcerative colitis or Crohn's disease), women who are pregnant or planning to conceive <3 months, HbA1c >10%, alcohol or drug dependency, members with safety critical job roles who are on insulin, sulphonylurea ≥2, hypoglycaemic agents.			✓		✓	✓		✓		✓	✓	✓		✓ Peer (Mentor) support Outcomes data tracking - physical and mental health scores	✓	✓				✓ ǂ					In-house behaviour change specialist , CBT practitioner
Second Nature (previously Our Path) Medication supported programme [Second Nature]	6 to 24 months (depending on programme)	✓ (liraglutide, semaglutide)	Varies depending on contract – but typically BMI >25 or non-diabetic hypoglycaemia, or T2DM	N/A	✓*	✓	✓	✓β	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓		
Wellbeing Way [Xyla Health and Wellbeing]	12 weeks to 12 months (programme specific)	× Not currently available but is being explored	Adults, no further details provided.	NR		✓			✓	✓	✓		✓	✓	✓	✓	✓	✓		✓		✓	✓	✓		

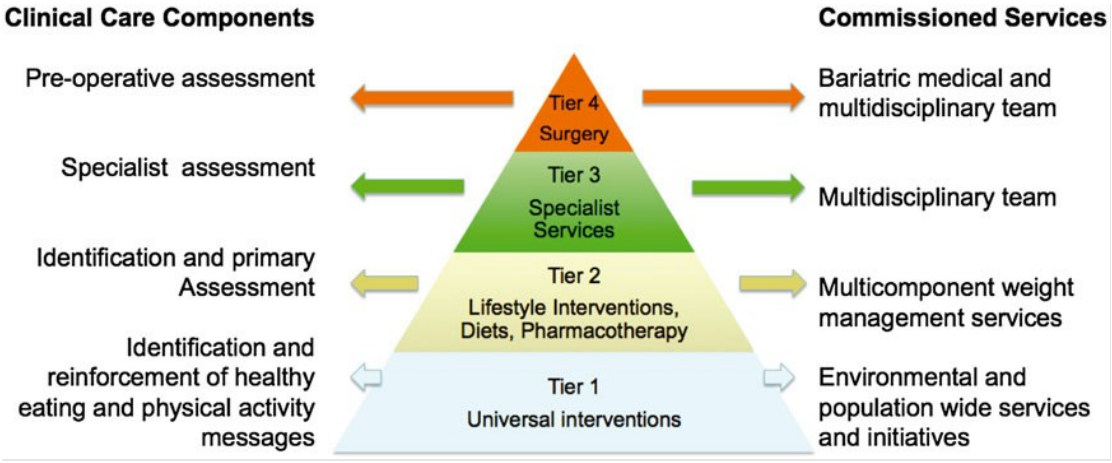
Key: *Only available in the top package, †referral to psychological or counselling services only, ǂPrivate partnerships in place with GPhC-regulated, β Bluetooth weighing scales ^for Roczen lifestyle programme only, not applicable to Roczen GLP-1 programme
Abbreviations: BED, binge eating disorder; BMI, body mass index; CBT, cognitive behavioural therapy; CKD, chronic kidney disease; GLP-1, glucagon-like peptide-1 (GLP-1) receptor agonists; HbA1c, glycated haemoglobin; MDT, multidisciplinary team; N/A, not applicable; NR, not reported; PC, personal computer; SmPC, summary of product characteristics; TA, technology appraisal; T1DM, Type 1 diabetes mellitus, T2DM, Type 2 diabetes mellitus

3 Clinical context

3.1 Specialist weight management services

Specialist weight management services were defined by The NHS England 'Joined up clinical pathways for obesity' report (2014). The target population for this assessment is adults within specialist weight management services (Tier 3 and 4 services). The 2019 Health Survey for England estimated the prevalence of obesity in adults in England to be 28%, with overweight affecting a further 36% (CG189, 2022). The aim of the current NICE guidelines (CG189, 2022) is to give recommendations on the identification, assessment and management of obesity.The management of obesity in the NHS is broadly structured into tiered services, Figure 1.

Figure 1: Tiered model of obesity services sourced from Welbourn et al. (2018)



Extracts from TA875 (2023) [section 3.2]:

- Tier 1 services provide universal interventions such as population level health promotion and advice (QS111, 2016).
- Tier 2 services include community-based diet, nutrition, lifestyle and behavior change advice for up to 12 weeks (PH53, 2014).

- Tier 3 services provide longer and more comprehensive MDT assessment and interventions. These include dietary, lifestyle and behavior modification advice, with or without drug therapy, and psychological support. The Clinical Experts explained that Tier 3 services are traditionally offered in secondary care but there are equivalent services with similar multidisciplinary team support in community settings in some places (Appendix F). The Clinical and Patient Experts explained that specialist weight management services such as Tier 3 services are not available everywhere across England and Wales (Appendix F). Patients with a BMI of 35 or more plus 1 or more comorbidities, or with a BMI of 40 or more with or without comorbidities are assessed for up to 2 years. The specific nature of the comorbidities needed for referral may differ between services. Also, the duration of the programme that can be accessed may be shorter than 2 years in different areas of the country.

- Tier 4 services provide similar multidisciplinary team interventions to Tier 3, but also involve weight loss surgery.

The National Obesity Audit confirmed (on 26 April 2023) that there is not a recognised list of all Tier 3 and Tier 4 service providers in England; and that they hope this will evolve as the audit progresses.

NICE's guideline on obesity: identification, assessment and management (CG189, 2014, updated in 2022) recommends that referral to a Tier 3 service is considered if the underlying causes of overweight or obesity need to be assessed, if the person has a complex condition or needs that cannot be managed adequately in Tier 2, conventional treatment has been unsuccessful, drug treatment is being considered for a person with a BMI greater than 50, specialist interventions (such as a very-low-calorie diet) may be needed, and surgery is being considered. The guideline also recommends the following strategies in behavioural interventions for adults including the following where appropriate: self-monitoring of behaviour and progress, stimulus control, goal setting, slowing rate of eating, promoting social support,

problem solving, assertiveness, cognitive restructuring, reinforcement of changes, relapse prevention, strategies for dealing with weight regain.

3.2 Approved NICE weight loss medications

The population defined in the Final Scope (2023) for this EVA refers to 'adults with obesity referred for treatment with weight management medication in line with NICE's guidance including but not limited to semaglutide and liraglutide'. The EAG note that eligibility criteria differs between these medications:

Semaglutide (TA875, 2023) is recommended as an option for weight management, including weight loss and weight maintenance, alongside a reduced-calorie diet and increased physical activity in adults, only if:

- it is used for a maximum of 2 years, and within a specialist weight management service providing multidisciplinary management of overweight or obesity (including, but not limited to, Tiers 3 and 4), and
- they have at least 1 weight-related comorbidity and:
    - a BMI of at least 35.0, or
    - a BMI of 30.0 to 34.9 and meet the criteria for referral to specialist weight management services in NICE's guideline on obesity: identification, assessment, and management (CG189, 2022).
    - Use lower BMI thresholds (usually reduced by 2.5) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family backgrounds.

Liraglutide (TA644, 2020) is recommended as an option for managing overweight and obesity alongside a reduced-calorie diet and increased physical activity in adults, only if:

- they have a BMI of at least 35.0 (or at least 32.5 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population), and

- they have non-diabetic hyperglycaemia (defined as a haemoglobin A1c level of 42.0 mmol/mol to 47.0 mmol/mol [6.0% to 6.4%] or a fasting plasma glucose level of 5.5 mmol/litre to 6.9 mmol/litre), and
- they have a high risk of cardiovascular disease based on risk factors such as hypertension and dyslipidaemia, and
- it is prescribed in secondary care by a specialist multidisciplinary Tier 3 weight management service, and
- the Company provides it according to the commercial arrangement.

In line with the Scope, the EAG note that other weight loss medications, which have undergone NICE appraisal, are also available, for example Orlistat (Xenical) (section 3.1, TA875, 2023). Tirzepatide (GID-TA11156) is an additional weight loss medication currently undergoing NICE evaluation with an expected publication date of 27 March 2024.

3.3 Additional NICE guidance on behaviour change

An element of the support provided by specialist weight management services focuses on behaviour change. While not exclusive or specific to specialist weight management services, the EAG note that NICE have published public health guidance on the delivery of behaviour change interventions:

- Behaviour change: general approaches (PH6, 2007).
- Behaviour change: individual approaches (PH49, 2014).

Furthermore, NICE have developed a guideline on the use of digital and mobile health interventions for supporting behaviour change interventions:

- Behaviour change: digital and mobile health interventions (NG183, 2020).

Section 1.4.3 of NG183 recommends technologies with self-monitoring should not be considered if a person is at risk of developing or resuming an eating disorder or other unhealthy behaviour such as excessive exercise. All technologies included in this EVA include clinical MDT oversight of patients within their specialist weight management programme, however the

technologies in Scope also support delivery of automated digital interventions (such as, availability of information resources or feedback alerts) alongside self-monitoring, with frequency of clinical oversight differing between technologies (Appendix E). Methods of patient risk assessment for the technologies included in this EVA have been summarised in Section 6.

3.4 Special considerations, including issues related to equality

From TA875 (2023) and TA664 (2020): People from some minority ethnic family backgrounds have an equivalent risk from obesity at a lower BMI than people from a White ethnic family background. NICE's guideline on obesity recommends using lower BMI thresholds for people from South Asian, Chinese, other Asian, Middle Eastern, Black African, or African-Caribbean family backgrounds when identifying the risk of developing T2DM and providing interventions to prevent it. Furthermore, NHS England's statistics report on Obesity, Physical activity and diet (2020) states that obesity rates increase with age for both sexes and people aged older than 45 years old. While prevalence of obesity might vary by UK region there is insufficient evidence of a statistically significant difference between regions.

The EAG identified several potential equality issues and special considerations. According to (CG189, 2022), the Committee agreed that a key benefit of using waist-to-height ratio is that the classification is the same for all ethnicities and sexes. Additionally, the Committee reported that obesity rates differ between socio-economic groups. There may also be challenges in using BMI or waist-to-height ratio in people who have a physical disability, are pregnant, some physical conditions (such as scoliosis) or learning difficulties because people may be unable to get on scales independently or be lifted safely. In such circumstances, reasonable adjustments would be needed for adults, for example using seated or hoist scales, or scales that can be used for wheelchairs (including molded wheelchairs). Measurements may also need to be modified, for example using sitting height instead of overall height, meaning specialist assessment may be needed. It may also be challenging to

take measurements in people who are housebound because it may not be possible to access equipment such as specialist scales during home visits.

Digital health technologies need internet access via a computer, tablet, or smartphone. There may therefore be barriers to access to these therapies for those with low familiarity or poor access to the requisite technological devices. Some people may be disadvantaged from living in a geographical area with poor digital coverage; this may affect access to the technology or limit virtual assessments via video calls (as they need higher bandwidth). Patients may also have differential access to devices and data plans because of socio-economic circumstances. Overcoming these barriers would increase resource costs.

Patient-facing digital health technologies may be unsuitable for those with cognitive impairment, problems with manual dexterity or learning disabilities. Carer or advocate assistance may be needed to navigate the programme and consideration of this should be made by the programme provider as well as the referring practitioner when considering appropriate intervention for the person. Some may prefer to be seen face-to-face as they may struggle to engage with a digitally enabled programme. Patient-facing digital health technologies should ensure their programme is accessible for those with visual or hearing impairments.

Three Companies have confirmed that their technology is available in multiple languages; Gro Health is available in 11 languages with additional languages being made available in November 2023 and a British Sign Language Interpreter is available for video consultations; Liva is available in 12 languages and team members can speak over 20 languages collectively; Second Nature is available in 10 languages. Where only English is fully available across the programme, translators are used in Oviva and the in-house clinical team can speak 25 languages collectively, while CheqUp uses online translation, Wellbeing Way also includes online resources available in Hindi and Polish. Currently Roczen is only available in English with plans to

make the programme available in multiple languages in the future (Appendix E).

None of the Companies have reported user access issues. For patients who lack internet access or digital proficiency, DDM (Gro Health) stated that they provide written information and DVDs and consultations are delivered over the phone. The Company also note that they provide an Easy Read version of the programme available for those with neurodiversity (Appendix E). Liva, Second Nature, and Wellbeing Way state that their support or coaching teams provide step-by-step guidance to users who are less familiar with digital technologies and need additional support. Liva also state that their technology may not be suitable for users with severe learning difficulties but that the team works with carers and family members to provide additional support. Oviva report that significant cognitive disabilities, visual impairment, no or limited digital literacy, or access to a smartphone and the internet are screened for prior to enrolment and programme content is also available in printed hardcopy and web text to speech formats. Roczen state they are working towards Web Content Accessibility Guidelines 2.0 Level AA conformance. CheqUp state that their system is very easy to use (Appendix E).

4 Clinical evidence selection

4.1 *Evidence search strategy and publication selection*

The initial search strategy was devised by the EAG to find a practicable number of results to sift within the timeline, comprehensively identifying results that refer to the technologies by name (5 of 6 of those stated in the original Scope due to their correspondence with NICE confirming eligibility), but also including other results likely to be relevant to the Scope. No additional technologies relevant to the Final Scope were identified during the EAG searches. A wide range of free-text, keyword and controlled vocabulary terms were used, based on NICE scoping searches, known relevant articles, and extensive further testing and development.

A publication date range of 2018 to current (search dates 22 and 23 May 2023) was applied and exclusively paediatric results were removed where

appropriate or possible. A date restriction was considered appropriate to ensure evidence was reflective of the current technology and its updates and generalisable to current practice. When considering all methods for literature searching and review, applying a 5-year date restriction was also considered pragmatic and most robust within the timescales of this EVA (such as 7 weeks to produce this report) and because of the volume of evidence and full paper retrieval rate (to check the intervention used). Resources searched included MEDLINE (Ovid), Embase (Ovid), CINAHL (EbscoHost), CENTRAL (Cochrane Library), Google Scholar, MedRxiv, WHO ICTRP, ScanMedicine, ClinicalTrials.gov, the International HTA database (INAHTA) and the NIHR Journals Library (Appendix A1a). Clinical effectiveness searches retrieved a total of 641 results, of which, 452 remained after deduplication.

On 12 June 2023, NICE were informed by NHSE that there were an additional 2 technologies within the Scope of the decision problem to be included within this EVA. On 19 June 2023, the EAG received information from Wellbeing Way (confirming eligibility) and for the 2 additional technologies (Roczen and Second Nature). A subsequent search was then conducted on 20 June 2023, which provided an additional 33 results after de-duplication, Appendix A1b.

References for unpublished data in confidence relating to real-world evidence or internal data was shared by 3 Companies and has been considered by the EAG.

Additional EAG considerations were made during evidence selection:

- Definition of adults varies across NHS (lower age cut-off ranges between 16 and 19 years). The EAG considered all evidence relating to patients aged 16 years and over.

- The population of interest is likely to have multiple comorbidities (diabetes, hypertension, non-alcoholic fatty liver disease), and therefore may be following additional care pathways. No subgroups were explicitly defined in this EVA, therefore have not been considered by the EAG.

- Patients may be eligible for weight loss medication, however some patients may not start or may stop pharmaceutical management due to side effects, comorbidities or patient preference. Therefore, evidence relating to the same patient group but who did not take medication was also considered relevant by the EAG.

4.2 *Included and excluded publications*

Across the 2 searches, a total of 485 records (title and abstract) were sifted according to the final scope (GID-HTE1007, 2023) by 2 reviewers (RP, PL), Appendix A2. Disagreements were discussed by the 2 reviewers and agreements reached for full paper retrieval. A total of 397 abstracts were subsequently excluded. Full papers were retrieved and reviewed by the same 2 reviewers (RP, PL) with any disagreements resolved through arbitration with a third reviewer (KK). After full paper sifting, 77 publications were excluded (Appendix B2) and 11 publications were subsequently included. An additional 6 publications were identified from hand searching, and 10 additional publications were provided by 3 Companies and included, of which 8 were provided in confidence (3 Liva, 3 Oviva, 2 Roczen). A total of 22 studies were reported across 27 included publications, of which 8 were available in abstract only (Appendix B1). Three studies were reported across multiple publications with outcomes reported across publications or by population subgroups:

- 4 full publications for 1 study [NCT03788915] (Christensen et al. 2022a, Christensen et al. 2022b, Hesseldal et al. 2022, Imeraj et al. 2022);
- 2 full publications for 1 study (Pedersen et al. 2019, Komkova et al. 2019;

[redacted]The EAG acknowledge possible

overlap between some abstracts due to similar study design and authors (Sutter et al. 2020 and Sutter et al. 2021; Falvey et al. 2023, Phung et al. 2023, Brown et al. 2022), however as these are unverified they have been considered by the EAG as separate studies.

5 Clinical evidence review

5.1 *Overview of methodologies of all included studies*

Evidence was available for 4 of the 8 technologies; Oviva (N=11), Liva (N=10), Roczen (N=5), and Gro Health (N=1); no evidence was identified for CheqUp, Juniper, or Wellbeing Way. Second Nature confirmed their digitally enabled specialist weight management programme with MDT support (representative of a Tier 3 specialist weight management service) is available for those taking weight management medication and those defined as having complex obesity. The EAG identified 4 full publications and 6 abstracts relating to the use of a Second Nature programme in patients not explicitly taking weight loss medication or defined as having complex obesity, however this evidence has been summarised separately in Section 5.5 for completeness. Furthermore, the EAG recognises that Oviva provide different programmes with and without MDT support across the UK NHS and worldwide settings. The EAG have excluded evidence that explicitly relates to an Oviva programme within a Tier 2 equivalent setting, such as the NHS DPP or digital weight management programme, however have summarised this evidence within Section 5.5 for completeness. The EAG have included evidence where a technology in Scope has been used for more than 3 months within a specialist weight management setting or in a population within scope of the decision problem or exclusively delivers a programme reflective of Tier 3 specialist weight management services with MDT oversight..

The evidence included in the report are:

- 5 publications relating to 1 RCT (Christensen et al. 2022a; Christensen et al. 2022b; Hesseldal et al. 2022; Imeraj et al. 2022) and 1 pilot RCT (McDiarmid et al. 2022);

- 7 publications relating to 6 single-arm cohort studies including 1 feasiblity study (Papathanail et al. 2022), 1 prospective (Hanson et al. 2023), 5 retrospective (Brown et al. 2022; Falvey et al. 2023; Komkova et al. 2019; Pedersen et al. 2019; Phung et al. 2023);

- 4 non-randomised comparative cohort studies (Huntriss et al. 2021; Sutter et al. 2020; Sutter et al. 2021; Tsai et al. 2023);

- 3 before-and-after studies (Haas et al. 2019; Huntriss et al. 2020; Lawson et al. 2022);

- 5 [redacted] in confidence from 2 Companies (Liva CiC-1, Liva CiC-2, Liva CiC-3, Oviva CiC-2, Oviva CiC-3).

- 3 [redacted] in confidence from 3 Companies (Oviva CiC-1; Roczen AiC-1, Roczen AiC-2).

The included evidence included a total of 8,745 participants (noting that the number of participants is not reported in 1 study).

5.2 *Critical appraisal of publications*

Due to the breadth of the decision problem (extensive populations with varying subgroup definition such as: BMI, weight management medication eligibility, co-morbidity status, 8 technologies, 24 outcomes, no setting restriction), heterogeneity in reporting, short timescales of the EVA process, and limited detail within the unpublished information shared in confidence, formal critical appraisal checklists were not applied by the EAG. The EAG have summarised elements of the study design and relevance to the decision problem (Appendix B1).

Of the included evidence, 11 were reported in full peer-reviewed publications (Christensen et al. 2022a; Christensen et al. 2022b; Haas et al. 2019; Hanson et al. 2023; Hesseldal et al. 2022; Huntriss et al. 2021; Imeraj et al. 2022; Komkova et al. 2019; Lawson et al. 2022; McDiarmid et al. 2022; Pedersen et al. 2019), and 8 were available in abstract form only (Brown et al. 2022;

Falvey et al. 2023; Huntriss et al. 2020; Papathanail et al. 2022; Phung et al. 2023; Sutter et al. 2020; Sutter et al. 2021; Tsai et al. 2023).

Of the 11 full peer-reviewed publications, 4 were set in the UK (Hanson et al. 2023; Huntriss et al. 2021; Lawson et al. 2022; McDiarmid et al. 2022), 6 publications were conducted in Denmark (Christensen et al. 2022a; Christensen et al. 2022b; Hesseldal et al. 2022; Imeraj et al. 2022; Komkova et al. 2019; Pedersen et al. 2019) and 1 in Switzerland (Haas et al. 2019).

The EAG identified 4 publications all related to the same RCT (digitally enabled weight management programme using Liva, when compared with standard care), which reported different outcome measures at different timepoints (Christensen et al. 2022a; Christensen et al. 2022b; Hesseldal et al. 2022; Imeraj et al. 2022). The study was powered to detect a 2 kg weight loss between arms with 95% power (Brandt et al. 2020), which accounted for dropout of 39% and 57% across the intervention and control groups respectively, and stratification (according to obese participants at risk of developing chronic diseases and those with diabetes). To avoid duplication when extracting results, the EAG selected the longest timepoint for each outcome measure from these 4 publications.

The eligibility criteria of 7 publications (6 of which were available in abstract form only) did not explicitly define an obese population, however the mean BMI was greater than 30 in 6 publications (Brown et al. 2022; Falvey et al. 2023; Haas et al. 2019, Huntriss et al. 2020, Phung et al. 2023; Sutter et al. 2020). The remaining feasibility study (Papathanail et al. 2022) included patients with a BMI greater than 27, however diabetic status and ethnicity were not reported, and outcomes were focused on patient experience.

The study duration varied across the digitally enabled technologies: between 14 days (retrospective cohort of 2,684 patients by Pedersen et al. 2019 using Liva), to 24 months (RCT of 340 patients by Christensen et al. 2022a).

Two publications explicitly excluded patients taking weight loss medications (McDiarmid et al. 2022; Haas et al. 2019). Of the published evidence, only 1

full publication and 1 abstract included patients taking weight loss medication (Huntriss et al. 2021: 5.3% Orlistat, 6.5% GLP-1 analogues, 4.1% sodium-glucose co-transporter-2 inhibitors; Phung et al. 2023: 12.2% taking injectables such as insulin or GLP-1 analogues not reported separately), which may confound results. Of the unpublished evidence, [redacted]

The use of weight loss medication together with digitally enabled weight management programmes reflect real-world interventions and may confound results thus require careful reporting.

Five publications combined digital technologies with a specified diet. Three abstracts (Brown et al. 2022; Falvey et al. 2023; Phung et al. 2023) reported the results of Roczen used alongside a time-restricted eating, low carbohydrate moderate protein plan. Two studies reported the results of the Oviva used alongside a low-energy low-calorie Optifast, with or without Mediterranean diet (Huntriss et al. 2020; McDiarmid et al. 2022). The EAG note that different diets used alongside the digitally enabled weight management programmes reflect real-world interventions but may confound results.

The EAG notes that outcomes were poorly described across the included evidence. The EAG has interpreted engagement outcome measure to be *initial* engagement with the digital technology, and adherence outcome measure to be *ongoing* engagement with the service (which was measured in a variety of ways across the included literature). The EAG notes that some clinical outcomes measures (for example, weight loss distributions) are expected to be non-normal and therefore would expect to see evidence of checking the distribution of data before applying statistical tests of comparison. This was not undertaken in all cases.

Due to the heterogeneity in population, intervention, comparator (duration of programme, frequency of review by a healthcare professional) and outcome measures (units and timepoints), analytical methods of synthesis were not considered to be appropriate.

5.3 *Results from the evidence base*

Each of the 27 included publications reported on the outcomes listed in the NICE Final Scope (2023), Table 3.

Table 3: Cross-tabulation of included publications against outcomes (N=27 related to 22 studies, with multiple publications related the same study separated by dashed lines; shaded rows relate to publications available as abstract only)

		Population							Intermediate measures					Clinical outcomes													PROMs		Health resource use		
Author (year); Country	Study design (number of patients)	Inclusion criteria	Diabetes	Dyslipidaemia	Hypertension*	Weight loss medication	Intervention [duration]	Comparator [duration]	Engagement	Adherence	Intervention-related adverse events	Weight management medication adherence	Inaccessibility to intervention (digital inequalities)	BMI	Weight loss	Body fat	Waist circumference	Hip circumference	Waist-to-hip ratio	Glycated haemoglobin (HbA1c)	Cardiovascular events	Mortality	Physical activity	Rate of referral for weight loss surgery	Eating habits	Patient reported outcomes (for example, PHQ9, HRQoL)	Satisfaction	Healthcare appointments	Medication use	Healthcare professional grade and time
Christensen et al. 2022a Denmark	RCT (n=340)	Adult (18-70 years) with BMI between 30-45	†				Liva [24 months]	Standard care (face-to-face) [24 months]		✓					✓						✓										
Hesseldal et al. 2022 Denmark	RCT (n=340)		†		†		Liva [12 months]	Standard care (face-to-face) [12 months]		✓				✓	✓		✓	✓	✓	✓						✓			✓	
Imeraj et al. 2022 Denmark	Secondary analysis of RCT (intervention arm, n=104)		†				Liva [12 months]	-		✓					✓															
Christensen et al. 2022b Denmark	RCT (n=170)		†				Liva [6 months]	Standard care (face-to-face) [6 months]		✓				✓	✓		✓	✓		✓			✓		✓	✓			✓	
Tsai et al. 2023 Germany [Abstract]	Non-randomised comparative cohort (n=63)	Adult German patients (>18 years) with T2DM, BMI 25-40 and with HbA1c between 6.5 to 11.0% [Not exclusively obese]	†				Liva [6 months]	NR		✓										✓										
Pedersen et al. 2019 Denmark	Retrospective cohort (n=2,684)	Adults [Not exclusively obese]	†				Liva [min 14 days, max 595]	-		✓																				
Komkova et al. 2019 Denmark	Cohort (n=103)	Adults with diabetes	✓				Liva [mean 7.3 months]	-						✓	✓															
Liva CiC-1 [redacted]	[redacted]							-		✓					✓												✓			
Liva CiC-2 [redacted]	[redacted]							-		✓					✓												✓			
Liva CiC-3	[redacted]							-		✓					✓															

Author (year); Country	Study design (number of patients)	Population: Inclusion criteria	Diabetes	Dyslipidaemia	Hypertension*	Weight loss medication	Intervention [duration]	Comparator [duration]	Intermediate measures: Engagement	Adherence	Intervention-related adverse events	Weight management medication adherence	Inaccessibility to intervention (digital inequalities)	Clinical outcomes: BMI	Weight loss	Body fat	Waist circumference	Hip circumference	Waist-to-hip ratio	Glycated haemoglobin (HbA1c)	Cardiovascular events	Mortality	Physical activity	Rate of referral for weight loss surgery	Eating habits	PROMs: Patient reported outcomes (for example, PHQ9, HRQoL)	Satisfaction	Health resource use: Healthcare appointments	Medication use	Healthcare professional grade and time
[redacted]	[redacted]	[redacted]					[redacted]																							
Hanson et al. 2023 UK	Prospective cohort (n=199)	Referral to hospital-based Tier 3 service, interest in using app					Gro Health (DDM) [between 3 and 8 months]	-	✓				✓																	
McDiarmid et al. 2022 UK	Pilot RCT (n=79)	Adult (18-75 years), with T2DM (<8 years), BMI>27 and <50 or >25 and <50 in high-risk ethnic minority groups. [Not exclusively obese]	✓		†		Intermittent low-energy diet [28 weeks] + Oviva [up to 12 months]	Continuous low energy diet [4 weeks] + Oviva [up to 12 months]	✓	✓					✓	✓	✓	✓	✓		✓					✓				✓	✓
Huntriss et al. 2021 UK	Retrospective non-randomised comparative cohort (n=169)	Adults, BMI ≥45, or ≥40 with complex comorbidity	†			†	Oviva [12 to 16 weeks]	Face-to-face or telephone appointment [12 to 16 weeks]	✓	✓				✓	✓												✓	✓		
Haas et al. 2019 Switzerland	Before-and after-study (n=43)	Adults, BMI between 26 and 33. [Not exclusively obese]		†	†		Oviva [12 months]	-		✓				✓	✓	✓	✓			✓			✓		✓	✓				
Lawson et al. 2022 UK	Before-and-after (n=54)	>35 with comorbidities					Oviva [up to 12 months]	-																		✓				
Sutter et al. 2020 Switzerland [Abstract]	Retrospective non-randomised cohort study (n=166)	Adults T2DM Receiving nutritional counselling [Not exclusively obese]	✓				Oviva with face-to-face counselling [3 to 12 months]	Face-to-face counselling [3-12 months]												✓										
Sutter et al. 2021 Switzerland [Abstract]	Retrospective non-randomised cohort study (n=86)	Adults Obese					Oviva with face-to-face counselling [6 months]	Face-to-face counselling [6 months]	✓						✓															
Papathanail et al. 2022 Switzerland	Cohort (feasibility)	BMI>27					Oviva [NR]	-																			✓			

		Population						Intermediate measures					Clinical outcomes												PROMs		Health resource use		
Author (year); Country	Study design (number of patients)	Inclusion criteria	Diabetes	Dyslipidaemia	Hypertension*	Weight loss medication	Intervention [duration]	Comparator [duration]	Engagement	Adherence	Intervention-related adverse events	Weight management medication adherence	Inaccessibility to intervention (digital inequalities)	BMI	Weight loss	Body fat	Waist circumference	Hip circumference	Waist-to-hip ratio	Glycated haemoglobin (HbA1c)	Cardiovascular events	Mortality	Physical activity	Rate of referral for weight loss surgery	Eating habits	Patient reported outcomes (for example, PHQ9, HRQoL)	Satisfaction	Healthcare appointments	Medication use	Healthcare professional grade and time
[Abstract]	(n=24)	[Not exclusively obese]																												
Huntriss et al. 2020 UK *[Abstract]*	Before-and-after (n=9)	T2DM	✓				Oviva [6 months]	-		✓					✓					✓							✓		✓	
Oviva CiC-1 [redacted]	[redacted]							-				✓			✓															
Oviva CiC-2 [redacted]	[redacted]							-		✓					✓														✓	
Oviva CiC-3 [redacted]	[redacted]							-	✓	✓					✓															
Falvey et al. 2023 UK [Abstract]	Cohort (n=732)	NR, mean BMI>30 [Not exclusively obese]	†				Roczen programme [6 to 12 months]	-		✓					✓		✓			✓							✓			
Brown et al. 2022 UK [Abstract]	Cohort (n=653)	NR, mean BMI>30 [Not exclusively obese]	†				Roczen programme [3 to 6 months]	-		✓					✓		✓			✓							✓ ǂ			
Phung et al. 2023 UK [Abstract]	Before-and-after (n=82)	NR, T2DM, mean BMI>30 [Not exclusively obese]	✓				Roczen programme [mean 49 weeks]	-							✓					✓									✓	
Roczen AiC-1 [redacted]	[redacted]							-		✓					✓											✓				
Roczen AiC-2 [redacted]	[redacted]							-						✓	✓		✓			✓						✓				

Key: *stated diagnosis or evidenced through medication; † not exclusively; ǂdata capture tool or survey not identified;
Abbreviations; AiC, academic in confidence; BMI, body mass index; CiC, commercial in confidence; HbA1c, glycated haemoglobin A1c; HRQoL, health-related quality of life; NR, not reported; PHQ9, Patient Health Questionnaire; PROMs, patient-related outcome measures; RCT, randomised controlled trial; T2DM, Type 2 diabetes mellitus

Intermediate measures

Engagement

Five studies reported on initial patient engagement (or uptake) of their digitally enabled specialist weight management services (Oviva N=4; Gro Health N=1), Table 4. The prospective cohort by Hanson et al. (2023) reported that approximately half of patients (51.3%) offered free access to Gro Health were interested in using the technology (102 of 199), and that of those 34.2% engaged with the technology (68 of 102). The authors reported reasons for non-engagement were:

- Already seen by a weight management clinician.
- Actively involved in research trial.
- No smartphone or internet (*digital inequalities*).
- Not interested in apps.
- Other reasons (died, no details provided).
- Only surgery wanted or lost weight already.
- Using other apps.

The authors reported that emotional eating and higher BMI were associated with interest in using Gro Health, but that male gender was associated with reduced engagement. The pilot RCT by McDiarmid et al. (2022), which randomised to intermittent or continuous low-energy diets but used Oviva in both arms, reported that withdrawal rates were higher in men, more socio-economically deprived groups and those with higher BMI.

Table 4: Summary of studies reporting initial engagement with digitally enabled weight management service (N=5, shaded rows relate to publications available as abstract only)

			Uptake of weight management service		
Author (year)	**Study design**	**Intervention**	**Digitally enabled**	**Face-to-face only**	**Telephone only**
McDiarmid et al. (2022)	Pilot RCT (n=79)	Oviva with intermittent or continuous low-energy diet	88.6% (70 of 79)	-	-
Huntriss et al. (2021)	Retrospective non-randomised comparative cohort (n=169)	Oviva	64.5% (109 of 169)	28.4% (48 of 169)	7.1% (12 of 169)
Oviva CiC-3 [redacted]	[redacted]	[redacted]	[redacted]	-	-
Sutter et al. (2021) *[Abstract]*	Retrospective non-randomised cohort (n=86)	Oviva	84.0% (72 of 86)*	16% (14 of 86)	-
Hanson et al. (2023)	Prospective cohort (n=199)	Gro Health	51.3% (102 of 199)	-	-

Key: *hybrid (Oviva and face-to-face)
Abbreviations: CiC, commercial in confidence; NR, not reported; RCT, randomised controlled trial

Adherence

Eighteen publications (reporting on 16 studies) report on adherence to the weight management service (Liva N=7; Oviva N=6; Roczen N=3), Table 5. However, the EAG note that the definition of adherence varied. For example, ongoing engagement with the technology was documented through logging of electronic food or activity diaries, upload of weight measurements, completion of education modules. Ongoing engagement with the service was also documented through attendance at follow-up appointments. There was a lack of consistency in reporting (definition and timepoint) of these outcomes, thus preventing concise narrative summary.

The largest study, the retrospective cohort by Pedersen et al. (2019), with 2,684 patients using Liva (not exclusively in an obese population), reported that 1 in 4 dropouts (27%) occurred within the first month, and that there was an association between dropouts, female sex and starting BMI.

Table 5: Summary of publications reporting adherence at defined timepoints (N=16, with publications related the same study separated by dashed lines; shaded rows relate to publications available as abstract only)

						Adherence	
Author (year)	**Study design**	**Intervention**	**Comparator**	**Definition of adherence**	**Timepoint**	**Intervention**	**Comparator**
Christensen et al. (2022a)†	RCT (n=340)	Liva	Standard care (face-to-face)	Attendance at follow-up	6 months	74.0% (148 of 200)	60.0% (84 of 140)
					12 months	63.5% (127 of 200)	52.1% (73 of 140)
					24 months	40.5% (81 of 200)	36.4% (51 of 140)
				Log in within last 6 weeks	12 months	97.6% (124 of 127)	-
Imeraj et al. (2022)	RCT (n=104 intervention arm)	Liva	-	Self-reported weight	12 months	56.0% (58 of 104)	-
Pedersen et al. (2019)	Retrospective cohort (n=2,684)	Liva	-	Attendance at follow-up	Between 14 and 31 days	85.5% (2,296 of 2,684)	-
					Between 2 and 4 months	62.0% (1,663 of 2,684)	-
					Between 5 and 8 months	50.8% (1,363 of 2,684)	-
					Between 9 and 12 months	46.0% (1,235 of 2,684)	-
				No attendance at follow-up	12 months	54.0%	-
				Still active	12 months	39.4%	-
				Completed programme	12 months	3.7%	-
				Retention	12 months	3.0%	-
Tsai et al. (2023) [Abstract]	Non-randomised cohort (n=63)	Liva		Participants retained after 3 months	3 months	94.0% (n=NR)	-
Liva CiC-1 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-
Liva CiC-2 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-
					[redacted]	[redacted]	-
Liva CiC-3 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-
					[redacted]	[redacted]	-
					[redacted]	[redacted]	-
					[redacted]	[redacted]	-
McDiarmid et al. (2022)	Pilot RCT (n=79)	Oviva with intermittent low energy diet (n=39)	Oviva with continuous low energy diet (n=40)	Attendance at follow-up	12 months	69.0% (27 of 39)	75.0% (30 of 40)
				Self-reported adherence to the Optifast low-energy days in the active weight loss phase	NR	79.0% [95% CI 70.0% to 88.0%]	89.0% [95% CI 82.0% to 97.0%]
				Adherence to food-based low-energy days during weight maintenance or continued weight loss phase	NR	24.0% [95% CI 14.0% to 22.0%]	NR
		Oviva (combined with intermittent or continuous low-energy diet)	-	Continued use of the app	12 weeks	91.4% (64 of 70)	-
					28 weeks	81.4% (57 of 70)	-
					40 weeks	71.4% (50 of 70)	-
					12 months	62.9% (44 of 70)	-
Huntriss et al. (2021)	Retrospective non-randomised comparative cohort (n=169)	Oviva	Face-to-face	Completed 50% of dietetic sessions and weight recorded	12 to 16 weeks	93.6% (102 of 109)	95.8% (46 of 48)
			Phone	Completed 50% of dietetic sessions and weight recorded	12 to 16 weeks	93.6% (102 of 109)	58.3% (7 of 12)

						Adherence	
Author (year)	**Study design**	**Intervention**	**Comparator**	**Definition of adherence**	**Timepoint**	**Intervention**	**Comparator**
			Face-to-face	Attended optional follow-up appointment	24 to 28 weeks*	42.2% (46 of 109)	43.8% (21 of 48)
			Phone	Attended optional follow-up appointment	24 to 28 weeks*	42.2% (46 of 109)	25.0% (3 of 12)
Haas et al. (2019)	Before-and-after (n=43)	Oviva	-	Completion of intervention	12 months	83.7% (36 of 43)	-
Oviva CiC-2 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-
							-
							-
							-
							-
							-
							-
Oviva CiC-3 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-
Huntriss et al. (2020) [Abstract]	Before-and-after (n=9)	Oviva	-	Completed programme	6 months	66.7% (6 of 9)	-
Falvey et al. (2023) [Abstract]	Cohort (n=732)	Roczen	-	Retention (Company defined as engaging with the clinical team by messaging on the app or attending follow up consultations)	6 months	69.0%	-
					12 months	43.0%	-
Brown et al. (2022) [Abstract]	Cohort (n=653)	Roczen	-	Completed 6 months of the programme with data	6 months	37.4% (244 of 653 enrolled)	-
Roczen AiC-1	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-

Key: †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Hesseldal et al. 2022, Christensen et al. 2022b); *12 weeks after completion of core programme
Abbreviations: CI, confidence interval; CiC, commercial in confidence; NR, not reported; RCT, randomised controlled trial

Weight management medication adherence

Only 1 study explicitly reported on this outcome (Oviva CiC-1). [redacted]

Inaccessibility to intervention (digital inequalities)

Only 1 study explicitly reported on this outcome. The prospective cohort study by Hanson et al. (2023) reported that of the 102 patients willing to engage with a digitally enabled weight management programme (using Gro Health), that 4% (n=4) were unable to participate because of a lack of smartphone or internet.

Clinical outcomes

BMI

Six publications (related to 5 studies) reported on change in BMI (Liva N=2; Oviva N=2; Roczen N=1); 2 reporting the absolute reduction (Table 6a) and 4 studies reported on proportionate reduction (Table 6b) in BMI measured from baseline. All studies reported a statistically significant change in BMI when compared with baseline (3 of which reporting outcomes up to 12 months).

None of the studies reported on the proportion of patients changing category based on their BMI (for example, underweight, healthy, overweight, obese, severely obese).

Table 6a: Summary of publications that report an absolute reduction in BMI, kg/m2 (N=2); reported as mean (SD) [95%CI] or median {range}

					BMI: Intervention		BMI: Comparator		p-value between groups (*compared with baseline)
Author (year)	**Study design**	**Intervention**	**Comparator**	**Timepoint**	**Absolute measurement**	**Change, kg/m2**	**Absolute measurement**	**Change, kg/m2**	
Haas et al. (2019)	Before-and-after study (n=43)	Oviva	-	Baseline	30.2 {26.4,33.0)	-	-	-	-
				3 months (n=40)	28.4 {24.3,33.5}	-1.4 {-4.5,1.1}	-	-	<0.001*
				12 months (n=36)	28.0 {24.1,33.5}	-1.8 {-6.9,2.5}	-	-	<0.001*
Roczen AiC-2 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	-	-	-	-
Abbreviations: AiC, academic in confidence; BMI, body mass index; CI, confidence interval; SD, standard deviation									

Table 6b: Summary of publications that report a proportionate reduction in BMI (N=4); reported as mean (SD) [95%CI] or median {range}

					BMI: Intervention		BMI: Comparator		p-value between groups (*compared with baseline)
Author (year)	**Study design**	**Intervention**	**Comparator**	**Timepoint**	**Absolute measurement**	**Change, %**	**Absolute measurement**	**Change, %**	
Hesseldal et al. (2022)†	RCT (n=340)	Liva	Face-to-face	Baseline	34.8 (3.7)	-	36.0 (3.8)	-	-
				6 months	-	-1.5 [-1.8, -1.2]	-	-0.1 [-0.4, 0.1]	<0.001
				12 months	-	-1.5 [-1.9, -1.2]	-	-0.5 [-0.9, -0.1]	<0.001
Komkova et al. (2019)	Cohort (n=103)	Liva	-	Baseline	36.0 (5.2)	-	-	-	-
				Mean 7.3 months	-	-1.58 (2.24)	-	-	NR
Huntriss et al. (2021)	Retrospective non-randomised comparative cohort (n=169)	Oviva	Face-to-face	Baseline	49.4 (6.9)	-	47.4 (6.2)	-	-
				12 to 16 weeks	46.5 (7.0)	-	44.7 (5.5)	-	0.061
				24 to 28 weeksł	46.1 (7.2)	-	44.6 (5.4)	-	0.135
Haas et al. (2019)	Before-and-after (n=43)	Oviva	-	Baseline	30.2 {26.4,33.0}	-	-	-	-
				3 months (n=40)	28.4 {24.3,33.5}	-4.8 {-15.6 to 3.9}	-	-	<0.001*
				12 months (n=36)	28.0 {24.1,33.5}	-6.2 {-21.3 to 8.6}	-	-	<0.001*
Key: †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Christensen et al. 2022b); ł12 weeks after completion of core programme Abbreviations: BMI, body mass index; CI, confidence interval; NR, not reported; RCT, randomised controlled trial; SD, standard deviation									

Weight loss

A total of 23 publications (related to 20 studies) reported on weight loss outcomes when compared with baseline (Liva N=6; Oviva N=9; Roczen N=5):

- 2 reported on the proportion of patients with weight gain, loss or weight maintenance at follow-up (Table 7a),
- 12 reported on absolute reduction (Table 7b),
- 8 reported on relative reduction (Table 7c),
- 10 reported on the proportion of patients achieving clinically significant weight loss using a defined threshold based on percentage weight loss (for example 3% or greater) or change in BMI (for example 1 BMI unit or greater) (Table 7d).

All studies showed a mean or median reduction in weight in the intervention and the comparator arms when compared with baseline. There was significant heterogeneity in definition of clinically significant weight loss (such as a minimum definition of 3% or greater or 1 or more BMI units) and timepoints (between 4 weeks and 12 months), however the results showed that not all patients achieved a weight loss deemed clinically significant up to 12 months following programme enrolment regardless of delivery method (digitally enabled or face-to-face).

Table 7a: Summary of studies reporting the proportion of patients losing, gaining or maintaining weight (N=2).

Author (year)	Study design	Intervention	Timepoint	Weight status
Komkova et al. (2019)	Cohort (n=103)	Liva	Mean 7.3 months	Weight loss: 85.4% (88 of 103)
				Maintained weight: 1% (1 of 103)
				Weight gain: 13.6% (14 of 103)
Haas et al. (2019)	Before-and-after (n=43)	Oviva	12 months	Weight gain: 13.9% (5 of 36)

Table 7b: Summary of studies which reported absolute weight reduction, kg (N=12, shaded rows relate to publications available as abstract only), reported as mean (SD) [95%CI], or median {range}

					Weight reduction, kg: Intervention		Weight reduction, kg: Comparator		p-value between groups (*compared with baseline)
Author (year)	**Study deign (number of patients)**	**Intervention**	**Comparator**	**Timepoint**	**Absolute measurement**	**Change**	**Absolute measurement**	**Change**	
Christensen et al. (2022a)†	RCT (n=340)	Liva	Face-to-face	Baseline	103.1 (17.2)	-	103.7 (16.0)	-	-
				6 months	-	-3.9 [-4.8,-3.1]	-	-0.6 [-1.4, -0.1]	<0.001
				12 months	-	-4.6 [-5.8,-3.4]	-	-1.4 [-2.6, -0.1]	<0.001
				24 months	-	-4.4 [-6.1,-2.8]	-	-2.5 [-3.9, -1.1]	0.101
Komkova et al. (2019)	Cohort (n=103)	Liva	-	Baseline	106.8 (18.8)	-	-	-	-
				Mean 7.3 months	-	-4.8 (6.7)	-	-	NR*
McDiarmid et al. (2022)	Pilot RCT (n=79, ITT)	Oviva with intermittent low-energy diet (n=39)	Oviva with continuous low-energy diet (n=40)	Baseline	102.0 [96.3,107.7]	-	102.9 [97.3,108.6]		NR
				12 weeks	-	-5.8 [-7.4,-4.3]	-	-9.8 [-11.4,-8.3]	NR
				28 weeks	-	-6.9 [-8.6,-5.2]	-	-7.6 [-9.3,-5.9]	NR
				52 weeks	-	-5.1 [-7.1,-3.2]	-	-6.0 [-7.9,-4.0]	NR
Huntriss et al. (2021)	Non-randomised comparative cohort (n=169)	Oviva	Face-to-face	Baseline	138.3 (22.6)	-	129.9 (17.0)	-	-
				12 to 16 weeks	130.2 (22.6)	-7.9 (4.8)	122.6 (15.8)	-7.3 (5.6)	0.061
				24 to 28 weeksł	129.1 (23.4)	-9.2 (7.6)	122.3 (16.7)	-7.6 (9.3)	0.061
Haas et al. (2019)	Before-and-after (n=43)	Oviva	-	Baseline	83.5 {67.7,105.0}	-	-	-	-
				3 months (n=40)	80.3 {64.3,105.0}	-3.8 {-15.0 to 2.4}	-	-	<0.001*
				12 months (n=36)	78.7 {62.8,107.5}	-4.9 {-21.9 to 7.5}	-	-	<0.001*
Oviva CiC-3 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	-	-	-	-
				[redacted]	-	[redacted]	-	-	[redacted]
				[redacted]	-	[redacted]	-	-	[redacted]
Sutter et al. (2021) [Abstract]	Retrospective, non-randomised (n=86)	Oviva and face-to-face (hybrid n=72)	Face-to-face (n=14)	Baseline	NR	-	-	-	-
				6 months	-	-6.6 (8.5)	-	-6.4 (6.0)	^
Huntriss et al. (2020) [Abstract]	Before-and-after (n=6)	Oviva	-	Baseline	109.6 (20.0)	-	-	-	-
				3 months	-	-15.4 (NR)	-	-	<0.001
				6 months	-	-16.6 (NR)	-	-	<0.0001
Roczen AiC-2 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]				
				[redacted]	[redacted]	[redacted]	-	-	[redacted]
Falvey et al. (2023) [Abstract]	Cohort (n=753)	Roczen	-	Baseline	NR	-	-	-	-
				12 months (n=121)	-	-8.9 (7.0)	-	-	NR
Brown et al. (2022) [Abstract]	Cohort (n=653)	Roczen	-	Baseline	NR	-	-	-	-
				12 weeks	-	-7.7 (4.4)	-	-	<0.001*
				24 weeks	-	-9.5 (5.9)	-	-	
Phung et al. (2023) [Abstract]	Before-and-after (n=82)	Roczen	-	Baseline	98.6 (21.2)	-	-	-	-
				Mean (SD): 49 (24) weeks	-	-7.3 (7.2)	-	-	NR

Key: †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Hesseldal et al. 2022, Christensen et al. 2022b; Imeraj et al. 2022); ł12 weeks after completion of core programme; ^stated p<6.0 assumed typographical error;
Abbreviations: AiC, academic in confidence; CiC, commercial in confidence; CI, confidence interval; ITT, intention to treat; NR, not reported; RCT, randomised controlled trial; SD, standard deviation

Table 7c: Summary of studies which reported relative weight reduction compared with baseline (N=8, shaded rows relate to publications available as abstract only); reported as mean (SD) [95%CI], or median {range}

					Change in weight, % mean (SD) [95%CI], or median {range}	
Author (year)	**Study design**	**Intervention**	**Comparator**	**Timepoint**	**Intervention**	**Comparator**
Komkova et al. (2019)	Cohort (n=103)	Liva	-	Mean 7.3 months	-4.3% (NR)	-
Liva [CiC-1] [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	-
				[redacted]	[redacted]	-
Liva [CiC-2] [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	-
				[redacted]	[redacted]	-
				[redacted]	[redacted]	-
				[redacted]	[redacted]	-
Liva [CiC-3] [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	-
				[redacted]	[redacted]	-
				[redacted]	[redacted]	-
				[redacted]	[redacted]	-
McDiarmid et al. (2022)	Pilot RCT (n=79, ITT)	Oviva with intermittent low-energy diet (n=39)	Oviva with continuous low-energy diet (n=40)	12 weeks	-5.8% [-7.0%,-4.6%]	-9.7% [-11.0%,-8.4%]
				28 weeks	-7.1% [-9.1%,-5.1%]	-7.6% [-9.3%,-5.9%]
				52 weeks	-5.4% [-7.6%,-3.1%]	-6.0% [-7.9%,-4.0%]
Haas et al. (2019)	Before-and-after (n=43)	Oviva	-	3 months	-4.6% {-15.6%,3.3%}	-
				12 months	-6.0% {-21.3%,8.6%}	-
Oviva [CiC-1] [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	-
Oviva		[redacted]	-	[redacted]	[redacted]	-

					Change in weight, % mean (SD) [95%CI], or median {range}	
Author (year)	**Study design**	**Intervention**	**Comparator**	**Timepoint**	**Intervention**	**Comparator**
[CiC-2] [redacted]	[redacted]			[redacted]	[redacted]	-
				[redacted]	[redacted]	-
				[redacted]	[redacted]	-
				[redacted]	[redacted]	-
				[redacted]	[redacted]	-
				[redacted]	[redacted]	-

Abbreviations: CiC, commercial in confidence; CI, confidence interval; ITT, intention to treat; RCT, randomised controlled trial; SD, standard deviation

Table 7d: Summary of studies reporting the proportion of patients achieving clinically significant weight loss (threshold defined) (N=10, shaded rows relate to publications available as abstract only)

						Significant weight loss, %		
Author (year)	**Study design**	**Intervention**	**Comparator**	**Definition of significant (applied at each time point)**	**Timepoint**	**Intervention**	**Comparator**	**p-value between groups (*compared with baseline)**
Komkova et al. (2019)	Cohort (n=103)	Liva	-	≥3% to 5.9% weight loss	Mean 7.3 months	50.5% (29 of 103)	-	NR*
				≥6% weight loss	Mean 7.3 months	22.3% (23 of 103)	-	NR*
Hesseldal et al. (2022)†	RCT (n=340)	Liva	Face-to-face	>5% weight loss	6 months	38.9% (49 of 126)	8.5% (6 of 71)	<0.001
					12 months	37.8% (48 of 127)	19.2% (14 of 73)	0.01
Huntriss et al. (2021)	Retrospective non-randomised comparative cohort (n=169)	Oviva	Face-to-face	≥5% weight loss	12 to 16 weeks	71.7%	66.7%	NR
					24 to 28 weeks‡	60.9%	47.6%	NR
				≥10% weight loss	12 to 16 weeks	26.1%	28.6%	NR
					24 to 28 weeks‡	23.9%	23.8%	NR
				≥1 BMI unit loss	12 to 16 weeks	89.1%	85.7%	NR
					24 to 28 weeks‡	87.0%	76.2%	NR
Haas et al. (2019)	Before-and-after (n=43)	Oviva	-	≥5% weight loss	12 months	58.0% (21 of 36)	-	NR*
McDiarmid et al. (2022)	Pilot RCT (n=79, ITT)	Oviva and intermittent low-energy diet (n=39)	Oviva and continuous low-energy diet (n=40)	≥10% weight loss	12 months	19.0%	20.0%	NR
				≥15% weight loss	12 months	6.0%	4.0%	NR
Oviva CiC-1 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
Oviva CiC-3 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-	NR*
Oviva CiC-2 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
Roczen AiC-2 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*
				[redacted]	[redacted]	[redacted]	-	NR*

						Significant weight loss, %		
Author (year)	**Study design**	**Intervention**	**Comparator**	**Definition of significant (applied at each time point)**	**Timepoint**	**Intervention**	**Comparator**	**p-value between groups (*compared with baseline)**
				[redacted]	[redacted]	[redacted]	-	NR*
Falvey et al. (2023) [Abstract]	Cohort (n=732)	Roczen	-	≥5% weight loss	12 months	71.0%	-	-

Key: †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Christensen et al. 2022b), ł12 weeks after completion of core programme
Abbreviations: AiC, academic in confidence; BMI, body mass index; CiC, commercial in confidence; ITT, intention to treat; NR, not reported; RCT, randomised controlled trial

Body fat

Two studies reported on body fat outcome measures. Both showed an absolute reduction (Table 8a) and relative reduction (Table 8b) in percentage body fat when compared with baseline.

Table 8a: Summary of studies reporting on absolute change in body fat, kg (N=2); reported as mean (SD) [95%CI] or median {range}

				Body fat: Intervention, kg		p-value (*compared with baseline)
Author (year)	**Study design**	**Intervention**	**Timepoint**	**Absolute**	**Change, kg**	
Haas et al. (2019)	Before-and-after (n=43)	Oviva	Baseline	32.6 {25.9, 45.0kg}	-	-
			3 months (n=40)	30.6 {18.1, 46.1}	-3.3 {-10.6,2.5}	<0.001*
			12 months (n=36)	29.2 {17.2, 43.3}	-4.0 {-16.9,6.4}	<0.001*
McDiarmid et al. (2022)	Pilot RCT (n=57 patients completing programme)	Oviva and intermittent low-energy diet (n=27)	Baseline	39.7 (13.3)	-	-
			12 weeks	-	-4.2 [-5.2,-3.1]	NR*
			28 weeks	-	-5.5 [-6.9,-4.0]	NR*
			52 weeks	-	-3.2 [-4.6, -1.9]	NR*
		Oviva and continuous low-energy diet (n=30)	Baseline	41.4 (12.2)	-	-
			12 weeks	-	-7.8 [-9.2,-6.5]	NR*
			28 weeks	-	-6.3 [-8.1,-4.6]	NR*
			52 weeks	-	-4.1 [-5.7, -2.5]	NR*

Abbreviations: CI, confidence interval; NR, not reported; RCT, randomised controlled trial; SD, standard deviation

Table 8b: Summary of studies reporting on relative change in body fat, % (N=2); reported as mean (SD) [95%CI] or median {range}

				Body fat: Intervention, %		p-value (*compared with baseline)
Author (year)	**Study design**	**Intervention**	**Timepoint**	**Absolute**	**Change**	
Haas et al. (2019)	Before-and-after (n=43)	Oviva	Baseline	40.5 {27.8,48.5}	-	-
			3 months (n=40)	39.0 {22.2,45}	-2.3 {-7.6,2.5}	<0.001*
			12 months (n=36)	37.9 {21.3,46.9}	-2.5 {-11.9,3.7}	<0.001*
McDiarmid et al. (2022)	Pilot RCT (n=57 patients completing programme)	Oviva and intermittent low-energy diet (n=27)	Baseline	40.4 (7.9)	-	-
			12 weeks	-	-1.8 [-2.7,-0.9]	NR*
			28 weeks	-	-3.0 [-4.1,-1.8]	NR*
			52 weeks	-	-1.6 [-2.6,-0.5]	NR*
		Oviva and continuous low-energy diet (n=30)	Baseline	41.0 (8.5)	-	-
			12 weeks	-	-4.2 [-5.2,-3.2]	NR*
			28 weeks	-	-3.0 [-4.2,-1.8]	NR*
			52 weeks	-	-1.5 [-2.6,-0.5]	NR*

Abbreviations: CI, confidence interval; NR, not reported; RCT, randomised controlled trial; SD, standard deviation

Waist circumference

Six studies reported on the change in waist circumference (Liva N=1; Oviva N=2; Roczen N=3), Table 9. Of the 4 published studies reporting outcomes at 12 months, all reported a mean or median reduction in waist circumference when compared with baseline. Furthermore, the RCT by Hesseldal et al. (2022) reported a greater reduction in waist circumference in 200 patients receiving Liva compared with 140 receiving face-to-face specialist weight management programmes at 6 and 12 months ($p<0.001$).

Table 9: Summary of studies reporting on change in waist circumference (N=6, shaded rows relate to publications available as abstract only); reported as mean (SD), [95%CI] or median {range}

					Waist circumference, cm: Intervention		Waist circumference, cm: Comparator		p-value between groups (*compared with baseline)
Author (year)	**Study design**	**Intervention**	**Comparator**	**Timepoint**	**Absolute measurement**	**Change**	**Absolute measurement**	**Change**	
Hesseldal et al. (2022)†	RCT (n=340)	Liva	Standard care (face-to-face)	Baseline	117.7 (11.4)	-	121.2 (11.7)	-	NR
				6 months	-	-8.9 [-10.2,-7.7]	-	-3.3 [-4.8,-1.8]	<0.001
				12 months	-	-9.9 [-11.3,-8.4]	-	-4.5 [-6.6,-2.5]	<0.001
McDiarmid et al. (2022)	Pilot RCT (n=57 patients completing programme)	Oviva with intermittent low-energy diet (n=27)	Oviva with continuous low-energy diet (n=29)	Baseline	114.6 (12.5)	-	116.0 (12.2)	-	NR
				12 weeks	-	-7.0 [-8.9,-5.0]	-	-9.8 [-11.5,-8.1]	NR
				28 weeks	-	-7.8 [-9.8,-5.9]	-	-8.5 [-10.0,-7.0]	NR
				52 weeks	-	-5.7 [-8.0,-3.5]	-	-6.9 [-8.9,-5.0]	NR
Haas et al. (2019)	Before-and-after study (n=43)	Oviva	-	Baseline	92.0 {74.0,112.0}	-	-	-	-
				3 months (n=40)	85.9 {73.3,108.0}	-3.5 {-23.0,5.0}	-	-	<0.001*
				12 months (n=36)	86.5 {78.5,110.5}	-3.8 {-17.8,9.0}	-	-	<0.001*
Roczen AiC-2 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	-	-	-	-
						-	-	-	[redacted]
Brown et al. (2022) [Abstract]	Cohort (n=653)	Roczen	-	Baseline	NR	-	-	-	-
				6 months (n=NR)	-	-11.0 (7.5)	-	-	<0.001*
Falvey et al. (2023) [Abstract]	Cohort (n=732)	Roczen	-	Baseline	NR	-	-	-	-
				12 months (n=101)	-	-10.9 (13.6)	-	-	NR*

Key: †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Christensen et al. 2022b)
Abbreviations: AiC, academic in confidence; CI, confidence interval; NR, not reported; RCT, randomised controlled trial

Hip circumference

Two studies reported on change in hip circumference (Liva N=1; Oviva N=1), Table 10. Both reported a reduction in hip circumference at 1 year when compared with baseline. Furthermore, the RCT by Hesseldal et al. (2022) reported a greater reduction in hip circumference in 200 patients receiving Liva compared with 140 receiving face-to-face specialist weight management programmes at 6 and 12 months ($p<0.001$).

Waist-to-hip ratio

No study reported waist-to-height ratio, however 1 study reported on change in waist-to-hip ratio circumference (Hesseldal et al. 2022), Table 11. Authors reported no evidence of a difference in this outcome measure between patients using Liva and those receiving standard care (face-to-face only) at 6- and 12- month timepoints.

Table 10: Summary of studies reporting on change in hip circumference (N=2); reported as mean (SD) [95%CI]

Author (year)	Study design	Intervention	Comparator	Timepoint	Hip circumference, cm: Intervention		Hip circumference, cm: Comparator		p-value between groups (*compared with baseline)
					Absolute	Change	Absolute	Change	
Hesseldal et al. (2022)†	RCT (n=340)	Liva	Standard care (face-to-face)	Baseline	121.1 (9.6)	-	121.7 (10.2)	-	-
				6 months	-	-5.5 [-6.5,-4.6]	-	-1.9 [-3.1,-0.7]	<0.001
				12 months	-	-5.9 [-7.0,-4.8]	-	-2.4 [-3.8,-1.0]	<0.001
McDiarmid et al. (2022)	Pilot RCT (n=57 patients completing programme)	Oviva with intermittent low-energy diet (n=27)	Oviva with continuous low-energy diet (n=29)	Baseline	117.4 (13.4)	-	120.4 (13.6ǂ)	-	-
				12 weeks	-	-5.5 [-6.9,-4.1]	-	-7.6 [-8.8,-6.4]	NR
				28 weeks	-	-5.8 [-7.9,-3.7]	-	-7.1 [-8.7,-5.4]	NR
				52 weeks	-	-4.4 [-6.4,-2.5]	-	-5.2 [-6.8,-3.6]	NR

Key: †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Christensen et al. 2022b); ǂEAG assumed typographical error in paper, SD stated as 113.6
Abbreviations: CI, confidence interval; RCT, randomised controlled trial; SD, standard deviation

Table 11: Summary of studies reporting on change in waist-to-hip ratio (N=1) reported as mean (SD) [95%CI]

Author (year)	Study design	Intervention	Comparator	Timepoint	Waist:hip ratio: Intervention		Waist:hip ratio: Comparator		p-value between groups (*compared with baseline)
					Absolute	Change	Absolute	Change	
Hesseldal et al. (2022)	RCT (n=340)	Liva	Standard care (face-to-face)	Baseline	1.0 (0.1)	-	1.0 (0.1)	-	-
				6 months	-	-0.03 [-0.04,-0.02]	-	-0.01 [-0.03,0.00]	0.05
				12 months	-	-0.04 [-0.05,-0.02]	-	-0.02 [-0.04,-0.00]	0.11

Abbreviations: CI, confidence interval; RCT, randomised controlled trial; SD, standard deviation

Glycated haemoglobin (HbA1c)

Eleven studies reported on change in HbA1c from baseline (Liva N=3; Oviva N=4; Roczen N=4):

- 7 reporting on an absolute change in HbA1c from baseline, Table 12a;
- 2 reporting on relative change in HbA1c, Table 12b;
- 3 reporting on the proportion achieving a significant reduction in HbA1c defined by a threshold, Table 12c.

The EAG note that only 4 of 11 publications reported exclusively in a diabetic population, which may confound results.

Table 12a: Summary of studies reporting in change in HbA1c, in mmol/mol, mean (SD) [95%CI] or median {range} (N=7, shaded rows relate to publications available as abstract only)

					HbA1c, mmol/mol: Intervention		**HbA1c, mmol/mol: Comparator**		**p-value between groups (*compared with baseline)**
Author (year)	**Study design**	**Intervention**	**Comparator**	**Timepoint**	Absolute measurement	Change	Absolute measurement	Change	
Christensen et al. (2022a)†	RCT (n=340)	Liva	Face-to-face	Baseline	48.9 (12.6)	-	47.6 (12.3)	-	-
				6 months	-	-4.7 [-6.4,-3.1]	-	-4.3 [-6.3,-2.4]	0.51
				12 months	-	-6.0 [-7.8,-4.3]	-	-4.7 [-7.3,-2.3]	0.34
				24 months	-	-3.1 [-5.0,-1.2]	-	-0.2 [-2.4,-2.0]	0.22
McDiarmid et al. (2022)‡	Pilot RCT (n=79, ITT)	Oviva and intermittent low-energy diet (n=39)	Oviva and continuous low-energy diet (n=40)	Baseline	60.3 [56.4, 64.2]	-	63.1 [59.2, 66.9]	-	-
				12 weeks	-	-9.9 [-13.4, -6.5]	-	-15.0 [-18.2,-11.6]	NR
				28 weeks	-	-9.6 [-13.2, -6.1]	-	-11.6 [-15.0,-8.2]	NR
				52 weeks	-	-7.9 [-11.5, -4.2]	-	-8.5 [-12.0,-4.9]	NR
Huntriss et al. (2020)‡ [Abstract]	Before-and-after (n=6)	Oviva	-	Baseline	72.3 (21.0)	-	-	-	-
				3 months	-	-29.3 (NR)	-	-	0.007
				6 months	-	-24.3 (NR)	-	-	0.001
Roczen AiC-2 [redacted]	[redacted]	[redacted]	-	[redacted]	[redacted]	-	-	-	-
						-	-	-	[redacted]
						-	-	-	[redacted]
Brown et al. (2022) [Abstract]	Cohort (n=653)	Roczen	-	Baseline	42.4 (12.5)	-	-	-	-
				NR	-	All patients: -4.5 (7.4) T2DM (n=56): -8.7 (9.2)	-	-	0.05 0.07
Falvey et al. (2023) [Abstract]	Cohort (n=732)	Roczen	-	Baseline	NR	-	-	-	-
				6 months	-	-10.8 (NR)	-	-	NR
				12 months	-	-15.1 (NR)	-	-	NR
Phung et al. (2023)‡ [Abstract]	Before-and-after (n=82)	Roczen	-	Baseline	57.0 (9.7)	-	-	-	-
				Mean (SD): 49 (24) weeks	-	-6.1 (9.5)	-	-	NR

Key: ‡exclusively diabetic population; †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Hesseldal et al. 2022, Christensen et al. 2022b)
Abbreviations: AiC, academic in confidence; CI, confidence interval; HbA1c, glycated haemoglobin; ITT, intention to treat; NR, not reported; RCT, randomised controlled trial; SD, standard deviation; T2DM, Type 2 diabetes mellitus

Table 12b: Summary of studies reporting in change in HbA1c, in %, (N=3, shaded rows relate to publications available as abstract only)

					Absolute HbA1c, % mean (SD)		
Author (year)	**Study design**	**Intervention**	**Comparator**	**Timepoint**	**Intervention**	**Comparator**	**p-value between groups (*compared with baseline)**
Tsai et al. (2023) [Abstract]	Non-randomised cohort (n=63)	Liva	-	Baseline	7.41	-	-
				3 months	7.02	-	NR*
Haas et al. (2019)	Before-and-after (n=43)	Oviva	-	Baseline	5.2 {4.7,5.9}	-	-
				3 months	5.1 {4.6,5.8}	-	0.36*
				12 months	5.2 {4.6,5.8}	-	0.08*
Sutter et al. (2020)‡ [Abstract]	Retrospective non-randomised cohort (n=166)	Oviva and face-to-face (n=52)	Face-to-face (n=114)	Baseline	8.1 (2.1)	7.9 (1.6)	-
				Between 3 and 12 months (according to local diabetes review schedules)	6.4 (0.8)	6.9 (1.2)	<0.05

Key: *compared with baseline; †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Hessedal et al. 2022, Christensen et al. 2022b); ‡exclusively diabetic population
Abbreviations: HbA1c, glycated haemoglobin; NR, not reported; SD, standard deviation

Table 12c: Summary of study reporting on the proportion of patients achieving a significant reduction in HbA1c (N=2)

						Significant reduction in HbA1c, %		
Author (year)	**Study design**	**Intervention**	**Comparator**	**Definition of significant reduction in HbA1c**	**Timepoint**	**Intervention**	**Comparator**	**p-value***
McDiarmid et al. (2022)‡	Pilot RCT (n=79, ITT)	Oviva and intermittent low-energy diet	Oviva and continuous low-energy diet	HbA1c <48 mmol/mol	12 months	42%	42%	NR
Hesseldal et al. (2022)†	RCT (n=340)	Liva	Standard care (face-to-face)	Reduction from >6.5% to <6.5%	6 months [with T2DM]	34.9% (22 of 63)	26.5% (9 of 34)	0.39
					12 months [with T2DM]	35.5% (22 of 62)	27.8% (10 of 36)	0.43

Key: *compared with baseline; †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Christensen et al. 2022b); ‡exclusively diabetic population
Abbreviations: HbA1c, glycated haemoglobin; ITT, intention to treat; NR, not reported; RCT, randomised controlled trial; T2DM, Type 2 diabetes mellitus

Physical activity

Two studies reported on the physical activity (Liva N=1, Oviva N=1), but used different measures at different timepoints, Table 13. The RCT by Christensen et al. (2022b) reported no evidence of a difference in moderate or everyday exercise between patients using Liva and those receiving standard care (face-to-face) at 6 months. The before-and-after study by Haas et al. (2019) reported a statistically significant change in Global Physical Activity Questionnaire (GPAQ) recreational activities metabolic equivalent minutes per week at 12 months when compared with baseline, but not in moderate to vigorous physical activity minutes at 3 or 12 months when compared with baseline for 43 patients using Oviva. Additionally, the authors reported no statistically significant change in activity at work or travel to and from places over the year, however no results were explicitly reported. It is possible that this result should be interpreted as the study providing imprecise data and failing to detect clinically important differences rather than as there being no difference.

Table 13: Summary of studies reporting on changes on physical activity (N=2); reported as mean (SD) [95%CI] or median {range}

						Intervention		Comparator		p-value between groups (*compared with baseline)
Author (year)	**Study design (n)**	**Intervention**	**Comparator**	**Physical activity measure**	**Timepoint**	**Absolute measurement**	**Change**	**Absolute measurement**	**Change**	
Christensen et al. (2022b)	RCT (n=170)	Liva (n=100)	Standard care (face-to-face, n=70)	Moderate exercise†	Baseline	2.41 (1.22)	-	2.54 (1.34)	-	-
					6 months	-	0.62 [0.33,0.90]	-	0.49 [0.10,0.87]	0.600
				Everyday exercise‡	Baseline	4.20 (1.76)	-	4.27 (1.67)	-	-
					6 months	-	0.41 [-0.06,0.88]	-	-0.08 [-0.62,0.46]	0.210
Haas et al. (2019)	Before-and-after (n=43)	Oviva (n=43)	-	GPAQ: total moderate-vigorous physical activity, MET min/week	Baseline	1,920 {NR}	-	-	-	-
					3 months	2,360 {NR}	-	-	-	0.060*
					12 months	2,740 {NR}	-	-	-	0.150*
				GPAQ: recreational activities, MET-min/week	Baseline	960 {NR}	-	-	-	-
					12 months	1,700 {NR}	-	-	-	0.007*

Key: †score 1 (worst) to 5 (best); ‡score 1 (worst) to 7 worst)
Abbreviations: CI, confidence interval; GPAQ, Global Physical Activity Questionnaire; MET-min, metabolic equivalent minutes per week; SD standard deviation

Eating habits

Three studies reported on eating habits (Liva N=1, Oviva N=2), however they reported on different measures at different timepoints, Table 14. The RCT by Christensen et al. (2022b) reported a statistically significant difference in quantity of fruit consumption between patients using Liva and standard care (face-to-face) at 6 months. However, the study found no evidence of a difference in eating sweets, eating fish or eating vegetables. The before-and-after study by Haas et al. (2019) used an 11-item simplified food frequency questionnaire to monitor food intake in 43 patients using Oviva. The authors reported higher fruit, vegetable, breakfast consumption, and lower alcohol, sweet and fat consumption at 3 and 12 months (when compared with baseline); however, no results were explicitly reported. The authors also reported a statistically significant reduction in total score for dietary consumption which indicated a healthier diet at both 3 months ($p<0.001$) and 12 months ($p<0.001$) when compared with baseline.

Table 14: Summary of study reporting on eating habits reported (N=3); reported as mean (SD), [95%CI] or median {range}

					Intervention		Comparator		p-value between groups (*compared with baseline)
Author (year)	**Intervention**	**Comparator**	**Eating habits**	**Timepoint**	**Absolute measurement**	**Change from baseline**	**Absolute measurement**	**Change from baseline**	
Christensen et al. (2022b)	Liva (n=100)	Standard care (face-to-face, n=70)	Eating sweets†	Baseline	2.89 (1.09)	-	2.59 (1.16)	-	-
				6 months	-	0.27 [0.05,0.50]	-	0.46 [0.19,0.73]	0.310
			Eating fish†	Baseline	1.67 (0.86)	-	1.67 (0.86)	-	-
				6 months	-	0.37 [0.20,0.54]	-	0.18 [-0.03,0.39]	0.180
			Eating fruit†	Baseline	2.17 (0.96)	-	2.68 (0.91)	-	-
				6 months	-	0.38 [0.15,0.62]	-	-0.03 [-0.30,0.25]	0.040
			Eating vegetables†	Baseline	2.68 (0.93)	-	2.71 (0.90)	-	-
				6 months	-	0.49 [0.29,0.69]	-	0.18 [-0.11,0.47]	0.080
Haas et al. (2019)	Oviva (n=43)	-	Dietary consumptionǂ	Baseline	6.0 {NR}	-	-	-	-
				3 months	4.0 {NR}	-	-	-	<0.001*
				12 months	4.0 {NR}	-	-	-	<0.001*
McDiarmid et al. (2022)	Oviva with intermittent low-energy diet (n=27)	Oviva with continuous low-energy diet (n=30)	Mediterranean diet score (from 0 to 12)	Baseline	5.3 (2.2)	-	6.2 (1.6)	-	-
				12 weeks	-	3.2 [2.2,4.1]	-	2.2 [1.5,2.9]	NR
				28 weeks	-	2.9 [1.9,3.9]	-	2.2 [1.4,2.9]	NR
				12 months	-	2.4 [1.5,3.3]	-	2.1 [1.3,2.9]	NR

Key: *between groups; †score 1 (worst) to 4 (best); ǂ11-item simplified food frequency questionnaire to monitor food intake
Abbreviations: CI, confidence interval; SD, standard deviation

Outcomes not reported

No study reported on intervention-related adverse events, cardiovascular events, mortality, or rate of referral for weight loss surgery clinical outcomes. These outcomes may inform future economic evaluations (see Section 7).

Relating to rate of referral for weight loss surgery, 4 Companies (Liva, Wellbeing Way, Roczen, Second Nature) advise that they do not have access to or monitor this data. Liva noted that this data could be captured with local health record data sharing. Gro Health report progression to weight loss surgery is captured within their platform and current rates are 24.4% (2022). Oviva reported around 10% of completers within delivery of an NHS Tier 3 specialist weight management in Wakefield between 2017 and 2020 progressed to weight loss surgery. CheqUp reported [redacted] (Appendix E).

Additional outcomes

The EAG note that additional objective measures were reported in the identified publications, including:

- Fasting blood glucose (Haas et al. 2019; McDiarmid et al. 2022);
- Fasting insulin (Haas et al. 2019);
- Total cholesterol (Christensen et al. 2022b; Hesseldal et al. 2022; McDiarmid et al. 2022);
- High-density lipoprotein, HDL (Christensen et al. 2022b; Haas et al. 2019; McDiarmid et al. 2022; Hesseldal et al. 2022);
- Low-density lipoprotein, LDL (Christensen et al. 2022b; Hesseldal et al. 2022; McDiarmid et al. 2022);
- Triglycerides (Christensen et al. 2022b; Hesseldal et al. 2022; McDiarmid et al. 2022);
- Systolic blood pressure (Brown et al. 2022; Christensen et al. 2022b; Falvey et al. 2023; Haas et al. 2019; Hesseldal et al. 2022; McDiarmid et al. 2022);

- Diastolic blood pressure (Brown et al. 2022; Christensen et al. 2022b; Falvey et al. 2023; Haas et al. 2019; Hesseldal et al. 2022; McDiarmid et al. 2022).

Patient reported outcomes

Health-related quality of life

Eight publications (related to 7 studies) reported on health-related quality of life (Liva N=1, Oviva N=2, Roczen N=4), each using different measures across different timepoints. Six studies are summarised in Table 15 (noting that Falvey et al. 2023 reported a reduction in PHQ-9 and Binge Eating Scales, however did not report any results).

The RCT by Hesseldal et al. (2022) reported that there was no evidence of a statistically significant change in EQ-5D-5L or Short Warwick-Edinburgh Mental Wellbeing scale between patients in those receiving Liva and those receiving standard care (face-to-face) at 6 or 12 months when compared with baseline. The before-and-after study by Haas et al. (2019) reported no evidence of change in mental or physical component summary scores (from SF-12) at 3 months when compared with baseline. However, Lawson et al. (2023) reported a statistically significant change in PHQ-9 at 3 and 6 months when compared with baseline, and that 20% of users reported a clinically significant change in PHQ-9 (reduction by 5 score or more) at 3 months, and 37% at 6 months. The abstract by Brown et al. (2022) also reported statistically significant improvements in depression, anxiety, emotional eating and binge eating scores at 6 months with Roczen when compared with baseline, however the tools used and baseline measurements were not explicitly reported.

Table 15: Summary of studies reporting health-related quality of life (N=6, shaded rows relate to publications available as abstract only); reported as mean (SD) [95%CI], median {IQR}

					Intervention		Comparator		p-value between groups (*compared with baseline)
Author (year)	**Study design**	**Intervention**	**Measure**	**Timepoint**	**Absolute**	**Change**	**Absolute**	**Change**	
Hesseldal et al. (2022)†	RCT (n=340)	Liva	EQ-5D-5L	Baseline	0.8 (0.1)	-	0.8 (0.1)	-	-
				6 months	-	0.0 [0.0,0.0]	-	0.0 [0.0,0.0]	0.14
				12 months	-	0.0 [0.0,0.0]	-	0.0 [0.0,0.0]	0.47
			SWEMWBS	Baseline	24.9 (3.2)	-	24.5 (3.9)	-	-
				6 months	-	-0.3 [-0.9,0.3]	-	0.3 [-0.6,1.2]	0.27
				12 months	-	0.4 [-0.2,1.0]	-	0.3 [-0.6,1.2]	0.84
Haas et al. (2019)	Before-and-after (n=43)	Oviva	SF-12 (MCS)	Baseline	53.2 (NR)	-	-	-	-
				3 months	54.9 (NR)	-	-	-	0.09*
			SF-12 (PCS)	Baseline	53.0 (NR)	-	-	-	-
				3 months	55.2 (NR)	-	-	-	0.08*
Lawson et al. (2022)	Before-and-after (n=54)	Oviva	PHQ-9	Baseline	9.3 (NR)	-	-	-	-
				3 months	7.3 (NR)	-	-	-	0.0026*
				6 months	6.9 (NR)	-	-	-	0.0022*
Roczen [AiC-1] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-	-	-	-
					-	[redacted]	-	-	[redacted]
					[redacted]	-	-	-	-
					-	[redacted]	-	-	[redacted]

Author (year)	Study design	Intervention	Measure	Timepoint	Intervention		Comparator		p-value between groups (*compared with baseline)
					Absolute	Change	Absolute	Change	
			[redacted]	[redacted]	[redacted]	-	-	-	-
				[redacted]	-	[redacted]	-	-	[redacted]
Roczen AiC-2 [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-	-	-	-
				[redacted]	[redacted]	[redacted]	-	-	[redacted]
			[redacted]	[redacted]	[redacted]	-	-	-	-
				[redacted]	[redacted]	[redacted]	-	-	[redacted]
			[redacted]	[redacted]	[redacted]	-	-	-	-
				[redacted]	[redacted]	[redacted]	-	-	[redacted]
			[redacted]	[redacted]	[redacted]	-	-	-	-
				[redacted]	[redacted]	[redacted]	-	-	[redacted]
			[redacted]	[redacted]	[redacted]	-	-	-	-
				[redacted]	[redacted]	[redacted]	-	-	[redacted]
Brown et al. (2022) *[Abstract]*	Cohort (n=653)	Roczen	Depression	Baseline	NR	-	-	-	-
				6 months	-	-2.2 (3.4)	-	-	<0.001*
			Anxiety	Baseline	NR	-	-	-	-
				6 months	-	-1.9 (4.0)	-	-	<0.001*
				Baseline	NR	-	-	-	-

					Intervention		Comparator		p-value between groups (*compared with baseline)
Author (year)	**Study design**	**Intervention**	**Measure**	**Timepoint**	**Absolute**	**Change**	**Absolute**	**Change**	
			Emotional eating	6 months	-	-0.7 (0.8)	-	-	<0.001*
			Binge eating score	Baseline	NR	-	-	-	-
				6 months	-	5.9 (8.1)	-	-	<0.001*

Key: †The EAG considered results from this paper which included longer follow-up than other papers reporting from the same study (Christensen et al. 2022b);
Abbreviations: AiC, academic in confidence; CI, confidence interval; IQR, interquartile range Q1,Q3; MCS, mental component summary; NR, not reported, PCS, physical component summary; PHQ-9, 9-question Patient Health Questionnaire; RCT, randomised controlled trial; SD, standard deviation; SF-12, short form survey 12-item; SWEMWBS, Short Warwick-Edinburgh Mental Wellbeing scale, TFEQ, Three Factor Eating Questionnaire

Patient satisfaction

Five publications reported on treatment satisfaction (Liva N=2, Oviva N=3), each measured satisfaction differently. Four publications are summarised in Table 16 (noting that Liva CiC-1 [redacted]).

Table 16: Summary of studies reporting satisfaction (N=4, shaded rows relate to publications available as abstract only); reported as mean (SD)

Author (Year)	Study design	Intervention	Measure	Results
Liva [CiC-2] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Huntriss et al. (2021)	Non-randomised comparative cohort (n=169)	Oviva	Family and friends test (score out of 10)†	Oviva: 9.6 (0.8) Face-to-face: 10 (0) Phone: 10 (0) p=0.261 (between groups)
Papathanail et al. (2022) [Abstract]	Cohort (n=24)	Oviva	Questionnaire	- 83.3% (20 of 24) expressed interest in using the newly developed (AI component providing nutrition care) feature - 87.5% (21 of 24) reporting that the recording of daily meals was straight forward and self-explanatory - 95.8% (23 of 24) were satisfied with weekly Mediterranean diet adherence report (score and personalised suggestions how to improve).
Huntriss et al. (2020) [Abstract]	Before-and-after (n=9)	Oviva	Acceptability	Remote support and app acceptable to all 6 patients who completed the 6-month programme. Patient goals reported as weight-loss, reduced medication and remission. Participants reported tolerating the low-calorie diet, liked the 'strict rules', and improved mood with food introduction through challenges meeting calorie targets.

Key: †Administered by text message, resulting in low response rate (24.9%)
Abbreviations: AI, artificial intelligence; CiC, commercial in confidence; SD, standard deviation

Health resource use

Healthcare appointments

One study reported on healthcare appointments. The retrospective non-randomised comparative cohort by Huntriss et al. (2021) reported a statistically significant difference in the mean number of psychology support sessions undertaken between patients using a Tier 3 specialist weight management service delivered by phone (0.8; SD 1.7) compared with face-to-face (2.2; SD 2.2) or digitally enabled programme using Oviva (2.2; SD 2.0), p=0.03. However, the authors also reported that there was no evidence of a statistically significant association between weight loss and the number of psychology sessions. The EAG notes that the number of patients in the telephone group was small (n=12).

Medication use

Five publications (2 from the same RCT) reported on medication use (Liva N=2, Oviva N=2, Roczen N=1), however each reported differently:

- Liva: The RCT by Hesseldal et al. (2022) reported that in general there was no evidence of a statistically significant difference between defined daily dose of glucose and blood pressure lowering medications between patients using Liva and those receiving standard care (face-to-face) at 12 months, other than for dipeptidyl peptidase-4 inhibitors (DPP4s), Table 17. Christensen et al. 2022b reported that there was a statistically significant difference in glucose-lowering medication status between arms at 6 months, but no evidence of a changes in cholesterol-lowering or blood pressure-lowering medication, Table 18.
- Oviva: The pilot RCT by McDiarmid (2022), comparing intermittent low-energy diet and Oviva, with continuous low-energy diet and Oviva, reported no change in the medication effect score (MES) from baseline to 12 months across arms, Table 19, no results from statistical analysis were reported. The study also reported a reduction in diabetes medication (including metformin and insulin) in 15% (6 of 39) of patients in the intermittent low-energy diet arm, and in 43% (17 of 40) in the continuous low energy diet arm. The cohort study by Huntriss et

al. 2020 (available in abstract only) also reported 4 patients with T2DM who completed 6 months follow-up, achieved remission, which was defined as HbA1c less than 48 mmol/mol without taking medications excluding metformin. It also reported that 4 of 5 patients who were on diabetes or blood pressure medications at baseline had stopped or reduced them at 6 months. Medications stopped included liraglutide (n=1), metformin (n=1), ramipril (n=1), amlodipine (n=1), telmisartan (n=1). Oviva CiC-2 [redacted]

- Roczen: The before-and-after study by Phung et al. (2023) (available in abstract only) reported that for those starting on anti-hyperglycaemic medication, 11% (n=9) had a dose reduction of 1 medication, and 4.9% (n=4) had a reduction in more than 1 medication.

Table 17: Summary of studies reporting change in defined daily dose of medication (N=1); reported as mean (SD) [Note baseline values not reported]

		Change in medication compared with baseline, defined daily dose; mean (SD)			
Author (year)	**Medication**	**Intervention group**	**Comparator group**	**Total**	**p-value**
Hesseldal et al. (2022) [Liva at 12 months]	Glucose lowering	-0.02 (0.45)	-0.01 (0.36)	-0.01 (0.42)	0.89
	- Metformin	-0.01 (0.17)	-0.04 (0.20)	-0.02 (0.18)	0.20
	- SGLT2	0.01 (0.14)	0.03 (0.22)	0.02 (0.17)	0.39
	- Insulin	-0.04 (0.25)	-0.01 (0.11)	-0.03 (0.21)	0.43
	- GLP-1	0.03 (0.23)	-0.01 (0.13)	0.01 (0.20)	0.19
	- DPP4	-0.02 (0.15)	0.03 (0.16)	-0.01 (0.16)	0.03
	- Sulfonylurea	0.02 (0.18)	0.00 (0.00)	0.01 (0.14)	0.45
	Blood pressure lowering	-0.05 (0.46)	-0.24 (1.13)	-0.12 (0.78)	0.11
	- ARB+ACE	-0.01 (0.24)	-0.17 (0.93)	-0.07 (0.59)	0.06
	- Calcium antagonist	-0.02 (0.32)	-0.02 (0.18)	-0.02 (0.28)	0.94
	- Diuretics	-0.02 (0.12)	-0.04 (0.20)	-0.03 (0.16)	0.45
	- Beta blocker	0.00 (0.00)	-0.00 (0.04)	-0.00 (0.02)	0.19

Abbreviations: ARB, angiotensin receptor blocker; ACE, angiotensin-converting enzyme inhibitors; DPP4, dipeptidyl peptidase-4 inhibitors; GLP-1, glucagon-like peptide-1 receptor agonist; SD, standard deviation; SGLT2, sodium-glucose co-transporter 2 inhibitor

Table 18: Summary of studies reporting a change in proportion of patients decreasing or stopping, or increasing or starting medication (N=1)

		Change in medication (compared with baseline)			
Author (year)	**Medication**	**Change**	**Intervention**	**Comparator**	**p-value**
Christensen et al. (2022b) [Liva at 6 months]	Glucose--lowering	Decreased or stopped	14.9% (11 of 74)	2.4% (1 of 41)	0.015
		Increased or started	2.7% (2 of 74)	17.1% (7 of 41)	0.021
	Cholesterol--lowering	Decreased or stopped	1.4% (1 of 74)	4.9% (2 of 41)	0.260
		Increased or started	4.1% (3 of 74)	7.3% (3 of 41)	0.460
	Blood pressure--lowering	Decreased or stopped	0% (0 of 74)	2.4% (1 of 41)	0.180
		Increased or started	2.7% (2 of 74)	0.0% (0 of 41)	0.290

Healthcare professional grade and time

The pilot RCT by McDiarmid et al. (2022) (comparing intermittent and continuous low-energy diets, both arms using Oviva) was the only study to report on the composition of the MDT support. The combined results across both arms are shown in Table 20. The authors also reported that 10 of 79 (13%) patients requested face-to-face contact with the dietitian in addition to the digitally enabled weight management programme and telephone support provided; the reasons for this were not reported.

Table 19: Summary of studies reporting change in medication effect score (N=1), reported as mean [95% CI]

					Intervention		Comparator		p-value between groups (*compared with baseline)
Author (year)	**Study design**	**Intervention**	**Comparator**	**Timepoint**	**Absolute measurement**	**Change**	**Absolute measurement**	**Change**	
McDiarmid et al. (2022)	Pilot RCT (n=79)	Oviva with intermittent low-energy diet	Oviva with continuous low-energy diet	Baseline	1.2 [0.9, 1.5]	-	1.4 [1.1, 1.7]	-	NR
				12 weeks	-	-0.2 [-0.5, 0.0]	-	-0.7 [-1.0, -0.5]	NR
				28 weeks	-	-0.2 [-0.5, 0.05]	-	-0.6 [-0.8, -0.3]	NR
				52 weeks	-	0.0 [-0.3, 0.3]	-	-0.5 [-0.8, -0.3]	NR

Key: *between groups
Abbreviations: ARB, angiotensin receptor blocker; ACE, angiotensin-converting enzyme inhibitors; CI, confidence interval; DPP4, dipeptidyl peptidase-4 inhibitors; GLP-1, glucagon-like peptide-1 receptor agonist; NR, not reported; RCT, randomised controlled trial; SD, standard deviation; SGLT2, sodium-glucose co-transporter 2 inhibitor

Table 20: Summary of studies which reported the grade and time of healthcare professionals (N=1)

Author (year)	Study design	Healthcare professional	Timepoint	Average time spent, hours (mean, 95% CI)	Requested face-to-face contact	Received input
McDiarmid et al. (2022) [Oviva]	Pilot RCT (n=79†)	Dietitian	Baseline to 28 weeks	8.8 (8.3, 9.3)	12.7% (10 of 79)	-
			29 to 52 weeks	3.6 (3.3, 4.0)	3.8% (3 of 79)	-
			Baseline to 52 weeks	12.4 (11.8, 13.0)	12.7% (10 of 79)	-
		Diabetes nurse	Baseline to 52 weeks	-	-	63.3% (50 of 79)
		Clinical psychologist	Baseline to 52 weeks	-	-	40.5% (32 of 79)
		Exercise specialist	Baseline to 52 weeks	-	-	93.7% (74 of 79)

Key: †Results reported for both arms of pilot RCT combined (continuous low-energy diet with Oviva, intermittent low-energy diet with Oviva)
Abbreviations: CI, confidence interval

5.4 *Ongoing studies*

Twenty ongoing studies were identified for 4 of the 8 technologies (Gro Health N=10, Liva N=4, Oviva N=4, and Second Nature N=2) from trial registries, manufacturer websites and shared directly by the Companies to NICE, Table21. Two additional studies, 1 using Low Carb programme and 1 using a Liva health coach only were identified (Appendix C), however this was not tabulated in Table 21 as the intervention is considered out of Scope of this EVA. No ongoing trials were identified by the EAG for CheqUp, Juniper, Roczen, or Wellbeing Way. At fact check Roczen confirmed that an ongoing real-world evidence study evaluating 1-year change in HbA1c, diabetes remission and change in diabetes medication outcomes in patients with T2DM and pre-diabetes is ongoing. Additionally, a longitudinal study, with outcomes up to 2 years evaluating weight loss maintenance and other health benefits, is ongoing. These studies have not been tabulated because of a lack of detail and information provided after submission of the EAG report.

Alignment with the NICE Scope could not be defined for all ongoing studies because of poor reporting or lack of available published information (Appendix C). Although the EAG note that UK audits or real-world studies relating to the technologies within specialist weight management services may provide evidence for the outcomes.

Table 21: Cross-tabulation of ongoing trials against outcomes (N=20; shaded rows not relevant to scope)

					Intermediate measures					Clinical outcomes											PROMs		Health resource use		
Study title [ref]	Study design (number of patients); [estimated completion date] Country	Population	Intervention	Comparator	Engagement with the programme	Intervention adherence, attrition, completion	Intervention-related adverse events	Weight management medication adherence	Inaccessibility to intervention	BMI	Weight loss	Body fat	Waist circumference	Hip circumference	Waist-to-hip ratio	Glycated haemoglobin (HbA1c)	Cardiovascular events	Mortality	Physical activity	Rate of referral for weight loss surgery	Eating habits	Patient reported outcomes	Satisfaction	Healthcare appointments	Medication use	Healthcare professional grade and time
*Gro Health [Ongoing-1]	[redacted]	NR	GREEN (Gro Health)	GREEN		✓					✓											✓				
*Gro Health [Ongoing-2]	[redacted]	NR	GREEN (Gro Health)	GREEN		✓					✓											✓				
*Gro Health [Ongoing-3]	[redacted]	NR	GREEN (Gro Health)	GREEN																				✓ cost-analysis		
*Gro Health [Ongoing-4]	[redacted]	NR	GREEN (Gro Health)	GREEN	✓																	✓				
*Gro Health [Ongoing-5]	[redacted]	NR	GREEN (Gro Health)	GREEN							✓					✓						✓				
*Gro Health [Ongoing-6]	[redacted]	NR	GREEN (Gro Health)	GREEN																						
*Gro Health [Ongoing-7]	[redacted]	NR	GREEN (Gro Health)	GREEN																						
*Gro Health [Ongoing-8]	[redacted]	NR	GREEN (Gro Health)	AMBER		✓					✓					✓									✓	
*Gro Health [Ongoing-9]	[redacted]	NR	GREEN (Gro Health)	NR		✓					✓					✓									✓	
*Gro Health [Ongoing-10]	[redacted]	NR	GREEN (Gro Health)	NR		✓					✓					✓									✓	
Digital Individualized and Collaborative Treatment of T2D in General Practice Based on Decision Aid (DICTA) [NCT04880005]	RCT (n=600) [May 2024] Denmark	RED	AMBER (Liva)	GREEN							✓				✓	✓			✓			✓			✓	
Bump2Baby and Me [ACTRN12620001240932]	RCT (n=800) [June 2024] UK, Ireland, Australia, Spain	RED	AMBER (Liva)	GREEN						✓	✓					✓			✓			✓				
*Clinical study assessing effectiveness of Liva compared to usual care	Prospective cohort (n=NR) [2024] UK	GREEN	GREEN (Liva)	GREEN																						
*Prevention Study	3-arm comparative cohort (n=NR) [July 2023] Denmark	NR	GREEN (Liva)	AMBER						✓														✓ Health resource use		
The DR-EAM Type 2 Diabetes Study [NCT05626842]	Cohort, with matched control arm (n=197) [September 2023] UK	AMBER	GREEN (Oviva)	RED						✓	✓					✓			✓			✓	✓			

					Intermediate measures					Clinical outcomes											PROMs		Health resource use		
Study title [ref]	Study design (number of patients); [estimated completion date] Country	Population	Intervention	Comparator	Engagement with the programme	Intervention adherence, attrition, completion	Intervention-related adverse events	Weight management medication adherence	Inaccessibility to intervention	BMI	Weight loss	Body fat	Waist circumference	Hip circumference	Waist-to-hip ratio	Glycated haemoglobin (HbA1c)	Cardiovascular events	Mortality	Physical activity	Rate of referral for weight loss surgery	Eating habits	Patient reported outcomes	Satisfaction	Healthcare appointments	Medication use	Healthcare professional grade and time
The Transform Type 2 Diabetes Study [NCT05648903]	Non-randomised controlled trial (n=120) [July 2024] UK	AMBER	GREEN (Oviva)	GREEN	✓					✓	✓					✓						✓		✓ NHS resource use and medication cost		
Manchester Intermittent and Daily Diet Type 1 Diabetes App Study (MIDDAS-Type 1) [NCT04674384]	RCT feasibility (n=12) [April 2024] UK	GREEN	GREEN (Oviva)	GREEN	✓	✓	✓														✓		✓			✓
A randomised controlled trial to determine safety and efficacy of a digital low-calorie diet programme for insulin-treated adults living with T2DM [SAFE-LCD]	RCT (n=NR) [Mid 2025] UK	NR	GREEN (Oviva)	RED		✓					✓					✓						✓	✓	✓	✓	✓
Remote Support for Low-Carbohydrate Treatment of Type 2 Diabetes (RESULT) [NCT04916314]	RCT (n=115) [December 2023] UK	GREEN	GREEN (Second Nature)	RED	✓						✓					✓					✓	✓	✓			
*Supported self-management for people with T2DM (BEATdiabetes)	Cohort (n=NR) [2023 or 2024] UK	RED	GREEN (Second Nature)	RED																						

Key: **GREEN** aspect of study in scope; **AMBER** aspect of study not in scope; **RED** aspect of study partially in scope, or elements of this are not in scope; *information provided from Company;
Abbreviations; BMI, body mass index, HbA1c, glycated haemoglobin; HRQoL, health-related quality of life; NR, not reported; PROMs, patient reported outcome measures; T2DM, Type 2 diabetes mellitus

5.5 *Other evidence*

NHS England currently offers behavioural and lifestyle change programmes to support Tier 2 weight management services (The NHS Digital Weight Management Programme) and patients at risk of developing T2DM (The NHS Diabetes Prevention Programme, DPP). Both programmes can be delivered digitally with the latter also being available as a face-to-face programme. The duration of programmes range from 12 weeks to 9 months.

Second Nature offers different weight management programmes depending on the level of support a person requires. Participants can self-refer or be referred via the NHS DPP or Weight Management Programme pathway to a programme that provides input from a health coach. A separate programme with access to an MDT is available at an additional cost and is offered through a medication-assisted programme with access to weight loss medication, or for complex patients (Appendix E).

The EAG conducted focused searches for evidence relative to the Scope of the decision problem. The non-comparative evidence identified by the EAG or shared with the EAG by the Company included patients related to the programme *without* MDT support or used in a population without obesity or not eligible for weight management medications is considered out of scope for this EVA. However, the generalisability of the findings should be carefully considered. As such they have been summarised separately to show the existing use of the technology without an MDT within current settings for completeness, Appendix B3. The evidence comprises 4 full publications (Hampton et al. 2017; Idris et al. 2020; Kar et al. 2020; Thomson et al. 2022) and 6 abstracts (Davies et al. 2022; Davies et al. 2023a; Davies et al. 2023b; Hampton et al. 2019a; Hampton et al. 2019b; Hampton et al. 2020). Of the publications, 5 accepted NHS-clinician and self-referrals to the programme, 4 included only GP or NHS referrals (as part of the NHS DPP), and 1 exclusively reported data from self-referred participants. Of the 5 publications reporting BMI, none included an exclusively in a population who are overweight or obese although the mean BMI was above 30 in all cases.

Hampton et al. (2017) included participants with a BMI above 23, which is considered to be within the healthy range.

Furthermore, DDM offer Gro Health and a Low Carb Tier 2 level programme, which has also been used within the NHS DPP. Similarly for completeness, the EAG have summarised 3 full publications (Hanson et al. 2021; Summers et al. 2021; Scott et al. 2022) and 2 abstracts (Abdelhameed et al. 2022; Kelly et al. 2020) identified with relevant outcomes relating to these technologies, an additional 1 full publication (Schirmann et al. 2022a) and 7 abstracts (Miller et al. 2021; Finnie et al. 2022; Miller et al. 2022a; Miller et al. 2022b; Miller et al. 2022c; Schirmann et al. 2022b; Miller et al. 2023) using Oviva within other NHS settings or populations, and a study shared in confidence using Liva [CiC-4] Appendix B3.

6 Adverse events

None of the included evidence explicitly reported adverse events relating to the technologies. One pilot RCT by McDiarmid et al. (2022) compared continuous low-energy diet with intermittent low-energy diet, both used alongside Oviva, reported serious adverse events, and adverse events potentially related to low-energy days not related to the digital technology. The EAG note that events related to digital technologies may relate to confidentiality breaches or issues relating to the accessibility or retrieval of data, none of which were reported across the included publications.

On 12 June 2023, the EAG searched for Medicines and Healthcare products Regulatory Agency (MHRA) field safety notices, using the individual technology and Company names, and found no results. The EAG noted that Juniper have amended their website at request of the MHRA regarding content and presentation of prescription-only medications (MHRA, 2023). Also on 12 June 2023, the EAG searched the Manufacturer and User Facility Device Experience (MAUDE) database using the individual technology brand and manufacturer names without any date restriction and found no results.

Patient risks, such as identification of disordered eating or medication misuse, are monitored by the clinical teams in 7 of 8 technologies (Appendix E) supported by staff training and internal policies and procedures for escalation and management. Oviva and Roczen use the Binge Eating Disorder Screener-7 scale (BED-7) to identify eating disorder risk for all patient referred to the programme. Patients identified at risk of disordered eating or other clinical risk during the programme are flagged for review by the MDT in 6 technologies (Gro Health, Liva, Oviva, Roczen, Second Nature, and Wellbeing Way). CheqUp noted that patients who have a history of eating disorders, low BMI or evidence provided at baseline deemed insufficient are rejected at time of initial consultation and that weight is monitored during the programme, however details surrounding escalation or further management were not provided. Second Nature noted that patients stopping medication would be referred back to their GP. Gro Health uses AI-monitoring to flag areas of risk (such as missed or excess medication, low or high calorie intake, linguistic analysis for stress, anxiety, or depression predicted risk), with patients flagged for human clinical review. Of the received Company responses, 4 of 7 technologies (CheqUp, Gro Health, Oviva, Roczen) reported monitoring patient weight loss trajectory against expected data trends (CheqUp also defined the use of trial data from the STEP, SCALE, and SURMOUNT studies).

7 Economic evidence

7.1 *Evidence search strategy and publication selection*

The search for economic evidence was undertaken alongside the search for clinical evidence. The economic literature searches were devised to find a practical number of results to sift (such as the time constraint of 7 weeks to produce this report). The searches were primarily structured around 3 elements: obesity and weight loss; health programmes or obesity drug treatment programmes; and an economic evaluation filter (adapted from the Centre for Reviews and Dissemination economic evaluation filters developed to populate NHS EED, 2015). A wide range of free-text, keyword and

controlled vocabulary terms were used, based on NICE scoping searches, known relevant articles, and extensive further testing and development.

A publication date range of 2018 to 'current' (the date of search: 19 to 22 May 2023) was applied and exclusively paediatric results were removed where appropriate or possible. A date restriction was considered appropriate to ensure evidence was reflective of the current technology and its updates and generalisable to current practice. Because of the volume of evidence and full paper retrieval rate (to check the intervention used), applying a 5-year date restriction was also considered pragmatic within the timescales of this EVA. Resources searched included MEDLINE (Ovid), Embase (Ovid), APA PsycInfo (Ovid), and RePEc/Ideas (for full details see Appendix D1).

A total of 678 records were identified; 482 remained after deduplication. After 2 reviewers (CF-G and TR) sifted through the results of the searches, 22 potentially relevant economic evaluations or related studies were identified (see Appendix D2). A further 17 relevant studies were identified through reference trawling, examining studies identified in the clinical searches, reviewing studies supplied to the EAG directly by the Companies and recent NICE guidance published on semaglutide (TA875, 2023) and liraglutide (TA664, 2020). A total of 39 studies were considered to be of potential relevance to the economic decision problem and are summarised in Appendix D3. Given the short time period for this report, the reporting standards of the included economic evaluation studies were not quality assessed in the standard manner using the CHEERS checklist (Husereau et al. 2022).

7.2 *Summary of economic evidence and key issues impacting cost-effectiveness*

None of the studies were directly relevant to the specific decision problem. Most studies were either an economic evaluation alongside an RCT of a weight management intervention (N=16) or an economic decision model (N=19). There were also 2 systematic reviews (1 related to commercial weight loss strategies and 1 related to weight loss surgery) and 2 costing studies.

For those studies (N=16) that included an economic evaluation alongside an RCT, most had a 12 month follow-ups (N=9) which ranged from 26 weeks (O'Brien et al. 2018) to 5 years (Ahern et al. 2017), with no extrapolation beyond the end of the trial in many cases. Given the chronic nature of obesity and its associated complications, it is likely that these studies have not adequately captured the impact of obesity on healthcare costs, patient quality of life, and mortality.

For those studies (N=19) that included an economic decision model, the most common model types were Markov and semi-Markov microsimulation. Some studies built de novo economic models for the purpose of analysis (for example, Elliot et al. 2021, Galvain et al. 2021, TA664, TA875) whereas others have utilised existing economic models. For example, Boyers et al. (2021) utilised the UK Health Forum's semi-Markov microsimulation model developed by Butland et al. (2007), which is able to predict the incidence and mortality associated with a range of obesity-related diseases according to current and projected future BMI. Most of the economic decision modelling studies had a time horizon of more than 20 years (for example, Avenell et al. 2018, TA664, TA875), with some having a lifetime time horizon (for example, Trueman et al. 2010, Meads et al. 2014).

A small number of studies were identified (N=4) that evaluated the cost-effectiveness of remotely delivered weight management programmes, with the evidence being mixed. For example, in an economic evaluation alongside an RCT, Little et al. (2017) concluded that an internet-based weight management programme (POWeR+) with regular face-to-face or remote support was cost-effective compared with brief advice, however the conclusions were limited by a lack of data on the maintenance of weight loss beyond 12 months. Furthermore, using an economic decision model with a lifetime time horizon, Miners et al. (2012) concluded that e-learning devices for weight management are unlikely to be cost-effective, driven by the relatively high fixed costs for the specific technology evaluated coupled with a negligible impact on BMI.

Rollo et al. (2017) analysed the potential costs of implementing an eHealth weight management service. They found that although the initial costs of setting up an eHealth service were high, the overall reoccurring costs per patient were lower compared with the in-person weight management service. Ritzwoller et al. (2013) found that the eHealth monitoring Be Well Be Fit programme was more expensive than other commercially available products in the US and unlikely to be re-imbursed by Medicare and Medicaid. These studies showed that costs were one of the main factors in the adoption of the technologies (Rollo et al. 2017, Ritzwoller et al. 2013, Miners et al. 2012). However, as the number of patients accessing the service increases the cost-effectiveness of the digitally enabled service will improve due to the lower per patient running costs (Rollo et al. 2017). Little et al. (2017) attributed the success of their internet-based programme to the fact that patients felt more enabled in managing their weight.

There are several key learnings related to the evidence base, model structure, and key issues which may impact the cost-effectiveness of the digitally enabled weight management programmes. First, there is no direct economic evidence related to the specific decision problem, and the few economic evaluations of remotely delivered weight management programmes have mixed findings. Second, the time horizon for the economic evaluation is important, as any short-term study may not adequately capture the impact on obesity (both in terms of costs and effects) over the long term. This was highlighted by Little et al. (2017) as one of the key limitations of their study. This is especially important as weight regain after a period of weight loss is a common occurrence (Sniehotta et al. 2019, Hartmann-Boyce et al. 2021). Modelling key weight related comorbidities (such as T2DM) is also important in order to fully reflect the natural history of obesity management.

The Company submissions in relation to NICE guidance published on semaglutide (TA875, 2023) and liraglutide (TA664, 2020) give a further indication on some of the potentially key model drivers in this literature. For instance, in TA664 the deterministic sensitivity analyses showed the top 3 model drivers to be the proportion of patients reverting from the prediabetes

health state to normal glucose tolerance health state, the level of weight reduction and HbA1c levels after the onset of T2DM. In TA875 the deterministic sensitivity analyses showed the top 3 model drivers to be the starting BMI of the cohort, the level of weight reduction and the discount rate for outcomes.

Oviva shared a cost savings model (developed in Excel) with the EAG; however due to its lack of direct relevance to the decision problem with respect to the comparator or population of interest this was not included within this evaluation. In summary, [redacted] However, the approach can, in principle, be applied to the comparator and population of interest in order to estimate whether the application of digital technology can lead to cost savings. As the Company acknowledges, this figure is uncertain due to the

variability in the delivery of specialist weight management services across regions.

7.3 *Potential value proposition*

The EAG considered the following value propositions for digitally enabled weight management programmes:

- The use of digitally enabled weight management programmes could expand reach and uptake of specialist weight management services by providing greater patient choice. This is important as there is unequal access across regions, which may be due to both the provision of a service but also the ability of participants to engage with the service. Equivalent or slightly less effective intervention may increase net population health outcomes.
- Some technologies rely on inclusion of NHS staff to deliver the Tier 3-like service, therefore it currently remains unclear how utilisation of digitally enabled weight management programmes will impact staff resource and capacity. However, if the digitally enabled services were able to release staff time it may be possible to expand current provision and therefore reduce waiting lists in areas with an existing service. For example, the bespoke W8Buddy programme using Gro Health is an adjunct to existing NHS MDT Tier 3 specialist weight management services whereas the W8Buddy+ programme uses in-house MDT and prescribing teams.
- Six technologies have in-house prescribing. This has the potential to release some hospital or GP staff resource. This would potentially allow an increase in capacity to deliver such services. Two Companies (Liva, Wellbeing Way) do not currently have an in-house prescriber with Liva noting that responsibility for medicines management remains with the referring clinician, therefore they would incur additional staff costs. It is plausible that a programme with an in-house prescribing function could be offered in an area where no current face-to-face service exists whereas programmes without this function would be

limited to areas with existing services or would need to be delivered with additional support perhaps at primary care level. At a system level the cost-effective approach might be to have a mixed delivery model.

- TA875 (2023) recommends the use of semaglutide for a maximum of 2 years within a specialist weight management service. However, evidence is emerging of weight gain after withdrawal of semaglutide. Wilding et al. (2022) reported data for 327 patients included in the STEP 1 trial where patients lost a mean of 17.3% (SD: 9.3%) of their body weight following once-weekly subcutaneous semaglutide 2.4 mg and lifestyle intervention, but regained two-thirds of what they had lost (mean weight loss relative to baseline of 56%) after 52 weeks of stopping treatment (including withdrawal of lifestyle intervention). The digitally enabled weight management programmes may provide patients with more regular 'contact' with healthcare professionals and may have a role to play in helping individuals to form life-long habits to maintain weight loss for longer over and above that of existing standard (non-digitally enabled) services. This would lead to greater health gains and could improve the overall cost-effectiveness.
- Given the health risks and comorbidities associated with obesity, broadening access to an MDT clinical team with the ability to monitor and manage medication may offer patients with holistic care leading to wider benefits.

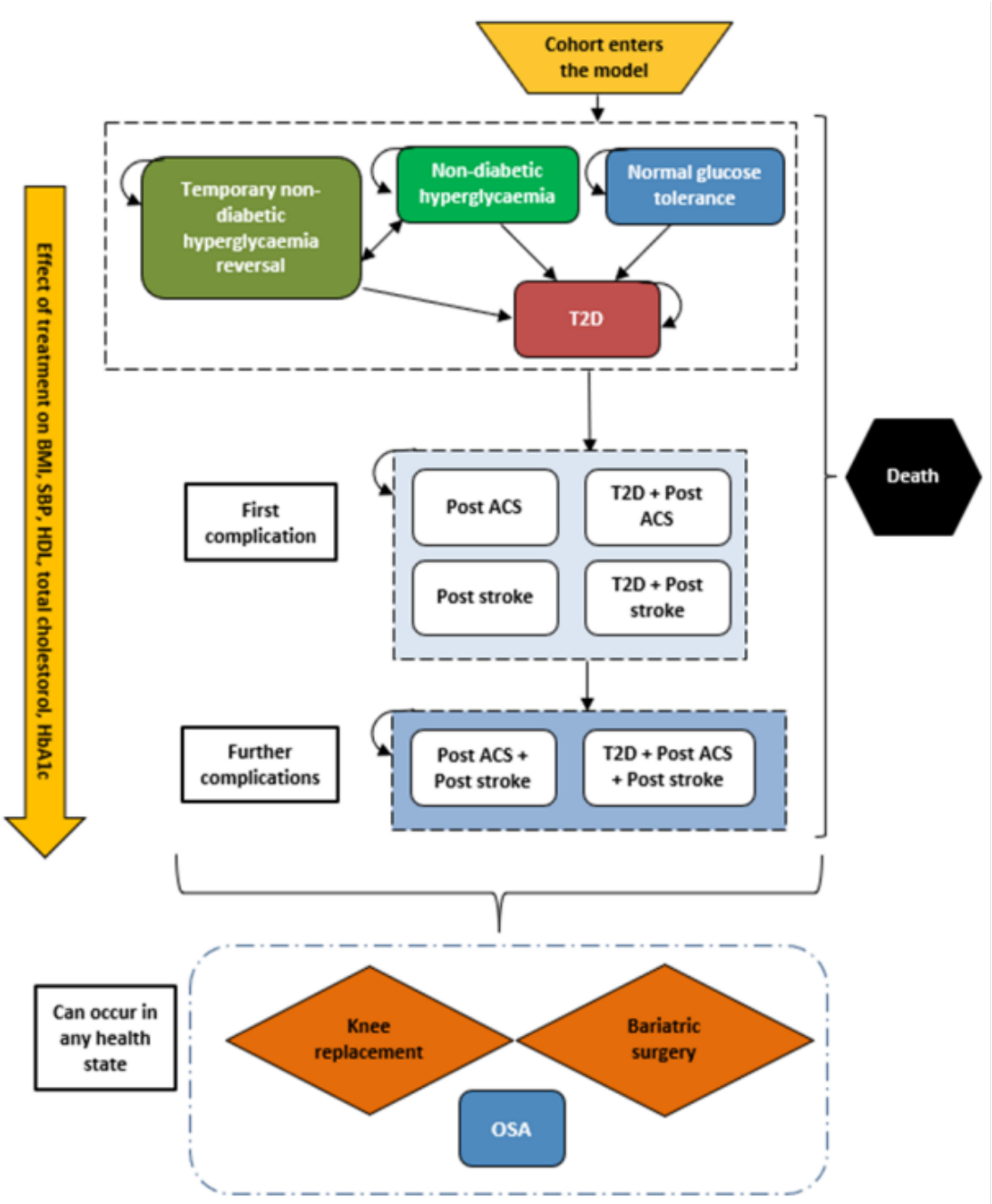
7.4 *Early economic modelling*

Model structure

To fully evaluate the cost-effectiveness of the digitally enabled weight management services compared with current standard practice, a long-term state-transition model (such as those used in the NICE guidance for semaglutide TA875 and liraglutide TA664) would be needed. State-transition models such as these are widely used in the modelling of chronic diseases such as diabetes and cardiovascular disease and are able to predict the incidence and mortality associated with a range of obesity-related diseases.

A schematic of the model structure used in the Company submission for semaglutide TA875 is shown in Figure 2. The model includes several different health states, including states related to T2DM, stroke, weight loss surgery, and death. The transition probabilities between the various health states are calculated from risk equations using several commonly reported surrogate outcomes (including BMI, total cholesterol, HDL cholesterol, and HbA1c).

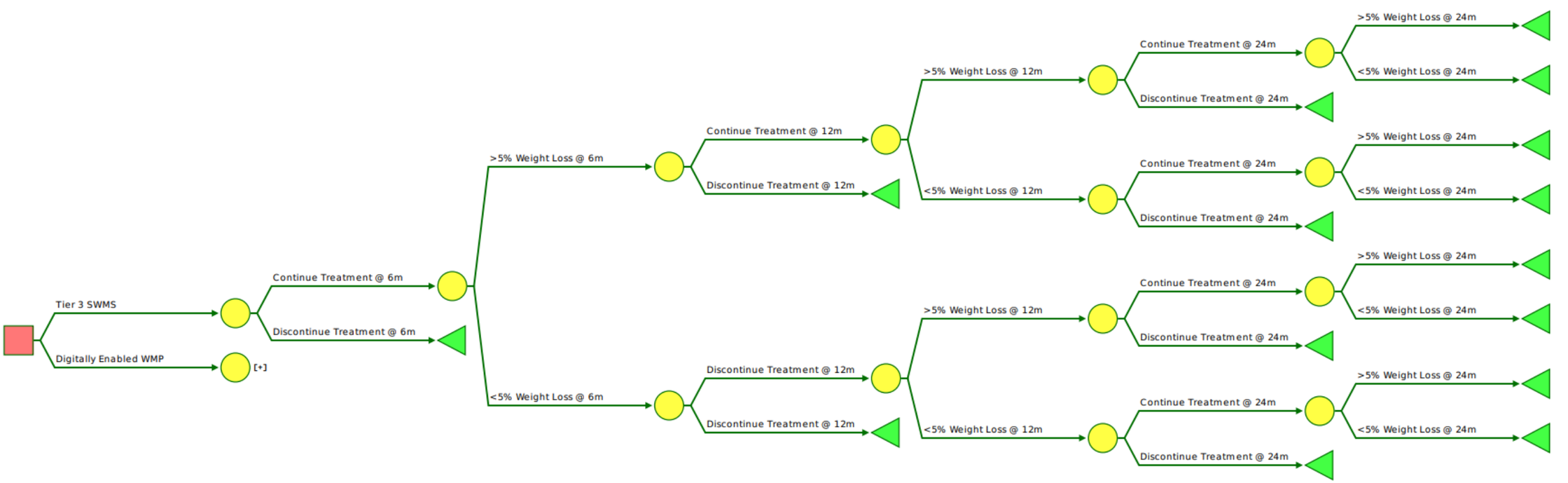
Figure 2: Schematic of model structure used in company submission for semaglutide TA875.



Given the time constraints and the lack of existing clinical and economic evidence for the digitally enabled technologies, it was not feasible to develop a comprehensive de novo Markov or microsimulation model or adapt an existing model such as the UK Health Forum microsimulation model (Butland et al. 2007) for this assessment. Instead, we undertook an early cost-utility analysis of the digital technologies and current Tier 3 specialist weight

management service. The primary purpose of this analysis is to assess whether there is a plausible prima facie case for the cost-effectiveness of the digital technologies included in this assessment. A highly simplified decision model was written in TreeAge. For both standard care (Tier 3 specialist weight management services) and the digitally enabled weight management services, we reported the costs, the QALYs and the mean net benefit calculated using the willingness to pay threshold of £20,000 per QALY gained. For cost and outcomes beyond 12 months, a discount rate of 3.5% was applied in line with NICE Health Technology Evaluations manual (PMG36, 2022). The model was run deterministically. Given the high level of uncertainty present in the early economic model a probabilistic sensitivity analysis was not undertaken. Instead, a series of targeted deterministic sensitivity analyses were undertaken to explore some of the key uncertainties in the key parameters. The structure of the decision model is shown in Figure 3.

Figure 3: Structure of the decision model (developed by EAG) drawn with Silver Decisions (Kamiński et al. 2022). Note: [+] indicates that the sub-tree is identical to the sub-tree above but has been collapsed for clarity.



The cohort included patients eligible for Tier 3 specialist weight management services. The patients are either provided with current standard care or provided with a digitally enabled programme delivering specialist weight management services. The model does not incorporate adherence to any medication prescribed, and its direct effect on weight loss, under each of the weight management programmes considered in the evaluation. To account for differences in the dropout or discontinuation rate and levels of weight loss, the model assesses response at several time points: 6 months, 12 months, and 24 months. A time horizon of 24 months was chosen to reflect the maximum recommended prescription period for semaglutide and the typical Tier 3 follow-up time as specified by our Clinical and Patient Experts. The EAG notes that a future technical appraisal for these digital technologies would need to consider a longer timeframe sufficiently long enough to capture in full the expected outcomes and the differences in resource use, costs, and benefits of adopting these digital technologies for the delivery of specialist weight management services. This approach is considered best practice in the development of health economic models (Gray et al. 2010) and is in keeping with the NICE Health Technology Evaluation manual (PMG36, 2022). At each time period (6 months, 12 months and 24 months), the patients can either remain in specialist weight management services or no longer engage and dropout of the weight management service. Those patients who remain in the weight management service can either lose less than 5% of their body weight or lose greater than 5% of their body weight. Horn et al. (2022) consider a change of 5% body weight as clinically significant. This threshold is also stated in TA875 (2023) where NICE recommend that stopping semaglutide should be considered if the initial weight loss is less than 5% after 6 months of treatment.

Evidence gap: The EAG has been unable to find data on costs and outcomes associated with the long-term use of digitally enabled weight management technologies. Evidence is also needed with regards to differences in medication adherence between those accessing weight management services via digitally enabled technologies or via in-person standard care.

Potential study: Long-term cohort study or real-world evidence needed to compare the costs and outcomes of digitally enabled weight management programmes with standard care, with the inclusion criteria reflective of NHS practice.

Population

The model included adults with obesity who were eligible to access to weight management medication in line with NICE's guidance, including but not limited to (TA875) and (TA664).

Interventions

Because of lack of data on costs and outcomes the economic model used data related to Liva, and assumed a class effect applicable to other 'like' technologies. In order to test the variability in costs and outcomes of the different digitally enabled technologies considered under this assessment we have included a number of sensitivity analyses as part of our evaluation.

Comparators

The comparator in the economic model was current standard care, which in the base case is assumed to be in-person Tier 3 MDT weight management services with no digitally enabled technologies provided as part of the programme. Tier 3 services can include the provision of psychological, behaviour, and lifestyle modification and dietary support delivered by an MDT. This support is primarily offered in secondary care settings although these services can also be found in community and primary care settings. The provision of Tier 3 services can vary across England and Wales and it may not be available in some areas. In sensitivity analyses, the EAG considered a Tier 3 model entirely delivered in a primary care by altering the cost of the provision of such a service.

Tier 3 services can also be offered virtually or over the phone as advised by our Clinical Experts. The responses from the Clinical Experts (Appendix F) indicated that the proportions of patients accessing different components of the Tier 3 services virtually or by telephone may vary considerably across geographical areas. In order to test how different settings and forms of delivery of 'standard care' can affect the cost-effectiveness of the interventions we have incorporated different scenarios as

part of our sensitivity analyses by using different cost estimates for service provision to act as proxy for a different mode of delivery.

Evidence gap: There is uncertainty surrounding the components and availability of Tier 3 services across England and Wales. The typical frequency, duration of appointments and follow-up is unclear and how it varies across regions. This uncertainty may have an important effect on the cost-effectiveness of digitally enabled weight management services.

Potential study: A mapping exercise or audit of current practice across the NHS is required. This could be complemented with an expert consensus meeting of likely future developments. This type of study could be helpful to reduce the uncertainty surrounding the components of Tier 3 services across England and Wales.

Outcomes

The EAG note that the evidence base for this EVA is very limited in terms of both quantity and quality, as shown by the results of the clinical and economic searches. Most of the scoped outcomes for which there was evidence were of limited benefit within the economic model (for example, change in waist or hip circumference). Furthermore, there was only 1 RCT relevant to the decision problem, comparing a digitally enabled weight management programme with standard care (face-to-face). There was no evidence available for mortality, cardiovascular events, rate of referral for weight loss surgery or healthcare costs. Adverse events were also poorly reported. There was limited evidence related to health-related quality of life. Therefore, the EAG relied on indirect evidence and modelled effectiveness and health related quality of life outcomes based on the best available data. These are described below in the Model Inputs section.

Model Inputs

Weight Loss

Weight loss is reported in several different ways in the relevant clinical studies (see Section 5.3) and the wider literature, including absolute and percentage of baseline weight in kilograms, BMI, and the proportion achieving clinically significant weight loss as defined by a specific threshold (for example, losing more or less than 5%

body weight). We used ‘losing less than 5%’ and ‘losing 5% or more of body weight’ as our measures of weight loss, as 5% is considered as a clinically significant level of weight loss by Horn et al. (2022), and considered a stopping criteria for semaglutide (TA875, 2023).

Only 1 RCT is available for the named technologies (Liva) (Hesseldal et al. 2022). Given the paucity of published evidence available for the specific digital technologies, the rates of clinically significant weight loss for both the digitally enabled services and standard care from this study were used in the base case of the economic model and assumed to apply to the other digital technologies. It is worth reiterating that the RCT took place in a different country (Denmark) and healthcare system and therefore the results may not be generalisable to the UK NHS setting. However, the EAG notes that this is the only available randomised evidence that is relevant to the scope of this assessment. The proportions of respondents achieving less than 5% body weight loss and more than 5% body weight loss at each time point for both the digital technologies and standard care used in the base case are shown in Table 22.

The EAG notes that there is a published systematic review reporting the level of clinically significant weight loss for Tier 3 specialist weight management services and pre-bariatric multi-component weight management programmes for adults with obesity living in the UK (Alkharaiji et al. 2019). These figures are alternative parameters for the standard care arm of the model and are used as part of the sensitivity analyses. Although these figures relate to NHS services, the EAG notes that the populations used in the Hesseldal et al. (2022) RCT and Alkharaiji et al. (2019) systematic review are substantially different. For instance, the baseline accumulated average BMI from the studies included in Alkharaiji et al. (2019) was reported as 42.5, whereas the mean BMI in the RCT reported by Hesseldal et al. (2022) was 35.0.

Evidence gap: The EAG notes that there is no available evidence on how percentage weight loss may differ for patients with different starting BMI indices when accessing digitally enabled technologies compared with those accessing in-person specialist weight management services in secondary care.

Table 22: Measures of weight loss used in the base case of the EAG economic model.

Variable	Digital Technologies	Source	EAG Comment	Standard care	Source	EAG Comment
> 5% Bodyweight Lost at 6 Months	0.389	Hesseldal et al. (2022)	-	0.085	Hesseldal et al. (2022)	-
> 5% Bodyweight Lost at 12 Months	0.378	Hesseldal et al. (2022)	-	0.192	Hesseldal et al. (2022)	-
> 5% Bodyweight Lost at 24 Months	0.378	Hesseldal et al. (2022)	Assumed to be the same as 12 months	0.192	Hesseldal et al. (2022)	Assumed to be the same as 12 months
Abbreviations: EAG, External Assessment Centre; Note: Figures correspond to those in Table 7d						

Evidence gap: RCT evidence is only available for 1 Company (Liva) for a study conducted in Denmark. Randomised evidence related to weight loss for both standard care and digitally enabled weight management programmes in a UK context is required for Liva and the other digitally enabled technologies.

Potential study: Long-term real-world evidence (24 months or longer) is needed to compare the levels of weight loss in digitally enabled weight management programmes with standard care, with the inclusion criteria reflective of NHS practice.

Discontinuation of Treatment

Dropout of specialist weight management services is common, and therefore it was deemed important to try to explicitly incorporate this in the simple decision model. Patients may discontinue treatment because of positive reasons (such as losing a significant amount of weight) or negative reasons (such as not losing a significant amount of weight and feeling dispirited). There is currently little empirical evidence on the reasons for the discontinuation of specialist weight management services. Therefore in the model, we pragmatically assumed that the probability of discontinuing treatment at each time point was the same for those who had lost 5% of body weight or more, and those who had lost less than 5% of body weight. It is possible that this could underestimate the health impact of both specialist weight

management services (digitally enabled and in-person Tier 3), as participants may be more likely to discontinue if they feel as if the service is not working for them.

We used the evidence relating to attendance at follow-up in the applicable clinical studies as proxies for the discontinuation rate (see Table 5). The dropout rates for the digital technologies and standard care were sourced from the identified clinical evidence (see Section 5.3). Once more, the dropout rates for a RCT based in Denmark for a single digital technology (Liva) were used in the economic model and assumed to be broadly applicable to the other digital technologies. All dropout rates were reported cumulatively and were therefore converted into a dropout rate specific to each time point to be entered into the decision model by dividing the difference in the cumulative dropout rate between the time points by the estimated proportion of participants present in the previous time point. Alternative dropout rates for usual care are available from the Alkharaiji et al. (2019) and included as part of a sensitivity analysis. The dropout rate at each time point for both the digital technologies and standard care are shown in Table 23.

Table 23: Measures of dropout rate used in the base case of EAG economic model

Variable	Intervention	Source	Control	Source
Dropout Rate at 6 Months	0.260	Christensen et al. (2022a)	0.400	Christensen et al. (2022a)
Dropout Rate at 12 Months	0.142^	Christensen et al. (2022a)	0.131^	Christensen et al. (2022a)
Dropout Rate at 24 Months	0.362^	Christensen et al. (2022a)	0.301^	Christensen et al. (2022a)
Notes: ^ EAG calculation from 'Attendance at follow-up' proportions reported at the different time points of Christensen et al. (2022a). Original proportions reported in Table 5.				

Evidence gap: Better quality data about discontinuation of treatment rates by clinically meaningful subgroups including reasons why patients dropout of the service for each of the different digital technologies.

Potential study: A comparative long-term cohort study or real-world evidence with statistical analysis to adjust for the impact of potential confounders is needed to compare the discontinuation rates of digitally enabled weight management programmes with standard care, with the inclusion criteria reflective of NHS practice.

Health State Utilities

The EAG identified little evidence on utility which would be appropriate for inclusion in an economic model (see Table 15). One abstract (Abdelhameed et al. 2022) reported that the average utility (as measured by the EQ-5D; it is unclear from the abstract whether the EQ-5D-3L or EQ-5D-5L version was used) for people with T2DM who engaged with Gro Health increased from 0.746 at baseline to 0.792 at 6 months. The authors reported this increase as being statistically significant ($p<0.0001$). However, the abstract did not provide further evidence on the change in weight, which came alongside this increase in utility and did not appear to include a comparator group. Hesseldal et al. (2022) reports the change in HRQoL (as measured by the EQ-5D-5L) between baseline and both 6 months and 12 months for patients with obesity using Liva, however these figures cannot be used to populate the economic model as they are not reported in relation to a specific health state (such as, change in weight status).

A targeted search of the Tufts CEA database with the terms 'weight change', 'obesity' and 'BMI' yielded no applicable health utility data related to changes in weight. The NICE technology appraisals for liraglutide (TA664, 2020) and semaglutide (TA875, 2023) previously carried out systematic reviews of the literature for HRQoL studies for use in their submitted economic models and found that there was a lack of comprehensive published utility data applicable to their economic models. In both studies, utility was calculated using evidence from Søltoft et al. (2009), which estimated age and sex-specific utility values for each participant in each health state of the economic model. Given the structure and simplicity of the decision model used in this EVA and a lack of data, this approach was not used.

To estimate the utility for the patients at baseline in the model and the subsequent utility increments on losing less than 5% body weight and losing 5% body weight or more, we used information from Breeze et al. (2022), which used longitudinal regression methods to investigate the impact of changes in weight and BMI on EQ-5D-3L utilities using evidence from a behavioural group-based weight loss intervention trial. Their analysis estimated that a unit increase in BMI was associated with a mean change of -0.011 in EQ-5D-3L utility, with 95% confidence intervals of

-0.015 and -0.009. Further analysis showed that changes in utility were smaller during *weight loss* (-0.009) as opposed to *weight gain* (-0.015). In the base case analysis, we assumed that a unit decrease in BMI was associated with a 0.009 increase in EQ-5D-3L utility.

To establish a baseline utility, we used a weighted average (0.777) of the mean EQ-5D-3L score in the 30 to 35 BMI group (0.813, n=577) and the greater than 35 BMI group (0.731, n=448) from Breeze et al. (2022), as these groups were both eligible for Tier 3 weight management services. This is similar to the baseline utility (0.800) reported in the RCT by Hesseldal et al. (2022).

To estimate the utility increment of losing less than 5% body weight, we pragmatically assumed that the mean percentage weight loss in this category was 2.5%. To estimate the increment of losing 5% body weight or more, we pragmatically assumed that the mean percentage weight loss in this category was 7.5%. To estimate the utility increments associated with these changes in body weight, we used the mean body weight (96.16 kg), height (1.69 m) and BMI (34.54) from the Breeze et al. (2022) study as our starting body weight. We then calculated the decrease in BMI units associated with a 2.5% decrease in body weight (0.863 units) and a 7.5% decrease in bodyweight (2.591 units) respectively using these figures. We then multiped these changes in BMI units by the associated change in EQ-5D-3L utility to generate the utility increment for losing less than 5% of body weight (0.008) and 5% or more body weight (0.023). This gave an estimated utility value of losing less than 5% body weight of 0.785 and an estimate utility value of losing 5% body weight or more of 0.800. It is worth noting that these increments in utility depend on the estimated starting body weight. For example, these increments would be higher if we had assumed a higher starting body weight. Furthermore, the simplified decision model does not explicitly take into account those patients who may gain weight during the 24 month time period and who may consequently experience a decrease in utility. Alternative utility increments are included as part of the sensitivity analyses to explore these uncertainties. The utility values used in the economic model are shown in Table 24.

The EAG note that the WRAP trial (Ahern et al. 2017), on which the Breeze et al. (2022) study is based, included participants with BMI greater than 28.0, with the mean baseline BMI of trial participants being 34.54. The Scope for this assessment specifies that the population should be in line with the NICE guidance for semaglutide and liraglutide. For semaglutide the population specified is a BMI greater than 35, a BMI greater than 32.5 for certain ethnic minorities or a BMI of 30 to 35 if meeting the criteria for specialist weight management services. For liraglutide the population specified is a BMI greater than 35, a BMI greater than 32.5 for certain ethnic minorities, those with non-diabetic hyperglycaemia or a high risk of cardiovascular disease. The population for the Breeze et al. (2022) study is therefore on average likely to be less obese than the Scope population. The utility increments may be higher in the Scope population which would result in an underestimate of the benefit for the digital intervention if more participants have access to services for longer (such as, lower dropout rate) and therefore lose more weight (such as, increased QoL). Alternative utility increments are included as part of the sensitivity analyses.

Table 24: Utility values used in the EAG decision model.

Health State	Utility Value	Source	EAG Comment
Baseline	0.777	Breeze et al. (2022)	Weighted average of EQ-5D-3L utilities in those with a BMI between 30 and 35, and those with a BMI > 35.
Discontinued Treatment	0.777	Breeze et al. (2022)	Assumed to be the same as baseline utility.
Less than 5% body weight loss	0.785	Breeze et al. (2022)	Assumed a 2.5% decrease in weight - utility increment of 0.008
5% body weight loss or more	0.800	Breeze et al. (2022)	Assumed a 7.5% decrease in weight - utility increment of 0.023
Abbreviations: BMI, body mass index; EAG, External Assessment Group;			

Evidence gap: Data on the relationship between sex, weight, or BMI and utility in the context of both Tier 3 and digitally enabled weight management services.

Potential study: Before-and-after study with measurements of BMI, height, weight, sex and EQ-5D (either 3L or 5L) at baseline and different follow-ups with inclusion criteria similar to the population specified in Scope of this early value assessment.

Costs were considered from an NHS and Personal Social Services perspective as per NICE Scope and in line with the NICE Process and Methods Guide (NICE, PMG36, 2022). A brief description of the cost categories included in our decision model is provided below.

Costs of technologies

Seven out of the 8 Companies considered in the Scope provided a per person licence cost, Table 25. Liva provided a cost per patient dependent on programme duration (6, 12, 18 or 24 months). This price included a full MDT initial assessment and review, weekly and bi-weekly sessions led by their clinical coaches and support from psychologists and prescribers. Patients are provided with weighing scales and monitors. Oviva provided a price per patient which included healthcare professional time, the Oviva app, and follow-up for up to 24 months. The Company stated that there were no maintenance or other costs to the healthcare system. The price structure followed a tiered system depending on the expected number of patients starting the programme. The Company provided an average per patient estimate for 500, 1,000 and 1,500 patients. DDM provided a per patient per year tiered pricing structure. The pricing provided depended on first, the type of programme offered (W8Buddy or W8Buddy+) and second whether the licence agreement covered more than or less than 1,000 participants per year. Extensions to the programme (3 months) incurred additional costs. CheqUp provided a non-app virtual-based approach and quoted an approximate price per month subject to availability of packages. Their tiered pricing depended on the number of patients offering a discount per patient for every additional 1,000 using the service. No NHS price was provided. Roczen provided a fixed per patient per month cost. Second Nature provided a fixed per patient per month cost for both the digital-dietitian-based health coaching programme and additional support from the MDT team. Xyla (Wellbeing Way) provided an illustrative example of the cost of the technology but did not provide a per patient per period cost.

Given the heterogeneity in the pricings provided by the Companies, in this early economic model we used the licensing cost estimates for a single technology (Liva). We made this pragmatic decision as this technology also has evidence regarding

weight loss and the dropout rate, which is used in the base case of the model and is broadly similar to the other technologies. It is currently unclear how generalisable this cost estimate is to the other digital technologies, given the different delivery models of each technology, for example the ratio of digital to in-person services provided by each of the technologies.

Digital inclusion costs

The nature of these technologies requires users to have access to adequate equipment and an ongoing internet connection. In order to incorporate this expenditure, we added the cost of a tablet computer (£100) and the monthly cost of a mobile internet connection (£21) to the costs of the digital interventions (Table 26). The inclusion of these costs was thought necessary to address the barriers to access to these technologies and equity concerns around digital exclusion. This approach was in line with the previous EVAs evaluating digital health technologies (MT588 and MT580). The EAG notes that using an average cost of a tablet computer and internet connection cost alongside the assumption that the NHS will provide all users with the technology, may not be reflective of real-world practice. The EAG also notes that only a proportion of these costs may be incurred as some people may not be eligible or may not need these resources in order to access digitally enabled services.

Costs of medication

The costs of the weight loss medication itself was not included in the economic model.

Table 25: Summary of technology costs for 7 technologies (no response from Juniper)

	CheqUp	W8Buddy (Gro Health)	W8Buddy+ (Gro Health)	Liva	Oviva	Roczen	Second Nature	Wellbeing Way
Licence costs per participant per year based on number of participants, with medication	Not provided	Not provided	Not provided	Not provided	Not provided	Not provided	£2,051.76 to £3,251.76*	£2,456***
Licence costs per participant per year based on number of participants, without medication				Not provided		£600	£503.76**	
500					£1,000			
1,000					£960			
1,500					£940			
<1,000	£1,200	£390	£840					
>1,000	£1,140	£300	£705					
Licence costs based on programme duration, without medication	Not provided	Not provided	Not provided		Not provided	Not provided	Not provided	Not provided
Per month								
6 months				£1,100				
12 months				£1,320				
18 months				£1,550				
24 months				£1,720				
Additional resources from	Price with fitbit scales adds £15 per patient	Price with weight scale adds £75	Price with weight scale adds £75	None stated	None stated	None stated	None stated	None stated

company information	per month to cost	per patient to cost	per patient to cost					

Key: * depending on semaglutide dose, includes digital scales and recipe book; **minimum volume of 100 users per month, ***assumed to be annual cost, includes total diet replacement products, all monitoring equipment and coaching time, however unclear whether with or without weight loss medication.

Cost of usual care (Tier 3 Weight Management Services)

The service included one-to-one and group sessions with a multidisciplinary team as detailed in the first row of Table 26. The costs associated with the typical staff component of a Tier 3 weight management service delivered in secondary care is utilised in our base case analysis. The staff salary bands and frequency of appointments that participants would be expected to have over the duration of the programme was informed by the advice received from the 11 Clinical Experts (Appendix F). The appointments varied in length and frequency and were delivered in a secondary care setting. These data were combined with unit costs obtained from routine data sources such as those collated in the Unit Costs of Health and Social Care (2022) by the 2022 Personal Social Services Research Unit (PSSRU) (Jones et al. 2023) and updated to 2023 prices using the CCEMG – EPPI-Centre Cost Converter. Unit costs for the staff component of the Tier 3 standard care service used in the base case analysis are outlined in Table 27. The alternative cost parameters for standard care used in the sensitivity analyses are detailed in the remaining rows of Table 26.

Table 26: Costs parameters for economic model (standard care arm and additional resources needed for the delivery of digitally enabled services).

Variable	Point estimate	Source	Base case or sensitivity analysis	Notes
Tier 3 service secondary care	£1,796 per patient per year	EAG calculation	Base case	MDT available annual service on offer to Tier 3 patients based on : - 1 x 30 minute F2F assessment with Bariatric Physician (Consultant medical scale); Clinical psychologist Band 8a; Specialist Nurse Band 5; Dietitian Band 6; & Physiotherapist Band 6; - 1 x 30 minute Group session (12 people) with 1 Dietitian Band 7 and 1 health practitioner Band 4 - 12 x 30 minute sessions with Dietitian Band 6 - 12 x 30 minute sessions with Clinical Psychologist Band 8A - 6 x 30minute session with Physiotherapist Band 6

Variable	Point estimate	Source	Base case or sensitivity analysis	Notes
				- 6 x 1 hour group sessions (12 people) with Clinical Psychologist Band 8a and Specialist nurse Band 5 and health practitioner Band 4 - 6 x 1 hour group sessions (12 people) with Specialist nurse Band 5; Dietitian Band 6 and Health Practitioner Band 4 - 2 x 30 minute appointments with Bariatric Physician (Consultant medical scale) - 26 x 15 minute appointments with Health Practitioner Band 4 Staff Unit prices taken from the 2022 PSSRU costs and uplifted to 2023 using the CCEMG – EPPI-Centre Cost Converter
Tier 3 service in a primary care setting	£1,057 to £1,469 per patient per year	Jennings et al. (2014) Brown et al. (2017)	Sensitivity analysis	Cost for the information for the Tier 3 Fakenham weight management service which included medical assessment, motivational interviewing to support behaviour change, dietary and activity advice, psychological therapies, drug therapy with orlistat, medically supervised low-energy liquid diets and assessment for suitability for weight loss surgery using the NHS East of England criteria. The programme was provided by a lead general practitioner with additional training as a bariatric physician (specialist certificate of obesity professional education), obesity specialist nurse, dietitian, psychological therapist, exercise professional, health trainer and supported by a consultant endocrinologist and public health consultant. Costing information from Jennings et al. reported an estimated cost of between £900 and £1,250 per year per patient. This was included in the Brown et al. (2017) systematic review. Original reference Jennings et al. (2014). Costs has been updated to 2023 prices using the CCEMG – EPPI-Centre Cost Converter

Variable	Point estimate	Source	Base case or sensitivity analysis	Notes
Tier 3 service	£469 per patient per year	Coulton et al. (2015)	Sensitivity analysis	Mapping review from 2015. Around 92% of services had a follow up of 12 months or more. Only 8% of services reported no follow up. Of the respondents, 100% reported using NICE guidance for the provision of weight management services. Most respondents reported average costs equal to, or greater than, £401 per participant. Cost has been updated to 2023 prices using the CCEMG – EPPI-Centre Cost Converter
Tier 3 service hybrid format	£1,417 per patient for year (year 1) £570 per patient per year (year 2)	NHS Cost collection 2022	Sensitivity analysis	We investigated the costs relating to 1 full episode of for a particular patient comprising a series of Out-Patient Attendances in respect of 1 referral, managed by the same consultant or, in the case of shared-care, by two or more consultant. In this case we included the costs associated with the provision of Bariatric care including an initial face to face MDT outpatient appointment and the cost associated with follow up MDT non face to face appointments: • Currency code: WF02B Multiprofessional Non-Admitted Face-to-Face Attendance, (First) £829.99 • Currency code: WF02C Multiprofessional Non-Admitted Non-Face-to-Face Attendance (Follow-up) £559.04 Costs taken by the 2022 NHS digital collection and updated to 2023 using the CCEMG – EPPI-Centre Cost Converter
Tablet	£100	UK Online retailer	Base case	Representative cost from large online retailer, June 2023. 10 inch Android tablet with sim card slot. A basic smart phone is similar cost.
Data SIM card per month	£21 per month	UK Telecom Company	Base case	Representative cost from price comparison website, January 2023. Unlimited 5G data-only plan, 1-month contract.

Abbreviations: CCEMG, Campbell and Cochrane Economic Methods Group; F2F, face-to-face; MDT, multidisciplinary team;

Table 27: Unit costs used for calculating the cost of Tier 3 services delivered in secondary care (standard care).

Role (Band)	Cost, per hour	Source [location]	Notes
Bariatric Physician (Consultant medical scale);	£145	Jones et al. (2023) [page 95]	Based on the mean full-time equivalent basic salary for Agenda for Change (AfC) 2022 NHS staff earnings estimates for doctors. Consultant medical scale. Overheads, qualification costs and on costs have been included. £143 hourly rate updated to 2023 prices (£145). Assumed 1,608 annual working hours per year.
Specialist Nurse (Band 5)	£43	Jones et al. (2023) [page 89]	Based on the mean full-time equivalent basic salary for AfC band 5 of the April 2022 NHS staff earnings estimates for nurses. Overheads, qualification costs and on costs have been included. £41 hourly rate updated to 2023 prices (£43). Assumed 1,554 annual working hours per year.
Clinical psychologist (Band 8a)	£76	Jones et al. (2023) [page 92]	Based on the mean full-time equivalent basic salary for AfC band 8a of the April 2022 NHS staff earnings estimates for hospital based scientific and professional staff Overheads, qualification costs and on costs have been included. £75 hourly rate updated to 2023 prices (£76). Assumed 1,554 annual working hours per year.
Dietitian (Band 6)	£56	Jones et al. (2023) [page 92]	Based on the mean full-time equivalent basic salary for AfC band 6 of the April 2022 NHS staff earnings estimates for hospital based scientific and professional staff. Overheads, qualification costs and on costs have been included. £55 hourly rate updated to 2023 prices (£56). Assumed 1,554 annual working hours per year.
Physiotherapist (Band 6)	£56	Jones et al. (2023) [page 92]	Based on the mean full-time equivalent basic salary for AfC band 6 of the April 2022 NHS staff earnings estimates for hospital based scientific and professional staff. Overheads, qualification costs and on costs have been included. £55 hourly rate updated to 2023 prices (£56). Assumed 1,554 annual working hours per year.
Health Practitioner (Band 4)	£38	Jones et al. (2023) [page 92]	Based on the mean full-time equivalent basic salary for AfC band 4 of the April 2022 NHS staff earnings estimates for hospital based scientific and professional staff. Overheads, qualification costs and on costs have been included. £37 hourly rate updated to 2023 prices (£38). Assumed 1,554 annual working hours per year.
Abbreviations: AfC, Agenda for Change			

Training, set up and administration costs

We did not include any costs associated with system set-up and integration with NHS systems, day-to-day administration and training of NHS staff to roll out these digital technologies. The EAG noted that these costs are unclear and could be substantial. We have tested the possibility of an increase in the costs of the digitally enabled technologies in the sensitivity analyses.

Sensitivity analysis

One-way sensitivity analyses and scenario analyses were undertaken for key parameters, with the details in Table 28. The choice of scenarios is based on the results of the base case analysis, by examining how changes to the key parameters impact on the cost-effectiveness of the digitally enabled weight management service such that the base case result is altered.

Table 28: Summary of one-way sensitivity and scenario analysis conducted by the EAG

Scenario	Parameter changed from base case	Base case	Updated value	Source and Explanation
1	Dropout rates & percentage weight loss rates (standard care)	Drop out rates: 6 months: 0.400 12 months: 0.131 24 months: 0.301 Percentage weight loss rates: >5% at 6 months: 0.085 >5% at 12 months: 0.192 >5% at 24 months: 0.192	Drop out rates: 6 months: 0.334 12 months: 0.161 24 months: 0.532 Percentage weight loss rates: >5% at 6 months: 0.392 >5% at 12 months: 0.436 >5% at 24 months: 0.440	Due to the uncertainty surrounding the transferability of the effectiveness parameters used in our base case to the UK NHS setting, we assumed that the dropout rates and effectiveness rates for standard care are equal to those in the comparator arm reported by the Alkharaiji et al. (2019) systematic review
2	Dropout rates (digitally enabled technologies)	Drop out rates: 6 months: 0.260 12 months: 0.142 24 months: 0.362	Drop out rates: 6 months: 0.400 12 months: 0.131 24 months: 0.301	We changed the dropout rate for digitally enabled technologies so that these were the same as those reported for the control arm in the RCT in order to determine the impact of the digitally enabled technology being as good as the Tier 3 service (control arm).
3	Utility value for those losing less than 5% body weight	0.785	0.777	To address the uncertainties surrounding the utility value for those losing less than 5% body weight, we assumed no utility increment in this health state.
4	Utility values	Utility values: <5% body weight:0.785 >5% body weight: 0.800	Utility values: <5% body weight:0.793 >5% body weight: 0.823	To address the uncertainties surrounding the utility increments used, we increased the magnitude of these increments by 100%.
5	Tier 3 cost	£1,796	£1,057	Cost information on Tier 3 services was changed to account for the possibility being delivered in a primary care setting. We used the lower and upper costs reported by Jennings et al. (2014) in their evaluation of the Fakenham weight management service. This service included medical assessment, motivational interviewing to support behaviour change, dietary and activity advice, psychological therapies, drug therapy with orlistat, medically supervised low energy liquid diet and assessment for suitability for weight loss surgery using the NHS East of England criteria.
6	Tier 3 cost	£1,796	£1,469	

Scenario	Parameter changed from base case	Base case	Updated value	Source and Explanation
7	Tier 3 cost	£1,796	£469	Cost information on Tier 3 services was changed to the costs reported for the delivery of Tier 3 services as a result of a weight management services audit done in 2015 by Public Health England (Coulton et al. 2015).
8	Tier 3 cost	£1,796	£1,417 (Year 1) £570 (Year 2)	We considered the costs of delivering a hybrid type of Tier 3 services, for example as a hybrid of 'in-person' and virtual or telephone appointments and its effect on the cost-effectiveness results. In order to incorporate this mode of service delivery we included the published costs (NHS National Cost Collection, 2021-22) associated with a referral to secondary care outpatient bariatric services. This included an initial face to face MDT outpatient appointment and a series of follow up MDT non-face-to-face appointments. Only costs were altered with the effectiveness being assumed the same.
9	Tier 3 cost	£1,796	£1,350	Threshold analysis – we decreased the costs of Tier 3 services by an amount which would reverse the results of our base case analysis to show the price at which Tier 3 services would have to be in order for this strategy to be cost-effective.
10	Digitally enabled technologies cost (Liva)	6 months: £1,100 12 months: £1,320 24 months: £1,720	6 months: £1,485 12 months: £1,782 24 months: £2,322	Threshold analysis – we increased intervention costs by a percentage point which would reverse the results of our base case analysis. This increase in costs would account for any currently unknown costs associated with the training of NHS staff, use and maintenance of these technologies if they were to become offered as part of the UK NHS weight management services.

Abbreviations: MDT, multidisciplinary team; RCT, randomised controlled trial;

7.5 *Results from the economic modelling*

Base case

Base case results are reported in Table 29. In the base case the digitally enabled weight management technologies are shown to be more effective and have a lower cost, and are therefore a dominant strategy.

Table 29: EAG base case results

	Standard Care (Tier 3 weight management services)	Digitally enabled weight management services (Liva)
Cost	£2,342	£1,982
QALYs	1.537	1.543
Mean NB @ £20,000	£43,774	£44,294
Interpretation		Dominant
Abbreviations: NB, Net Benefit; QALY, Quality Adjusted Life Year		

Sensitivity analysis

The results of the sensitivity analysis are shown in Table 30. As Table 30 shows for most of the scenarios considered, digitally enabled services are less costly but more effective and hence digitally enabled services are the dominant strategy. For some strategies (for example strategy 5 where alternative, lower, costs of standard care are used) standard care is less costly but less effective. In this circumstance the extra QALY would be worth the extra cost at conventional thresholds for society's willingness to pay for a QALY.

Table 30: Results of sensitivity analysis

Scenario		Standard care			Digitally enabled weight management services (Liva)			Interpretation
#	Description	Cost	QALYs	Mean Net Benefit at £20,000	Cost	QALYs	Mean Net Benefit at £20,000	
Base case	-	£2,342	1.537	£43,774	£1,982	1.543	£44,294	Digitally enabled services dominant
1	Dropout rates and weight loss % for standard care from Alkharaiji et al. (2019)	£2,456	1.540	£43,737	£1,982	1.543	£44,294	Digitally enabled services dominant
2	Assumed dropout rate of digitally enabled services equal to standard care	£2,342	1.537	£43,774	£1,862	1.540	£44,346	Digitally enabled services dominant
3	No utility increment for those losing <5% weight	£2,342	1.531	£43,589	£1,982	1.537	£44,134	Digitally enabled services dominant
4	Increase utility increments by 100%	£2,342	1.547	£44,057	£1,982	1.557	£44,738	Digitally enabled services dominant
5	Standard care cost from Jennings et al. (2014) - Lower	£1,378	1.537	£44,737	£1,982	1.543	£44,294	Standard care cost-effective
6	Standard care cost from Jennings et al. (2014) - Upper	£1,915	1.537	£44,200	£1,982	1.543	£44,294	Digitally enabled services cost-effective
7	Standard care cost from Public Health England Audit	£611	1.537	£45,504	£1,982	1.543	£44,294	Standard care cost-effective
8	Standard care cost - Hybrid Services	£1,421	1.537	£44,695	£1,982	1.543	£44,294	Standard care cost-effective
9	Threshold analysis – standard care costs reduced to £1,350	£1,760	1.537	£44,355	£1,982	1.543	£44,294	Standard care cost-effective
10	Threshold analysis – digitally enabled services cost increased by 35%	£2,342	1.537	£43,774	£2,510	1.543	£43,766	Standard care cost-effective

Abbreviations: QALY, Quality Adjusted Life Year

Summary

Based on the very limited evidence and simple decision modelling, there appears to be a prima facie case for digitally enabled services being cost-effective compared with current standard practice. In the base case analysis (Table 29), the digitally enabled technologies were shown to be both less costly and more effective than current Tier 3 services meaning use of digitally enabled technologies was the dominant strategy. The differences in net monetary benefit between the alternative treatments (Tier 3 and digitally enabled technologies) were relatively small for the average patient. Sensitivity analyses explored changes to the key model parameters.

Sensitivity analyses exploring changes to the dropout rate and proportions of patients achieving a clinically significant body weight loss in standard care (Sensitivity Analysis #1 and Sensitivity Analysis #2) and changes to the utility values (Sensitivity Analysis #3 & Sensitivity Analysis #4) did not change the results markedly, with the digitally enabled services remaining less costly and more effective and therefore the dominant strategy. With regards to dropout rate, sensitivity analysis (#2) shows that the digitally enabled weight management service could potentially be cost-effective if the drop out rates for digitally-enabled technologies were equal to those in Tier 3 services. For all these sensitivity analyses the differences in net monetary benefit between the treatment arms were relatively small.

A number of sensitivity analyses were conducted relating to the cost of Tier 3 weight management programmes (standard care) based on estimates previously reported in the literature and source by the EAG. In Sensitivity Analyses (#5 and #6), the cost of standard care was adjusted using the estimates of providing the service in a primary care setting as reported by Jennings et al. (2014). Using the upper estimate, the digitally enabled services were not dominant but still cost-effective as they provided more QALYs at a higher cost but the net monetary benefit was positive (or higher) compared with standard care and therefore deemed worth investing in. Using the lower estimate, standard care was found to be cost-effective. Using the cost estimate for Tier 3 services reported by Coulton et al. (2015) as part of the 2015 Public Health England weight management services audit (Sensitivity Analysis #7), standard care was again found to be cost-effective. Using an estimated cost of using hybrid Tier 3

weight management services (Sensitivity analysis #8), standard care was found to be cost-effective.

Finally, we conducted threshold analyses related to the costs of both digitally enabled services and standard care. Results indicated that if the estimated costs of standard care were to reduce to £1,350 (a reduction of approximately 25%) then standard care would be cost-effective (Sensitivity Analysis #9). Similar analysis indicated that if the costs of the digitally enabled services were to increase by approximately 35%, then standard care would be the cost-effective strategy (Sensitivity Analysis #10).

Limitations

The evidence base for the digitally enabled weight management programmes is extremely limited and uncertain, and therefore the results from the early economic modelling should be treated with considerable caution. As stated previously, the early economic model has several key limitations. Some of which are summarised below.

The early economic model has a simple decision tree format with a limited time horizon (24 months). The type of model and chosen time horizon were pragmatic decisions based on the limited time available to conduct the EVA and the available evidence to populate the model. A future model with a longer-term framework should take into account several of the key parameters that would usually be included in a comprehensive economic model evaluating the cost-effectiveness of weight management interventions. These may include the patients' previous obesity related disease history, and healthcare costs and dis-utilities associated with the co-morbidities related to obesity such as stroke, coronary heart disease and diabetes, which reflect the natural history of obesity alongside these co-morbidities.

The costs, dropout rates and estimates of weight loss for the digital health technologies and standard care in the base case were sourced for a single digital technology (Liva) due to the lack of available data, we assumed a class effect applicable to other 'like' technologies. It is currently unclear how generalisable these estimates are to the other digital technologies, given the different delivery models of each technology, for example the ratio of digital to in-person services provided by

each of the digital technologies. However, the sensitivity analyses conducted suggest that there is some scope for variation in both the cost of the digitally enabled weight management services and the effectiveness with respect to drop-out rate and the different technologies considered by the EAG are likely to reside within the range of scenarios considered in our analyses. Furthermore, the evidence for the single digital technology is taken from a single RCT set in Denmark, and it is not clear how comparable this study is to the care that would be provided as part of NHS services. However, this was the best evidence that the EAG found to be representative of the adherence and effectiveness of a Tier 3 service delivered in the UK NHS setting. The dropout rates and estimates of weight loss for standard care (Tier 3 weight management services) used in the sensitivity analysis were sourced from a systematic review of the related literature (Alkharaiji et al. 2019), which mostly included prospective and retrospective cohort studies. Although the evidence from this systematic review was directly applicable to the UK NHS setting, the authors concluded that all included studies showed high risk of bias in terms of selection, performance, detection and attrition.

The increment in utility associated with weight loss were estimated using a recent study that has estimated the impact of changes in weight and BMI on EQ-5D-3L utility values using longitudinal regression methods. However, as previously mentioned, several strong assumptions were used to incorporate these estimated increments into the model.

The estimated costs of the digitally enabled weight management programmes were provided to the EAG by the Companies. The cost of current Tier 3 weight management services is very uncertain given the heterogeneity of how the services are provided across the NHS and this will impact on the cost of such services between regions. The EAG has conducted several sensitivity analyses to counter this limitation, showing its impact on the cost-effectiveness. A clearer definition of these services alongside a detailed outline of the resources needed for their delivery is needed for a future robust economic evaluation.

The economic model did not include the cost of weight loss medication. By extension, the economic model did not take into account adherence to the weight

loss medication, which may differ between digitally enabled services and current standard care. The implicit assumption is that adherence is the same between the 2 modes of delivery. By including dropout rates specific to the 2 interventions within the model we have allowed for this difference in rate to occur as a result of a potential difference in adherence to medication or due to other aspects of the programme. As shown in Table 5, although there is some evidence related to adherence to the digitally enabled technologies at defined timepoints, there is currently no applicable published evidence specifically related to adherence to weight loss medication and this requires further exploration. Due to supply issues of semaglutide and liraglutide, it is not currently possible to quantify the proportion of eligible patients taking weight management medication for obesity, however this could be an outcome of interest in future research.

The economic model did not take into account alternative treatment pathways aside from Tier 3 specialist weight management services (either digitally enabled or in line with current standard care) that may occur during the time horizon of the model. For example, it did not take into account that a proportion of the patients may move on to Tier 4 weight management services (including weight loss surgery) during the time horizon of the model and by extension the potential costs and outcomes associated with engaging with these services. The model did not account for any medication stopping rules related to weight loss. Published NICE guidance for semaglutide states that stopping the medication should be considered if less than 5% of the initial weight has been lost after 6 months of treatment.

The economic model does not take into account issues related to access and uptake. For example, it assumes that both treatment options (digitally enabled services and current standard care) are available to all eligible patients where the provision of a service exists. Access to specialist weight management services varies substantially across England and Wales, and therefore use of digitally enabled services may enable a proportion of patients to access services they previously could not. It is also unclear what the uptake rates would be for areas which currently offer Tier 3 services and those that do not. Clinical Experts consulted by the EAG estimated that up to 20% of patients may not be able to access digital services, and

so it may be that all regions would need to retain the ability to deliver an in-person service.

Finally, the model does not take into account local capacity constraints for technologies that use existing NHS resources. If the digitally enabled services were to increase accessibility to Tier 3 specialist weight management services, more staff may be required to conduct MDTs, reviews, or manage possible adverse events. There is no guarantee that these resources would be available in each local commissioning group due to the heterogeneity in local priorities.

8 Interpretation of the evidence

8.1 *Interpretation of the clinical evidence*

The current evidence base, including unpublished and non-peer reviewed, comprises 27 publications reporting on 22 studies. There is evidence available for 20 of the 24 outcomes across 4 of the 8 technologies for which there is evidence relevant to the decision problem (Gro Health, Liva, Oviva, Roczen). Relating to generalisability, approximately half of the evidence base is set within the UK (largely in an NHS setting). The EAG note that there is limited evidence relating to medication adherence or intervention-related adverse events, which should be captured to ensure patient safety during delivery of specialist weight management services, either digitally or in-person.

The included evidence generally reports weight loss (mean or median) when compared with baseline, and greater magnitude of weight loss with digitally enabled programmes compared with standard care (non-digitally enabled programmes), however the clinical significance of this difference, and statistical significance of this difference beyond 1 year are uncertain. Equivalent effectiveness of the digitally enabled technologies in facilitating or providing specialist weight management, including safety and medication monitoring, for patients with obesity would likely support adoption in the NHS. Four of the included technologies (CheqUp, Gro Health, Oviva, Roczen) report the use of expected weight loss data trends relating to medication use alongside standard care as part of safety monitoring. Possible differences in weight loss between digitally enabled and standard care specialist weight management and the robustness of self-reported weight measurements

should be carefully considered with patient safety in a complex condition, such as obesity, and in the ongoing monitoring of weight loss medication and patient health.

There was no evidence relating to weight loss outcomes for Gro Health. Additionally, there is no published evidence relating to CheqUp, Juniper, or Wellbeing Way or for Second Nature relevant to this NICE EVA Scope. No comparison between technologies has been identified and respective differences in technology and programme delivery may limit the generalisability of the available evidence.

The EAG acknowledges that collecting evidence relating to digitally enabled specialist weight management programmes is a new field and note the existing evidence base lacks clinical consensus on important outcome measures and is affected by poor reporting of important covariates. There is limited consensus in the reviewed literature for the definition of clinically significant weight loss. Furthermore, the proportion of patients taking weight loss medication and their adherence to medication were poorly reported. Addressing these issues for planned studies and identifying key outcomes for data collection would help future technology assessments and Committee decision-making.

The EAG acknowledges that heterogeneity in uptake and adherence of digitally enabled and standard care weight management programmes may lead to bias because of differences in baseline characteristics and dropout rates between arms. However, the limited evidence base available for review suggests that use of digitally enabled weight management programmes may improve or broaden accessibility of specialist weight management services across the NHS.

8.2 *Interpretation of the economic evidence*

There is no direct economic evaluation related to the specified decision problem included in the Scope. Four studies were identified that evaluated the cost-effectiveness of remotely delivered weight management programmes, however, none of the comparators included MDT Tier 3 services and the conclusions were limited by a lack of data on the maintenance of weight loss beyond 12 months. This limited time horizon fails to provide longer-term evidence and therefore may not adequately capture the longer-term health impact of obesity.

Based on the very limited evidence and decision modelling undertaken by the EAG, there appears to be a prima facie case that the digitally enabled weight management services may be cost-effective compared with current standard practice in areas where this service is offered, given that the digitally enabled services may be as effective as current standard care and potentially provided at a lower cost. Sensitivity and threshold analysis showed that the results were most sensitive to the estimate of cost used for current Tier 3 services and providing an accurate estimate for delivery of current provision should be an area of research that should be prioritised.

Despite the base case results suggesting that the digitally enabled weight management service is dominant to standard care, the EAG reiterates that given the limited evidence base available for review, these conclusions should be treated with considerable caution. Further comparative data collection for the various digitally enabled technologies together with more sophisticated economic modelling is needed to establish whether the digitally enabled technologies are truly a cost-effective use of NHS resources over an appropriate time horizon for decision makers.

8.3 *Integration into the NHS*

Current use of technologies in the NHS

Currently, Gro Health, Liva and Oviva are used within Tier 3 specialist weight management services in the NHS (Appendix E). At fact check, Second Nature reported that they deliver Tier 3 specialist weight management services in partnership with the NHS. Four technologies are currently used within other NHS settings; Liva, Oviva, Second Nature and Wellbeing Way offer programmes to support the NHS Weight Management Programme and Oviva, Liva and Second Nature also deliver a Diabetes Prevention Programme (see Section 5.5). Approximately one third of the included 27 publications were completed in a UK NHS setting.

UK weight management services

Responses from 12 Clinical Experts highlight variation across NHS specialist weight management services, however all responses suggest that current standard of care uses a hybrid approach to service delivery including both face-to-face and virtual or

telephone appointments (Appendix F). One Clinical Expert stated that Tier 3 and Tier 4 specialist weight management services are set up differently across the NHS, 2 Clinical Experts stated that the differences in Tiers will depend on individual patient needs, 2 Experts stated that more regular support was provided in Tier 3, however that a consultant surgeon would be involved in Tier 4. Four Clinical Experts stated that Tier 4 would have a higher proportion of face-to-face follow-up appointments than Tier 3, 1 explaining that this was needed because of the need for bariatric blood tests, 1 stated the need to physically examine the patient or perform procedures, and 1 said that Tier 4 was 100% face-to-face because its focus relates to weight loss surgery.

The 12 Clinical Experts estimated that the proportion of Tier 3 specialist weight management services delivered face-to-face ranged between 20% and 100% for the first appointment and between 10% and 100% for follow-up appointments. Two Clinical Experts gave details of how follow-up face-to-face proportion varied across disciplines with 90% to 100% for medical reviews, 70% to 80% for nursing reviews; 55% to 70% for dietetic reviews, and 0% to 90% for psychology reviews. Another Expert noted that non-attendance to appointments differed by specialism; higher non-attendances are seen for dietetic and psychology appointments than those with surgeons or clinical nurse specialists.

The Experts advised that access to appropriate Tier 3 specialist weight management services was a concern across the NHS, with 3 Clinical Experts noting that referrals would not be made if a service was not geographically available, 1 reported taking referrals from a large service requiring patients to make extended journeys, 4 Clinical Experts estimated between 30 to 70% of people have no access to local Tier 3 services. Another Expert advised that the number of patients without Tier 3 specialist weight management services will increase as only 3 of 13 Local Authorities have access to Tier 2 services plus NHS Digital Weight Management Programme is restricted to patients with BMI greater than 30 plus diabetes or hypertension. Five Clinical Experts estimated that between 10% and 30% of patients may be unable to attend face-to-face appointments, with 1 Clinical Expert stated that main reasons are often related to childcare, work commitments and mental health, 1 Clinical Expert reported that those who had difficulty with face-to-face would also have difficulty with

a digital app, and 1 Clinical Expert stating that digitally enabled programmes might improve access for patients receiving domiciliary support (estimated as 2 to 3 people out of over 1,000 annual referrals).

Eight Clinical Experts estimated that between 7% and 30% of users would find a digitally enabled programme unsuitable, for example because of poor manual dexterity, learning difficulties or digital inequality, and 2 felt that the proportion would be less than 20%. One Clinical Expert noted that it could be region specific particularly where language is a main barrier. Two Clinical Experts felt that digital health technologies would be unsuitable for all Tier 3 weight management service users, as they would be unable to assess and treat obesity as a disease because a digital system would not capture the complexities including comorbidities, psychological health and personal circumstances. Another Clinical Expert considered digitally enabled technologies may not provide the appropriate level of a personal touch or compassionate support to overcome past events that may have caused weight gain, noting 30% of those accessing the service had a history of abuse (Appendix F). Patients being seen by specialist weight management services often present with several issues that need assessing by an MDT to determine the most appropriate treatment and support required.

Weight management medication

The EAG acknowledge supply issues for weight management medications within the NHS (SPS, 2023). Five Clinical Experts estimated that between 4% to 30% of Tier 3 specialist weight management service users would be taking liraglutide and 3 Clinical Experts reported that those taking medication would increase significantly when semaglutide becomes available. Two Clinical Experts stated that in some Tier 3 specialist weight management services no patients would be taking weight loss medication because of lack of medications or prescribers, and 1 Clinical Expert was unable to comment because of lack of data systems recording this information. Relating to Tier 4 specialist weight management services, 4 Clinical Experts reported fewer than 5% of patients would be taking weight loss medication, and 2 Clinical Experts reported 10%; 5 Clinical Experts were unable to provide an estimate. Only 2 publications included in this EVA explicitly excluded participants receiving weight loss medications which may confound results. Concerns were raised at the scoping

meeting regarding patient safety when remotely monitoring medications and overall wellbeing in managing a complex condition, such as obesity.

NHS Diabetes Prevention Programme (DPP)

In 2016, the NHS DPP was launched and included digital health technologies to deliver programmes for patients with and at risk of T2DM. While the clinical areas are different, there is significant overlap in these patients and those with obesity. Barron et al. (2023) showed comparative weight change in patients receiving digital programmes compared with those receiving face-to-face programmes, and McGough et al. (2019) noted that participants preferring a digital intervention were younger than those opting for a face-to-face NHS DPP delivery (58.0, SD 12.4 years versus 64.0, SD 12.4 years, $p<0.001$). Early economic modelling has shown that there is scope for investment in interventions that improve uptake to the NHS DPP (Frempong et al. 2022) as participation in the programme was a challenge. Considering strategies for the implementation of the digital NHS DPP within Tier 3 and 4 specialist weight management services may be appropriate.

Training

Information relating to technology training was provided directly to NICE by 7 of the 8 Companies, with 6 providing training to professionals delivering the digitally enabled weight management programmes and the patients accessing the digital health technology. Wellbeing Way explicitly does not offer training for the technology and states that the app is intuitive to use with prompts, notifications and reminders given to the service user during the programme course. The EAG considers that training resources relevant to implementation of the technologies within the NHS should focus on supporting referrers to the digitally enabled specialist weight management programmes. Oviva provides GP and primary care referrer training to identify eligible patients and referral routes (Appendix E).

Additional factors

The level of input from NHS staff varies across the technologies, with some programmes using existing NHS MDT staff and others providing all services in-house, with some staff also having secondary employment within the NHS (Appendix E). The Health Survey for England 2021 estimated that 25.9% of adults are living

with obesity in England. Therefore, if the technologies included within this EVA increase accessibility to specialist weight management services across the NHS, it is unclear how these technologies will affect NHS resource use (for example, staff time, waiting lists).

Some patients may also have a preference for a combination of face-to-face and digitally enabled specialist weight management services; only 1 study reported composition and level of MDT support reporting 13% (10 of 79) patients requested face-to-face contact with a dietitian in addition to the digitally enabled weight management programme and telephone support, however reasons for this were not provided. However, reduction in face-to-face patient contact may limit the opportunity to adequately assess or evaluate a patient's health and wellbeing or identify adverse events and may impact the ability to identify comorbidities or new diagnoses, such as those that necessitate physical examination. Therefore, introduction of a digitally enabled pathway may impact other areas of the NHS system.

None of the included technologies within the Scope of this assessment include a bariatric surgeon, therefore the level of support from digitally enabled technologies in Tier 4 weight management services remains uncertain.

Three Clinical Experts estimated that between 10% and 30% of patients would have the medication withdrawn due to the stopping criteria of semaglutide (TA875) where less than 5% of the initial weight has been lost after 6 months, 2 Clinical Experts predicted that most patients would have the medication withdrawn for this reason. One commercial in confidence study (Oviva CiC-1) [redacted] Furthermore, Imeraj et al. (2022) stated that self-reported body weight was lower than the weight measured in clinic at 6 and 12 months by 1.03 kg (95% CI 1.01 to 1.05; p<0.001) and 1.03 kg (95% CI 0.99 to 1.04; p<0.001) respectively. However, reported that difference in weight was unlikely to be clinically significant due to weight fluctuations during the day and uncertainty associated with typical bathroom scales.

8.4 *Evidence gap analysis*

A summary of the evidence gaps across the published evidence, unpublished evidence and ongoing studies, is shown in Table 31 and Table 32 respectively. When determining whether the level of evidence meets or partially meets the outcomes in Scope, the EAG considered the relevance of the available evidence to the decision problem and the generalisability of findings in addition to the evidence quality (for example, published, peer-reviewed, appropriately powered, or statistical analysis).

Table 31: Evidence Gap Analysis: Available evidence [Key: studies available in abstract only are highlighted in grey; studies provided academic or commercial in confidence have been incorporated and shown in bold]

	Outcome measure	CheqUp (N=0)	Gro Health (N=1)	Juniper (N=0)	Liva (N=7)	Oviva (N=9)	Roczen (N=3)	Second Nature (N=0)	Wellbeing Way (N=0)
Intermediate measures	Engagement with the programme	**RED** None	**AMBER** Hanson et al. (2023) prospective cohort (n=199)	**RED** None	**RED** None	**GREEN** McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79); Huntriss et al. (2021) retrospective non-randomised comparative cohort (n=169); [redacted] **Oviva CiC-3**	**RED** None	**RED** None	**RED** None
	Intervention adherence, rates of attrition and completion	**RED** None	**RED** None	**RED** None	**GREEN** Christensen et al. (2022a), Hesseldal et al. (2018), Christensen et al. (2022b), Imeraj et al. (2022) 3 publications and 1 secondary analysis from same RCT (n=340); Pedersen et al. (2019) retrospective cohort (n=2,684); **Liva CiC-1**; **Liva CiC-2**; **Liva CiC-3**;	**GREEN** McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79); Huntriss et al. (2021) retrospective non-randomised comparative cohort (n=169); Haas et al. (2019) before-and-after study (n=43); [redacted] **Oviva CiC-2**; **Oviva CiC-3**	**AMBER** [redacted]	**RED** None	**RED** None
	Intervention-related adverse events	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None
	Weight management medication adherence and medication-related adverse events	**RED** None	**RED** None	**RED** None	**RED** None	**AMBER** **Oviva CiC-1**	**RED** None	**RED** None	**RED** None
	Inaccessibility to intervention (digital inequalities)	**RED** None	**AMBER** Hanson et al. (2023) prospective cohort (n=199)	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None
Clinical outcomes	BMI	**RED** None	**RED** None	**RED** None	**GREEN** Hesseldal et al. (2022) RCT (n=340); Komkova et al. (2019) before-and-after (n=103)	**AMBER** Haas et al. (2019) before-and-after (n=43); Huntriss et al. (2021) retrospective non-randomised comparative cohort (n=169)	**AMBER** **Roczen AiC-2**	**RED** None	**RED** None
	Weight loss	**RED** None	**RED** None	**RED** None	**GREEN**	**GREEN**	**AMBER**	**RED** None	**RED** None

Outcome measure	CheqUp (N=0)	Gro Health (N=1)	Juniper (N=0)	Liva (N=7)	Oviva (N=9)	Roczen (N=3)	Second Nature (N=0)	Wellbeing Way (N=0)
				Christensen et al. (2022a), Hesseldal et al. (2022) and Imeraj et al. (2022) all from same RCT (n=340); Komkova et al. (2019) before-and-after (n=103); **Liva CiC-1**; **Liva CiC-2**; **Liva CiC-3**;	Huntriss et al. (2021) retrospective non-randomised comparative cohort (n=169) Haas et al. (2019) before-and-after (n=43); McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79); Sutter et al. (2021) non-randomised cohort (n=86); **Oviva CiC-1**; **Oviva CiC-2**; **Oviva CiC-3**	[redacted]; **Roczen AiC-1**; **Roczen AiC-2**		
Body fat	**RED** None	**RED** None	**RED** None	**RED** None	**AMBER** Haas et al. (2019) before-and-after (n=43); McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79)	**RED** None	**RED** None	**RED** None
Waist circumference	**RED** None	**RED** None	**RED** None	**AMBER** Hesseldal et al. (2022) RCT (n=340)	**AMBER** Haas et al. (2019) before-and-after (n=43); McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79)	**AMBER** [redacted]; **Roczen AiC-2**	**RED** None	**RED** None
Waist-to-hip ratio	**RED** None	**RED** None	**RED** None	**AMBER** Hesseldal et al. (2022) RCT (n=340)	**RED** None	**RED** None	**RED** None	**RED** None
Hip circumference	**RED** None	**RED** None	**RED** None	**AMBER** Hesseldal et al. (2022) RCT (n=340)	**AMBER**McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79)	**RED** None	**RED** None	**RED** None
HbA1c	**RED** None	**RED** None	**RED** None	**AMBER** Christensen et al. (2022a) and Hesseldal et al. (2022) from the same RCT (n=340); [redacted]	**AMBER** Haas et al. (2019) before-and-after (n=43); McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79); [redacted]; [redacted]	**AMBER** [redacted]; **Roczen AiC-2**	**RED** None	**RED** None
Cardiovascular events	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None
Mortality	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None
Physical activity	**RED** None	**RED** None	**RED** None	**AMBER** Christensen et al. (2022b) RCT (n=340)	**AMBER** Haas et al. (2019) before-and-after (n=43)	**RED** None	**RED** None	**RED** None

	Outcome measure	CheqUp (N=0)	Gro Health (N=1)	Juniper (N=0)	Liva (N=7)	Oviva (N=9)	Roczen (N=3)	Second Nature (N=0)	Wellbeing Way (N=0)
PROMs	Rate of referral for weight loss surgery	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None	**RED** None
	Eating habits	**RED** None	**RED** None	**RED** None	**AMBER** Christensen et al. (2022b) RCT (n=340)	**AMBER** Haas et al. (2019) before-and-after (n=43); McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79);	**RED** None	**RED** None	**RED** None
	Health-related quality of life	**RED** None	**RED** None	**RED** None	**AMBER** Hesseldal et al. (2022) RCT (n=340)	**AMBER** Lawson et al. (2022) before-and-after (n-54); Haas et al. (2019) before-and-after (n=43)	**AMBER** [redacted]; **Roczen AiC-2**	**RED** None	**RED** None
	Patient satisfaction	**RED** None	**RED** None	**RED** None	**GREEN** **Liva CiC-1**; **Liva CiC-2**	**GREEN** Huntriss et al. (2021) retrospective non-randomised comparative cohort (n=169); [redacted]	**RED** None	**RED** None	**RED** None
Economics	Healthcare appointments	**RED** None	**RED** None	**RED** None	**RED** None	**AMBER** Huntriss et al. (2021) retrospective non-randomised comparative cohort (n=169)	**RED** None	**RED** None	**RED** None
	Medication use and adverse events	**RED** None	**RED** None	**RED** None	**AMBER** Christensen et al. (2022b) and Hesseldal et al. (2022) from the same RCT (n=340)	**AMBER** McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79); [redacted]; **Oviva CiC-2**	**AMBER** [redacted]	**RED** None	**RED** None
	Healthcare professional grade and time	**RED** None	**RED** None	**RED** None	**RED** None	**AMBER** McDiarmid et al. (2022) pilot RCT programme used in both arms (n=79)	**RED** None	**RED** None	**RED** None

Key: **GREEN**, evidence available; **AMBER**, partial evidence available; **RED**, no evidence available
Abbreviations: AiC, academic in confidence; BMI, body mass index; CiC, commercial in confidence; HbA1c, glycated haemoglobin; RCT, randomised controlled trial

Table 32: Evidence Gap Analysis: Ongoing studies

	Outcome measure	CheqUp	Gro Health	Juniper	Liva	Oviva	Roczen	Second Nature	Wellbeing Way
Intermediate measures	Engagement with the programme	RED None	AMBER Single study	RED None	RED None	AMBER Multiple studies	RED None	RED None	RED None
	Intervention adherence, rates of attrition and completion	RED None	AMBER Multiple studies	RED None	RED None	AMBER Multiple studies	RED None	RED None	RED None
	Intervention-related adverse events	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Weight management medication adherence and medication-related adverse events	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Inaccessibility to intervention (digital inequalities)	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
Clinical outcomes	BMI	RED None	RED None	RED None	AMBER Single study	AMBER Multiple studies	RED None	RED None	RED None
	Weight loss	RED None	AMBER Multiple studies	RED None	RED None	AMBER Multiple studies	RED None	AMBER Single study	RED None
	Body fat	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Waist circumference	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Waist-to-hip ratio	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Hip circumference	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	HbA1c	RED None	AMBER Multiple studies	RED None	RED None	AMBER Multiple studies	RED None	AMBER Single study	RED None
	Cardiovascular events	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Mortality	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Physical activity	RED None	RED None	RED None	RED None	AMBER Single study	RED None	RED None	RED None
	Rate of referral for weight loss surgery	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Eating habits	RED None	RED None	RED None	RED None	AMBER Single study	RED None	AMBER Single study	RED None
PROMs	Health-related quality of life	RED None	AMBER Multiple studies	RED None	RED None	AMBER Multiple studies	RED None	AMBER Single study	RED None
	Patient satisfaction	RED None	RED None	RED None	RED None	AMBER Multiple studies	RED None	AMBER Single study	RED None
Economics	Healthcare appointments	RED None	AMBER Single study	RED None	AMBER Single study	AMBER Multiple studies	RED None	RED None	RED None
	Medication use and adverse events	RED None	AMBER Multiple studies	RED None	AMBER Single study	AMBER Multiple studies	RED None	RED None	RED None
	Healthcare professional grade and time	RED None	AMBER Single study	RED None	AMBER Single study	AMBER Multiple studies	RED None	RED None	RED None

Key: GREEN, study may provide evidence for the outcome; AMBER, ongoing study could partially address this outcome; RED, no ongoing planned study to address outcome
Abbreviations: BMI, body mass index; HbA1c, glycated haemoglobin; RCT, randomised controlled trial

8.5 *Summary and conclusions of evidence gap analysis*

The evidence gaps identified by the EAG are summarised below.

Study design gaps

There is 1 RCT (based in Denmark) which compared digitally enabled weight loss programme (using Liva) with standard care (face-to-face consultations); with no weight loss medication reported in either arm. There is a lack of randomised evidence to show effect on weight loss for the remaining 5 technologies. The EAG acknowledge the challenges of designing an RCT with patient-level randomisation with external validity that is generalisable to the NHS. Challenges include differences in the level of intervention engagement in the population eligible for the intervention (NICE, 2022), with some patients unable or unwilling to access digital health technologies, and others who may have a strong preference for doing so; and local and regional differences in standard care practices. Furthermore, conducting an RCT to explore the impact of digitally enabled specialist weight management programmes compared with no intervention would not be ethical. The EAG has not identified any ongoing RCTs directly relevant to the Scope.

Real-world evidence is available for Oviva, Liva and Roczen. Limited evidence was identified for Gro Health and no evidence relevant to the scope of this EVA was identified for Second Nature. No evidence was identified for CheqUp, Juniper or Wellbeing Way technologies. Comparative real-world studies are likely to add evidence to address uncertainties relating to the use and benefit of the technology within the NHS. Ongoing UK-based real-world studies for Gro Health, Liva, Oviva and Second Nature and reported by the Company at fact check for Roczen have been identified that may address some of the real-world evidence gaps.

Longitudinal evidence is limited to 2 years for Liva, 1 year for Oviva, mean 1 year for Roczen, and 8 months for Gro Health. The EAG recommend a minimum of 2 years follow-up should be conducted for all technologies in line with current weight management programmes. Follow-up data from the RCT set in Denmark reports that there was no evidence of a difference in weight loss between arms (Liva versus standard care) at 24 months. Long-term outcomes should focus on maintenance of

weight loss and other health benefits associated with the interventions. No ongoing studies have been identified to address this evidence gap. The NHS Obesity Audit may provide a way of monitoring long-term weight loss in patients attending specialist weight management services. However, it is unclear how this information could be obtained from patients not engaging in specialist weight management services as a comparator group (those either on waiting list for specialist weight management or declining intervention).

Population gaps

Only 1 published study reported the proportion of patients taking weight loss medication; this was within baseline patient characteristics, not as an outcome. No published evidence was identified exclusively in patients taking weight loss medication, such as semaglutide and liraglutide. Of the evidence shared in confidence with the EAG, [redacted] only 1 study reported medication adherence and medication-related adverse events outcomes. Only 2 publications explicitly excluded patients taking weight loss medication; which may confound results. No ongoing studies have been identified to address this evidence gap. Evidence on how different patient groups may engage and use a digitally enabled weight management programme is also lacking.

Intervention gaps

Limited evidence was identified for Gro Health. No evidence was identified for CheqUp, Juniper or Wellbeing Way technologies. No evidence relevant to the scope of this EVA was identified for Second Nature. No comparison between technologies has been identified. No ongoing studies for CheqUp, Juniper, Roczen or Wellbeing Way have been identified. At fact check, Roczen reported 2 ongoing studies.

Comparator gaps

The number of Tier 3 specialist weight management service providers in the NHS, and total number of patients accessing these services remains unknown. The NHS Obesity Audit will enable monitoring of accessibility to these services over time.

Outcome gaps

Outcomes are broad and may be difficult to isolate the effect size of a digital technology. There are a large number of outcomes within the Final Scope. Only 1 commercial in confidence study reported on medication adherence. No evidence was identified that reports on intervention-related adverse events, cardiovascular events, mortality or rate of referral for weight loss surgery. No ongoing studies explicitly listing these outcomes have been identified to address this evidence gap.

Decision modelling gaps

No direct economic evaluations related to the 8 included technologies were identified. The EAG notes that the following evidence will need to be generated for inclusion in future economic evaluations:

- Robust comparative data on costs and outcomes associated with the long-term use of digitally enabled weight management technologies. These include effectiveness measures, adherence rates and the longer-term costs associated with the maintenance of the technologies and the potential costs of incorporating these services in the NHS pathways. The EAG notes that some of these costs may be context specific and will vary considerably across regions depending on how the service is provided.

- Comparative evidence on medication adherence for patients accessing weight management services via digitally enabled technologies.

- Information on the typical frequency, duration of appointments and follow-up in Tier 3 services across England. As found in the literature and as stated by our clinical experts, it is currently unclear what MDT weight management services in secondary care looks like. This uncertainty may have an important impact on cost-effectiveness. The results from the economic analysis indicated that the cost of delivering weight management services is the main driver in the cost-effectiveness of these services.

- A future economic model should incorporate a previous obesity-related disease history and a longer-term time horizon able to account for the longer-term impact of health outcomes associated with obesity. This would involve

including a wider range of healthcare costs associated with the comorbidities associated with obesity such as stroke, coronary heart disease and diabetes. Modelling key weight related comorbidities is key to fully reflect the natural history of being obese.

- A future model should include transitions from Tier 3 to Tier 4 specialist weight management services and the NHS costs associated with patients transferring to weight loss surgery as this may differ between current service provision and digitally enabled weight management services.

- Outcomes, uptake and dropout rate will also be affected by medical and socio-economic factors. Differential access to digitally enabled technologies may have a negative impact on health inequalities. Further evidence is needed on how the roll-out of these technologies may affect those most disadvantaged.

8.6 *Key areas for evidence generation*

The EAG considered recommendations for evidence generation, Table 33.

Key outcome recommendations

The level of evidence relating to each outcome differs across the 4 digitally enabled weight management programmes for which there is published evidence (Table 31). The EAG recommend that *key* outcomes relevant to the decision problem are identified to inform future evidence generation to enable a focused and appropriate future evaluation of the technologies. Outcomes may align with existing technology appraisals, such as those for semaglutide (TA875) or liraglutide (TA644), which have 9 and 11 outcomes in Scope respectively, for which economic evaluations have been completed. The EAG has suggested possible categorical prioritisation for the outcomes in Scope that could support future Committee decisions and guidance production for the technologies in Scope (Table 34).

Reporting recommendations

Future studies on technologies providing digitally enabled weight management programmes should be published in peer-reviewed publications and made available in the public domain. These should explicitly report:

- the technology name in the title and abstract to assist with future literature searches,
- the proportion of patients taking weight loss medications,
- a focused subset of outcome measures in a standardised format, for example:
    - initial engagement with the programme (and the proportion maintained on standard care) and ongoing commitment in using the programme;
    - clinically significant weight loss as defined as 5% of baseline weight or greater;
    - health-reported quality of life measures.

Impact on services and resource use

Collaborating with the NHS Obesity Audit team would be beneficial in monitoring whether technologies providing digitally enabled weight management programmes benefits the total number and uptake of NHS specialist weight management services over time.

Table 33: Evidence generation recommendations

Key research question	Study design	Population	Intervention	Comparator	Outcome measures or data collection methods	EAG Comments
Is a digitally enabled weight management programme as effective as standard care?	Non-randomised comparative cohort with suitable statistical approaches to adjust for potential confounders	Adults eligible for referral to specialist weight management services for management of obesity.	Digitally enabled weight management programme. Patients may also take weight management medication as per standard care.	Standard care delivery of existing specialist weight management services.	Changes in clinical outcomes and health-related quality of life. Additional outcomes: • Time to intervention completion or dropout • Digital health technology use • Referral for weight loss surgery • Mortality • Device-related feedback • Complications • Medication use and medication-related adverse events (where appropriate) • GP or secondary care appointments • Number of patients declining or ineligible for participation in RCT because of digital accessibility reasons through screening log review (digital inaccessibility)	The EAG acknowledge that there may be some patients who would be unable to access digital health technologies and others who may have a preference for digitally enabled programmes and so comparative real-world studies are also likely to add evidence to address uncertainties relating to the use and benefit of the technology within the NHS. Furthermore, access to weight management medication depends on the availability of weight management services, capturing adherence and medication-related adverse events is important to understand the accessibility and use of such medications in weight management for obesity.
Is a digitally enabled weight management programme effective for long-term weight management?	Individual patient Interrupted time-series	Adults eligible for referral to specialist weight management services for management of obesity.	Digitally enabled weight management programme. Patients may also take weight management medication as per standard care.	Baseline characteristics (prior to digitally enabled weight management programme)	Changes in clinical outcomes and health-related quality of life. Additional outcomes: • Device-related feedback • Time to intervention completion or dropout • Digital health technology use • Referral for weight loss surgery • Complications • Medication use • GP or secondary care appointments • Number of patients declining or ineligible for participation in RCT because of digital accessibility reasons through screening log review (digital inaccessibility)	Using patients as their own control over a longitudinal study will enable monitoring of weight loss and maintenance.
What is the impact of digitally enabled technologies on existing specialist weight management services?	Centre-based Interrupted time-series	Professionals delivering weight management services.	Digitally enabled weight management programme.	Standard care delivery of existing specialist weight management services.	• Method and uptake of service delivery (in-person, telephone, videocall, digitally enabled programme) • Time • Job title or band • Number of staff • Geographical location of weight management services • Patient catchment area for service • Number of referrals to service • Attendance rates	Data could be used to show current uptake and accessibility of specialist weight management services. Repeat audits could show changes over time. This could be captured by the NHS National Obesity audit.
What is the uptake of digitally enabled technologies to support weight management services in the NHS?	Centre-based Interrupted time-series	Adult referred or currently under a digitally enabled weight management programme	Digitally enabled weight management programme.	Not applicable	• Company-collected feedback • Number of referrals to service over time • Retention • Intervention adherence • Reason for intervention withdrawal or dropout	Company-collected data could be used to show uptake, adherence, and safety outcomes over time in addition to impact and capacity of digitally enabled weight management programmes in the NHS.
What is the patient experience of digitally enabled weight management programmes?	Interview, focus group or survey study	Adult referred or currently under specialist weight management services for management of obesity. Participants may also be professionals delivering	Digitally enabled weight management programme.	Participants may have received or be receiving standard care delivery under existing specialist weight management services.	• Participant questionnaires • Semi-structured interviews • Focus groups • Company-collected feedback • Reason for intervention withdrawal or dropout	A study to understand the reasons for lack of engagement of digital health technologies providing weight management programmes would be helpful in understanding patient and system barriers in implementing these programmes across the NHS.

Key research question	Study design	Population	Intervention	Comparator	Outcome measures or data collection methods	EAG Comments
		weight management services.				
What are the reasons for non-acceptance of digitally enabled weight management programmes?	Interview, focus group, online survey or patient preference study	Adults eligible for referral to specialist weight management services for management of obesity declining referral to digitally enabled weight management programmes	Focus groups, semi-structured, survey	Not applicable	• Participant questionnaires • Semi-structured interviews • Focus groups • Company-collected feedback • Online survey • Quantitative patient preference study (for example Discrete Choice Experiment)	This study would provide evidence and patient feedback on barriers to implementation and acceptability of digitally enabled weight management programmes. This research question could be combined with the question above in a barriers and facilitators to uptake study.
What proportion of eligible patients for specialist weight management services are appropriate for referral to a digitally enabled weight management programme?	Audit, cross-sectional study (A longitudinal study may provide trend data useful for planning)	Adults eligible for referral to specialist weight management services for management of obesity	Adults referred to specialist weight management services	Adults not referred to specialist weight management services	• Number patients eligible for referral to specialist weight management services (and the subset who specifically get referred to Tier 4) • Number of patients referred to specialist weight management services over time • Number of patients referred to digitally enabled weight management programmes	Understanding uptake and referral trends can provide evidence for the impact on weight management services in the NHS and barriers for implementation.
Is a digitally enabled weight management programme a cost-effective use of NHS resources compared with standard care?	Long-term economic modelling study (for example state transition model, patient level simulation model, system model)	Adults eligible for referral to specialist weight management services for management of obesity	Digitally enabled weight management programme.	Standard care delivery of existing specialist weight management services.	• Changes in healthcare costs • Changes in health-related quality of life • Incremental cost per quality-adjusted life year/net monetary benefit	Using the results from the relevant clinical studies, this long-term economic modelling study would use an appropriate modelling framework to estimate the cost-effectiveness of the digitally enabled services over a sufficiently long time horizon. One sensitivity analysis could focus on the ratio of digital to in person services, given the that the different digital technologies will each have different provisions of digital and in person services, which may have an impact on both effectiveness and cost.
Could a digitally enabled weight management programme free up healthcare professional resources and reduce waiting lists for Tier 3 specialist weight management programmes?	Centre-based Interrupted time-series	Professionals delivering weight management services.	Digitally enabled weight management programme.	Standard care delivery of existing specialist weight management services.	• Number of weight management consultations conducted by healthcare professionals • Number of eligible patients on the waiting list for Tier 3 weight management services	Understanding if the digitally enabled services could free up healthcare professional resources could provide evidence for the cost-effectiveness of the digitally enabled services.
Could a digitally enabled weight management programme expand the reach and uptake of Tier 3 specialist weight management programmes?	Audit	Adults eligible for referral to specialist weight management services for management of obesity	Digitally enabled weight management programme with and without an in-house prescribing team.	Standard care delivery of existing specialist weight management services.	• Number of eligible patients engaging in digitally enabled weight management programmes in areas where in person services are currently available • Number of eligible patients engaging in digitally enabled weight management programmes in areas where in person services are not currently available	Understanding if the digitally enabled services could expand the reach and uptake of Tier 3 specialist weight management services could provide evidence regarding the equitable provision of these services across geographical regions.

Abbreviations: EAG, External Assessment Group; RCT, randomised controlled trial;

Table 34: EAG suggested outcome prioritisation to support Committee decision-making and future guidance production

		Essential	Important	Supportive
Intermediate measures	Engagement *[Defined as: initial uptake of digitally enabled weight management services]*	✓		
	Intervention adherence, attrition, completion *[Separated as continued engagement with the digital technology and continued engagement with the service]*	✓		
	Intervention-related adverse events *[Defined as all adverse events during the course of service delivery]*	✓		
	Weight management medication adherence *[Defined as uptake and ongoing adherence of named medication]*	✓		
	Inaccessibility to intervention		✓	
Clinical outcomes	BMI	✓		
	Weight loss	✓		
	Body fat			✓
	Waist circumference			✓
	Hip circumference			✓
	Waist-to-hip ratio			✓
	HbA1c		✓	
	Cardiovascular events			✓
	Mortality			✓
	Physical activity		✓	
	Rate of referral for weight loss surgery		✓	
	Eating habits			✓
PROMs	Health related quality of life	✓		
	Satisfaction		✓	
Health resource use	Healthcare appointments	✓		
	Medication use	✓		
	Healthcare professional grade and time		✓	

Abbreviations: BMI, body mass index; HbA1c, glycated haemoglobin; PROMs, patient reported outcome measures

9 Conclusions

9.1 *Conclusions from the clinical evidence*

Currently, there is no published evidence in scope of this EVA available for 4 of the 8 technologies (CheqUp, Juniper, Second Nature, or Wellbeing Way). All identified evidence reporting on weight outcome measures have stated a reduction in weight when compared with baseline. Studies comparing digitally enabled weight loss progammes with in-person standard care have reported a greater magnitude of weight loss with the former, however the clinical significance of this difference, and statistical significance of this difference beyond 1 year is uncertain. One RCT, comparing a digital technology with standard care (in-person) and set in Denmark, was available for Liva with results reported up to 2 years. The RCT provided no evidence of difference in EQ-5D-5L between arms at 6 and 12 month timepoints.

Approximately half of the evidence base is set in the UK, largely cohort studies in an NHS setting. There is significant heterogeneity in the evidence base including in the reporting of results. Of the included evidence, 7 publications did not explicitly define an obese population, although the mean BMI was above 30 in 6 studies and above 27 in 1 study. Five studies combined a digital technology with a specific diet, which may reflect real-world interventions, however may confound results. Only 1 published study and 5 in confidence studies reported the proportion of patients taking weight loss medication. Only 1 commercial in confidence study reported on weight loss medication adherence. No evidence was identified that reported on cardiovascular events, mortality, rate of referral for weight loss surgery.

The uptake of digitally enabled weight management programmes will be guided by patient choice and convenience. However, in a condition as complex as obesity with associated broader health risks, methods for monitoring and assessing patients is important to ensure safety, particularly for those prescribed weight loss medication. The appropriateness of using self-reported weight measurements against anticipated weight loss trends based on medication or in-person specialist weight management interventions for patient monitoring and risk assessment should be carefully considered across all delivery options for specialist weight management services.

The EAG acknowledge engagement and uptake of digitally enabled and standard care weight management programmes may differ, including the influence of patient preference, which may lead to potential differences in baseline characteristics and dropout rates between arms, which may influence results. Use of digitally enabled weight management programmes may improve or broaden accessibility of services across the NHS. However, there remains significant uncertainty regarding their long-term use.

9.2 *Conclusions from the economic evidence*

No direct economic evaluations were found which were directly relevant to the decision problem, including no comparative evaluations across the digital technologies. The EAG developed a de novo early economic model, which made several assumptions with major limitations because of lack of available data. The early modelling conducted by the EAG suggests that a digitally enabled weight management programmes are potentially less costly and more effective than care delivered as part of an in-person specialist weight management service delivered in a secondary care setting. Sensitivity and threshold analysis showed that results were sensitive to the estimate of cost used for current specialist weight management services. Therefore providing a robust estimate of this should be prioritised. An economic modelling study with an appropriate modelling framework (taking into account the various complexities of obesity) and a sufficient time-horizon is needed to fully evaluate the cost-effectiveness of delivering (or part-delivering) weight management services using the digitally enabled technologies over an appropriate time horizon.

10 Summary of the combined clinical and economic sections

Effectiveness evidence is available for 3 of 8 technologies showing mean or median weight loss when compared with baseline or in-person standard care although uncertainties remain relating to long-term outcomes. Use of digitally enabled weight management programmes may increase accessibility of services in the NHS. The uptake and accessibility of specialist weight management services is currently unknown; this may be captured by the NHS National Obesity audit and could be

monitored over time. Early economic modelling has shown that there is a prima facie for the digitally enabled technologies being cost-effective (indeed potentially dominant) compared with current specialist weight management services, however this analysis is highly uncertain and subject to the assumptions included within the model. The long-term clinical and economic benefits of technologies that provide digitally enabled weight management programmes remain uncertain. Key evidence requirements should focus on a subset of outcomes (for example, proportion utilising a digitally enabled weight management programme, proportion attending follow-up, proportion achieving clinically significant weight loss, utilities). Professional consensus for definitions of clinically significant weight loss should be determined to enable future health technology assessment.

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Appendices

Appendix A: Clinical literature search

Appendix A1a - Search strategy (clinical evidence)

The search strategies were based around several concepts, each of which was represented by a wide range of free-text and subject terms. Technology names were searched on all resources. On broader resources (journal article databases), these were qualified with the basic requirement to mention obesity or weight loss.

On those broader resources, attempts were also made to find results that didn't name the technologies (or that were about technologies other than those identified in advance). This was challenging as there are many non-relevant digital interventions for obesity and the nature of the relevant technologies are not always clearly distinguished in reporting.

The structure of the searches included searching for the concepts of: obesity and weight loss; the idea of a 'programme' (fairly disparate terms designed to pick up results about some type of weight loss programme); obesity drugs; digital or remote interventions and consultation (one of the aspects of these interventions that distinguish them from the myriad other weight loss apps/digital products). These elements were combined requiring obesity/weight loss and 'programme' and either: drugs and digital; or digital and consultation (or one of several terms representing the description of 'hybrid' interventions).

A 2018 to 'current' (to search dates 22 and 23 May 2023, the most recently available records at the time of searching) publication limit was applied and paediatric-only results excluded where possible. To achieve a practically manageable number of results to sift, a further requirement was applied – to either mention the UK or have one of the most relevant major subject headings (or keyword terms).

While there was some risk of missing relevant material, the searches were designed to mitigate this by having several 'routes' to inclusion and identify

the results most likely to be relevant while avoiding the majority of records about out-of-remit interventions.

Database/Source (and years covered by database where relevant/available)	**Platform/URL**	**Date searched**	**Retrieved Results**
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions (1946 to May 22, 2023)	OVID	23/05/2023	137
Embase (1974 to 2023 May 22)	OVID	23/05/2023	176
CINAHL (January 1982 to search date: 22/5/2023)	EBSCOhost	22/05/2023	75
CENTRAL (2023, issue 5)	Cochrane Library	23/05/2023	80
Google Scholar	https://scholar.google.com/	20/06/2023	153
MedRxiv (Pre-print repository)	https://www.medrxiv.org/	23/05/2023	1
WHO ICTRP	https://trialsearch.who.int/Default.aspx	23/05/2023	3
ScanMedicine	https://scanmedicine.com/	23/05/2023	2
ClinicalTrials.gov	https://clinicaltrials.gov/	23/05/2023	7
International HTA Database	https://database.inahta.org/	23/05/2023	6
NIHR Journals Library	https://www.journalslibrary.nihr.ac.uk/#/	23/05/2023	1
Total			**641**
Total after deduplication			**452**

DATABASE/PLATFORM: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to May 22, 2023>
Platform/URL: OVID

Line #	Search terms	Results
1	(CheqUp$ or Cheq up$ or Gro Health$ or grohealth$ or grocare$ or gro care$ or W8Buddy$ or "w8 buddy$" or DDM Health or Juniper Technologies$ or Liva UK$ or liva health$ or Oviva$).ti,ab,kf,in. or liva.ti,ab.	55
2	(juniper$.in. not ((junipero or juniperus or juniper house or juniper gardens or juniper pharma$).in. or juniper$.au.)) or (liva.in. not liva $.au.)	268

Line #	Search terms	Results
3	(1 or 2) and (obes$ or preobes$ or overweight or over weight or ((bmi or body mass index$) and "kg m") or (weight$ adj5 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).mp.	27
4	limit 3 to yr="2018 -Current"	26
5	obesity management/ or bariatrics/	732
6	obesity management.kf.	174
7	(overweight/ or obesity/ or obesity, abdominal/ or obesity, morbid/) and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	46261
8	(obes$ or preobes$ or overweight or over weight).ti,kf. and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	35803
9	or/5-8	54966
10	Weight Reduction Programs/	2817
11	*Metabolic Syndrome/	30805
12	*Weight Loss/	17369
13	*Body Weight Maintenance/	264
14	*body weight/ and (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ab.	4737
15	weight management.kf.	1228
16	(weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ti.	26094
17	obes$.ab. /freq=2 or preobes$.ab. /freq=2 or overweight.ab. /freq=2 or over weight.ab. /freq=2	195156
18	weight$.ab. /freq=3 and (obes$ or preobes$ or overweight or over weight).ab.	47787
19	((obes$ or preobese$ or overweight$ or over-weight$) and (weight$ adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ab,ti.	53724
20	((bmi or body mass index$) and "kg m").ab.	26485
21	((or/10-16) and (or/17-20)) or 9	64663
22	Weight Reduction Programs/	2817
23	Government Programs/	6394
24	Program Development/	30293
25	obesity management/ or bariatrics/	732
26	overweight/dh, rh, th, pc or obesity/dh, rh, th, pc or obesity, abdominal/dh, rh, th, pc or obesity, morbid/dh, rh, th, pc	47094
27	Life Style/	63458
28	Behavior Therapy/	30205
29	((weight or lifestyle) adj3 (intervention$ or program$)).ti,kf.	7917
30	((weight management or weight loss) adj3 program$).mp.	4776
31	health services/ or dietary services/	28977
32	Medication Therapy Management/	2763
33	"Referral and Consultation"/	75797

Line #	Search terms	Results
34	(tier or tiers).mp.	11773
35	(commissione$ or commissioning).mp.	12726
36	Dietetics/	8228
37	clinical effectiveness.kf.	246
38	((clinical or treatment) adj3 pathway$).mp. or (nhs.af. and pathway$.mp.) or pathway$.ti.	284847
39	clinical decision-making/ or clinical reasoning/ or clinical relevance/	15358
40	Specialization/	25469
41	Patient Care Team/	69396
42	(or/22-41) and (intervention$ or program$ or app or apps or application$ or service$).mp.	240417
43	exp Anti-Obesity Agents/	20470
44	exp obesity/dt	13048
45	Liraglutide/	2463
46	glucagon-like peptides/ or glucagon-like peptide 1/ or glucagon-like peptide 2/	11267
47	Bupropion/	3313
48	lorcaserin.mp.	485
49	Medication Therapy Management/	2763
50	patient compliance/ or medication adherence/	84004
51	Prescription Drugs/	7018
52	(*obesity management/ or *bariatrics/ or *Weight Reduction Programs/ or *overweight/ or *obesity/ or *obesity, abdominal/ or *obesity, morbid/) and drug$.hw,kf.	4427
53	(semaglutide$ or liraglutide$ or orlistat$ or Ozempic$ or Wegovy$ or Rybelsus$ or Victoza$ or Saxenda$ or Xenical$ or TA875 or tirzepatide$ or mounjaro$).mp.	7068
54	or/43-53	140407
55	Mobile Applications/	11344
56	cell phone/ or smartphone/ or text messaging/	22177
57	Computers, Handheld/	4061
58	Therapy, Computer-Assisted/	6971
59	Digital Technology/	672
60	digital therapeutics.kf.	163
61	digital health.kw.	3582
62	Mobile health applications.kw.	60
63	(app or apps or smartphone$ or mhealth or ehealth or m-health or e-health or remote or digital$).ti.	109986
64	remote$.ab. /freq=3	9975
65	app.ab. /freq=3	15255
66	((program or programs or programme or programmes or intervention or interventions) adj5 (weight or lifestyle) adj5 (app or apps or smartphone$ or mhealth or ehealth or m-health or e-health or phone or phones or mobile or digital$)).ab,ti.	569
67	Telemedicine/	37059

Line #	Search terms	Results
68	(telehealth$ or telecare or telemedicine or (tele adj1 (health$ or care or medicine))).ti.	15657
69	or/55-68	181507
70	Mentoring/	3869
71	Videoconferencing/	2315
72	Remote Consultation/	5707
73	(telecoach$ or teleconsult$ or coach$ or consult$).mp.	244443
74	(feedback or tailor$ or commercial).mp.	535278
75	directive counseling/ or motivational interviewing/ or distance counseling/	5026
76	"Referral and Consultation"/	75797
77	or/70-76	777379
78	((blended or hybrid or virtual) adj5 (care or intervention$ or program$)).ti,ab.	7713
79	((mdt or multidisciplin$ or multi disciplin$ or multimodal or multi modal) and (lifestyle or weight) and (app or application or digital or remote or tele$)).ab,ti.	486
80	78 or 79	8193
81	69 and 77	21420
82	54 and 69	2850
83	21 and 42 and (81 or 82 or 80)	432
84	limit 83 to yr="2018 -Current"	251
85	limit 84 to ("all adult (19 plus years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)") or (84 and adult$.ti.)	128
86	limit 84 to ("all infant (birth to 23 months)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)") or (84 and (child$ or paediatr$ or pediatr$).ti.)	35
87	84 not (86 not 85)	220
88	exp United Kingdom/	389591
89	(national health service* or nhs*).ti,ab,in.	267668
90	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.	49050
91	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jw,in.	2431663
92	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or	212843

Line #	Search terms	Results
	"coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab.	
93	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab.	3398
94	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab.	41074
95	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab.	1553
96	or/88-95	2822685
97	(exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp australia/ or exp oceania/) not (exp united kingdom/ or europe/)	3317759
98	96 not 97	2684809
99	87 and 98	28
100	87 and (*Weight Reduction Programs/ or *obesity management/ or *bariatrics/ or *overweight/th or *obesity/th or *obesity, abdominal/th or *obesity, morbid/th or telemedicine/mt or "tier$ 3".mp. or "tier$ 4".mp.)	97
101	4 or 99 or 100	137

Link to strategy:
https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=4n05jJsL1ji4FTF87qkNYBeKd8LYK5bMq2YTf6R5HuhNPoBVYk1nJZ4mzzj8UwfX5

DATABASE/PLATFORM: Embase <1974 to 2023 May 22>
Platform/URL: OVID

Line #	Search terms	Results
1	(CheqUp$ or Cheq up$ or Gro Health$ or grohealth$ or grocare$ or gro care$ or W8Buddy$ or "w8 buddy$" or DDM Health or Juniper Technologies$ or Liva UK$ or liva health$ or Oviva$).ti,ab,kf,dm,dv,in. or liva.ti,ab.	97
2	(juniper$.dm,dv,in. not ((junipero or juniperus or juniper house or juniper gardens or juniper pharma$).dm,dv,in. or juniper$.au.)) or (liva.dm,dv,in. not liva $.au.)	221
3	(1 or 2) and (obes$ or preobes$ or overweight or overweight or ((bmi or body mass index$) and "kg m") or (weight$ adj5 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).mp.	47
4	limit 3 to yr="2018 -Current"	42
5	obesity management/	1557
6	obesity management.kf.	264
7	*obesity/ or *abdominal obesity/ or *diabetic obesity/ or *morbid obesity/ or *obese patient/ or *metabolically unhealthy obese/	229512
8	(obesity/ or abdominal obesity/ or diabetic obesity/ or morbid obesity/) and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	77572
9	(obese patient/ or metabolically unhealthy obese/) and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	3257
10	(obes$ or preobes$ or overweight or over weight).ti,kf. and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	55162
11	or/5-10	269147
12	weight loss program/	3236
13	*metabolic syndrome x/	48099
14	*body weight management/	986
15	*body weight loss/	10759
16	*body weight control/	561
17	*body weight management/	986
18	*body weight maintenance/	200
19	*body weight change/	1229
20	*"weight trajectory (body weight)"/	136
21	*weight reduction/	26155
22	*body weight/ and (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ab.	6581
23	weight management.kf.	1632
24	(weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ti.	36695
25	obes$.ab. /freq=2 or preobes$.ab. /freq=2 or overweight.ab. /freq=2 or over weight.ab. /freq=2	299942
26	weight$.ab. /freq=3 and (obes$ or preobes$ or overweight or over weight).ab.	75348

Line #	Search terms	Results
27	((obes$ or preobese$ or overweight$ or over-weight$) and (weight$ adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ab,ti.	84330
28	((bmi or body mass index$) and "kg m").ab.	99777
29	((or/12-24) and (or/25-28)) or 11	280461
30	weight loss program/	3236
31	health program/ or exp program evaluation/	151347
32	obesity management/	1557
33	obesity/dm, rh, th or abdominal obesity/dm, rh, th or diabetic obesity/dm, rh, th or morbid obesity/dm, rh, th	23671
34	lifestyle modification/	50706
35	behavior change/	49804
36	behavior therapy/	45615
37	((weight or lifestyle) adj3 (intervention$ or program$)).ti,kf.	11117
38	((weight management or weight loss) adj3 program$).mp.	8772
39	health service/ or dietary service/ or hospital service/ or medical service/ or medication therapy management/ or nutrition service/ or public health service/	291277
40	patient referral/	155082
41	(tier or tiers).mp.	16075
42	(commissione$ or commissioning).mp.	19054
43	dietetics/	6311
44	clinical effectiveness/	176622
45	((clinical or treatment) adj3 pathway$).mp. or (nhs.af. and pathway$.mp.) or pathway$.ti.	368438
46	medical decision making/	93820
47	medical specialist/	88240
48	multidisciplinary team/ or collaborative care team/	27372
49	(or/30-48) and (intervention$ or program$ or app or apps or application$).mp.	456043
50	exp antiobesity agent/	7363
51	obesity/dt or abdominal obesity/dt or diabetic obesity/dt or morbid obesity/dt	18121
52	exp anorexigenic agent/	88404
53	antidiabetic agent/ or liraglutide/ or semaglutide/ or tirzepatide/	75042
54	amfebutamone plus naltrexone/ or amfebutamone/ or lorcaserin/	21975
55	medication therapy management/	14844
56	medication compliance/	45672
57	prescription drug/	13157
58	(*obesity management/ or *weight loss program/ or *obesity/ or *abdominal obesity/ or *diabetic obesity/ or *morbid obesity/) and drug$.hw,kf.	32898
59	(semaglutide$ or liraglutide$ or orlistat$ or Ozempic$ or Wegovy$ or Rybelsus$ or Victoza$ or Saxenda$ or Xenical$ or TA875 or tirzepatide$ or mounjaro$).mp,tn,du.	18694
60	or/51-59	282302

Line #	Search terms	Results
61	mobile health application/ or mobile application/ or self-care software/	24747
62	mobile phone/ or smartphone/	47217
63	personal digital assistant/	1785
64	computer assisted therapy/	4841
65	digital technology/	3755
66	digital therapeutics.dj.	23
67	digital health.kw.	2899
68	Mobile health applications.kw.	62
69	(app or apps or smartphone$ or mhealth or ehealth or m-health or e-health or remote or digital$).ti.	124489
70	remote$.ab. /freq=3	13759
71	app.ab. /freq=3	20271
72	((program or programs or programme or programmes or intervention or interventions) adj5 (weight or lifestyle) adj5 (app or apps or smartphone$ or mhealth or ehealth or m-health or e-health or phone or phones or mobile or digital$)).ab,ti.	682
73	telehealth/ or telecare/ or telemedicine/	60890
74	(telehealth$ or telecare or telemedicine or (tele adj1 (health$ or care or medicine))).ti.	20751
75	or/61-72	192749
76	mentoring/	6525
77	videoconferencing/	8777
78	teleconsultation/ or electronic consultation/ or video consultation/	16188
79	(telecoach$ or teleconsult$ or coach$ or consult$).mp.	355705
80	(feedback or tailor$ or commercial).mp.	738237
81	motivational interviewing/	6836
82	consultation/	145552
83	or/76-82	1090696
84	((blended or hybrid or virtual) adj5 (care or intervention$ or program$)).ti,ab.	10779
85	((mdt or multidisciplin$ or multi disciplin$ or multimodal or multi modal) and (lifestyle or weight) and (app or application or digital or remote or tele$)).ab,ti.	985
86	or/84-85	11747
87	75 and 83	21706
88	29 and 49 and (87 or (60 and 75) or 86)	558
89	limit 88 to yr="2018 -Current"	384
90	limit 89 to (adult <18 to 64 years> or aged <65+ years>) or (89 and adult$.ti.)	285
91	limit 89 to (infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years>) or (89 and (child$ or paediatr$ or pediatr$).ti.)	59
92	89 not (91 not 90)	339
93	exp United Kingdom/	462149
94	(national health service* or nhs*).ti,ab,in,ad.	472265

Line #	Search terms	Results
95	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.	59757
96	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jx,in,ad.	3741118
97	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab.	371203
98	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab.	4760
99	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab.	55836
100	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab.	2164
101	or/93-100	4199010

Line #	Search terms	Results
102	(exp "arctic and antarctic"/ or exp oceanic regions/ or exp western hemisphere/ or exp africa/ or exp asia/ or exp "australia and new zealand"/) not (exp united kingdom/ or europe/)	3734777
103	101 not 102	3959726
104	92 and 103	42
105	92 and (*weight loss program/ or *health program/ or exp *program evaluation/ or *obesity management/ or *obesity/th or *abdominal obesity/th or *diabetic obesity/th or *morbid obesity/th or "tier$ 3".mp. or "tier$ 4".mp.) [results plus best terms]	117
106	4 or 104 or 105 [named or UK filter or best MeSH]	176
107	limit 106 to conference abstracts	64
108	106 not 107	112

Please note: the results of lines 107 (n = 64) and line 108 (n = 112) were both downloaded for sifting – separately, to enable labelling of conference abstracts to help inform decision-making in the sifting process.
Link to strategy:
https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=4UvaiNdP9SLPNTxHu0RqZEL860BZ5DyzdDHdsHzXCzluB92GNQsucFbjOFM8RKAY1

DATABASE/PLATFORM: CINAHL (1 January 1982 to date of search: 22/5/2023)
Platform/URL: EBSCOhost

#	Query	Limiters/ Expanders	Results
S1	(TX (obes* or preobes* or overweight or "over weight" or ((bmi or body mass index*) and "kg m") or (weight* N5 (loss or lose or losing or loses or lost or manag* or reduc* or control*))) AND TX (CheqUp* or "Cheq up*" or "Gro Health*" or grohealth* or grocare* or "gro care*" or W8Buddy* or "w8 buddy*" or "DDM Health" or Liva or juniper or oviva*)) NOT AU liva	Limiters - Published Date: 20180101- Search modes - Boolean/Phrase	13
S2	((MH "Obesity, Morbid") OR (MH "Obesity") OR TI (obes* or preobes* or overweight or "over weight")) AND (TI ((obesity N3 manag*) or (weight N3 (loss or lose or losing or loses or lost or manag* or reduc* or control*))) OR AB ((obesity N3 manag*) or (weight N3 (loss or lose or losing or loses or lost or manag* or reduc* or control*))))	Search modes - Boolean/Phrase	18,669
S3	(MH "Weight Reduction Programs")	Search modes - Boolean/Phrase	3,312
S4	(MM "Metabolic Syndrome X")	Search modes - Boolean/Phrase	9,558

#	Query	Limiters/ Expanders	Results
S5	(MM "Weight Loss")	Search modes - Boolean/Phrase	10,921
S6	(MM "Weight Control")	Search modes - Boolean/Phrase	4,568
S7	(MM "Body Weight") AND (TI (weight N3 (loss or lose or losing or loses or lost or manag* or reduc* or control*)) OR AB (weight N3 (loss or lose or losing or loses or lost or manag* or reduc* or control*)))	Search modes - Boolean/Phrase	1,831
S8	TI (weight N3 (loss or lose or losing or loses or lost or manag* or reduc* or control*))	Search modes - Boolean/Phrase	14,959
S9	TI (obes* or preobes* or overweight or "over weight")	Search modes - Boolean/Phrase	64,009
S10	AB ((obes* or preobese* or overweight* or over-weight*) and (weight* N3 (loss or lose or losing or loses or lost or manag* or reduc* or control*)))	Search modes - Boolean/Phrase	17,054
S11	AB ((bmi or "body mass index*") and "kg m")	Search modes - Boolean/Phrase	8,144
S12	(S3 OR S4 OR S5 OR S6 OR S7 OR S8) AND (S9 OR S10 OR S11)	Search modes - Boolean/Phrase	10,598
S13	S2 OR S12	Search modes - Boolean/Phrase	22,329
S14	(MH "Weight Reduction Programs")	Search modes - Boolean/Phrase	3,312
S15	(MH "Government Programs") OR (MH "Program Development") OR (MH "Hospital Programs")	Search modes - Boolean/Phrase	41,370
S16	(MH "Obesity/DH/RH/TH/PC") OR (MH "Obesity, Morbid/DH/PC/RH/TH")	Search modes - Boolean/Phrase	21,404
S17	(MH "Life Style Changes")	Search modes - Boolean/Phrase	14,067
S18	(MH "Behavior Therapy")	Search modes - Boolean/Phrase	12,712
S19	TI ((weight or lifestyle) N3 (intervention* or program*))	Search modes - Boolean/Phrase	5,190
S20	TX (("weight management" or "weight loss") N3 program*)	Search modes - Boolean/Phrase	2,898
S21	(MH "Nutrition Services") OR (MH "Nutritional Counseling") OR (MH "Health Services")	Search modes - Boolean/Phrase	18,939

#	Query	Limiters/ Expanders	Results
S22	(MH "Medication Management")	Search modes - Boolean/Phrase	1,591
S23	(MH "Referral and Consultation")	Search modes - Boolean/Phrase	41,645
S24	TX (tier or tiers or commissione* or commissioning)	Search modes - Boolean/Phrase	16,909
S25	(MH "Dietetics")	Search modes - Boolean/Phrase	2,543
S26	(MH "Clinical Effectiveness")	Search modes - Boolean/Phrase	2,307
S27	TX((clinical or treatment) N3 pathway*) or TX (nhs and pathway*) or TI (pathway*)	Search modes - Boolean/Phrase	38,538
S28	(MH "Clinical Reasoning") OR (MH "Decision Making, Clinical")	Search modes - Boolean/Phrase	35,967
S29	(MH "Specialization")	Search modes - Boolean/Phrase	5,554
S30	(MH "Multidisciplinary Care Team") OR (MH "Nutritional Support Team")	Search modes - Boolean/Phrase	49,982
S31	(TI (intervention* or program* or app or apps or application* or service*)) OR (AB ((intervention* or program* or app or apps or application* or service*))	Search modes - Boolean/Phrase	1,296,100
S32	(S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30)	Search modes - Boolean/Phrase	290,532
S33	S31 AND S32	Search modes - Boolean/Phrase	108,380
S34	(MH "Antiobesity Agents+")	Search modes - Boolean/Phrase	7,801
S35	(MH "Obesity+/DT")	Search modes - Boolean/Phrase	3,651
S36	(MH "Glucagon-Like Peptide-1 Receptor Agonists")	Search modes - Boolean/Phrase	792
S37	(MH "Bupropion")	Search modes - Boolean/Phrase	1,752
S38	TX (lorcaserin)	Search modes - Boolean/Phrase	176
S39	(MH "Medication Management")	Search modes - Boolean/Phrase	1,591

#	Query	Limiters/ Expanders	Results
S40	(MH "Medication Compliance") OR (MH "Patient Compliance")	Search modes - Boolean/Phrase	56,317
S41	(MH "Drugs, Prescription")	Search modes - Boolean/Phrase	20,744
S42	((MM "Obesity, Morbid") OR (MM "Obesity")) AND MW (drug*)	Search modes - Boolean/Phrase	6,298
S43	TX (semaglutide* or liraglutide* or orlistat* or Ozempic* or Wegovy* or Rybelsus* or Victoza* or Saxenda* or Xenical* or TA875 or tirzepatide* or mounjaro*)	Search modes - Boolean/Phrase	2,347
S44	(S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43)	Search modes - Boolean/Phrase	94,289
S45	(MH "Mobile Applications")	Search modes - Boolean/Phrase	12,020
S46	(MH "Cellular Phone") OR (MH "Text Messaging") OR (MH "Smartphone") OR (MH "Computers, Hand-Held") OR (MH "Computers, Portable")	Search modes - Boolean/Phrase	15,531
S47	(MH "Drug Therapy, Computer Assisted") OR (MH "Therapy, Computer Assisted")	Search modes - Boolean/Phrase	5,960
S48	(MH "Digital Technology")	Search modes - Boolean/Phrase	2,136
S49	TI (app or apps or smartphone* or mhealth or ehealth or m-health or e-health or remote or digital*)	Search modes - Boolean/Phrase	41,232
S50	(TI ((program or programs or programme or programmes or intervention or interventions) N5 (weight or lifestyle) N5 (app or apps or smartphone* or mhealth or ehealth or m-health or e-health or phone or phones or mobile or digital*))) OR (AB ((program or programs or programme or programmes or intervention or interventions) N5 (weight or lifestyle) N5 (app or apps or smartphone* or mhealth or ehealth or m-health or e-health or phone or phones or mobile or digital*)))	Search modes - Boolean/Phrase	323
S51	(MH "Telehealth") OR (MH "Telemedicine") OR (MH "Telenutrition")	Search modes - Boolean/Phrase	28,768
S52	TI (telehealth* or telecare or telemedicine or (tele N1 (health* or care or medicine)))	Search modes - Boolean/Phrase	10,280
S53	(S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52)	Search modes - Boolean/Phrase	91,152

#	Query	Limiters/ Expanders	Results
S54	(MH "Videoconferencing")	Search modes - Boolean/Phrase	3,036
S55	(MH "Remote Consultation")	Search modes - Boolean/Phrase	3,061
S56	(TI (telecoach* or teleconsult* or coach* or consult*)) OR (AB (telecoach* or teleconsult* or coach* or consult*))	Search modes - Boolean/Phrase	88,011
S57	(TI (feedback or tailor* or commercial)) OR (AB (feedback or tailor* or commercial))	Search modes - Boolean/Phrase	101,446
S58	(MH "Motivational Interviewing") OR (MH "Counseling")	Search modes - Boolean/Phrase	36,804
S59	(MH "Referral and Consultation")	Search modes - Boolean/Phrase	41,645
S60	(S54 OR S55 OR S56 OR S57 OR S58 OR S59)	Search modes - Boolean/Phrase	253,194
S61	(TI ((blended or hybrid or virtual) N5 (care or intervention* or program*))) OR (AB ((blended or hybrid or virtual) N5 (care or intervention* or program*)))	Search modes - Boolean/Phrase	4,822
S62	(TI ((mdt or multidisciplin* or "multi disciplin*" or multimodal or "multi modal") and (lifestyle or weight) and (app or application or digital or remote or tele*))) OR (AB ((mdt or multidisciplin* or "multi disciplin*" or multimodal or "multi modal") and (lifestyle or weight) and (app or application or digital or remote or tele*)))	Search modes - Boolean/Phrase	193
S63	S61 OR S62	Search modes - Boolean/Phrase	5,015
S64	S53 and S60	Search modes - Boolean/Phrase	11,165
S65	S44 AND S53	Search modes - Boolean/Phrase	2,459
S66	(S63 OR S64 OR S65)	Search modes - Boolean/Phrase	17,835
S67	S13 AND S33 AND S66	Limiters - Published Date: 20180101- Search modes - Boolean/Phrase	99
S68	S67	Limiters - Age Groups: Fetus,	23

#	Query	Limiters/ Expanders	Results
		Conception to Birth, Infant, Newborn: birth-1 month, Infant: 1-23 months, Child, Preschool: 2-5 years, Child: 6-12 years, All Infant, All Child Search modes - Boolean/Phrase	
S69	S67 AND TI (pediatr* or paediatr* or child*)	Search modes - Boolean/Phrase	13
S70	S67 AND TI (adult*)	Search modes - Boolean/Phrase	13
S71	S67	Limiters - Age Groups: Adult: 19-44 years, Middle Aged: 45-64 years, Aged: 65+ years, Aged, 80 and over, All Adult Search modes - Boolean/Phrase	44
S72	S67 NOT ((S68 OR S69) NOT (S70 OR S71))	Search modes - Boolean/Phrase	80
S73	(MH "United Kingdom+")	Search modes - Boolean/Phrase	322,096
S74	TX (nhs* OR "national health service*" OR "united kingdom" OR UK OR "U.K." OR "britain" OR british OR england OR scotland OR scottish OR wales OR welsh OR ireland OR irish)	Search modes - Boolean/Phrase	2,387,687
S75	S72 AND (S73 OR S74)	Search modes - Boolean/Phrase	32
S76	((MH "Africa+") OR (MH "America+") OR (MH "Antarctic Regions") OR (MH "Arctic Regions") OR (MH "Asia+") OR (MH "Atlantic Islands+") OR (MH "Australia+") OR (MH "Indian Ocean Islands") OR (MH "Pacific Islands+") OR (MH "Scandinavia+") OR (MH "Spain") OR (MH "San Marino") OR (MH "Portugal") OR (MH "Netherlands") OR (MH "Monaco") OR (MH "Mediterranean Region+") OR (MH "Liechtenstein") OR (MH "Iceland") OR (MH "Greece") OR (MH "Gibraltar") OR (MH "Germany+") OR (MH "Georgia (Republic)") OR	Search modes - Boolean/Phrase	1,699,198

#	Query	Limiters/ Expanders	Results
	(MH "France") OR (MH "Europe, Eastern+") OR (MH "Belgium") OR (MH "Austria") OR (MH "Armenia") OR (MH "Andorra")) NOT ((MH "United Kingdom+") OR (MH "Europe"))		
S77	S75 NOT S76	Search modes - Boolean/Phrase	25
S78	S72 AND ((MM "Obesity/DH/RH/TH/PC") OR (MM "Obesity, Morbid/DH/PC/RH/TH") OR MM "Weight Reduction Programs" OR TX ("tier$ 3" OR "tier$ 4"))	Search modes - Boolean/Phrase	56
S79	S1 OR S77 OR S78	Search modes - Boolean/Phrase	75

DATABASE/PLATFORM: Cochrane Library CENTRAL (2023, Issue 5)
Platform/URL: https://www.cochranelibrary.com/advanced-search

ID	Search	Hits
#1	((obes* or preobes* or overweight or "over weight" or ((bmi or body mass index*) and "kg m") or (weight* NEAR/5 (loss or lose or losing or loses or lost or manag* or reduc* or control*))) AND (CheqUp* or "Cheq up*" or "Gro Health*" or grohealth* or grocare* or "gro care*" or W8Buddy* or "w8 buddy*" or "DDM Health" or Liva or juniper or oviva*))	38
#2	(liva):au (Word variations have been searched)	24
#3	#1 not #2 with Publication Year from 2018 to present, in Trials	18
#4	MeSH descriptor: [Obesity Management] this term only	37
#5	MeSH descriptor: [Bariatrics] this term only	11
#6	("obesity management"):kw	118
#7	MeSH descriptor: [Overweight] this term only	6669
#8	MeSH descriptor: [Obesity] this term only	17660
#9	MeSH descriptor: [Obesity, Abdominal] this term only	508
#10	MeSH descriptor: [Obesity, Morbid] this term only	1639
#11	((obesity NEAR/3 manag*) or (weight NEAR/3 (loss or lose or losing or loses or lost or manag* or reduc* or control*))):ti,ab	31253
#12	(#7 or #8 or #9 or #10) and #11	9600
#13	(obes* or preobes* or overweight or "over weight"):ti,kw	42530
#14	((obesity NEAR/3 manag*) or (weight NEAR/3 (loss or lose or losing or loses or lost or manag* or reduc* or control*))):ti,ab	31253
#15	#13 and #14	15069
#16	#4 or #5 or #6 or #12 or #15	15091
#17	[mh ^"Weight Reduction Programs"]	980
#18	[mh ^"Metabolic Syndrome"[mj]]	1
#19	[mh ^"weight loss"[mj]]	21

ID	Search	Hits
#20	[mh ^"body weight maintenance"[mj]]	0
#21	[mh ^"body weight"[mj]] and (weight NEAR/3 (loss or lose or losing or loses or lost or manag* or reduc* or control*)):ab	4
#22	("weight management"):kw	226
#23	(weight NEAR/3 (loss or lose or losing or loses or lost or manag* or reduc* or control*)):ti	9328
#24	((obes* or preobese* or overweight* or "over-weight*") and (weight* NEAR/3 (loss or lose or losing or loses or lost or manag* or reduc* or control*))):ab,ti	16446
#25	((bmi or body mass index*) and "kg m"):ab	6699
#26	(#17 or #18 or #19 or #20 or #21 or #22 or #23) and (#24 or #25)	6907
#27	#16 or #26	16246
#28	[mh ^"weight reduction programs"]	980
#29	[mh ^"government programs"]	61
#30	[mh ^"program development"]	893
#31	[mh ^"obesity management"] or [mh ^"bariatrics"]	48
#32	[mh ^"overweight"/DH,RH,TH,PC] or [mh ^"obesity"/DH,RH,TH,PC] or [mh ^"obesity, abdominal"/DH,RH,TH,PC] or [mh ^"obesity, morbid"/DH,RH,TH,PC]	8068
#33	[mh ^"life style"]	4396
#34	[mh ^"behaviour therapy"]	0
#35	((weight or lifestyle) NEAR/3 (intervention* or program*)):ti,kw	6295
#36	(("weight management" or "weight loss") NEAR/3 program*):ti,ab,kw	2776
#37	[mh ^"health services"] or [mh ^"dietary services"]	611
#38	[mh ^"Medication Therapy Management"]	288
#39	[mh ^"Referral and Consultation"]	2478
#40	(tier or tiers or commissione* or commissioning):ti,ab,kw	1308
#41	[mh ^"dietetics"]	125
#42	("clinical effectiveness"):kw	15073
#43	((clinical or treatment) NEAR/3 pathway*):ti,ab,kw or ((nhs) and ((pathway*):ti,ab,kw)) or (pathway*):ti	4525
#44	[mh ^"clinical decision-making"] or [mh ^"clinical reasoning"] or [mh ^"clinical relevance"]	534
#45	[mh ^"Specialization"]	151
#46	[mh ^"Patient Care Team"]	2016
#47	(intervention* or program* or app or apps or application* or service*):ti,ab,kw	674040
#48	(#28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46) and #47	28447
#49	[mh "Anti-Obesity Agents"]	974
#50	[mh obesity/DT]	2164
#51	[mh Liraglutide]	908

ID	Search	Hits
#52	[mh ^"glucagon-like peptides"] or [mh ^"glucagon-like peptide 1"] or [mh ^"glucagon-like peptide 2"]	1704
#53	[mh ^Bupropion]	961
#54	lorcaserin:ti,ab,kw	145
#55	[mh ^"Medication Therapy Management"]	288
#56	[mh "patient compliance"] or [mh "medication adherence"]	15171
#57	[mh ^"prescription drugs"]	147
#58	([mh ^"overweight"[mj]] or [mh ^"obesity"[mj]] or [mh ^"obesity, abdominal"[mj]] or [mh ^"obesity, morbid"[mj]] or [mh ^"obesity management"[mj]] or [mh ^"bariatrics"[mj]] or [mh ^"weight reduction programs"[mj]]) and drug*:kw	8
#59	(semaglutide* or liraglutide* or orlistat* or Ozempic* or Wegovy* or Rybelsus* or Victoza* or Saxenda* or Xenical* or TA875 or tirzepatide* or mounjaro*):ti,ab,kw	3718
#60	#49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58 or #59	23679
#61	[mh ^"mobile applications"]	1538
#62	[mh ^"cell phone"] or [mh ^"smartphone"] or [mh ^"text messaging"]	3099
#63	[mh ^"Computers, Handheld"]	351
#64	[mh ^"Therapy, Computer-Assisted"]	1476
#65	[mh ^"Digital Technology"]	29
#66	("digital therapeutics"):kw	1
#67	("digital health"):kw	10
#68	("Mobile health applications"):kw	0
#69	(app or apps or smartphone* or mhealth or ehealth or "m-health" or "e-health" or remote or digital*):ti	12325
#70	((program or programs or programme or programmes or intervention or interventions) NEAR/5 (weight or lifestyle) NEAR/5 (app or apps or smartphone* or mhealth or ehealth or m-health or e-health or phone or phones or mobile or digital*)):ab,ti	534
#71	[mh ^"Telemedicine"]	3522
#72	(telehealth* or telecare or telemedicine or (tele NEAR/1 (health* or care or medicine))):ti	2335
#73	#61 or #62 or #63 or #64 or #65 or #66 or #67 or #68 or #69 or #70 or #71 or #72	20568
#74	[mh ^Mentoring]	429
#75	[mh ^Videoconferencing]	330
#76	[mh ^"Remote Consultation"]	415
#77	(telecoach* or teleconsult* or coach* or consult*):ti,ab,kw	31719
#78	(feedback or tailor* or commercial):ti,ab,kw	44385
#79	[mh ^"directive counseling"] or [mh ^"motivational interviewing"] or [mh ^"distance counseling"]	1768
#80	[mh ^"Referral and Consultation"]	2478
#81	#74 or #75 or #76 or #77 or #78 or #79 or #80	74060

ID	Search	Hits
#82	((blended or hybrid or virtual) NEAR/5 (care or intervention* or program*)):ti,ab	2698
#83	((mdt or multidisciplin* or "multi disciplin*" or multimodal or "multi modal") and (lifestyle or weight) and (app or application or digital or remote or tele*)):ti,ab	265
#84	#82 or #83	2959
#85	#73 and #81	4656
#86	#73 and #60	1028
#87	#27 and #48 and (#84 or #85 or #86)	248
#88	#87 with Publication Year from 2018 to present, in Trials	134
#89	#88 NOT ((child* or pediatr* or paediatr*):ti not (adult*):ti)	127
#90	[mh ^"United Kingdom"]	5378
#91	("national health service*" or nhs*)	16802
#92	("united kingdom" OR UK OR "U.K." OR "britain" OR british OR england OR scotland OR scottish OR wales OR welsh OR ireland OR irish)	178450
#93	#90 or #91 or #92	180630
#94	#93 and #89	3
#95	[mh ^"Weight Reduction Programs"[mj]] or [mh ^"obesity management"[mj]] or [mh ^"bariatrics"[mj]] or [mh overweight/TH] or [mh ^telemedicine/MT] or ("tier 3" or "tier 4"):ti,ab,kw	6015
#96	#89 and #95	61
#97	#96 or #94 or #3	80

Link to search: https://www.cochranelibrary.com/advanced-search/search-manager?search=7212382

DATABASE/PLATFORM: Google Scholar
URL: https://scholar.google.com/
("CheqUp" OR "Cheq up" OR "Gro Health" OR "grohealth" OR "grocare" OR "gro care") AND ("obesity" OR "obese" OR "overweight") AND ("blended" OR "hybrid" OR "digital" OR "remote" OR "app" OR "smartphone" OR "telehealth" OR "telemedicine" OR "telecare")
or
("liva health" OR "W8Buddy" OR "w8 buddy" OR "DDM Health") AND ("obesity" OR "obese" OR "overweight") AND ("blended" OR "hybrid" OR "digital" OR "remote" OR "app" OR "smartphone" OR "telehealth" OR "telemedicine" OR "telecare")
or
("juniper technologies" OR "Oviva") AND ("obesity" OR "obese" OR "overweight") AND ("blended" OR "hybrid" OR "digital" OR "remote" OR "app" OR "smartphone" OR "telehealth" OR "telemedicine" OR "telecare")
2018-2023
Deduplicated: 153 results

DATABASE/PLATFORM: MedRxiv (Pre-print repository)
URL: https://www.medrxiv.org/
ad hoc based on named technologies
1 result

DATABASE/PLATFORM: WHO ICTRP
URL: https://trialsearch.who.int/Default.aspx
(CheqUp OR "Cheq up" OR "Gro Health" OR grohealth OR grocare OR "gro care" OR W8Buddy OR "w8 buddy" OR "DDM Health" OR juniper OR liva OR Oviva) AND (obesity OR overweight OR "over weight")
3 results

DATABASE/PLATFORM: ScanMedicine
URL: https://scanmedicine.com/
(CheqUp | "Cheq up" | "Gro Health" | grohealth | grocare | "gro care" | W8Buddy | "w8 buddy" | "DDM Health" | juniper | liva |Oviva) + (obesity | "over weight" | overweight)
2 results
Link to strategy:
https://scanmedicine.com/clinicaltrials/search?q=%28CheqUp%20%7C%20%22Cheq%20up%22%20%7C%20%22Gro%20Health%22%20%7C%20grohealth%20%7C%20grocare%20%7C%20%22gro%20care%22%20%7C%20W8Buddy%20%7C%20%22w8%20buddy%22%20%7C%20%22DDM%20Health%22%20%7C%20juniper%20%7C%20liva%20%7COviva%29%20%2B%20%28obesity%20%7C%20%22over%20weight%22%20%7C%20overweight%29

DATABASE/PLATFORM: ClinicalTrials.gov
URL: https://clinicaltrials.gov/
CheqUp OR "Cheq up" OR "Gro Health" OR grohealth OR grocare OR "gro care" OR W8Buddy OR "w8 buddy" OR "DDM Health" OR juniper OR liva OR Oviva | obesity OR overweight or "over weight"
7 results
Link to strategy:
https://www.clinicaltrials.gov/ct2/results?cond=obesity+OR+overweight+or+%22over+weight%22&term=CheqUp+OR+%22Cheq+up%22+OR+%22Gro+Health%22+OR+grohealth+OR+grocare+OR+%22gro+care%22+OR+W8Buddy+OR+%22w8+buddy%22+OR+%22DDM+Health%22+OR+juniper+OR+liva+OR+Oviva&cntry=&state=&city=&dist=&Search=Search

DATABASE/PLATFORM: International HTA Database (INAHTA)
Platform/URL: https://database.inahta.org/
(((blended OR hybrid OR virtual OR digital OR remote OR app OR apps OR phone OR smartphone OR telehealth OR telemedicine OR telecare OR teleconsultation) AND (obesity OR overweight OR "over weight"))) OR (CheqUp OR "Cheq up" OR "Gro Health" OR grohealth OR grocare OR "gro care" OR W8Buddy OR "w8 buddy" OR "DDM Health" OR juniper OR liva OR Oviva)
2018-2023
6 results
Link to strategy:
https://database.inahta.org/search?limit=&terms=%28%28%28blended+OR+hybrid+OR+virtual+OR+digital+OR+remote+OR+app+OR+apps+OR+phone+OR+smartphone+OR+telehealth+OR+telemedicine+OR+telecare+OR+teleconsultation%29+AND+%28obesity+OR+overweight+OR+%22over+weight%22%29%29%29+OR+%28CheqUp+OR+%22Cheq+up%22+OR+%22Gro+Health%22+OR+grohealth+OR+grocare+OR+%22gro+care%22+OR+W8Budd

y+OR+%22w8+buddy%22+OR+%22DDM+Health%22+OR+juniper+OR+liva+OR+Oviva%29&client=user&filter-year-from=2018&filter-year-to=2023

DATABASE/PLATFORM: NIHR Journals Library
Platform/URL: https://www.journalslibrary.nihr.ac.uk/#/

(CheqUp OR "Cheq up" OR "Gro Health" OR grohealth OR grocare OR "gro care" OR W8Buddy OR "w8 buddy" OR "DDM Health" OR juniper OR liva OR Oviva)
1 result (not relevant)
Link to strategy:
https://www.journalslibrary.nihr.ac.uk/search/#/?search=(CheqUp%20OR%20%22Cheq%20up%22%20OR%20%22Gro%20Health%22%20OR%20grohealth%20OR%20grocare%20OR%20%22gro%20care%22%20OR%20W8Buddy%20OR%20%22w8%20buddy%22%20OR%20%22DDM%20Health%22%20OR%20juniper%20OR%20liva%20OR%20Oviva)&indexname=full-index&selected_facets=

Appendix A1b - Search strategy (clinical evidence) – additional technologies

The search strategies were equivalent to the prior technology-name-specific searches. Results were deduplicated against all existing results.

Database/Source (and years covered by database where relevant/available)	**Platform/URL**	**Date searched**	**Retrieved Results**
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions (1946 to May 22, 2023)	OVID	19/06/2023	3
Embase (1974 to 2023 May 22)	OVID	19/06/2023	13
CINAHL (January 1982 to search date: 22/5/2023)	EBSCOhost	19/06/2023	1
CENTRAL (2023, issue 5)	Cochrane Library	19/06/2023	1
Google Scholar	https://scholar.google.com/	19/06/2023	32
MedRxiv (Pre-print repository)	https://www.medrxiv.org/	19/06/2023	0
WHO ICTRP	https://trialsearch.who.int/Default.aspx	19/06/2023	0
ScanMedicine	https://scanmedicine.com/	19/06/2023	0
ClinicalTrials.gov	https://clinicaltrials.gov/	19/06/2023	1
International HTA Database	https://database.inahta.org/	19/06/2023	0
NIHR Journals Library	https://www.journalslibrary.nihr.ac.uk/#/	19/06/2023	0
Total			**51**
Total after deduplication (including deduplication with the original clinical evidence search)			**33**

DATABASE/PLATFORM: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to June 19, 2023>, 2023>
Platform/URL: OVID

Line #	Search terms	Results
1	(Second Nature* or secondnature* or OurPath* or (our path* not (our patho* or our pathw*)) or Roczen* or Reset Health* or Wellbeing Way* or well being way* or Xyla or xylatm).ti,ab,kf,in.	546
2	1 and (obes$ or preobes$ or overweight or over weight or ((bmi or body mass index$) and "kg m") or (weight$ adj5 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).mp.	9
3	limit 2 to yr="2018 -Current"	3

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=5F52OiFxKpvEY2mR4KDBDKiJt9cwnnyf3mL8tz75ujFDlWsvFeTyN609kjHT2cKH5

DATABASE/PLATFORM: Embase <1974 to 2023 May 22>
Platform/URL: OVID

Line #	Search terms	Results
1	(Second Nature* or secondnature* or OurPath* or (our path* not (our patho* or our pathw*)) or Roczen* or Reset Health* or Wellbeing Way* or well being way* or Xyla or xylatm).ti,ab,kf,dm,dv,in.	651
2	1 and (obes$ or preobes$ or overweight or over weight or ((bmi or body mass index$) and "kg m") or (weight$ adj5 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).mp.	21
3	limit 2 to yr="2018 -Current"	13

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=5HTnjiNtWXL68bakP9RwkjpjAJ2EbRjWDkeYhwkN9JTQf3TLHbYwmmZrURLSOcz5M

DATABASE/PLATFORM: CINAHL (1 January 1982 to date of search: 20/6/2023)
Platform/URL: EBSCOhost
TX (obes* OR preobes* OR overweight OR "over weight" OR ((bmi OR "body mass index*") and "kg m") OR (weight* N5 (loss OR lose OR losing OR loses OR lost OR manag* OR reduc* OR control*))) AND (TX ("Second Nature*" OR secondnature* OR OurPath* OR Roczen* OR "Reset Health*" OR "Wellbeing Way*" OR "well being way*" OR Xyla) OR TI ("our path*" not ("our patho*" OR "our pathw*")) OR AB ("our path*" not ("our patho*" OR "our pathw*")))
2018-2023
1 result

DATABASE/PLATFORM: Cochrane Library CENTRAL (2023, Issue 5)
Platform/URL: https://www.cochranelibrary.com/advanced-search
((obes* or preobes* or overweight or "over weight" or ((bmi or body mass index*) and "kg m") or (weight* NEAR/5 (loss or lose or losing or loses or lost or manag* or reduc* or control*))) AND ((Second NEXT Nature*) or secondnature* or OurPath* or ((our NEXT path*) not ((our NEXT patho*) or (our NEXT pathw*))) or Roczen* or (Reset NEXT Health*) or (Wellbeing NEXT Way*) or ("well being" NEXT way*) or Xyla or xylatm))
2018-2023
1 result

DATABASE/PLATFORM: Google Scholar
URL: https://scholar.google.com/
("second nature programme" OR "second nature program" OR "second nature app") AND ("obesity" OR "obese" OR "overweight") AND ("blended" OR "hybrid" OR "digital" OR "remote" OR "app" OR "smartphone" OR "telehealth" OR "telemedicine" OR "telecare")
or

("OurPath" OR "Roczen Health" OR "Wellbeing Way" OR "well being way" OR "xyla health")) AND ("obesity" OR "obese" OR "overweight") AND ("blended" OR "hybrid" OR "digital" OR "remote" OR "app" OR "smartphone" OR "telehealth" OR "telemedicine" OR "telecare")
or
("Reset Health" -"shareholder in reset" -"shareholder of reset") AND ("obesity" OR "obese" OR "overweight") AND ("blended" OR "hybrid" OR "digital" OR "remote" OR "app" OR "smartphone" OR "telehealth" OR "telemedicine" OR "telecare")

32 results after deduplication

DATABASE/PLATFORM: MedRxiv (Pre-print repository)
URL: https://www.medrxiv.org/
ad hoc based on named technologies
0 result

DATABASE/PLATFORM: WHO ICTRP
URL: https://trialsearch.who.int/Default.aspx
("second nature" OR "secondnature" OR Ourpath OR "our path" OR Roczen OR "Reset Health" OR "Wellbeing Way" OR "well being way" OR xyla) AND (obesity OR overweight OR "over weight")
0 results

DATABASE/PLATFORM: ScanMedicine
URL: https://scanmedicine.com/
("second nature" | "secondnature" | Ourpath | "our path" | Roczen | "Reset Health" | "Wellbeing Way" | "well being way" | xyla) + (obesity | "over weight" | overweight)
Link to strategy:
https://scanmedicine.com/clinicaltrials/search?q=%28%22second%20nature%22%20%7C%20%22secondnature%22%20%7C%20Ourpath%20%7C%20%22our%20path%22%20%7C%20Roczen%20%7C%20%22Reset%20Health%22%20%7C%20%22Wellbeing%20Way%22%20%7C%20%22well%20being%20way%22%20%7C%20xyla%29%20%2B%20%28obesity%20%7C%20%22over%20weight%22%20%7C%20overweight%29
0 results

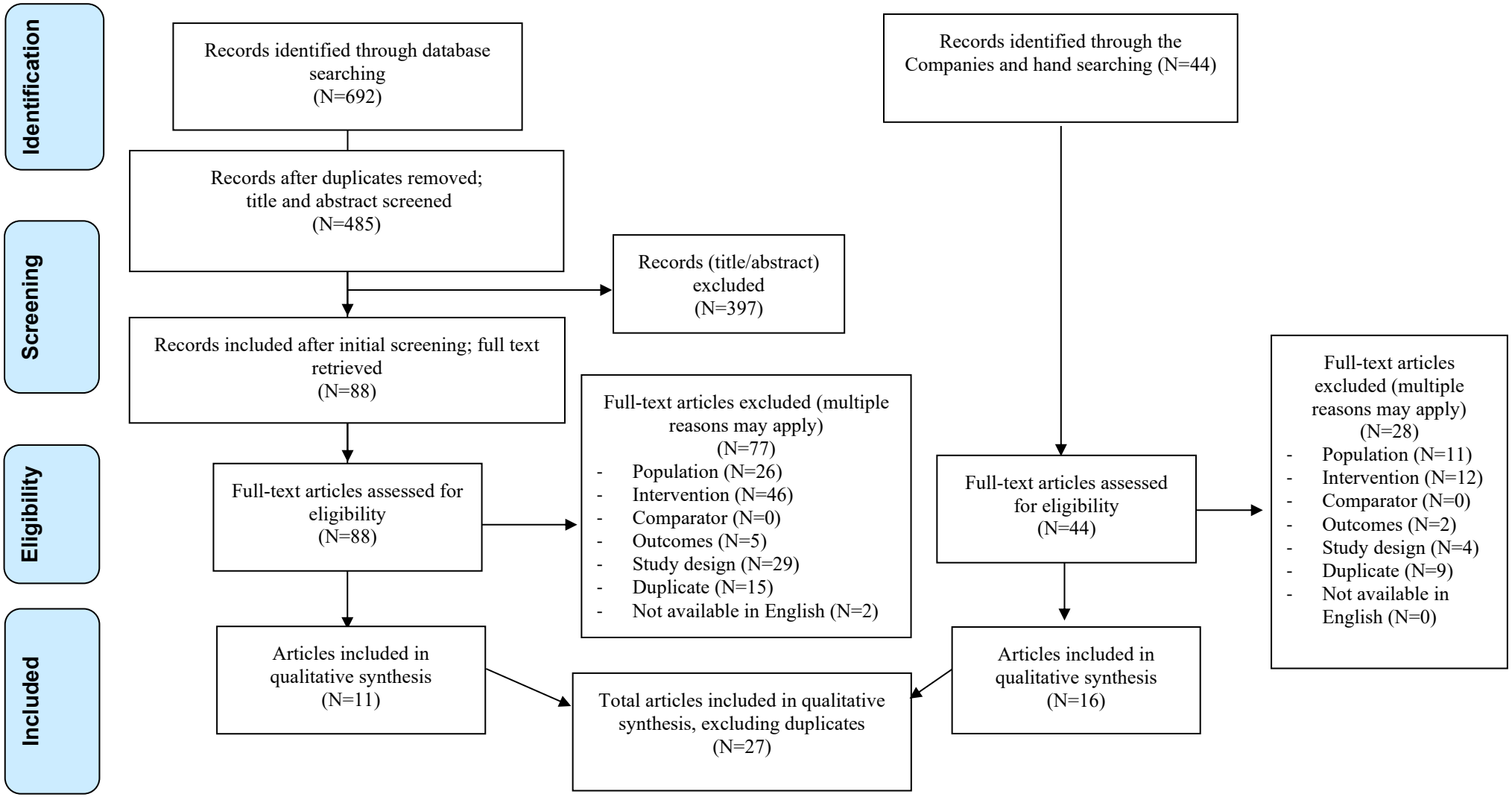
DATABASE/PLATFORM: ClinicalTrials.gov
URL: https://clinicaltrials.gov/
obesity OR overweight or "over weight" | ("second nature" OR "secondnature" OR Ourpath OR "our path" OR Roczen OR "Reset Health" OR "Wellbeing Way" OR "well being way" OR xyla)
https://www.clinicaltrials.gov/ct2/results?cond=obesity+OR+overweight+or+%22over+weight%22&term=%28%22second+nature%22+OR+%22secondnature%22+OR+Ourpath+OR+%22our+path%22+OR+Roczen+OR+%22Reset+Health%22+OR+%22Wellbeing+Way%22+OR+%22well+being+way%22+OR+xyla%29&cntry=&state=&city=&dist=&Search=Search
1 result

DATABASE/PLATFORM: International HTA Database (INAHTA)
Platform/URL: https://database.inahta.org/
(blended OR hybrid OR virtual OR digital OR remote OR app OR apps OR phone OR smartphone OR telehealth OR telemedicine OR telecare OR teleconsultation) AND (obesity OR overweight OR "over weight") AND ("second nature" OR "secondnature" OR Ourpath OR "our path" OR Roczen OR "Reset Health" OR "Wellbeing Way" OR "well being way" OR xyla)
Link to strategy:
https://database.inahta.org/search?limit=&terms=%28blended+OR+hybrid+OR+virtual+OR+digital+OR+remote+OR+app+OR+apps+OR+phone+OR+smartphone+OR+telehealth+OR+telemedicine+OR+telecare+OR+teleconsultation%29+AND+%28obesity+OR+overweight+OR+%22over+weight%22%29+AND+%28%22second+nature%22+OR+%22secondnature%22+OR+Ourpath+OR+%22our+path%22+OR+Roczen+OR+%22Reset+Health%22+OR+%22Wellbeing+Way%22+OR+%22well+being+way%22+OR+xyla%29&client=user
0 results

DATABASE/PLATFORM: NIHR Journals Library
Platform/URL: https://www.journalslibrary.nihr.ac.uk/#/
(obesity OR obese OR overweight OR "over weight") AND ("second nature" OR "secondnature" OR Ourpath OR "our path" OR Roczen OR "Reset Health" OR "Wellbeing Way" OR "well being way" OR xyla)
Link to strategy:
https://www.journalslibrary.nihr.ac.uk/search/#/?search=(obesity%20OR%20obese%20OR%20overweight%20OR%20%22over%20weight%22)%20AND%20(%22second%20nature%22%20OR%20%22secondnature%22%20OR%20Ourpath%20OR%20%22our%20path%22%20OR%20Roczen%20OR%20%22Reset%20Health%22%20OR%20%22Wellbeing%20Way%22%20OR%20%22well%20being%20way%22%20OR%20xyla)&indexname=full-index&selected_facets=
0 results

Medrxiv – ad hoc based on named technologies
0 results

Appendix A2 - PRISMA diagram (clinical evidence)



Appendix B: Included and excluded publications

Appendix B1 - Included publications (N=27)

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
Christensen et al. 2022a Denmark [NCT03788915; Protocol in Brandt et al. 2020] Reporting outcomes at 24 months	**Study design** (n=340)**:** RCT (6:4 ratio, stratified by diabetes status as reported in the published protocol; Brandt et al. 2020); allocated via an automated computer algorithm in a sequential block of 10. **Intervention** (n=200): Liva app; first session synchronous online face-to-face consultation, asynchronous coaching weekly for first 6 months, biweekly for next 6 months, structured educational material and after 12 months lifestyle coaching every third month [up to 24 months] ☑ **Comparator** (n=140): standard secondary or tertiary preventative care service [up to 24 months] (n=140) ☑	**Inclusion criteria:** BMI 30 to 45 kg/m2, aged 18 to 70 years ☑ **Exclusion criteria**: lack of internet access through computer or smartphone, pregnancy or planned pregnancy, serious or life-threatening disease defined as less than 1-year life expectancy ☑ **Recruitment period:** April 2018 to April 2019, with 24-month follow-up ending October 2021 **Setting:** multi-centre (N=NR)	**Primary:** Change in weight **Secondary:** Change in HbA1c, attendance at follow-up ☑	Overlap with Hesseldal et al. 2022 and Christensen et al. 2022b. High drop-out rate at 2 years (60% in intervention and 64% in control group). **Demographics:** In 136 patients with 24-month follow-up: - *BMI, mean (SD):* 34.7 (3.9) intervention, 35.7 (3.8) comparator - *Diabetes:* 49.4% intervention, 45.5% comparator arm - *Weight loss medication:* NR **Funding:** No financial support for the research. Conflict of interest declared by multiple authors (Liva).
Hesseldal et al. 2022 Denmark [NCT03788915] Reporting outcomes at 6 and 12 months	**Study design** (n=340): RCT (6:4 ratio); in groups of 10 **Intervention** (n=200)**:** Liva app; first session synchronous online face-to-face consultation, asynchronous coaching weekly	**Inclusion criteria:** BMI 30 to 45 kg/m2, aged 18 to 70 years ☑ **Exclusion criteria:** lack of internet access through computer or smartphone, pregnancy or planned pregnancy, serious or life-threatening	**Primary:** Change in body weight at 12 months (compared with baseline) **Secondary:**	Overlap with Hesseldal et al. 2022 and Christensen et al. 2022a. High drop-out rate at 1 year (41%); authors acknowledge

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
	for first 6 months, monthly for next 6 months (n=200) ☑ **Comparator** (n=140)**:** standard secondary or tertiary preventative care service [up to 12 months] (n=140) ☑	disease defined as less than 1-year life expectancy ☑ **Recruitment period:** April 2018 to April 2019, with 24 month follow-up ending October 2021. **Setting**: multi-centre (N=NR)	Attendance at follow-up, change in HbA1c at 6 and 12 months (compared with baseline), BMI, hip, waist, waist-to-hip ratio, lipid levels (total cholesterol, LDL, HDL, triglyceride), blood pressure, medication changes, changes in mental health and quality of life ☑☒	this may have been impacted by Covid-19. Secondary analysis of the intervention arm reported in Imeraj et al. 2022. **Demographics:** In 200 patients with 12 month follow-up: - *BMI, mean (SD):* 35.3 (3.8) - *Diabetes:* 49% - *Weight loss medication:* NR **Funding:** No external funding. Conflict of interest declared by multiple authors (Liva).
Imeraj et al. 2022. Denmark [NCT03788915] Reporting outcomes at 6 and 12 months	**Study design** (n=104): Intervention arm of RCT **Intervention** (n=104): Liva app ☑ **Comparator**: N/A ☑	**Inclusion:** BMI 30 to 45 kg/m2, aged 18 to 70 years ☑ **Exclusion:** lack of internet access through computer or smartphone, pregnancy or planned pregnancy, serious or life-threatening disease. Additional patients were excluded if they did not have a home measurement of weight within 1 and 21 days prior to their clinical weight measurement, withdrawal of consent, unrealistic self-reported weight (stated as a 42 kg difference) ☑	Number of patients self-reporting weight, and difference between self-reported and clinical measurement of weight at 6 and 12 months follow-up. Prediction of discrepancy (between clinical measurement and self-reporting of weight) by those achieving 5%	Analysis focuses on agreement between clinically measured and self-reported weight; which would impact the weight loss and BMI outcome measures. 97 and 58 participants had data available at 6 and 12 months respectively. **Demographics:** For 104 with valid home measurements: - *BMI, mean (SD):* 34.9 (3.6) - *Diabetes:* 47.1%

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
		Recruitment period: Data collected between March 2019 and October 2021 **Setting:** Two regions in Denmark (Region of Southern Denmark with 22 municipalities and the Capital Region of Denmark with 28 municipalities)	weight loss at 6 and 12 months ☑	- *Weight loss medication:* NR **Funding:** Partly funded by Liva Healthcare. Conflict of interest declared by multiple authors (Liva).
Christensen et al. 2022b Denmark [NCT03788915] Reporting 6 month outcomes	**Study design** (n=170): RCT (6:4 ratio); in groups of 10 **Intervention** (n=100): Liva app; first session synchronous online face-to-face consultation, asynchronous coaching weekly for first 3 months, biweekly for next 3 months ☑ **Comparator** (n=70): standard secondary or tertiary preventative care service [up to 6 months] ☑	**Inclusion:** BMI 30 to 45 kg/m2, aged 18 to 70 years, diagnosed with T2DM ☑ **Exclusion**: lack of internet access through computer or smartphone, pregnancy or planned pregnancy, serious or life-threatening disease defined as less than 1-year life expectancy ☑ **Recruitment period:** March 2018 to March 2019. **Setting:** multi-centre (N=NR)	**Primary:** mean weight, number of patients losing threshold (3%, 5%, 10%) baseline weight **Secondary:** attendance at follow-up, mean HbA1c at 6 months (compared with baseline), proportion of patients whose HbA1c decreased or normalised to less than 6.5% at 6 months, BMI, hip and waist circumference, lipids, blood pressure, exercise and diet habits, quality of life and	Overlap with Hesseldal et al. 2022 and Christensen et al. 2022a. High drop-out rate at 6 months (25%). **Demographics:** - *BMI, mean (SD):* 34.7 (3.3) intervention, 35.0 (4.4) comparator - *Diabetes:* 100% - *Weight loss medication:* NR **Funding:** No external funding. Conflict of interest declared by multiple authors (Liva).

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
			mental wellbeing, use of medication (glucose, cholesterol and blood pressure lowering), activity ☑	
Tsai et al. 2023 Germany *[Abstract]*	**Study design** (n=63): Non-randomised comparative cohort **Intervention** (n=NR): Liva [6 months] ☑ **Comparative** (n=NR): NR ☑	**Inclusion:** Adult (greater than 18 years old), T2DM, BMI 25 to 40kg/m2 and with HbA1c between 6.5 and 11.0%, recruited from social media campaigns ☑☒ **Exclusion:** Not stated ☑ **Recruitment period:** April 2022 to October 2022 **Setting**: Not reported	HbA1c, participant retention ☑	Limited information on study due to abstract poster. No information on the comparative cohort group. **Demographics:** - *BMI, mean (SD):* 33.4 (NR) - *Diabetes:* 100% - *Weight loss medication:* NR **Funding:** NR
Pedersen et al. 2019 Denmark	**Study design** (n=2,684): Retrospective cohort **Intervention** (n=2,684) Liva ☑ **Comparator**: N/A ☑	**Inclusion:** All patients available on the Liva Healthcare database, referred to the platform by their doctor or municipality, who showed commitment to the intervention by being properly set up with the app, received 3 or more advices from their coach, and had been active on the app for at least 14 days ☑☒ **Exclusion**: Extreme outliers and unrealistic values (weight differences of greater than 3.5 kg/week on average for weight registrations over	**Primary:** Rate of dropout **Secondary:** analysis of predictors of engagement ☑☒	Early dropouts (less than 14 days) were excluded. Reasons for the dropouts were not reported. Dropouts may include patients who have achieved their desired weight goal, or the clinician has advised the patient to stop the programme for a clinical reason. Not exclusively in obese population. **Demographics:** - *BMI, mean (SD):* 33.6 (6.0)

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
		30 days or more and BMI greater than 100 kg/m2) ☑ **Recruitment period:** 07 June 2016 to 21 March 2018 **Setting:** Danish municipalities (n=NR)		- *Diabetes:* 17% - *Weight loss medication:* NR **Funding:** University of Southern Denmark, Health Informatics. Liva Healthcare provided data and allocated resources to conduct and assist in research and creation of publication. Conflict of interest declared by multiple authors (Liva).
Komkova et al. 2019 Denmark	**Study design** (n=103): Cohort **Intervention** (n=103): Liva app (first 3 months patients were guided by a municipal healthcare professional once a week, following 2 months, consultations every second week, then monthly guidance until 12 months) ☑ **Comparator**: N/A ☑	**Inclusion:** patients with diabetes and BMI greater or equal to 30, had registered to use the platform because of their diabetes, had at least 90 days and maximum 365 days between first and last weight measurement registration and have no registrations of unrealistic rapid weight change (defined as greater than 0.5 kg/day) ☑ **Exclusion:** NR ☑ **Recruitment period:** 07 June 2016 to 02 May 2018 **Setting:** 8 Danish municipalities (not specified)	Average time on intervention, proportion of patients losing or maintaining/gaining weight (compared with baseline), change in BMI, predictors of weight loss ☑☒	First meeting was face-to-face for 45 to 60 minutes. Potential subset of Pedersen et al. 2019. **Demographics:** - *BMI, mean (SD):* 36.0 (5.2) - *Diabetes:* 100% - *Weight loss medication:* NR **Funding:** Liva Healthcare, the University of Southern Denmark and the Region for Southern Denmark. Conflict of interest declared by multiple authors (Liva).

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
Liva CiC-1 [redacted]	[redacted]	[redacted]	[redacted]	Information obtained only from information shared by Company. [redacted] Not exclusively in obese population [redacted]
Liva CiC-2 [redacted]	[redacted]	[redacted]	[redacted]	Information obtained only from information shared by Company. [redacted] Not exclusively in obese population [redacted]
Liva CiC-3 [redacted]	[redacted]	[redacted]	[redacted]	Information obtained only from information shared by Company. [redacted]

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
				[redacted] Not exclusively in obese population [redacted]
Hanson et al. 2023 UK	**Study design** (n=832): Original design as prospective single-arm cohort [however the EAG note that the authors have compared baseline characteristics to a comparator group, non-randomised] **Intervention** (n=199): Gro Health app (DDM) ☑ **Comparator:** N/A ☑	**Inclusion:** All patients awaiting their first appointment with the hospital-based Tier 3 specialist weight management team ☑ **Exclusion:** NR ☑ **Recruitment period:** January 2021 and April 2021, engagement with the app assessed in August 2021. **Setting:** Single-centre hospital	Proportion of patients willing to use the app and reasons for declining app, differences in demographics and baseline clinical parameters between those interested or refusing the app ☑	Psychological measures were taken at baseline only (used in analysis to determine whether different for those engaging or not engaging with the app, a sample of 633 from standard care) and not outcome measures. **Demographics:** For the 199 in the intervention group - *BMI, median [IQR]:* 45.5 [41.9 to 51] - *Diabetes:* NR - *Weight loss medication:* NR **Funding:** Study was undertaken as part of a Topol Digital Fellowship funded by Health Education England. Conflict of interest declared by multiple authors (DDM).
McDiarmid et al. 2022 UK	**Study design** (n=79): Pilot RCT (1:1 ratio) feasibility outcomes, minimisation	**Inclusion criteria:** Willing and able to provide informed consent, male or female aged 18 to 75 years,	**Primary:** Study uptake, retention, app	Multiphase diet controlling study. App used in both arms.

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
[ISRCTN15394285; Protocol in McDiarmid et al. 2021]	programme stratified by BMI (greater than or equal to 34 or less than 34 kg/m^2), duration of diabetes (less than 4 or greater than or equal to years), sex, and whether prescribed/not prescribed insulin **Intervention** (n=40): Intermittent Low energy diet (2 consecutive days of Optifast and 5 days of portion controlled Mediterranean diet for 28 weeks) and Oviva app for 52 weeks **Comparator** (n=39): Continuous low energy diet (56 days of daily Optifast 820kcal diet) followed by stepped food reintroduction (from 1000kcal to 1500kcal) over 4 weeks and Oviva app for 52 weeks ☑☒ Participants who could not tolerate Optifast were offered a food-based calorie equivalent low-energy diet ☑☒	diagnosed with T2DM less than 8 years, diet controlled only or receiving any type of diabetes medications including insulin, HbA1c greater than or equal to 48 mmol/mol (6.5%) at baseline (venous blood sample), BMI greater than 27 kg/m2 and less than 50 kg/m2 or greater than 25 kg/m2 and less than 50 kg/m2 in high risk ethnic minority groups (such as, South Asian, Black African and African Caribbean), access to and ability to use the Oviva app or a telephone, willing to be randomised to an intermittent or continuous low-energy diet total diet replacement drinks ☑☒ **Exclusion criteria:** Routine HbA1c greater than or equal to 108 mmol/mol during the last 3 months, unstable retinopathy or grade R2 or later, or no retinopathy screen within last 12 months, pregnant or considering pregnancy, prior bariatric surgery, current treatment with Orlistat, unintentional weight loss greater than or equal to 5 kg within last 6 months, learning difficulties, lacking capacity or unable to understand English, known sensitivity to ingredients in the total diet replacement, diagnosed eating disorder (also severe binge eating or	usage, dietary adherence, weight loss and change in HbA1c at 1 year **Secondary:** Level of multidisciplinary support, adverse events (not specifically related to digital component of intervention), diabetes medication changes ☑ **Exploratory outcomes:** Systolic and diastolic blood pressure, therapeutic intensity score, fasting plasma glucose, body fat, fat mass, fat-free mass, waist circumference, hip circumference, cholesterol, HDL, LDL, triglycerides ☑☒	Authors acknowledge failure to maximise the potential of the digital component due to workforce constraints (support not introduced until after 6 months). Comprehensive data on medication prescription was collected however medication adherence was not assessed. As a pilot study not appropriate to formally combine groups. Exclusion criteria may exclude some ethnic minorities. **Demographics:** - *BMI, mean (SD):* 36.4 (5.8) - *Diabetes:* 100% - *Weight loss medication:* NR **Funding:** Néstle Health Science, as the funder of the trial, is also the manufacturer of the nutritional products used in the trial. Oviva provided the smartphone application used on the trial.

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
		very low eating self-efficacy as assessed by the Binge Eating Scale score greater than or equal to 27, and Weight Efficacy Lifestyle Questionnaire Short Form score less than or equal to 35. Severe anxiety or depression as assessed by the Generalised Anxiety Disorder-7 scale greater than or equal to 15 and Patient Health Questionnaire-9 greater than or equal to 15. Hazardous or harmful drinking as indicated by the Alcohol Use Disorders Identification Test score greater than or equal to 16. Active symptoms associated with Emotionally Unstable Personality Disorder, Bipolar Disorders, Psychotic Disorders, Post-Traumatic Stress Disorder or current self-harm or suicidal behaviour. Participants with these issues were potentially eligible dependent on further information from their GP and responses to the baseline study questionnaires. Current treatment with lithium, anti-psychotics, or other psychotropic medications that may cause excessive weight gain. Chronic use of steroids, Medical conditions which in the opinion of the treating physician were at risk of deterioration (e.g. severe systemic or organ disease, active cancer, liver,		

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
		gall bladder disease or pancreatitis). Current participation in a diabetes drug trial ☑ **Recruitment period:** between February 2018 and February 2019. **Setting:** 46% recruited from primary care, 37% from NH hospital trust, 13% from a volunteer research register, and 4% from other sources.		
Huntriss et al. 2021 UK	**Study design** (n=169)**:** Retrospective, non-randomised comparative cohort **Intervention** (n=109): 2 hours of online coaching (Oviva smartphone app) as part of tier 3 weight management programme [12 to 16 weeks] ☑ **Comparator** (n=12): Four 30-minute face-to-face appointments (n=48) Four 30-minute telephone appointments [12 to 16 weeks] ☑ Patients first attended a consultation and medical review with and NHS Consultant Physician. Patients were then offered an initial 45-minute face-to-face	**Inclusion criteria:** Aged older than 18 years, BMI greater or equal to 45 kg/m2 or greater or equal to 40 kg/m2 with a complex comorbidity. In exceptional circumstances, patients were considered eligible if they did not meet the BMI criteria but was agreed by the local commissioner and programme provider that weight management support from other tiers would be inadequate ☑ **Exclusion criteria:** Active eating disorder, unstable medical condition, unstable psychiatric disorder, women who were pregnant or breastfeeding, patients who were not ready to change (did not sign a pledge to declare commitment to programme) ☑	**Primary:** Change in BMI and weight **Secondary:** Uptake of service, intervention adherence, number of psychology support sessions, Family and Friends Test (patient satisfaction) ☑	Clinician and patient chose intervention arm (demographic differences between arms; apps younger and fewer patients with diabetes). Due to commissioning other elements of the Tier 3 service were delivered by other providers (including NHS consultant provision, and physical activity services). Those attending 12-week follow-up requested the additional follow-up or were those who wanted to pursue weight loss surgery. **Demographics:** - *BMI, mean (SD):* 48.3 (6.2) - *Diabetes:* 26.6% app, 45.8% face-to-face, 41.7% telephone

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
	consultation and a final 30-minute face-to-face session with a specialist weight management dietitian. Between sessions patients were offered 1 of 3 interventions.	**Recruitment period:** Patient that started care from 1 January 2018 and were discharged from the core programme before 31 December 2018. **Setting**: One town (Wakefield).		- *Weight loss medication:* Orlistat (5.3%), glucagon-like peptide-1 analogues (6.5%) and sodium-glucose co-transporter-2 inhibitors (4.1%); authors reported that proportions did not different between groups. **Funding:** NR. Two authors employed by Oviva. Data analysis was completed independently by an author who declared no conflict of interest.
Haas et al. 2019 Switzerland [NCT02694614]	**Study design** (n=43)**:** Before-and-after study **Intervention**: coaching with 3 registered dietitians (via Oviva app) [12 months] ☑ **Comparator**: standard care (prior to Oviva app) ☑	**Inclusion criteria:** 18 years and over, BMI between 26 and 33 kg/m2, fluent in German, mobile phone user (iOS or Android) and capable of sending and receiving SMS text messages and pictures ☑☒ **Exclusion criteria:** Pregnant or breastfeeding, were diagnosed with conditions other than dyslipidaemia, hypertension, and insulin resistance requiring nutrition therapy, had serious disease requiring continuous drug therapy, were on a weight reduction diet during the last 6 months, took medication for weight loss in the	**Primary:** Completion of intervention, weight loss at 3 and 12 months (compared with baseline) **Secondary**: Change in BMI, waist circumference, body fat, HbA1c, fasting glucose, fasting insulin, triglyceride, high-density lipoprotein (HDL) cholesterol, and blood	Uncertainty regarding the sample size calculation (based on weight loss of 0.5 SD, but non-parametric test applied). **Demographics:** - *BMI, mean {range}:* 30.2 {26.4, 33} - *Diabetes:* 0% (1 was pre-diabetes) - *Weight loss medication:* 0% (exclusion criteria) Not exclusively in obese population **Funding:** Innosuisse-Suisse Innovation Agency and Oviva.

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
		past, or enrolled in another weight loss programme ☑ **Recruitment period:** March 2016 (first participant in) to May 2018 (last participant out) **Setting**: Centre for Obesity and Metabolism Medicine (N=1 centre)	pressure. Socioeconomic data, dietary assessment, physical activity (Global Physical Activity Questionnaire), and quality of life (12-item Short-Form Health Survey) ☑	Conflict of interest declared by multiple authors (Oviva).
Lawson et al. 2022 UK	**Study design** (n=54)**:** Before-and-after study **Intervention**: Tier 3 weight management programme using Oviva app alongside 2 telephone assessments (1 with dietitian, 1 with psychology) [up to 12 months] ☑☒ **Comparator**: standard care (prior to Oviva app) ☑ All participants referred to the service by their local NHS service provider, usually GP.	**Inclusion criteria**: Referred to the service by the local NHS provider, BMI greater than 35 kg/m2 with comorbidities. All participants have been able to use the technology effectively and engage in remote telephone or text support ☑ **Exclusion criteria:** NR ☑☒ **Recruitment period**: NR **Setting**: Not specified (N=NR; multi-centre across England and Scotland)	**Primary:** Self-reported Patient Health Questionnaire-9 score at 3 months and 6 months (when compared with baseline) ☑	Use of Oviva app assumed from author affiliations. **Demographics:** - *BMI, mean (SD):* NR (but greater than 35 in inclusion criteria) - *Diabetes:* NR - *Weight loss medication:* NR **Funding:** NR. 7 of 8 authors employed by Oviva.
Sutter et al. 2020 Switzerland *[Abstract]*	**Study design** (n=166): Retrospective non-randomised comparative cohort	**Inclusion:** T2DM, receiving individual nutritional counselling by registered dietitians ☑☒ **Exclusion:** NR ☑	HbA1c ☑	Limited information on study due to abstract. Oviva app assumed from author affiliations.

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
	Intervention (n=52): Hybrid face-to-face counselling and Oviva app ☑☒ **Comparator** (n=114): Patient choice: face-to-face counselling ☑	**Recruitment period:** NR **Setting:** Swiss GP practices		The term 'obese' is not included in the abstract, however BMI is recorded with patients having T2DM. Second HbA1c measurement varied between 3 and 12 months after first measurement, as was dependent on local diabetes review schedule. Potential overlap with Sutter et al. (2021) **Demographics:** - *BMI, mean (SD):* 33.0 (6.0) intervention, 32.6 (5.3) comparator - *Diabetes:* 100% - *Weight loss medication:* NR Not exclusively in obese population **Funding:** NR. Authors employed by Oviva
Sutter et al. 2021 Switzerland *[Abstract]*	**Study design** (n=86): Retrospective non-randomised comparative cohort **Intervention** (n=72): Hybrid counselling, including Oviva Diet app and face-to-face consultations ☑	**Inclusion:** Patients living with obesity under individual nutritional therapy (from referral) ☑ **Exclusion:** NR ☑ **Recruitment period:** NR	Patient uptake of service, weight loss by treatment type ☑	Limited information on study due to abstract. Oviva app assumed from author affiliations. Patients chose treatment type (hybrid or face-to-face).

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
	Comparator (n=14): Patient choice: face-to-face counselling ☑	**Setting**: Swiss GP practices (not defined)		Potential overlap with Sutter et al. (2020) **Demographics:** - *BMI, mean (SD):* 36.6 (6.3) - *Diabetes:* NR - *Weight loss medication:* NR **Funding:** NR. Authors employed by Oviva
Papathanail et al. 2022 Switzerland *[Abstract]*	**Study design** (n=24): Cohort (feasibility study) **Intervention** (n=24): Oviva app ☑ **Comparator**: N/A ☑	**Inclusion**: BMI greater than 27 kg/m2 ☑☒ **Exclusion:** NR ☑ **Recruitment**: NR **Setting**: NR	**Primary:** Feedback on functionality ☑ **Secondary:** NR	Limited information on study due to abstract. Oviva app assumed from author affiliations. No outcome data on BMI, weight loss or HbA1c recorded. **Demographics:** - *BMI, mean (SD):* NR (greater than 27, inclusion criteria) - *Diabetes:* NR - *Weight loss medication:* NR Not exclusively in obese population **Funding:** NR. Authors employed by Oviva
Huntriss et al. (2020) UK *[Abstract]*	**Study design** (n=9): Before-and-after	**Inclusion:** T2DM ☑☒ **Exclusion:** NR ☑	Weight loss, remission of T2DM (measured via	Limited information on study due to abstract. Oviva app assumed from author

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
	Intervention (n=9): Oviva app, phone calls (6 months) along with 8-12 week low calorie diet with Optifast, 4-week food reintroduction and maintenance support ☑ **Comparator**: N/A ☑	**Recruitment period:** NR **Setting:** North Lincolnshire GP practice	HbA1c), changes in blood pressure and cholesterol (including medication changes), patient experience, acceptability, and adherence of remote support and app ☑	affiliations. Small sample size recruited from small area. The term 'obese' is not included in the abstract, however BMI is recorded with patients having T2DM. **Demographics:** - *BMI, mean (SD):* 39.1 (6.7) - *Diabetes:* 100% - *Weight loss medication:* NR Not exclusively in obese population **Funding:** NR. Authors employed by Oviva
Oviva CiC-1 [redacted]	[redacted]	[redacted]	[redacted]	Information obtained only from information shared by Company. [redacted] [redacted] [redacted] Unclear if exclusively in obese population [redacted]

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
				[redacted]
Oviva CiC-2 [redacted]	[redacted]	[redacted]	[redacted]	Information obtained only from information shared by Company. [redacted] Unclear if exclusively in obese population [redacted]
Oviva CiC-3 [redacted]	[redacted]	[redacted]	[redacted]	Information obtained only from information shared by Company. [redacted] Unclear if exclusively in obese population [redacted]

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
Falvey et al. (2023) UK *[Abstract]*	**Study design** (n=732): Cohort **Intervention** (n=732): Time-restricted eating, low-carbohydrate moderate protein plan and Roczen (Reset Health); 1 year ☑☒ **Comparator**: Baseline ☑	**Inclusion:** NR, adults completing programme (data from 52-weeks) ☑☒ **Exclusion:** NR ☑ **Recruitment period:** NR **Setting:** NR	Weight loss, waist circumference, HbA1c, systolic and diastolic blood pressure, PHQ-9 depression score, Binge-Eating Scale, retention ☑	Limited information on study due to abstract, such as difficulty in determining inclusion criteria. Potential overlap with Phung et al. (2023) and Brown et al. (2022). **Demographics:** - *BMI, mean (SD):* 34.9 (6.3) - *Diabetes:* 12.3% T2DM; 8.9% pre-diabetic - *Weight loss medication:* NR Not exclusively in obese population **Funding:** All authors listed as affiliated with Reset Health, all listed as stakeholders in Reset Health.
Phung et al. (2023) UK *[Abstract]*	**Study design** (n=82): Cohort **Intervention** (n=82): Time-restricted eating and low carbohydrate, moderate protein diet and Roczen programme (Reset Health); mean (SD) of 49 (24) weeks ☑☒ **Comparator**: Baseline ☑	**Inclusion:** NR, participants enrolled on intervention with T2DM ☑☒ **Exclusion:** NR ☑ **Recruitment period:** NR **Setting:** NR	Weight loss, HbA1c, changes in medication (anti-hyperglycaemic, anti-hypertensives, analgesics) ☑☒	Limited information on study due to abstract. Likely subset of Falvey et al. (2023) and overlap with Brown et al. (2022) **Demographics:** - *BMI, mean (SD):* 35.0 (6.7) - *Diabetes:* 100% - *Weight loss medication:* 12.2% taking injectables (such as insulin or GLP-1

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
				analogues; not reported separately). Not exclusively in obese population **Funding:** NR, 4 of 7 authors affiliated with Reset Health.
Brown et al. (2022) UK *[Abstract]*	**Study design** (n=653): Cohort **Intervention** (n=653): Time-restricted eating, low-carbohydrate moderate protein plan and Roczen (Reset Health) ☑☒ **Comparator**: N/A ☑	**Inclusion:** NR, adult participant enrolled on intervention, employee health initiative referred or self-referral ☑☒ **Exclusion:** NR ☑ **Recruitment period:** NR, collected over Covid-19 pandemic **Setting:** NR	Weight loss, HbA1c, waist circumference, systolic and diastolic blood pressure, quality of life (depression or anxiety; measure or tool used NR), eating behaviour (binge-eating, emotional eating; tool or measure used NR), completion at 24 weeks ☑☒	Limited information on study due to conference poster. Overlap in authorship with Phung et al. (2023) and Falvey et al. (2023). **Demographics:** - *BMI, mean (SD):* 35.2 (6.4) - *Diabetes:* 8.6% T2DM; 9.0% pre-diabetic - *Weight loss medication:* NR Not exclusively in obese population **Funding:** NR, all authors affiliated with Reset Health.
Roczen AiC-1 [redacted]	[redacted]	[redacted]	[redacted]	Information obtained only from information shared by Company. [redacted]

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
				[redacted] Not exclusively in obese population [redacted]
Roczen AiC-2 [redacted]	[redacted]	[redacted]	[redacted]	Information obtained only from information shared by Company. [redacted] **Demographics:** [redacted] Not exclusively in obese population [redacted]

Author (year); location	Design and intervention(s)	Participants & Setting	Outcomes	EAC comments
		[redacted]		
Key: ☑aspect of study in scope; ☑☒ aspect of study partially in scope, or ☒ elements of this are not in scope **Abbreviations**: BES, Binge Eating Scale; BMI, body mass index; HbA1c, haemoglobin A1c; HDL, high-density lipoprotein; LDL, low-density lipoprotein; N/A, not applicable; NR, not reported; SD, standard deviation; TFEQ, Three Factor Eating Questionnaire; T2DM, type 2 diabetes mellitus				

Appendix B2 - Excluded publications (N=97)

#	Source	Sift ref #	Study reference	Reason for exclusion
1.	EAG search	4	Bizhanova et al. (Medicine & Science in Sports & Exercise, 2023; 55(5): 856-864)	Intervention: Fitbit and text messages
2.	EAG search	5	Bretschneider & Schwarz (Diabetes aktuell, 2023; 21(03): 110-111)	Language: Non-English
3.	EAG search	10	Daud et al. (Journal of Clinical and Health Sciences, 2023; 8(1): 6-33)	Study design: Review
4.	EAG search	11	Forman et al. (Contemporary Clinical Trials, 2023; 124: 107029)	Intervention: Mixed intervention Study design: Protocol
5.	EAG search	12	Hawkes et al. (Preventive Medicine Reports, 2023; 102112)	Population: NHS-DPP Outcomes: Anonymised Study design: Review
6.	EAG search	14	Kanehl et al. (Diabetes Technology and Therapeutics, 2023; 25(2): A43)	Outcomes: Predictive modelling development
7.	EAG search	17	Miller et al. (Diabetes Technology and Therapeutics, 2023; 25(2): A226-A227)	Population: BMI or obesity not stated Intervention: Not reported
8.	EAG search	18	Miller et al. (Contemporary Clinical Trials, 2023; 129: 107201)	Intervention: Fitbit and group and coach intervention Study design: Protocol
9.	EAG search	20	Putra et al. (Alauddin Scientific Journal of Nursing, 2023; 4(1): 34-43)	Study design: Narrative summary Language: Non-English
10.	EAG search	32	Yen et al. (International Journal of Nursing Studies, 2023; 137: 104384)	Intervention: No interventions included in scope Study design: Meta-analysis
11.	EAG search	34	Al-Badri et al. (Therapeutic Advances in Endocrinology and Metabolism, 2022; 13)	Intervention: Weight Achievement and Intensive Treatment (Why WAIT) programme
12.	EAG search	40	Brandt et al. (Diabetologie und Stoffwechsel, 2022; 17(1): S59)	Duplicate: Poster abstract (full paper reviewed and included)
13.	EAG search	47	Fichtner et al. (International Journal of Environmental Research and Public Health, 2022; 19(22): 15157)	Intervention: Web-based coaching
14.	EAG search	48	Finnie et al. (British Journal of Diabetes, 2022; 22(2): 164)	Population: BMI or obesity not stated Intervention: diabetes structured education, unable to determine app used

#	Source	Sift ref #	Study reference	Reason for exclusion
15.	EAG search	54	Hanson, P. (Journal of Diabetes Nursing, 2022; 26(6): 1-2)	Study design: online article narrative summary
16.	EAG search	57	Hesseldal et al. (Diabetologia, 2022; 65(1): S116)	Duplicate: Abstract (full paper reviewed and included)
17.	EAG search	66	ClinicalTrials.gov, NCT04674384	Study design: Clinical trial registry, no outcomes reported Duplicate: related to MIDDAS trial (tabulated in Ongoing Studies)
18.	EAG search	69	Miller et al. (British Journal of Diabetes, 2022; 22(2): 167-168)	Population: BMI or obesity not stated Intervention: Not reported
19.	EAG search	70	Miller et al. (British Journal of Diabetes, 2022; 22(2): 165)	Population: BMI or obesity not stated Intervention: Not reported
20.	EAG search	71	Miller et al. (Diabetic Medicine, 2022; 39(1): 83)	Population: BMI or obesity not stated Intervention: Not reported
21.	EAG search	73	Mohanty et al. (Cardiovascular Digital Health Journal, 2022; 3(2): 75-79)	Intervention: RFMx digital monitoring platform (smartphone app)
22.	EAG search	78	Nezami et al. (Obesity, 2022; 30(3): 628-638)	Intervention: FitBit and PATH study-specific smartphone app
23.	EAG search	80	O'Boyle and Davidson. (Topics in Clinical Nutrition, 2022; 37(1): 69-84)	Intervention: No interventions included in scope Study design: Systematic review
24.	EAG search	83	German Clinical Trials Register, DRKS00025291	Study design: Clinical trials registration (no reported completion date)
25.	EAG search	97	Schirmann et al. (Obesity Facts, 2022b; 15(suppl.1): 274)	Intervention: 3-month programme with coaching from dietitians only, not representative of a Tier 3 specialist weight management service
26.	EAG search	98	Scott et al. (BJGP Open, 2022; 6(1))	Population: Type 2 diabetics and pre-diabetics
27.	EAG search	108	Miller et al. (ABCD Abstracts 350 & 351. Br J Diabetes, 2021; 21(2): 293-296)	Population: BMI or obesity not stated Intervention: Not reported Duplicate: Interim analysis (full paper reviewed)
28.	EAG search	113	Schirmann et al. (Diabetologie und Stoffwechsel, 2021; 16(1): S66-S67)	Population: BMI or obesity not stated
29.	EAG search	116	Behr et al. (International Journal of Environmental Research & Public Health, 2021; 18(12): 19)	Intervention: Noom diet weight loss programme Outcomes: Linguistic analysis
30.	EAG search	127	Debrou et al. (Obesity Surgery, 2021; 31(1): S14)	Study design: Outline of planned service evaluation

#	Source	Sift ref #	Study reference	Reason for exclusion
31.	EAG search	130	Duarte et al. (Journal of Health Psychology, 2021; 26(10): 1700-1715)	Population: BMI 20 to 70 kg/m2 Intervention: Slimming World
32.	EAG search	134	Hanson et al. (JMIR Formative Research. 2021; 5(9): e29110	Intervention: Low Carb app
33.	EAG search	136	Ho et al. (Obesity, 2021; 29(2): 78-79)	Intervention: Not reported
34.	EAG search	139	Huntriss et al. (Obesity Facts, 2021; 14(1): 56)	Population: BMI or obesity not stated Intervention: Not reported Duplicate: Abstract (full paper reviewed and included)
35.	EAG search	150	McDiarmid et al. (JMIR Research Protocols, 2021; 10(3): e21116)	Study design: Protocol
36.	EAG search	157	Morrison, C. (Digital Health & Care Institute, Glasgow, 2021)	Study design: Framework guidance (Scotland)
37.	EAG search	165	Rambiritch et al. (Obesity, 2021; 29(2): 108	Population: BMI not stated Intervention: Not stated Outcomes: genomic and microbiome
38.	EAG search	173	Stubbs et al. (Obesity Facts, 2021; 14(3): 320-333)	Intervention: NoHoW trial toolkit, Slimming World and Fitbit
39.	EAG search	174	Summers et al. (JMIR Diabetes, 2021; 6(3): e25751)	Population: pre-diabetics, BMI not stated
40.	EAG search	183	Axelbaum et al. (Obesity, 2020; 28(2): 50)	Intervention: Not stated
41.	EAG search	188	Brandt et al. (JMIR Research Protocols, 2020; 9(6): e19172)	Study design: Protocol, no outcomes reported
42.	EAG search	199	Haas et al. (Proceedings of the Nutrition Society, 2020; 79(OCE2): E276)	Duplicate: Abstract (full paper reviewed and included)
43.	EAG search	200	Harvie et al. (Diabetic Medicine, 2020; 37(1): 88)	Duplicate: Abstract (full paper reviewed and included)
44.	EAG search	201	Hernandez-Reyes et al. (BMC Medical Informatics & Decision Making, 2020; 20(1): 40)	Intervention: Nutrición Sur app
45.	EAG search	204	Issa et al. (Diabetologia, 2020; 63(1): S104-S105)	Duplicate: Abstract (full paper reviewed and included)
46.	EAG search	209	Kelly et al. (Obesity Reviews, 2020; 21(1))	Population: BMI or obesity not stated. Self-referral to app
47.	EAG search	214	Lau et al. (Preventive Medicine, 2020; 132: 106001)	Intervention: No interventions included in scope Study design: Systematic review
48.	EAG search	227	Reik & Holzapfel. (Frontiers in Nutrition, 2020; 7: 586985)	Study design: Protocol, no outcomes reported

#	Source	Sift ref #	Study reference	Reason for exclusion
49.	EAG search	230	Rumbo-Rodriguez et al. (Nutrients, 2020; 12(12): 26)	Intervention: No interventions included in scope Study design: Systematic review
50.	EAG search	234	Simpson et al. (Public Health Research, 2020; 8(3))	Intervention: HelpMeDoIt app (NIHR funded)
51.	EAG search	239	Summers & Curtis. (JMIR Diabetes, 2020; 5(1): e15030)	Population: Type 2 diabetes only, BMI or obesity not stated Study design: Narrative summary, no outcomes reported
52.	EAG search	244	Wang et al. (JMIR MHealth and UHealth, 2020; 8(4): e15400)	Population: BMI or obesity not stated Intervention: No interventions included in scope Study design: Systematic review
53.	EAG search	250	Beleigoli et al. (Journal of Medical Internet Research, 2019; 21(1): e298)	Intervention: No interventions included in scope Study design: Systematic review
54.	EAG search	269	Holzmann & Holzapfel. (Journal of Personalized Medicine, 2019; 9(2): 31)	Intervention: No interventions included in scope Study design: Narrative summary
55.	EAG search	289	Pfammatter et al. (Contemporary Clinical Trials, 2019; 82: 36-45)	Intervention: SMART app and Fitbit Study Design: Protocol, no outcomes reported
56.	EAG search	307	Arens et al. (Journal of Diabetes Science & Technology, 2018; 12(4): 831-838)	Population: BMI or obesity not stated Intervention: Accu-check app
57.	EAG search	309	Azar et al. (Translational Behavioral Medicine, 2018; 8(2): 280-294)	Population: BMI or obesity not stated Intervention: No interventions included in scope Study design: Framework for eHealth
58.	EAG search	336	ClinicalTrials.gov, NCT03788915	Study design: Clinical trial registration Duplicate: full paper reviewed and included
59.	EAG search	339	ClinicalTrials.gov, NCT02694614	Study design: Clinical trial registration Duplicate: full paper reviewed and included
60.	EAG search	347	LaRose et al. (JAMA Network Open, 2022; 5(9): e2231903)	Intervention: LoseIt! app
61.	EAG search	349	Thorgeirsson et al. (Journal of diabetes science and technology, 2022; 15(5): 1150-1158)	Intervention: Sidekick app
62.	EAG search	352	ClinicalTrials.gov, NCT04880005	Study design: Clinical trial registration, no outcomes reported

#	Source	Sift ref #	Study reference	Reason for exclusion
63.	EAG search	356	ISRCTN15358157	Study design: Clinical trial registration, no outcomes reported
64.	EAG search	357	Chen et al. (Journal of adolescent health, 2019; 64(4): 443-449)	Population: mixed (adults and paediatrics) results not exclusively in adults (13 to 18 years) Intervention: iStart Smart for Teens Program
65.	EAG search	360	ISRCTN15394285	Study design: Clinical trial registration Duplicate: full paper reviewed and included
66.	Company search (Gro Health W8Buddy)	-	Abdelhameed et al. (Endocrine Abstracts, 2022; 81: 334)	Population: BMI not stated, diabetic and pre-diabetic
67.	Company search (Gro Health W8Buddy)	-	Green (Warwickshire World Online, 2022)	Study design: website news article
68.	Company search (Gro Health W8Buddy)	-	Hanson et al. (Endocrine Abstracts, 2017; 49: EP668)	Intervention: 8-week mindfulness course in addition to standard care.
69.	Company search (Gro Health W8Buddy)	-	Summers et al. 2023a (unable to identify article from details provided to EAG)	Study design: article
70.	Company search (Gro Health W8Buddy)	-	Summers et al. 2023b (unable to identify publication from details provided to EAG, assumed to be reference JMIR Human Factors in-press)	Population: participants accessing Tier 2 weight management services
71.	Company search (Liva)	-	Haste et al. (JMIR Diabetes, 2017; 2(2): e14)	Intervention: My Dietitian website (PraksisCare)
72.	Company search (Liva)	-	McGough et al. (Diabetes Medicine, 2019; 36(11): 1510-1)	Population: participants with non-diabetic hyperglycaemia, NHS DPP
73.	Company search (Liva)	-	Ravindrarajah et al. (PLoS Medicine, 2023; 20(2): e1004177)	Population: NHS DPP
74.	Company search (Liva)	-	Ross et al. (BMJ Open Diabetes Research Care, 2022; 10(3): e002736)	Population: NHS DPP Outcomes: unable to determine outcomes by intervention
75.	Company search (Oviva)	-	Barron et al. (Diabetes Medicine, 2023; 40(5): e15028)	Population: NHS DPP
76.	Company search (Oviva)	-	Finnie et al. (2022) (unable to identify publication within UK Congress on Obesity 2022 abstract book, details provided directly by Company	Intervention: Mixed, participants chose app or telephone coaching alongside 1 of 2 dietary interventions, results not reported exclusively. App not named.

#	Source	Sift ref #	Study reference	Reason for exclusion
77.	Company search (Oviva)	-	Hawkes et al. (Preventative Medicines Report, 2023; 32: 102112)	Population: NHS DPP
78.	Company search (Second Nature)	-	Hampton et al. (Future Healthcare Journal; 2017; 4(3): 173-177)	Intervention: initial 6-week core programme, mentoring with a registered dietitian only (not MDT), more representative of Tier 2 service. Population: included participants with a BMI within the healthy range, not exclusively in an overweight or obese population or those accessing specialist weight management services.
79.	Company search (Second Nature)	-	Davies et al. (Diabetic Medicine. 2023a; 40(suppl.1): 116	Population: participants accessing Tier 2 weight management services, 3 month 'core' programme, BMI or obesity not stated.
80.	Company search (Second Nature)	-	Hampton et al. (Diabetes Technology and Therapeutics. 2019b; 21(s1): A-145)	Intervention: mentoring with a registered dietitian only (not MDT), not representative of a Tier 3 specialist weight management service
81.	Company search (Second Nature)	-	Idris et al. (JMIR Diabetes, 2020; 5(10): e15189)	Intervention: mentoring with a registered dietitian only (not MDT), 3 month programme, not representative of a Tier 3 specialist weight management service
82.	Company search (Second Nature)	-	Thomson et al. (Clinical Obesity, 2022; 12(3): e12512)	Intervention: 12 week programme, mentoring with a registered dietitian only (not MDT), not representative of a Tier 3 specialist weight management service
83.	EAG search	7b	Davies et al. (Diabetic Medicine. 2023b; 40(suppl.1): 115	Intervention: mentoring with a registered dietitian or nutritionist (not MDT), not representative of a Tier 3 specialist weight management service
84.	EAG search	31b	Davies et al. (Diabetic Medicine. 2022; 39(suppl.1): 85	Intervention: mentoring with a registered dietitian or nutritionist (not MDT), not representative of a Tier 3 specialist weight management service
85.	EAG search	51b	Schirmann et al. (Nutrients. 2022a; 14(14):2999)	Population: BMI or obesity not stated
86.	EAG search	70b	ClinicalTrials.gov, NCT04916314	Study design: Clinical trial registry, no outcomes reported, tabulated in Ongoing Studies
87.	EAG search	76b	Scott et al. (BJGP Open. 2021)	Population: Type 2 diabetics and pre-diabetics Duplicate: pre-release of Scott et al. 2022

#	Source	Sift ref #	Study reference	Reason for exclusion
88.	EAG search	90b	Hampton et al. (Diabetic Medicine. 2020; 37(suppl.1): 30-179)	Population: BMI not stated, overweight or T2DM Intervention: mentoring with a registered dietitian only (not MDT), not representative of a Tier 3 specialist weight management service
89.	EAG search	93b	Kar et al. (Practical Diabetes 2020; 37(5): 167-172a)	Intervention: mentoring with a registered dietitian or nutritionist (not MDT) during 3 month programme, not representative of a Tier 3 specialist weight management service
90.	EAG search	104b	Edson et al. (Future Healthcare Journal. 2019; 6(suppl.1): 95)	Intervention: mentoring with a registered dietitian or nutritionist (not MDT), not representative of a Tier 3 specialist weight management service Duplicate: full results in Hampton et al. 2017.
91.	EAG search	105b	Hampton et al. (Diabetes Medicine. 2019: 36(Suppl 1): 110-111) [abstract]	Intervention: health coaching (not MDT), more representative of Tier 2 service.
92.	EAG search	114b	Aceves-Martins et al. (Int J Obesity. 2018; 8: 14-60) [abstract]	Intervention: digital technologies not reported, narrative for interventions following weight loss surgery Study design: Systematic review Duplicate: full paper Avenell et al. (2018) included in economics
93.	EAG search	119b	Arnrich et al. (Digital Health Connected Healthcare, 2020)	Intervention: SensorHub app and wearable
94.	EAG search	126b	Szypula et al. 2023, poster	Population: Patients accessing Tier 2 NHS DPP Outcomes: views on psychological strategies
95.	EAG search	-	Carr et al. (Diabetes Technology and Therapeutics. 2019; 22(2): 142-67)	Population: BMI not stated, overweight or T2DM Intervention: mentoring with a registered dietitian only (not MDT), not representative of a Tier 3 specialist weight management service Outcomes: No outcomes reported
96.	Company search (Oviva)	-	Oviva CiC-4 [redacted]	Intervention: non-MDT programme
97.	Company search (Liva)	-	Liva CiC-4 Abbott Freestyle Libre Pilot Study	Population: BMI or obesity not stated.
Abbreviations: NHS-DPP, National Health Service Diabetes Prevention Programme				

Appendix B3 – Publications using technologies non-MDT weight management programmes (N=25)

#	Study (year) [design, n]	Population	Intervention and comparator	Key results
1.	Hampton et al. (2017), abstract also available at Edson et al. (2019) [prospective cohort, n=98] UK	Inclusion: Adults aged ≥18 years with a BMI of ≥23 self-referring to OurPath (Second Nature) Exclusion: NR	Intervention (n=98): Second Nature (OurPath) Diabetes Prevention Programme (initial 'core' progamme 6 weeks, less intensive 'sustain' programme up to 6 months) Comparator: N/A	Mean weight loss: Compared with baseline: - 5.3% [6 weeks] - 6.7% [3 months] - 8.2% [6 months] Retention: - 78.6% (77 of 98) completed 6 weeks - 70.4% (69 of 98) completed 3 months - 29.6% (29 of 98) completed 6 months Adherence: - 42.9% (42 of 98) submitted weight readings at 3 months - 15.3% (15 of 98) submitted weight readings at 6 months
2.	Idris et al. (2020) [retrospective cohort, n=3,649] UK	Inclusion: Adults aged ≥18 years self-referred (n=2,788) or GP referred with T2DM (n=861) for weight management or diabetes-related weight management and structured education Exclusion: NR	Intervention (n=3,649): Second Nature (3 months) Comparator: N/A	Mean weight loss (SD) [%]: - 7.1 (6.4) kg [7.5%] [6 months compared with baseline] - 6.1 (7.0) kg [6.5%] [12 months compared with baseline] Adherence: - 24.6% (896 of 3,649) had data available at baseline, 6, and 12 months for analysis - 47.2% (406 of 861) NHS referred patients had data at baseline, 6, and 12 months - 17.6% (490 of 2,788) self-referred patients had data at baseline, 6, and 12 months
3.	Kar et al. (2020) [retrospective cohort, n=190) UK	Inclusion: Adults with T2DM, BMI >29, referred from GPs or diabetes programmes Exclusion: NR	Intervention (n=190): Second Nature (3 months) Comparator: N/A	Mean weight loss: - 7.8 (SD 8.6) kg [12 months compared with baseline] - 60.6% (57 of 94) >5% weight loss - 28.7% (27 of 94) >10% weight loss Mean change in HbA1c (n=41) - -10.4 mmol/mol (SD 8.6), p<0.001 compared with baseline Retention: - 190 referred - 150 completed registration process - 144 started the programme - 94 had data available at 12 months Engagement: - 360.9 (SD 285.8) total interactions across Learn, Track, and Support programme modules
4.	Thomson et al. (2022) [retrospective cohort, n=48] UK	Inclusion: Adults aged ≥18 years, BMI ≥25 who self-enrolled on Second Nature programme Exclusion: NR	Intervention (n=48): Second Nature (12 weeks) Comparator: N/A	Weight change 12 weeks compared with baseline: - 14.6% (7 of 48) >10% weight loss - 41.7% (20 of 48) >5% weight - 29.2% (14 of 48) <5 weight loss - 4.2% (2 of 48) no change in weight - 10.4% (5 of 48) gained weight Retention: - 35.4% (17 of 48) completed programme and continuing use - 20.8% (10 of 48) completed programme and stopped using - 37.5% (18 of 48) did not complete the programme - 6.3% (3 of 38) lost contact
5.	Davies et al. (2022) [retrospective cohort, n=1,072] *[abstract]* UK	Inclusion: Participants self-referred (n=585) or GP referred with T2DM (n=487) for weight management or diabetes-related weight management and structured education Exclusion: NR	Intervention (n=1,072): Second Nature (36 months) Comparator: N/A	Mean weight loss 36 months compared with baseline: - 5.68 (SD 9.41) kg, [5.83%] all participants - 5.51 (SD 10.10) kg, [5.65%] for self-funded participants - 5.87 (SD 8.51) kg, [6.05%] for participants with T2DM

#	Study (year) [design, n]	Population	Intervention and comparator	Key results
6.	Davies et al. (2023a) [retrospective cohort, n=53] *[abstract]* UK	Inclusion: Patients referred to Tier 2 weight management services. Exclusion: NR	Intervention (n=53): Second Nature (3-month core programme, 3-month support) Comparator: N/A	Mean weight loss Compared with baseline - 6.47 (SD 8.13) kg, [6.02%] at 3 months - 7.06 (SD 12.47) kg, [6.45%] at 6 months - 7.14 (SD 8.76] kg, [6.53%] at 12 months
7.	Davies et al. (2023b) [retrospective cohort, n=344] *[abstract]* UK	Inclusion: Participants self-referred (n=229) or GP referred to Tier 2 weight management services (n=115) Exclusion: NR	Intervention (n=344): Second Nature (5 years) Comparator: N/A	Mean weight loss 5 years compared with baseline - 5.71 (SD 11.26) kg, [5.65%] all participants - 4.85 (SD 11.99) kg, [4.71%] self-funded participants - 7.42 (SD 9.45) kg, [7.52%] GP-referred
8.	Hampton et al. (2019a) [retrospective cohort, n=NR] *[abstract-246]* UK	Inclusion: Participants self-referred (n=NR) or GP referred to Tier 2 weight management services (n=NR) Exclusion: NR	Intervention (n=NR): Second Nature (6 months) Comparator: N/A	Mean weight loss 3 months compared with baseline: - 7.1% for self-funded participants - 7.5% for GP-referred participants 6 months compared with baseline: - 8.6% for self-funded participants - 9.2% for GP-referred participants Adherence Higher proportion of females in both arms: - Self-funded proportion of males 12% - GP-referred proportion of males 41%
9.	Hampton et al. (2019b) [before-and-after, n=240] *[abstract - 325]* UK	Inclusion: T2DM, referred by NHS practice and specialist nurses for digital lifestyle intervention Exclusion: NR	Intervention (n=240, EAG calculation): OurPath (Second Nature, 3 months) Comparator: N/A	Mean weight loss - -6.6% (n=112) 3 months compared with baseline (p<0.01) - -8.3% (n=51) 6 months compared with baseline HbA1c - Mean reduction of 13.6 mmol/mol (n=50) 3 months compared with baseline (p<0.001) - 40% (20 of 50) participants with HbA1c had level <48 mmol/mol. Retention - 240 patients referred to programme - 79% (190 of 240) enrolled on programme - 63% (150 of 240) completed programme
10	Hampton et al. (2020) [retrospective cohort, n=304] *[abstract]* UK	Inclusion: Participants-referred (n=203) or GP referred with T2DM (n=101) for weight management or diabetes-related weight management and structured education. Exclusion: NR	Intervention (n=304): Second Nature (24 months) Comparator: N/A	Mean weight loss 24 months compared with baseline: - 5.7 (SD 8.3) kg, [6.0%] all participants - 4.8 (SD 7.8) kg, [5.0%] for self-funded participants - 7.5 (SD 9.0) kg, [7.9%] for GP-referred participants
11	Hanson et al. (2021) [non-randomised cohort with retrospective comparator, n=231] UK	Inclusion: all patients referred to Tier 3 obesity service. Exclusion: Inability to understand English.	Intervention (n=105): Low Carb app Comparator (n=126): face-to-face standard care	Mean weight loss 6 months compared with control group: - 1.7 (95% CI -0.4 to 3.7) kg p=0.12 6 months compared with baseline: - 2.7 (SD 5.5) kg (intervention group, n=48), p<0.001 - 1.1 (SD 6.5) kg (control group, n=92) (p=NR) HbA1c 6 months compared with control group: - 2.7 (95% CI -0.7 to 6.2) p=0.12 6 months compared with baseline: - -3.3 (SD 7.7) (intervention group, n=41), p=0.01 - -0.5 (SD 11.9) (control group, n=87), p=NR Engagement - 84% (88 of 105) actively engaged with the app within the previous 30 day period. - 18% (19 of 105) completed ≥9 of 12 education modules available.

#	Study (year) [design, n]	Population	Intervention and comparator	Key results
12	Summers et al. (2021) [retrospective cohort, n=100] UK	Inclusion: Adults aged ≥18 years with T2DM or pre-diabetes presenting to GP practice. Exclusion: NR	Intervention (n=100): Low Carb app Comparator: N/A	Mean weight loss 12 months compared with baseline - 3.01 (SD 2.80)%, p<0.001 (all participants, n=45) - 2.78 (SD 2.34)%, p<0.001 (T2DM, n=18) - 3.16 (SD 3.11)%, p<0.001 (pre-diabetics, n=27) HbA1c 12 months compared with baseline - 6.28 (SD 5.49)%, p<0.001 (all participants, n=45) - 7.96 (SD 6.67)%, p<0.001 (T2DM, n=18) - 5.16 (SD 4.31)%, p<0.001 (pre-diabetics, n=27) Retention: - 55% (55 of 100) referred to programme but did not enrol - 45% (45 of 100) enrolled and completed baseline data - 37% (37 of 100) completed data at baseline and 12 months - 8% (8 of 100) lost to follow-up Engagement - 18% (8 of 45) did not report health outcomes but logged into app within the previous 30 day period. - 100% (45 of 45) completed ≥40% of the lessons. - 71% (32 of 45) completed ≥9 of 12 education modules available. - 64% (29 of 45) completed all 12 core modules.
13	Scott et al. (2022) [feasibility study, n=351] UK	Inclusion: Adults aged ≥18 years with BMI ≥25 and T2DM or pre-diabetes presenting to GP practice. Exclusion: signposting deemed inappropriate by consulting healthcare professional.	Intervention (n=351): Low Carb app Comparator: N/A	Mean weight loss 6 months compared with baseline - 7.2 (SD 5.0) kg (completers, n=43) - 1.6 (SD 1.5) kg (partial completers, n=34) Retention: - 54.4% (191 of 351) declined signposting to programme - 64.4% (103 of 160) accessed the programme following signposting Engagement - 41.7% (43 of 103) completed ≥9 of 12 education modules available. - 33.0% (34 of 103) completed 2 to 8 modules. - 25.2% (26 of 103) completed ≤1 module.
14	Abdelhameed et al. (2022) [before-and-after, n=NR] *[abstract]* UK	Inclusion: patients with pre-diabetes or T2DM Exclusion: NR	Intervention (n=NR): Gro Health app Comparator: N/A	EQ-5D health index score (1= full health, 0=moribund): - Baseline: 0.746 (SD 0.234) - 6 months: 0.792 (SD 0.224), p<0.001 compared with baseline EQ-5D visual analogue scale - Baseline: 61.7 (SD 18.1) - 6 months: 73.0 (SD 18.8), p<0.001 compared with baseline - Mean change: 18.3% (SD NR)
15	Kelly et al. (2020) [retrospective cohort, n=334] *[abstract]* Ireland	Inclusion: patients self-referring to Low Carb programme completing at least 8 of 12 nutrition-focused modules. Exclusion: NR	Intervention (n=334): Low Carb app Comparator: N/A	Mean weight loss - Baseline mean weight: 97.9 (SD 22.6) kg - Mean weight at 12 months: 91.0 (SD 20.6) kg - Mean weight loss: 6.7 (SD NR) kg p<0.0001 HbA1c - Baseline mean HbA1c: 76.0 (SD 10.4) mmol/mol - Mean HbA1c at 12 months: 58.0 (SD 12) mmol/mol - Mean change in HbA1c: 18.0 (SD NR) mmol/mol
16	Schirmann et al. (2022a) [retrospective cohort, n=25,706] UK, Germany, Switzerland	Inclusion: patients receiving blended-care behaviour change intervention using Oviva. Exclusion: NR	Intervention (n=25,706): Oviva health coach and digital self-monitoring, self-management, education. Comparator: N/A	Weight loss, %: - 1 month (n=15,012): -1.63 (SD 5.94) - 3 months (n=9,526): -3.61 (SD 5.82) - 6 months (n=4,204): -5.28 (SD 6.94) - 12 months (n=979): -6.55 (SD 8.22) Weight loss, kg:

#	Study (year) [design, n]	Population	Intervention and comparator	Key results
				- 1 month (n=15,012): -1.89 (SD 7.82) - 3 months (n=9,526): -4.02 (SD 7.82) - 6 months (n=4,204): -5.82 (SD 9.10) - 12 months (n=979): -7.22 (SD 9.67) Predictors of weight loss: - Coaching, self-monitoring, self-management positively correlated with weight loss at 3 and 6 months
17	Miller et al. (2021) [before-and-after, n=598] *[abstract]* UK	Inclusion: Adults with T2DM referred to digitally enabled diabetes structured education programme. Exclusion: NR	Intervention (n=598): Oviva (12 weeks) Comparator: N/A	Mean weight loss - 3.62 (SD NR) kg, (3.68%) 12 weeks compared with baseline Retention - 73% referrals started the programme - 73% of starters finished the programme - 31% (188 of 598) of finishers provided weight measurements at 12 weeks
18	Finnie et al. (2022) [before-and-after, n=2,578] *[abstract- 444]* UK	Inclusion: Participants referred to digitally enabled diabetes structured education programme Exclusion: NR	Intervention (n=2,578): Oviva app [n=NR] or Oviva telephone support [n=NR], (12 weeks). Comparator: N/A	Mean weight loss - 33.6% (490 of 1,459) completers had weight data available at 12 weeks of which, 81% had lost weight - 3.7 (SD NR) (3.8%) kg, (n=490) 12 weeks compared with baseline - 4.9% (SD NR) (app users, n=230) 12 weeks compared with baseline - 2.9% (SD NR) (telephone support, n=260) 12 weeks compared with baseline HbA1c - 6.9% (101 of 1,459) completers had HbA1c data available at 12 weeks of which, 86.1% had reduced HbA1c - Mean reduction 14 (SD NR) mmol/mol Retention - 56.6% (1,459 of 2,578) completed 12-week programme
19	Miller et al. (2022a) [before-and-after, n=1,384] *[abstract-414]* UK	Inclusion: Adults with T2DM referred to digitally enabled diabetes structured education programme. Exclusion: NR	Intervention (n=1,384): Oviva (12 weeks) Comparator: N/A	Mean weight loss - 2.94 (SD NR) kg, (3.22%) 12 weeks compared with baseline Retention - 72% referrals started the programme - 64% of starters finished the programme - 14% (199 of 1,384) of finishers provided weight measurements at 12 weeks
20	Miller et al. (2022b) [before-and-after, n=37] *[abstract - 426]* UK	Inclusion: Adults with T2DM. Exclusion: NR	Intervention (n=37): Digital low-calorie diet programme (12 weeks) with behaviour change support Oviva (12 months) Comparator: N/A	Mean weight loss - 10.9 (SD NR) kg, (n=30) 12 weeks compared with baseline - 11.0 (SD NR) kg, (n=27) 6 months compared with baseline - 11.5 (SD NR) kg, (n=11) 12 months compared with baseline HbA1c - Mean reduction 10.9 (SD NR) mmol/mol, (n=11) 6 months compared with baseline Medication change - 78 prescriptions stopped, mean 2.2 (SD NR) prescriptions per patient (n=NR) Retention - 81% (30 of 37) completed the 12-week diet replacement programme - 73% (27 of 37) completed 6 months of the programme
21	Miller et al. (2022c) [before-and-after, n=28] *[abstract]* UK	Inclusion: Adults with T2DM Exclusion: NR	Intervention (n=28): Digital low-calorie diet programme (12 weeks), 4 weeks food reintroduction with behaviour change support (Oviva, 8 months). Comparator: N/A	Mean weight loss - 13.7 (SD NR) kg, (n=26) 12 weeks compared with baseline - 14.2 (SD NR) kg, (n=25) 6 months compared with baseline - 14.7 (SD NR) kg, (n=19) 12 months compared with baseline - 29% (8 of 28) regained 2 kg and commenced a 'Refocus' phase (time point and details not specified) HbA1c - Improvement in HbA1c noted in 75% of participants 12 months compared with baseline (n=NR) - Mean reduction 33.4% (SD NR, n=NR) 12 months compared with baseline Medication change - 96 prescriptions stopped, mean 3.3 (SD NR) prescriptions per patient (n=NR) - Metformin restarted in 6 patients - Remission achieved in 62.5% of patients (n=NR)

#	Study (year) [design, n]	Population	Intervention and comparator	Key results
				Retention - 93% (26 of 28) completed the 12-week diet replacement programme - 89% (25 of 28) completed the 4-week food reintroduction phase - 68% (19 of 28) completed 12 months of the programme
22	Schirmann et al. (2022b) [prospective cohort, n=20] *[abstract]* Germany	Inclusion: patients living with obesity, first 20 to complete 12-week programme. Exclusion: NR	Intervention (n=20): Oviva (12 weeks) Comparator: N/A	Mean weight loss: - 4 weeks: -1.65% (SD NR) - 8 weeks: -2.86% (SD NR) - 12 weeks: -3.06% (SD NR) Adherence: - Participants completed 65.% of all health-related tasks via the app - 14 (SD NR) minutes per day or 98 (SD NR) minutes per week spent on learning content - 2.45 (SD NR) meal logs per day - 206 (SD NR) photos of meals
23	Oviva [CiC-4] [redacted]	[redacted]	[redacted]	[redacted]
24	Miller et al. (2023) [before-and-after, n=122] *[abstract]* UK	Inclusion: Adults with T2DM Exclusion: NR	Intervention (n=28): 1 of 3 low-calorie diet programmes (low carbohydrate, total diet replacement, 5:2; 12 weeks), 4 weeks food reintroduction with behaviour change support delivered as 1:1 or group support (Oviva, 8 months). Comparator: N/A	Mean weight loss - Low carbohydrate diet with 1:1 support: 2.7 (SD NR) kg, 2.6% or group support: 3.4 (SD NR) kg, 3.2% - Total diet replacement with 1:1 support: 8.9 (SD NR) kg, 9.1% or group support: 10.3 (SD NR) kg, 9.7% - 5:2 diet with 1:1 support: 4.0 (SD NR) kg, 4.6% or group support: 1.0 (SD NR) kg, 1.2% Retention at 12 weeks - 63.9% (78 of 122) across all diets and 1:1 or group support
25	Liva CiC-4 [redacted]	[redacted]	[redacted]	- [redacted]

Abbreviations: BMI, body mass index; CI, confidence interval; N/A, not appropriate; NR, not reported; SD, standard deviation; T2DM, type II diabetes mellitus

Appendix C: Ongoing studies (N=22)

Technology	Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
CheqUp	No ongoing studies identified by the EAG or the Company.				
DDM (Low Carb, Gro Health)	Effect of a low-carb dietary intervention in obese patients (NCT04234373) Germany	Pilot comparative cohort Intervention: Low carb diet in pre-diabetic or diabetic patients living with obesity (Group B) Comparator: low carb diet in healthy lean controls (Group A). All patients receive the Low Carb programme from DDM Health Ltd with health coach. ☒ Status: Recruiting (last update 08 November 2022) Estimated completion date: June 2024 Sponsor: University Hospital, Switzerland Funder: Unknown	Target enrolment: 40 participants Inclusion criteria: Group A: • Aged between 18 and 55 years • BMI between 19.0 to 24.9 • HbA1c <5.7% • Fasting glucose <5.6 mmol/l • Normal eating habits • Stable weight for ≥3 months Group B: • BMI >30 • HbA1c >5.7% or fasting glucose >5.6 mmol/l • Normal eating habits • Stable body weight for ≥3 months Exclusion criteria: Group A and B: • Pre-existing low carb diet (<45% of daily energy intake by carbohydrates) • Pre-existing diet (vegetarian, vegan, gluten-free) • Psychiatric illness • Alcohol abuse • Regular intake of medication (except oral contraceptives) • Antibiotics within last 3 months • Regular intake or pro- or pre-biotics • Chronic diseases of gastrointestinal tract, history of gastrointestinal surgery with major changes to the gastrointestinal tract • Clinically relevant acute or chronic inflammatory disease • Pregnancy • Participation in another study with investigational drug <30 days of enrolment ☑☒	Blood glucose level 2 hours after an oral glucose tolerance test (change from baseline to 6 months). ☒	• Change in body composition measured with dual-energy x-ray absorptiometry • Metabolomics in plasma, urine and stool samples • Gut microbiota composition • Brain activity (fMRI) • Liver fat fraction. ☒
	Gro Health [Ongoing-1] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-2] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-3] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-4] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Technology	Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-5] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-6] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-7] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-8] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-9] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Gro Health [Ongoing-10] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Juniper	No ongoing studies identified by the EAG or the Company.				
Liva	Digital Individualized and Collaborative Treatment of T2D in General Practice Based on Decision Aid (DICTA) [NCT04880005] Denmark	RCT Intervention: Clinical decision support + Digital lifestyle coaching (Liva) + Integration to standard electronic health record. ☑☒ Comparator: Standard care. ☑☒	Estimated enrolment: 600 participants Inclusion criteria: • Diabetes type 2 in up to 10 years.☒ Exclusion criteria: • Fails to complete the initial questionnaire • No internet access in own home through computer or smart phone • Is pregnant or actively trying to get pregnant • Has a serious or life-threatening disease	• Change in binary indicator (composed by a composite endpoint of HbA1c, systolic blood pressure, low-density lipoprotein cholesterol, no smoking and normal albuminuria) [12 months]. ☑☒	• Change in HbA1c [12 months] • Numbers change in level of use of hypertension, hypercholesterolemic and glucose-lowering drugs [12 months] • Change in quality of life, EQ-5D-5L [12 months] • Change in weight [12 months]

Technology	Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
		Status: Not yet recruiting (last update 10 May 2021) Estimated completion date: May 2024 Sponsor: University of Southern Denmark			• Change in abdominal circumference to hip circumference [12 months] • Change in physical activity measured through AX3 [12 months] • Change in systolic blood pressure [12 months] • Change in low-density lipoprotein cholesterol [12 months] • Change in number of patients not smoking [12 months] • Change in level of albuminuria [12 months] • Change in HbA1c [12 months] • Change in quality of life, EQ VAS [12 months]. ☑☒
	Bump2Baby and Me [ACTRN12620001240932] UK, Ireland, Australia, Spain Funding information available from EU Horizon 2020 Research and Innovation grant 847984. Protocol available at O'Reilly et al. (2021).	RCT Intervention: Standard care + digital lifestyle coaching (Liva). ☑☒ Comparator: Standard care. ☒ Status: Active, recruiting (last update 16 July 2021) Estimated completion date: 28 June 2024 Sponsor: University College Dublin	Estimated enrolment: 800 participants Actual enrolment: 18 participants (as of 16 July 2021) Inclusion criteria: • Aged between 18 and 50 years • Women attending 1 of 4 participating maternity services for maternity care • Identified as at high risk of developing gestational diabetes mellitus (Monash Screening Questionnaire ≥3) • No current involvement in any other lifestyle-related clinical trial • Smartphone ownership • Gestation <24 weeks.☒ Exclusion criteria: • Established or previously known Type 1 or Type 2 diabetes mellitus • Cancer (not in remission) • Severe mental illness in the last 3 months • Substance abuse in the last 3 months • Myocardial infarction in the last 3 months • Difficulty with using English language for (Irish, English, Australian sites) • Difficulty with using Spanish language (Spanish site) • Smartphone unable to host intervention app • Gestation >24 weeks • Current multiple pregnancy.	• Difference in maternal BMI of 0.8 kg/m2 at 12 months postpartum. ☒	• Gestational weight gain and status • Maternal blood pressure • Maternal physical activity and sleep • Maternal psychological health • Maternal and infant diet • Metabolic markers including blood glucose and blood lipids • Glycaemic status and gestational diabetes mellitus diagnosis • Birth data (mode of delivery, birth weight, placental weight, complications) • Newborn and infant anthropometry (weight centiles, BMI z-scores) • Breastfeeding (any and exclusivity) and duration • Infant development • Infant physical activity and sedentary time. ☒
	Clinical study assessing effectiveness of Liva compared to usual care* UK	Prospective cohort Intervention: 6-month programme (Liva) with initial 45-minute video-consultation followed by 3 months weekly interventions, then 3 months bi-weekly interventions and peer support groups ☑ Comparator: standard care ☑ Status: Unknown Estimated completion date: 2024	Target enrolment: NR Inclusion criteria: • Aged ≥18 years • BMI ≥35 • Referred to Somerset NHS Foundation Trust Weight Management Service ☑ Exclusion criteria: NR	Specific outcomes unclear. Outcomes will be used to understand if non-complex patient with obesity can be managed remotely. ☑☒	NR
	Prevention Study* Denmark	3-arm comparative cohort Intervention and comparators: 1) personal and family health coaching	Target enrolment: NR Inclusion criteria: NR	Weight loss • BMI • Comorbidities • Healthcare resource use	NR

Technology	Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
		via app (Liva); 2) health coaching via app (Liva) and online purchase of suggested meals (Coop MAD); 3) health coaching via app (Liva), online mean purchase (Coop MAD) and wearable (Garmin). ☑☒ All intervention arms receive Liva. Status: Unknown Estimated completion: July 2023 Sponsor: NR	Exclusion criteria: NR	• Reduction in development in lifestyle-related diseases ☑☒	
	Defeat Obesity* Denmark	Pilot study Intervention: 12 months review with doctor from Medstart and health coach from Liva Healthcare ☒ Comparator: None Status: Unknown Estimated completion: January 2024 Sponsor: Novo Nordisk	Target enrolment: 100 participants Inclusion criteria: NR Exclusion criteria: NR	• Change in weight • Change in BMI ☑	• Change in body lipid profile • Change in physical activity • Pain • Health and wellbeing questionnaires ☑☒
Oviva	The DR-EAM Type 2 Diabetes Study [NCT05626842] UK	Cohort (with matched control arm) Intervention: Total Diet Replacement (800kcal/day), specialist dietitian support and learning materials via Oviva. ☑ Comparator: Matched control group from comparable GP practices. ☒ Status: Active, not recruiting (last update 25 Nov 2022) Estimated completion: Sep 2023 Sponsor: Oviva UK Ltd	Actual enrolment: 197 participants Inclusion criteria: • Min age 18 years • Max age 65 years • Male or female • Min BMI of 27kg/m2 (adjusted to 25kg/m2 in people of South Asian or Chinese origin) • BMI <45kg/m2 • T2DM diagnosed at any time • HbA1c eligibility, most recent value, which must be within 12 months • HbA1c ≥ 43 mmol/mol if on diabetes medication • HbA1c ≥ 48 mmol/mol if on diet alone • HBA1c <108 mmol/mol • If HbA1c 90-108 mmol/mol, the value must be within 3 months of referral • On, or about to start, a second-line diabetes-related medication (metformin is first-line) • Access to blood glucose monitoring equipment if on a sulphonylurea prior to referral • Ability to speak, read and receive care in English • Access to and willing to use an iOS or Android smart phone for the duration of the intervention. ☑☒ Exclusion criteria: • T2DM either diet-controlled alone, or on metformin alone • Current insulin use • Pregnant or breastfeeding or considering pregnancy during next 6 months • Significant physical comorbidities • Active cancer • Myocardial infarction or stroke within previous 6 months • Severe heart failure defined as equivalent to the New York Heart Association grade 3 (NYHA) • Recent eGFR <30 mls/min/1.73 m2	• Change in weight (kg) and BMI (kg/m2) continuously via BodyTrace scales [at baseline, 3, 6, 9,12 & 24 months] • Change in HbA1c- Diabetes remission defined as 2 HbA1c readings <48mmol/mol without diabetes medications at least 6 months apart [at baseline, 6, 12 and 24 months].☑☒	• Blood pressure [at baseline, 12 & 24 months] • Lipids [at baseline, 12 & 24 months] • Physical activity [at baseline, 3, 6, 9,12 & 24 months] • Quality of Life [at baseline, 6, 12 and 24 months] • Participant experience [at 12 months].☑

Technology	Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
			• Active liver disease (except for NAFLD), or a history of hepatoma, or <6 months of onset of acute hepatitis • Severe angina, cardiac arrythmia including atrial fibrillation or prolonged QT syndrome • Active substance use disorder / eating disorder • Porphyria • Weight loss >5% body weight within last 6 months or on current weight management programme or had/awaiting bariatric surgery (unless willing to come off waiting list) • Health professional assessment that the person is unable to understand or meet the demands of the treatment programme and/or monitoring requirements, which may include -Learning disabilities • Taking monoamine-oxidase inhibitor medication • Taking warfarin • Taking varenicline (smoking cessation medication) • Retinopathy diagnosis or lack of retinal screening in the last year • Active/investigation for gastric or duodenal ulcers • People currently participating in another clinical trial. ☑		
	The Transform Type 2 Diabetes Study [NCT05648903] UK	Non-randomised controlled trial (open-label) Intervention 1: Total diet replacement, intermittent fasting 5:2 and a low-carbohydrate diet, access to Oviva diabetes specialist dietitians and access through app.☑ Intervention 2: Two modes of remote care delivery will be used (group and one-to-one), all delivered through Oviva resources.☑ Comparator: N/A.☑ Status: Active, not recruiting (last update 13 Dec 2022) Estimated completion date: July 2024 Sponsor: Oviva UK Ltd	Target enrolment: 120 participants Inclusion criteria: • Registered with one of the Nexus Group GP Practices • Willing to give consent for participation including collection of clinical outcomes • Diagnosis of T2DM • Min age of 18 years • Max age 70 years • Min BMI of 27kg/m² (adjusted to 25kg/m² in people of South Asian or Chinese origin) • Upper weight limit of 180kg (due to upper weight limit of BodyTrace scales) • HbA1c eligibility: If on diabetes medication, HbA1c ≥ 43 mmol/mol If on diet alone, HbA1c ≥ 48 mmol/mol • HbA1c <108mml/mol • Ability to speak, read and receive care in English • Access to internet and email address. ☑☒ Exclusion criteria: • Currently taking insulin • Pregnant or planning to be pregnant in the next 6 months • Current breastfeeding • Significant physical comorbidities • Active cancer, receiving treatment • Myocardial infarction or stroke in last 6 months • Severe heart failure defined as equivalent to the NYHA grade 3 or 4 • eGFR <30 mls/min/1.73m2 • Active liver disease (except NAFLD), severe angina, cardiac arrhythmia including atrial fibrillation or prolonged QT syndrome • Active substance use disorder • Active eating disorder • Porphyria • On current weight management programme / had or awaiting bariatric surgery (unless willing to come off waiting list) • Health professional assessment that the person is unable to understand or meet the demands of the programme and/or monitoring requirements • Taking monoamine-oxidase inhibitor medication • Taking warfarin • Taking varenicline (smoking cessation medication) • Have attended for monitoring and diabetes review when this was last offered, including retinal screening, and commit to continue attending reviews, even if remission is achieved • Active/investigation for gastric or duodenal ulcers. ☑	• Change in HbA1c (mmol/l) [at 6, 12 & 24 months].☑	• Weight and BMI [at 6, 12 & 24 months] • Lipids [12 & 24 months] • Blood pressure [12 & 24 months] • NHS resource use including medication cost [12 & 24 months] • Change in quality of life [Baseline & 12 months] • Diabetes remission [12 & 24 months] • Patient questionnaires on acceptability, motivations and preferences [4 & 12 months] • Engagement with the programme [12 months].☑☒

Technology	Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
	Manchester Intermittent and Daily Diet Type 1 Diabetes App Study (MIDDAS-Type 1) [NCT04674384] UK [Associated with [McDiarmid et al. 2022]	Randomised controlled study (open label); feasibility study Intervention: Intermittent Low Energy Diet (ILED) Comparator: Continuous Low Energy Diet (CLED) Both arms receive access to Oviva.☑ Status: Recruiting Estimated completion date: April 2024 Sponsor: Manchester University NHS Foundation Trust	Target enrolment: 12 Inclusion criteria: • Type 1 diabetes mellitus for 12 months or longer • HbA1c 53-108 mmol/mol • BMI ≥ 30 kg/m2 and <50kg/ m2 or ≥27.5 kg/ m2 and <50kg/ m2 in high-risk minority ethnic groups i.e. South Asian, Black African and African Caribbean • Multiple daily injections (MDI) or continuous subcutaneous insulin infusion • Completed Dose Adjustment For Normal Eating (DAFNE) education • Access to a Freestyle Libre handset and sensors to monitor blood glucose • Willing to use the Freestyle Libre flash glucose monitoring system to monitor blood glucose (flash and capillary) and blood ketones and to record carbohydrate and insulin. • Access to and ability to use a telephone. If no access to a smartphone running iOS or Android (to view the LibreLink app) then access to a computer (to upload results to the LibreView website). • Willing to undertake Optifast LEDs and have previously sampled Optifast. • Negative urine pregnancy test at screening and agreement to maintain contraception or abstinence for the trial (where appropriate) • Ability to read, understand and communicate in English.☑ Exclusion criteria: • Evidence of severe hypoglycaemia in the last 12 months (more than one episode requiring third party assistance) or hypoglycaemia unawareness. • Patients with non-stable retinopathy, or grade R2 or later, or had no retinopathy screen within 12 months. • Patients who lack capacity or are unable to read or understand written or verbal instructions in English or those diagnosed with learning difficulties. • Confirmed pregnant via a pregnancy test at screening, planning pregnancy in the next 3 months, or currently breast feeding. • Participants who are currently on treatment with Orlistat or other pharmacological treatments for weight loss e.g. Glucagon-like-peptide-1 . • Participants who are currently taking a Sodium-Glucose Co-Transporter-2 inhibitor. • Diagnosed Gastroparesis. • Participants who have previously had bariatric surgery for weight loss including gastric bypass and sleeve gastrectomy. • Patients who are on chronic use of steroids (more than 20mg daily of prednisolone or its equivalent). • Patients with known hypersensitivity to any of the ingredients of Optifast® e.g. fish, milk, soy. • Taking prohibited medications (see Appendix 3) including warfarin or novel anticoagulants, low molecular weight heparin or equivalent anti-coagulants and anti-psychotic medication or other psychotropic medications that may cause excessive weight gain. • Substance abuse or harmful alcohol use as indicated by a score of 16 or above on the Alcohol Use Disorders Identification Test .[36] • Participants with a diagnosed eating disorder, or patients with severe binge eating assessed by a score of 27 or more on the Binge Eating Scale.[37] • Participants with severe depression assessed by a score of 15 or more on the Patient Health Questionnaire-9.[29] • Participants with severe anxiety assessed by a score of 15 or more on the General Anxiety Disorder 7 questionnaire.[28] • Participants with very low self-efficacy assessed by a score of 35 or less on the Weight Efficacy Lifestyle Questionnaire – Short Form.[30] • Participants with severe loss of renal function (eGFR less than 30mL/min/1.73m2). • Participants with psychiatric or physical comorbidity or scheduled for major surgery, which in the opinion of the treating medical physician, Chief Investigator or MDT would compromise their safety or adherence to the study.	• Number of episodes of severe hypoglycaemia i.e. capillary blood glucose < 3.0 mmol/l or requiring 3rd party assistance or any episodes of nocturnal hypoglycaemia <3.0 mmol/l. [14 weeks] • Time spent in target (3.9-10mmol/l), below target (<3.9mmol/l and <3.0mmol/l) and above target (>10 mmol/l) on the Freestyle Libre® flash glucose monitoring system over 12 weeks. [14 weeks] • Number of episodes of Diabetic Ketoacidosis and blood ketone β-hydroxybutyrate levels above 1.0mmol/l. [14 weeks] • Occurrence of Serious Adverse Events deemed potentially related to the dietary programmes. [14 weeks].☑☒	• Uptake to the trial i.e. percentage of those invited who are eligible and interested to take part. [14 weeks] • Number of participants who complete the trial measured by attendance at the 12 week appointment (for ILED and CLED) [14 weeks] • Adherence to blood glucose and ketone monitoring i.e. frequency of capillary blood tests and scans [14 weeks] • Percentage of low energy days completed (for ILED and CLED) [14 weeks] • Dietary intake (7 day food diary). Food diaries will be analysed using Nutritics nutrition analysis software to estimate energy, fat, saturated fat, carbohydrate and protein intake [14 weeks] • Anonymous patient evaluation of the dietary programmes using an end of study questionnaire [14 weeks] • Percentage of multi-disciplinary team contacts with participants achieved (for ILED and CLED). [14 weeks] • Uptake to and continued use of the Oviva app [14 weeks] • Number of other adverse effects potentially associated with the dietary programmes e.g. constipation, fatigue. [14 weeks] • Number of participants preferring food-based low energy days (for ILED and CLED) [14 weeks] • Average time spent by the MDT (for ILED and CLED) [14 weeks] • Percentage of contacts with Dietitian conducted face to face after baseline (for ILED and CLED) [14 weeks].☑☒

Technology	Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
			• Unsatisfactory use of the Freestyle Libre flash glucose monitoring system or unsafe use of DAFNE/insulin adjustment principles during the 14-day "run-in" period that in the opinion of the medical team may undermine the participant's safety on the trial. This includes flash and capillary monitoring of blood glucose and ketone testing. • Patients who are currently participating in a diabetes drug trial.☑		
	A randomised controlled trial to determine safety and efficacy of a digital low-calorie diet programme for insulin-treated adults living with T2DM SAFE-LCD UK	RCT [redacted] Intervention: [redacted] Comparator: [redacted] Status: [redacted] Estimated completion date: [redacted] Sponsor: [redacted] Funder: Innovate UK	Target enrolment: [redacted] Inclusion criteria: [redacted] Exclusion criteria: [redacted]	[redacted]	[redacted]
Roczen	No ongoing studies identified by the EAG or the Company.				
Second Nature	Remote Support for Low-Carbohydrate Treatment of Type 2 Diabetes (RESULT) [NCT04916314] UK	RCT Intervention: Second Nature, 12-week programme. ☑ Comparator: Standard NHS T2DM care. ☒ Status: Active, not recruiting (last update 11 May 2023) Estimated completion date: December 2023 Sponsor: University of Oxford	Actual enrolment: 115 Inclusion criteria: • Adult aged ≥40 years • Diagnosed with T2DM within last 6 years • BMI ≥27 or ≥30 if ethnically recorded as white • Has a smartphone or computer and internet access • Able to complete eligibility and baseline assessments online • Willingness to make changes to their diet or lifestyle to improve their diabetes control, lose weight, or improve general health.☑ Exclusion criteria: • Unable to understand study materials and interventions • Currently following a structured, prescribed and monitored weight-loss programme • Pregnant, breastfeeding, or planning to become pregnant during the study • History of bariatric surgery including gastric banding • Currently using insulin therapy • Proliferative diabetic retinopathy or maculopathy • Recent myocardial infarction of stroke within last 3 months • Renal failure (chronic kidney disease stage 4 or 5) • Current active treatment for cancer (other than skin cancer treated with curative intent by local treatment only) Medical opinion that participation is not appropriate.☑	• Change in HbAc1 at 3 and 12 months ☑	• Diabetes remission at 12 months Outcomes at 3 and 12 months: • Changes in weight, systolic and diastolic blood pressure, cholesterol (LDL and HDL), triglycerides, ALT • QoL (Problem Areas in Diabetes [PAID]; EQ-5D scores) Additional outcomes at baseline, 3 and 12 months: • Self-reported dietary intake patterns • Programme engagement (Learn, Track, and Support components) • Participant experience (interviews). ☑
	Supported self-management for people with T2DM (BEATdiabetes)* UK	Observational cohort Intervention and comparators: digital technologies for diabetes self-management 1)Second Nature; 2) SilverCloud; 3) Commit to Change ☒ Status: Active Estimated completion date: Final evaluation of clinical delated expected 2023 or 2024 Sponsor: NR	Target enrolment: NR Inclusion criteria: patients with T2DM ☒ Exclusion criteria: NR	NR	NR

Technology	Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
Wellbeing Way	No ongoing studies identified by the EAG or the Company.				

Key: □ aspect of study in scope; □ aspect of study not in scope; □□ aspect of study partially in scope, or elements of this are not in scope; *information provided from Company
Abbreviations: BMI, body mass index; CLED, continuous low energy diet; DAFNE, Dose Adjustment For Normal Eating; eGFR, estimated glomerular filtration rate; ILED, intermittent low energy diet; MDT, multi-disciplinary team; N/A, not appropriate; NAFLD, non-alcoholic fatty liver disease; NR, not reported; NYHA, New York Heart Association; T2DM, type 2 diabetes mellitus; QoL, quality of life

Appendix D: Economic literature search

Appendix D1 - Search strategy (economic evidence)

The searches were primarily structured around 3 elements: obesity and weight loss; obesity drug programmes or health programmes (a conceptually disparate range of terms but which helped narrow results from potentially any intervention for obesity), and an economic evaluation filter (adapted from the Centre for Reviews and Dissemination economic evaluation filters developed to populate NHS EED, 2015). NHS EED was not searched as, although it is still available, it only covers years up to and including 2014.

As with the clinical effectiveness literature searches, a 2018 to 'current' (date of search 19 to 22 May 2023) publication limit was applied, paediatric-only results were excluded, and a final requirement (of having a UK aspect or a highly relevant major subject heading or keyword) narrowed results to practically manageable numbers.

Database/Source (and years covered by database where relevant/available)	**Platform/URL**	**Date searched**	**Retrieved Results**
MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions (1946 to May 18, 2023)	OVID	19/5/2023	283
Embase (1974 to 2023 May 19)	OVID	20/5/2023	351
APA PsycInfo (2002 to May Week 2 2023)	OVID	22/5/2023	30
RePEC IDEAS	https://ideas.repec.org/	22/5/2023	14
Total			**678**
Total after deduplication			**482**

DATABASE/PLATFORM: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to May 18, 2023>

1	obesity management/ or bariatrics/	732
2	obesity management.kf.	174
3	*overweight/dh, rh, th, pc or *obesity/dh, rh, th, pc or *obesity, abdominal/dh, rh, th, pc or *obesity, morbid/dh, rh, th, pc	27225
4	(overweight/ or obesity/ or obesity, abdominal/ or obesity, morbid/) and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	46240

5	(obes$ or preobes$ or overweight or over weight).ti,kf. and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	35800
6	or/1-5	70525
7	Weight Reduction Programs/	2816
8	*Metabolic Syndrome/	30786
9	*Weight Loss/	17364
10	*Body Weight Maintenance/	264
11	*body weight/ and (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ab.	4736
12	weight management.kf.	1228
13	(weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ti.	26090
14	obes$.ab. /freq=2 or preobes$.ab. /freq=2 or overweight.ab. /freq=2 or over weight.ab. /freq=2	195106
15	weight$.ab. /freq=3 and (obes$ or preobes$ or overweight or over weight).ab.	47775
16	((obes$ or preobese$ or overweight$ or over-weight$) and (weight$ adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ab,ti.	53715
17	((bmi or body mass index$) and "kg m").ab.	26482
18	((or/7-13) and (or/14-17)) or 6	79921
19	Weight Reduction Programs/	2816
20	Government Programs/	6393
21	obesity management/ or bariatrics/	732
22	overweight/dh, rh, th, pc or obesity/dh, rh, th, pc or obesity, abdominal/dh, rh, th, pc or obesity, morbid/dh, rh, th, pc	47079
23	Life Style/	63446
24	Behavior Therapy/	30198
25	((weight or lifestyle) adj3 (intervention$ or program$)).ti,kf.	7911
26	((weight management or weight loss) adj3 program$).mp.	4775
27	health services/ or dietary services/	28967
28	Medication Therapy Management/	2761
29	"Referral and Consultation"/	75774
30	(tier or tiers).mp.	11769
31	(commissione$ or commissioning).mp.	12721
32	Dietetics/	8225
33	Treatment Outcome/	1146690
34	((clinical or treatment) adj3 pathway$).mp. or (nhs.af. and pathway$.mp.) or pathway$.ti.	284708
35	clinical decision-making/ or clinical reasoning/ or clinical relevance/	15343
36	Specialization/	25469
37	Patient Care Team/	69394
38	((blended or hybrid or virtual) adj5 (care or intervention$ or program$)).ti,ab.	7714
39	((mdt or multidisciplin$ or multi disciplin$ or multimodal or multi modal) and (lifestyle or weight) and (app or application or digital or remote or tele$)).ab,ti.	486

40	(or/19-39) and (intervention$ or program$ or app or apps or application$ or service$).mp.	445351
41	exp Anti-Obesity Agents/	20464
42	exp obesity/dt	13044
43	Liraglutide/	2460
44	glucagon-like peptides/ or glucagon-like peptide 1/ or glucagon-like peptide 2/	11260
45	Bupropion/	3312
46	lorcaserin.mp.	485
47	Medication Therapy Management/	2761
48	patient compliance/ or medication adherence/	83985
49	Prescription Drugs/	7012
50	(*obesity management/ or *bariatrics/ or *Weight Reduction Programs/ or *overweight/ or *obesity/ or *obesity, abdominal/ or *obesity, morbid/) and drug$.hw,kf.	4427
51	(semaglutide$ or liraglutide$ or orlistat$ or Ozempic$ or Wegovy$ or Rybelsus$ or Victoza$ or Saxenda$ or Xenical$ or TA875 or tirzepatide$ or mounjaro$).mp.	7060
52	(or/41-51) and (weight adj4 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).mp.	11614
53	18 and (40 or 52)	27145
54	limit 53 to yr="2018 -Current"	7579
55	limit 54 to ("all adult (19 plus years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)") or (54 and adult$.ti.)	3452
56	limit 54 to ("all infant (birth to 23 months)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)") or (54 and (child$ or paediatr$ or pediatr$).ti.)	881
57	54 not (56 not 55)	6931
58	Economics/	27500
59	exp "costs and cost analysis"/	264374
60	Economics, Dental/	1921
61	exp economics, hospital/	25712
62	Economics, Medical/	9246
63	Economics, Nursing/	4013
64	Economics, Pharmaceutical/	3104
65	(economic$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab.	1032479
66	(expenditure$ not energy).ti,ab.	36595
67	value for money.ti,ab.	2109
68	budget$.ti,ab.	35247
69	(cost marginal analysis or ((CBA or CUA or CEA or CMA) and cost$) or prioriti?ation or priority-setting or economic evaluation or programme budgeting marginal analysis or PBMA or (multi$ adj2 decision analysis) or MCDA or ration or rations or rationing or rationed or "tier$ 3" or "tier$ 4").mp.	62181
70	or/58-69	1234240

71	70 not (((energy or oxygen) adj cost) or (metabolic adj cost) or ((energy or oxygen) adj expenditure)).ti,ab.	1226242
72	71 not (letter or editorial or historical article).pt.	1184586
73	72 not (exp animals/ not humans/)	1101941
74	57 and 73	564
75	exp United Kingdom/	389548
76	(national health service* or nhs*).ti,ab,in.	267587
77	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.	49020
78	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jw,in.	2431127
79	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab.	212779
80	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab.	3396

81	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab.	41057
82	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab.	1553
83	or/75-82	2822049
84	(exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp australia/ or exp oceania/) not (exp united kingdom/ or europe/)	3316858
85	83 not 84	2684244
86	74 and 85	129
87	74 and (*Weight Reduction Programs/ or *obesity management/ or *bariatrics/ or *overweight/th or *obesity/th or *obesity, abdominal/th or *obesity, morbid/th or exp *"costs and cost analysis"/ or "tier$ 3".mp. or "tier$ 4".mp.)	221
88	86 or 87	283

Link to stategy:

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=6oyt0iKOCxzrMHnhPCUXLuDEg6vYb4OUs0vhParXvLiLm4jpTO8xc3bOdPeOcbMWA

DATABASE/PLATFORM: OVID Embase <1974 to 2023 May 19>

1	obesity management/	1556
2	obesity management.kf.	264
3	*obesity/dm, rh, th or *abdominal obesity/dm, rh, th or *diabetic obesity/dm, rh, th or *morbid obesity/dm, rh, th or *obese patient/ or *metabolically unhealthy obese/	21716
4	(obesity/ or abdominal obesity/ or diabetic obesity/ or morbid obesity/) and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	77551
5	(obese patient/ or metabolically unhealthy obese/) and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	3257
6	(obes$ or preobes$ or overweight or over weight).ti,kf. and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	55147
7	or/1-6	99703
8	weight loss program/	3236
9	*metabolic syndrome x/	48087
10	*body weight loss/	10740
11	*body weight control/	560

12	*body weight management/	986
13	*body weight maintenance/	200
14	*body weight change/	1229
15	*"weight trajectory (body weight)"/	136
16	*weight reduction/	26136
17	*body weight/ and (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ab.	6574
18	weight management.kf.	1630
19	(weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ti.	36677
20	obes$.ab. /freq=2 or preobes$.ab. /freq=2 or overweight.ab. /freq=2 or over weight.ab. /freq=2	299862
21	weight$.ab. /freq=3 and (obes$ or preobes$ or overweight or over weight).ab.	75333
22	((obes$ or preobese$ or overweight$ or over-weight$) and (weight$ adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ab,ti.	84313
23	((bmi or body mass index$) and "kg m").ab.	99751
24	((or/8-19) and (or/20-23)) or 7	114953
25	weight loss program/	3236
26	health program/ or exp program evaluation/	151337
27	obesity management/	1556
28	obesity/dm, rh, th or abdominal obesity/dm, rh, th or diabetic obesity/dm, rh, th or morbid obesity/dm, rh, th	23671
29	lifestyle modification/	50697
30	behavior change/	49787
31	behavior therapy/	45613
32	((weight or lifestyle) adj3 (intervention$ or program$)).ti,kf.	11110
33	((weight management or weight loss) adj3 program$).mp.	8770
34	health service/ or dietary service/ or hospital service/ or medical service/ or medication therapy management/ or nutrition service/ or public health service/	291236
35	patient referral/	155007
36	(tier or tiers).mp.	16064
37	(commissione$ or commissioning).mp.	19036
38	dietetics/	6309
39	clinical effectiveness/	176622
40	((clinical or treatment) adj3 pathway$).mp. or (nhs.af. and pathway$.mp.) or pathway$.ti.	368302
41	medical decision making/	93817
42	medical specialist/	88239
43	multidisciplinary team/ or collaborative care team/	27342
44	((blended or hybrid or virtual) adj5 (care or intervention$ or program$)).ti,ab.	10772
45	((mdt or multidisciplin$ or multi disciplin$ or multimodal or multi modal) and (lifestyle or weight) and (app or application or digital or remote or tele$)).ab,ti.	985

46	(or/25-45) and (intervention$ or program$ or app or apps or application$ or service$).mp.	714426
47	exp antiobesity agent/	7357
48	obesity/dt or abdominal obesity/dt or diabetic obesity/dt or morbid obesity/dt	18121
49	exp anorexigenic agent/	88395
50	antidiabetic agent/ or liraglutide/ or semaglutide/ or tirzepatide/	75018
51	amfebutamone plus naltrexone/ or amfebutamone/ or lorcaserin/	21973
52	medication therapy management/	14841
53	medication compliance/	45664
54	prescription drug/	13154
55	(*obesity management/ or *weight loss program/ or *obesity/ or *abdominal obesity/ or *diabetic obesity/ or *morbid obesity/) and drug$.hw,kf.	32878
56	(semaglutide$ or liraglutide$ or orlistat$ or Ozempic$ or Wegovy$ or Rybelsus$ or Victoza$ or Saxenda$ or Xenical$ or TA875 or tirzepatide$ or mounjaro$).mp,tn,du.	18685
57	(or/47-56) and (weight adj4 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).mp.	32290
58	24 and (46 or 57)	37492
59	limit 58 to yr="2018 -Current"	12151
60	limit 59 to (adult <18 to 64 years> or aged <65+ years>) or (59 and adult$.ti.)	7462
61	limit 59 to (infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years>) or (59 and (child$ or paediatr$ or pediatr$).ti.)	1257
62	59 not (61 not 60)	11281
63	Health Economics/	35604
64	exp Economic Evaluation/	353023
65	exp Health Care Cost/	337045
66	pharmacoeconomics/	9179
67	(econom$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab.	1382932
68	(expenditure$ not energy).ti,ab.	50291
69	(value adj2 money).ti,ab.	2978
70	budget$.ti,ab.	46914
71	(cost marginal analysis or ((CBA or CUA or CEA or CMA) and cost$) or prioriti?ation or priority-setting or economic evaluation or programme budgeting marginal analysis or PBMA or (multi$ adj2 decision analysis) or MCDA or ration or rations or rationing or rationed or "tier$ 3" or "tier$ 4").mp.	81158
72	or/63-71	1712458
73	72 not (letter or editorial or note or conference abstract).pt.	1321053
74	73 not ((metabolic adj cost) or ((energy or oxygen) adj cost) or ((energy or oxygen) adj expenditure)).ti,ab.	1313039
75	74 not ((animal/ or exp animal experiment/ or nonhuman/ or (rat or rats or mouse or mice or hamster or hamsters or animal or	1157474

	animals or dog or dogs or cat or cats or bovine or sheep).ti,ab,sh.) not (exp human/ or human experiment/))	
76	62 and 75	692
77	exp United Kingdom/	462061
78	(national health service* or nhs*).ti,ab,in,ad.	471867
79	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.	59731
80	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jx,in,ad.	3739764
81	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab.	371093
82	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab.	4759
83	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth	55822

	not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab.	
84	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab.	2163
85	or/77-84	4197589
86	(exp "arctic and antarctic"/ or exp oceanic regions/ or exp western hemisphere/ or exp africa/ or exp asia/ or exp "australia and new zealand"/) not (exp united kingdom/ or europe/)	3733751
87	85 not 86	3958438
88	76 and 87	147
89	76 and (*weight loss program/ or *health program/ or exp *program evaluation/ or *obesity management/ or *obesity/th or *abdominal obesity/th or *diabetic obesity/th or *morbid obesity/th or exp *Economic Evaluation/ or "tier$ 3".mp. or "tier$ 4".mp.)	287
90	88 or 89	351

Link to strategy:

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=1IUMtfvO5hHyhBz0sRBURr2sLoNnG7is0npPGSh6ehfWPnJoJRptgVPLULfbTHRJa

DATABASE/PLATFORM: OVID APA PsycInfo <2002 to May Week 2 2023>

1	(overweight/ or obesity/) and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	6448
2	(obes$ or preobes$ or overweight or over weight).ti,id. and ((obesity adj3 manag$) or (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ti,ab.	6340
3	1 or 2	6932
4	*weight loss/	2769
5	*weight control/	3085
6	*body weight/ and (weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ab.	1705
7	weight management.id.	1005
8	(weight adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).ti.	4168
9	obes$.ab. /freq=2 or preobes$.ab. /freq=2 or overweight.ab. /freq=2 or over weight.ab. /freq=2	24632
10	weight$.ab. /freq=3 and (obes$ or preobes$ or overweight or over weight).ab.	9103
11	((obes$ or preobese$ or overweight$ or over-weight$) and (weight$ adj3 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$))).ab,ti.	8197

12	((bmi or body mass index$) and "kg m").ab.	326
13	(or/4-8) or (or/9-12) or 3 [obesity]	31795
14	hospital programs/ or program development/	6515
15	program evaluation/	9096
16	lifestyle changes/ or behavior change/ or readiness to change/ or "stages of change"/	12375
17	((weight or lifestyle) adj3 (intervention$ or program$)).ti,id.	2387
18	((weight management or weight loss) adj3 program$).mp.	1516
19	health care services/ or behavioral health services/ or "continuum of care"/ or hospital programs/ or patient centered care/	47256
20	professional referral/	1908
21	(tier or tiers).mp.	3985
22	(commissione$ or commissioning).mp.	3842
23	dietetic$.ti,id.	201
24	treatment effectiveness evaluation/	22561
25	((clinical or treatment) adj3 pathway$).mp. or (nhs.af. and pathway$.mp.) or pathway$.ti.	17556
26	decision making/	71371
27	clinicians/	11831
28	interdisciplinary treatment approach/	4527
29	((blended or hybrid or virtual) adj5 (care or intervention$ or program$)).ti,ab.	2252
30	((mdt or multidisciplin$ or multi disciplin$ or multimodal or multi modal) and (lifestyle or weight) and (app or application or digital or remote or tele$)).ab,ti.	72
31	(or/14-30) and (intervention$ or program$ or app or apps or application$ or service$).mp. [programme]	118073
32	treatment compliance/	13235
33	prescription drugs/	6073
34	(*overweight/ or *obesity/) and drug$.hw,id.	811
35	(semaglutide$ or liraglutide$ or orlistat$ or Ozempic$ or Wegovy$ or Rybelsus$ or Victoza$ or Saxenda$ or Xenical$ or TA875 or tirzepatide$ or mounjaro$).mp.	232
36	(or/32-35) and (weight adj4 (loss or lose or losing or loses or lost or manag$ or reduc$ or control$)).mp.	596
37	13 and (31 or 36)	3834
38	limit 37 to yr="2018 -Current"	1066
39	limit 38 to ("300 adulthood <age 18 yrs and older>" or 320 young adulthood <age 18 to 29 yrs> or 340 thirties <age 30 to 39 yrs> or 360 middle age <age 40 to 64 yrs> or "380 aged <age 65 yrs and older>" or "390 very old <age 85 yrs and older>") or (38 and adult$.ti.)	744
40	limit 38 to (100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs>) or (38 and (child$ or paediatr$ or pediatr$).ti.)	212
41	38 not (40 not 39)	947
42	"costs and cost analysis"/	14471

43	"Cost Containment"/	504
44	(economic adj2 evaluation$).ti,ab.	1985
45	(economic adj2 analy$).ti,ab.	1408
46	(economic adj2 (study or studies)).ti,ab.	808
47	(cost adj2 evaluation$).ti,ab.	320
48	(cost adj2 analy$).ti,ab.	3595
49	(cost adj2 (study or studies)).ti,ab.	852
50	(cost adj2 effective$).ti,ab.	14955
51	(cost adj2 benefit$).ti,ab.	2970
52	(cost adj2 utili$).ti,ab.	1344
53	(cost adj2 minimi$).ti,ab.	359
54	(cost adj2 consequence$).ti,ab.	105
55	(cost adj2 comparison$).ti,ab.	156
56	(cost adj2 identificat$).ti,ab.	21
57	(pharmacoeconomic$ or pharmaco-economic$).ti,ab.	271
58	(cost marginal analysis or ((CBA or CUA or CEA or CMA) and cost$) or prioriti?ation or priority-setting or economic evaluation or programme budgeting marginal analysis or PBMA or (multi$ adj2 decision analysis) or MCDA or ration or rations or rationing or rationed or "tier$ 3" or "tier$ 4").mp.	7239
59	((task adj2 cost$) or (switch$ adj2 cost$) or (metabolic adj cost) or ((energy or oxygen) adj cost) or ((energy or oxygen) adj expenditure)).ti,ab,id.	4754
60	(animal or animals or rat or rats or mouse or mice or hamster or hamsters or dog or dogs or cat or cats or bovine or sheep or ovine or pig or pigs).ab,ti,id,de.	239668
61	(editorial or letter).dt. or dissertation abstract.pt.	381204
62	(0003-4819 or 0003-9926 or 0959-8146 or 0098-7484 or 0140-6736 or 0028-4793 or 1469-493X).is.	10041
63	(or/42-58) not (or/59-62)	31861
64	41 and 63	30

Link to strategy:

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=1shwSc93kL7XWEuk82QQ7W77OBXygAhlt4Aprlq4453clRj2MHbktusbYlLsJQkaL

DATABASE/PLATFORM: RePEC IDEAS database
URL: https://ideas.repec.org/

(obesity | obese | preobese | preobesity | overweight | "over weight") + ("weight loss" | "weight management") + (intervention | interventions | program | programs | programme | programmes | service | services) + (UK | united kingdom | britain |

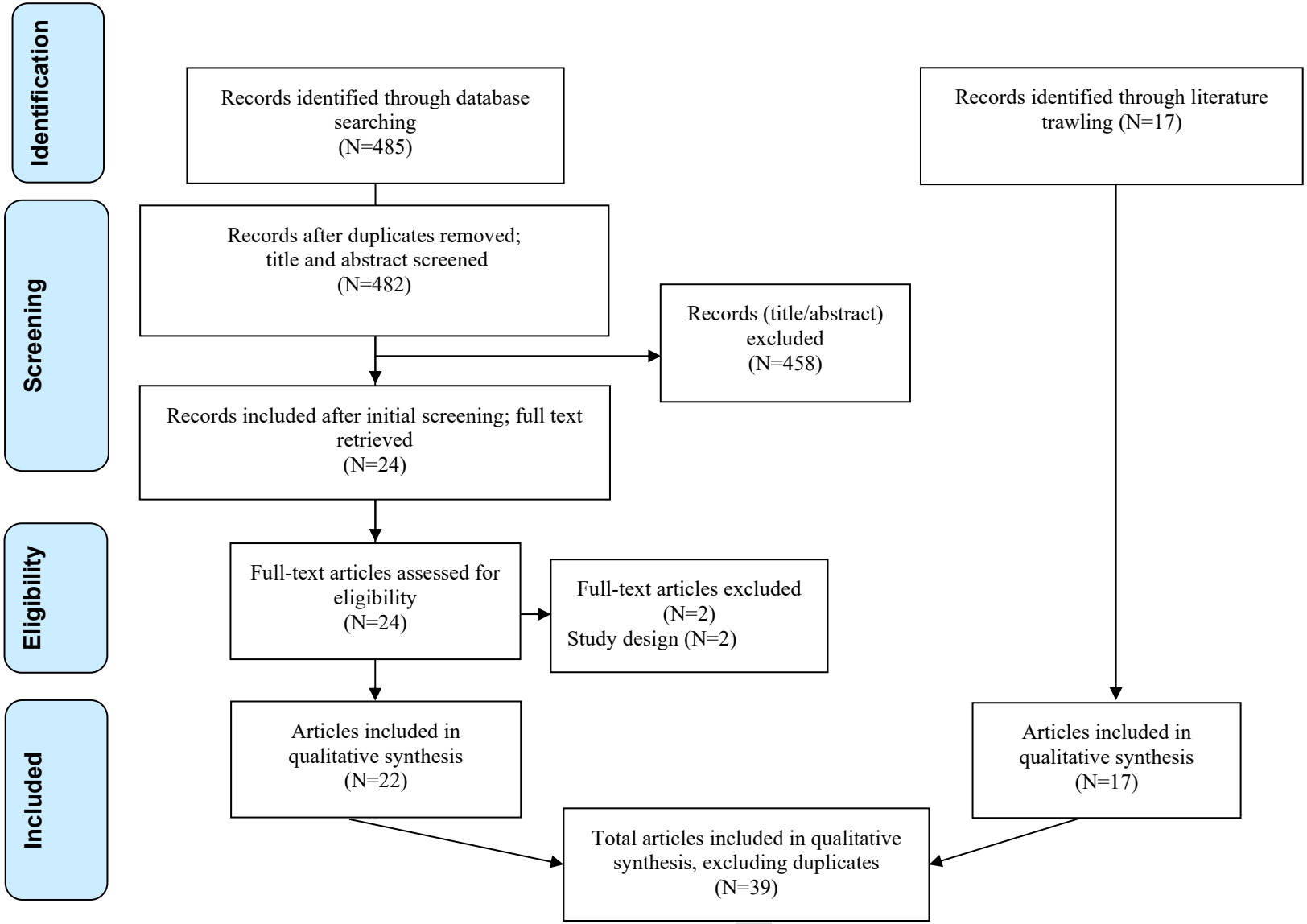
british | england | english | scotland | scottish | wales | welsh | ireland | irish | nhs | "national health service")

2018-2023

14 results

Link to strategy: https://ideas.repec.org/cgi-bin/htsearch?form=extended&wm=wrd&dt=range&ul=&q=%28obesity+%7C+obese+%7C+preobese+%7C+preobesity+%7C+overweight+%7C+%22over+weight%22%29+%2B+%28%22weight+loss%22+%7C+%22weight+management%22%29+%2B+%28intervention+%7C+interventions+%7C+program+%7C+programs+%7C+programme+%7C+programmes+%7C+service+%7C+services%29+%2B+%28UK+%7C+united+kingdom+%7C+britain+%7C+british+%7C+england+%7C+english+%7C+scotland+%7C+scottish+%7C+wales+%7C+welsh+%7C+ireland+%7C+irish+%7C+nhs+%7C+%22national+health+service%22%29&cmd=Search%21&wf=4BFF&s=R&db=01%2F01%2F2018&de=31%2F12%2F2023

Appendix D2 - PRISMA diagram (economic evidence)



Appendix D3 – Narrative summary of published economic evidence

Author (year)	Title	Study Type	Narrative Summary
Aguiar et al. (2021)	The Health Economic Evaluation of Bariatric Surgery Versus a Community Weight Management Intervention Analysis from the Idiopathic Intracranial Hypertension Weight Trial (IIH:WT)	Economic Evaluation alongside Randomised Control Trial	UK based study taking a UK National Health Service (NHS) and Personal Social Service perspective. Economic evaluation alongside an RCT (n=67, 24-month follow up post completion) for patients with Idiopathic Intracranial Hypertension randomised to bariatric surgery or a community weight management intervention. The proportion of patients who achieved a 12.5% reduction in intracranial pressure at 24 months were 85% with bariatric surgery and 39% with Weight Watchers. This represents a mean difference of 45% in favour of bariatric surgery (95% CI: 24% to 66%). The mean total healthcare costs were £1,353 for the community weight management arm and £5,400 for the bariatric surgery arm over 24 months. The cost-effectiveness of bariatric surgery improved overtime and therefore the incremental cost of surgery when offset against the incremental reduction of intracranial pressure improved after 24 months, as compared with 12 months follow up.
Ahern et al. (2022)	Effectiveness and cost-effectiveness of referral to a commercial open group behavioural weight management programme in adults with overweight and obesity: 5-year follow-up of the WRAP randomised controlled trial.	Economic Evaluation alongside Randomised Control Trial	UK based study taking a UK National Health Service (NHS) and Personal Social Service perspective. Economic evaluation alongside RCT (n=1267, 5 year follow up post randomisation) comparing a brief intervention, 12-week open-group behavioural programme and 52-week open group behavioural programme. During the trial, the 12-week programme incurred the lowest cost and produced the highest quality-adjusted life-years (QALY). Simulations beyond 5 years suggested that the 52-week programme would deliver the highest QALYs at the lowest cost and would be the most cost-effective.
Avenell et al. (2018)	Bariatric surgery, lifestyle interventions and orlistat for severe obesity: the	Economic Decision Model	UK based study taking a UK National Health Service (NHS) and Personal Social Service perspective. Model based economic evaluation as part of a NIHR HTA comparing Bariatric

Author (year)	Title	Study Type	Narrative Summary
	REBALANCE mixed-methods systematic review and economic evaluation		surgery, lifestyle interventions and orlistat for severe obesity. Microsimulation model (populated with data from meta-analyses) predicted costs, outcomes and cost-effectiveness of Roux-en-Y gastric bypass (RYGB) surgery and the most effective lifestyle WMPs over a 30-year time horizon compared with current UK population obesity trends. The microsimulation model found that WMPs were generally cost-effective compared with population obesity trends. Long-term WMP weight regain was very uncertain. Bariatric surgery was cost-effective compared with no surgery and WMPs, but the model did not replicate long-term cost savings found in previous studies.
Boyers et al. (2021)	Cost-effectiveness of bariatric surgery and non-surgical weight management programmes for adults with severe obesity: a decision analysis model	Economic Decision Model	Journal article based on the NIHR HTA reported by Avenell *et al* 2018. Microsimulation model (populated with data from meta-analyses) predicted costs, outcomes and cost-effectiveness of Roux-en-Y gastric bypass (RYGB) surgery and the most effective lifestyle WMPs over a 30-year time horizon from an NHS perspective, compared with current UK population obesity trends. RYGB surgery was the most effective and cost-effective use of scarce NHS funding resources. However, where fixed healthcare budgets or patient preferences exclude surgery as an option, a standard 12-week behavioural WMP was the next most cost-effective intervention.
Elliot et al. (2021)	Cost-effectiveness of bariatric surgery versus community weight management to treat obesity-related idiopathic intracranial hypertension: evidence from a single-payer healthcare system	Economic Decision Model	Model based economic evaluation comparing bariatric surgery or a community weight management intervention for patients with Idiopathic Intracranial Hypertension. A Markov model was developed comparing bariatric surgery with a community weight management intervention over 5-, 10-, and 20-year time horizons. Transition probabilities, utilities, and resource use were informed by the IIH Weight Trial. alongside the published literature. In the base case analysis, over a 20-year time horizon, bariatric surgery

Author (year)	Title	Study Type	Narrative Summary
			was dominant and led to cost savings of £49,500 and generated an additional 1.16 QALYs in comparison to the community weight management intervention. The probabilistic sensitivity analysis indicated a probability of 98% that bariatric surgery is the dominant option in terms of cost-effectiveness.
Finklestein & Kruger (2014)	Meta- and Cost-Effectiveness Analysis of Commercial Weight Loss Strategies	Systematic Review	US based study assessing the cost-effectiveness of three commercial nonsurgical weight loss strategies (Weight Watchers; Vtrim and Jenny Craig), and three weight loss medications (Qsymia, Lorcaserin, and Orlistat). The authors report average and incremental cost-effectiveness ratios (ACERs and ICERs) in terms of cost per kilogram of weight lost and cost per QALYs gained are presented. Results show that average cost per kilogram of weight lost ranged from $155 (95% CI: $110-$218) for Weight Watchers to $546 (95% CI: $390-$736) for Orlistat. The incremental cost per QALY gained for Weight Watchers and Qsymia was $34,630 and $54,130, respectively.
Galvain et al. (2021)	Cost-effectiveness of bariatric and metabolic surgery, and implications of Covid-19 in the United Kingdom	Economic Decision Model	UK based study taking a UK National Health Service (NHS) perspective. Markov model evaluating the economic benefits of bariatric and metabolic surgery in the NHS. Markov model compared lifetime costs and outcomes of BMS and conventional treatment among patients with BMI>40, BMI>35 obesity-related co-morbidities or BMI>35 T2D. Inputs were sourced from clinical audit data and literature sources; direct and indirect costs were considered. In both groups, BMS was dominant versus conventional treatment, at a willingness-to-pay threshold of £25,000/QALY. Delaying BMS by 5 years resulted in higher costs and lower QALYs in both groups compared with not delaying treatment.
Hollenbeak et al. (2016)	Cost-effectiveness of	Economic Evaluation	US based study. 12-month follow up EE comparing the DPP lifestyle

Author (year)	Title	Study Type	Narrative Summary
	SHINE: A Telephone Translation of the Diabetes Prevention Program	alongside Randomised Control Trial	behavioural intervention delivered as an individual call (IC) (n = 129) compared with a conference call (CC) (n = 128) core. The purpose of this study was to assess whether the CC intervention was cost-effective relative to the IC intervention. The authors reported incremental cost-effectiveness ratio (ICER). Four ICERs were estimated: (1) incremental cost per QALYs gained, (2) incremental cost per centimetre of waist circumference reduced, (3) incremental cost per kilogram of weight lost, and (4) incremental cost per unit of BMI lost. Average total costs per patient were $2,831 (range: $308–46,306) for the CC group subjects and $2,933 (range: $248–79,281) for the IC group (P = 0.95). Participants in the CC group reduced their waist circumference by a mean of 6.5 cm, compared with 5.9 cm for those who received the IC intervention (P = 0.69). CC participants also lost a mean of 6.2 kg of weight, while IC participants lost 5.1 kg (P = 0.48). And those in the CC group reduced their BMI by a mean of 2.1 units, while those in the IC group reduced their BMI by 1.9 units (P = 0.62) Participants in the CC group achieved 0.635 QALYs and participants in the IC group achieved 0.646 QALYs. The incremental cost-effectiveness ratio was $9,250 per additional QALY
Hunt et al. (2014)	A gender-sensitised weight loss and healthy living programme for overweight and obese men delivered by Scottish Premier League football clubs (FFIT): a pragmatic randomised controlled trial	Economic Evaluation alongside Randomised Control Trial	UK based study, NHS and Personal Social Services perspective. Intervention (n=374): Football Fans in Training (FFIT) is a 12-session weight loss and healthy living programme delivered to fans in Scottish professional football clubs Comparator (n=374) : waiting list for 12 months. The cost-effectiveness of FFIT was estimated at 12 months follow up and it equalled £862 per additional man achieving and maintaining a 5% weight reduction at 12 months. The programme was also associated with a gain in QALYs of 0·015 (0·003–0·027) and an

Author (year)	Title	Study Type	Narrative Summary
			incremental cost-effectiveness of £13 847 per QALY gained.
Ismail et al. (2019)	Reducing weight and increasing physical activity in people at high risk of cardiovascular disease: a randomised controlled trial comparing the effectiveness of enhanced motivational interviewing intervention with usual care.	Economic Evaluation alongside Randomised Control Trial	UK based study taking a UK National Health Service (NHS) perspective. Economic evaluation alongside RCT (n=1,742, 24-month follow up) comparing the effectiveness of enhanced motivational interviewing intervention (in either an individual or group format) with usual care for those at high risk of cardiovascular disease in the UK. Service costs were similar for inpatient care, outpatient attendances and community contacts were similar between arms. The intervention cost was highest for those in the individual arm. The group arm was dominated by usual care. The ICER for the individual arm was £55,313 per QALY. The ICER of the individual arm compared with the group arm was £8,267 per QALY. The individual, group and usual care arms had a 38.1%, 3.2% and 58.7% likelihood of being the most cost-effective option.
Krukowski et al.. (2011)	Comparing Behavioral Weight Loss Modalities: Incremental Cost-Effectiveness of an Internet-Based Versus an In-Person Condition	Economic Evaluation alongside Randomised Control Trial	US based cost-effectiveness analysis comparing Internet-based weight loss intervention (n=161) compared with an identical intervention conducted in-person (n=157). Incremental cost-effectiveness ratios calculated as incremental costs per life yeas gained (LYG). In-person participants had significantly greater weight losses (−8.0 ± 6.1 kg) than Internet participants (−5.5 ± 5.6 kg), whereas differences in LYG were insignificant. Estimated LYG was 0.58 (95% confidence interval: 0.45, 0.71) and 0.47 (95% confidence interval: 0.34, 0.60) for the in-person and Internet condition, respectively. Total cost of conducting the in-person condition was $706 per person and the Internet condition was $372 per person with the difference mainly due to increased travel cost of $158 per person. The incremental cost-effectiveness ratio was $2,160 per (discounted) LYG for the Internet modality relative to no intervention/no weight loss and $7,177 per

Author (year)	Title	Study Type	Narrative Summary
			(discounted) LYG for the in-person modality relative to the Internet modality
Lee et al. (2019)	The cost-effectiveness of pharmacotherapy and lifestyle intervention in the treatment of obesity.	Economic Decision Model	US based study assuming a healthcare system cost perspective. Economic decision model assessing the cost-effectiveness of six pharmacotherapies and lifestyle intervention for people with mild obesity (BMI 30 to 35) in the USA. A microsimulation model was constructed to compare seven weight loss strategies plus no treatment: intensive lifestyle intervention, orlistat, phentermine, phentermine/topiramate, lorcaserin, liraglutide, and semaglutide Results were analysed at 1-,3-, and 5-year time horizons. At each of the three follow-up periods, phentermine was the cost-effective strategy, with ICERs of $46 258/QALY, $20 157/QALY, and $17880/QALY after 1, 3, and 5 years, respectively. Semaglutide was the most effective strategy in the 3-and 5-year time horizons, with total QALYs of 2.224 and 3.711, respectively. However, the ICERs were high at $1,437,340/QALY after 3 years and $576,931/QALY after 5 years.
Lewis et al. (2014)	The cost-effectiveness of the LighterLife weight management programme as an intervention for obesity in England	Economic Decision Model	UK based study form an NHS perspective and a 10-year time horizon. Intervention- LighterLife - very low-calorie diet (VLCD) total dietary replacement weight reduction programme. Comparators were no treatment, Weight Watchers, Counterweight,Slimming World, gastric banding and gastric bypass depending on the weight category of the patient. Authors calculated the total costs and QALYs for each intervention, and from these to calculate the incremental costs, QALYs and incremental cost-effectiveness ratio (ICER) for a number of comparisons. Two sets of analyses were conducted: one for each of the two BMI groups (30+ and 40+). For the 30+ BMI group, the ICERs for each intervention vs. LighterLife were £11 895 vs. no

Author (year)	Title	Study Type	Narrative Summary
			treatment, £12,453 vs. Counterweight, £12,585 vs. Weight Watchers, and £12 233 vs. Slimming World. In the 40+ BMI group, LighterLife was less effective than both gastric banding and bypass, but the ICER vs. no treatment was £4,356.
Little et al. (2017)	Randomised controlled trial and economic analysis of an internet-based weight management programme: POWeR+ (Positive Online Weight Reduction)	Economic Evaluation alongside Randomised Control Trial	Economic evaluation alongside 3 arm parallel RCT with an NHS and Personal Social Services perspective. Participants were randomised to a control group (n=279), face to face (n=269) or remote (n=270) groups. The control group received evidence-based advice and simple materials to support behaviour change. The face-to-face group (POWeR+F) received a web intervention with face-to-face appointments for nurse support. The remote group (POWeR+R) received the web intervention with remote support.The outcomes were weight lost and QALYs. ICERs (Incremental cost per kg lost and incremental cost per QALY gained) were calculated at 12 months follow up. The total unadjusted cost is £398 (95% CI £296 to £500) in the control group; £401 (95% CI £296 to £506) in POWeR+F and £349 (95% CI £266 to £432) in POWeR+R group. The probability of each intervention being cost-effective compared with the control was > 80%, using the NICE's suggested threshold of £100 per kilogram lost.
Losina et al. (2019)	Cost Effectiveness of Diet and Exercise for Overweight and Obese Patients With Knee Osteoarthritis	Economic Decision Model	US based study assuming a both a healthcare sector and societal perspective. Economic decision model assessing the cost-effectiveness of an intensive diet and exercise (D+E) programme as compared with standard care for weight reduction for patients with knee Osteoarthritis in the USA. The Osteoarthritis Policy Model (a patient level simulation model) used to calculate lifetime QALYs and costs. In the base case, D+E led to 0.054 QALYs gained per person and cost $1,845 from the healthcare sector perspective and $1,624 from the

Author (year)	Title	Study Type	Narrative Summary
			societal perspective. This resulted in ICERs of $34,100/QALY and $30,000/QALY. D+E had 58% and 100% likelihoods of being cost-effective with thresholds of $50,000/QALY and $100,000/QALY, respectively. Authors concluded that adding D+E to usual care for patients who are overweight or living with obesity with knee OA is cost-effective.
Lymer et al. (2011)	The Population Cost-Effectiveness of Weight Watchers with General Practitioner Referral Compared with Standard Care	Economic Decision Model	Australian study taking a health system perspective. Economic decision model estimating the cost-effectiveness of weight watchers with a doctor referral compared with standard care in an Australian population with overweight and obesity. The 'NCDMod' microsimulation model was used with a 10-year time horizon. The modelled Weight Watchers (WW) had an incremental cost-effectiveness ratio of A$35,195 in savings per case of obesity averted in ten years. WW remained dominant over SC for the different scenarios in the sensitivity analysis. Authors concluded that the WW intervention represented good value for money.
McGlone et al. (2020)	Bariatric surgery for patients with type2 diabetes mellitus requiring insulin: Clinical outcome and cost-effectiveness analyses	Economic Decision Model	UK based study taking UK National Health Service (NHS) perspective. Economic decision model estimating the cost-effectiveness of bariatric surgery for patients with obesity and T2D in the UK compared with best medical treatment. State-transition micro-simulation model implemented using inputs from the National Bariatric Surgical Registry, with a five-year time horizon. Over five years, bariatric surgery was dominant as compared with BMT, with higher average QALYs and lower average costs.
McRobbie et al (2019)	Randomised controlled trial and economic evaluation of a task-based weight management group programme	Economic Evaluation alongside Randomised Control Trial	Economic evaluation alongside an RCT (n=230, 12-month follow up) comparing the cost-effectiveness of a task-based weight management programme with standard care. There was a mean incremental gain in QALYs (0.0104) for the weight management programme and a mean

Author (year)	Title	Study Type	Narrative Summary
			incremental increase in costs (£80). The base case ICER was £7,742 per QALY gained, and the authors concluded that it was likely to represent good value for money for the NHS.
Meads et al. (2014)	The cost-effectiveness of primary care referral to a UK commercial weight loss programme	Economic Decision Model	UK based study from a personal health and social services persepctive. Costs and effects were estimated for participants in annual cycles from 12 months over a lifetime. A cost-utility analysis was conducted with the main outcome being cost per incremental QALY. Decision-analytic Markov model was developed to estimate the cost-effectiveness of the commercial programme compared with usual care. The intervention was a 12-week primary care referral to a commercial weight loss programme (CWLP) The control was information provision (i.e. verbally or using printed material such as a leaflet) but no 'active' component.The incremental cost-effectiveness ratio at 12 months of referral vs usual practice was £6,906. Over a lifetime, referral to the commercial programme was dominant being £924 cheaper and yielding an incremental benefit of 0.22 QALY over usual care.
Meenan et al. (2015)	An Economic Evaluation of a Weight Loss Intervention Program for People with Serious Mental Illnesses Taking Antipsychotic Medications	Economic Evaluation alongside Randomised Control Trial	US based study – health system, payer perspective. Intervention: tailored intervention for people with serious mental illnesses with two facilitators (mental health counselor, nutritional interventionist) and using repetition, multiple teaching modalities (e.g., verbal, visual), skill-building exercises, and practice assignments to overcome cognitive barriers. Usual care: no treatment. The authors estimated ICERs for the study outcomes of weight lost (in kilograms) and reduced fasting glucose levels (in mg/dL). Costs per participant ranged from $4,365 to $5,687. Costs to reduce weight by one kilogram ranged from $1,623 to $2,114; costs to reduce fasting glucose by 1 mg/dL ranged from $467 to $608. Medical hospitalization costs were reduced by $137,500.

Author (year)	Title	Study Type	Narrative Summary
			ICERs ranged from $1,940 (intervention delivery plus recruitment costs minus the value of reduced hospitalizations) to $2,527 (intervention delivery plus recruitment costs) per kg lost, and $558 to $727 per mg/dL of fasting glucose reduced.
Miners et al. (2012)	An economic evaluation of adaptive e-learning devices to promote weight loss via dietary change for people with obesity	Economic Decision Model	Lifetime model consisting of a cost-utility analysis (CUA). The intervention was defined as a single hypothetical/generic package reflecting the design and cost of a previously evaluated internet-based intervention, which included a website providing advice, tools and information to support behaviour change in terms of dietary and physical activity patterns. Conventional care (CC) arm was defined as being able to include a number of interventions such as generic dietary information and/or exercise but excluding interventions based on e-learing device (eLD) or pharmacological treatment. All individuals were assumed to receive treatment with either an e-LD or CC for 12 months, or until they developed a disease (type 2 diabetes or cardiovascular disease), died or dropped-out from treatment. Costs were assessed from a UK health services perspective, and expressed in 2009 prices.The base case results from the Model reported an incremental cost-effectiveness ratio of £102,000 per QALY compared with standard care. Expected value of perfect information (EVPI) analysis showed that while the individual level EVPI was arguably negligible, the population level value was between £37 M and £170 M at a willingness to pay between £20,000 to £30,000 per additional QALY
NICE (2019)	Liraglutide 3.0mg in the management of overweight and obesity (TA664)	Economic Decision Model	State transition, Markov cohort model estimating the cost-effectiveness of Liraglutide in the management of overweight and obesity compared with specialist Tier 3 services in the NHS. Clinicial effectiveness of the

Author (year)	Title	Study Type	Narrative Summary
			intervention introduced through changes in BMI and cardio-metabolic risk factors, which were then used in risk equations to calculate transition probabilities. Cycle length was every three months for the first year and then yearly cycles after that. Time horizon was stated as 40 years. Treatment was expected to wane in a linear fashion within three years following discontinuation. In the company base case, Liraglutide 3.0mg was estimated to be cost-effective, with an ICER of £13,059 per QALY gained.
NICE (2021)	Semaglutide for managing overweight and obesity (TA875)	Economic Decision Model	State transition, Markov cohort model estimating the cost-effectiveness of Semaglutide for managing overweight and obesity in the NHS. Model adapted from TA664, using the committee preferred assumptions and improvements including validation against real world data.
O'Brien et al. (2018)	Economic evaluation of telephone-based weight loss support for patients with knee osteoarthritis: a randomised controlled trial	Economic Evaluation alongside Randomised Control Trial	Australian study taking a healthcare payer and a broader societal perspective. Economic evaluation alongside an RCT (n=120, 26 weeks follow up) comparing the cost-effectiveness of telephone-base weight loss support for patients with known osteoarthritis in an Australian population from a societal perspective. From a healthcare perspective, the ICER for a QALY gained was $387,820, indicating that telephone-based weight loss support was not cost-effective.
Panca et al. (2018)	Cost-effectiveness of a community-delivered multicomponent intervention compared with enhanced standard care of obese adolescents: cost-utility analysis alongside a randomised	Economic Evaluation alongside Randomised Control Trial	UK based study taking a UK National Health Service (NHS) perspective. Economic evaluation alongside an RCT (n=174, 12-month follow up) comparing the cost-effectiveness of a motivational multicomponent lifestyle-modification intervention in a community setting compared with enhanced standard care for obese adolescents in a UK setting. Mean intervention costs per participant were £918 for the intervention and £68 for enhanced standard care. There were no significant differences between the two groups in mean resource use per participant for any

Author (year)	Title	Study Type	Narrative Summary
	controlled trial (the HELPtrial)		type of healthcare contact. There were no differences in adjusted QALYs between groups. The ICER of the intervention versus enhanced standard care was £120,630 per QALY gained, indicating that the intervention was not cost-effective.
Patel et al. (2018)	Cost-effectiveness of habit-based advice for weight control versus usual care in general practice in the Ten Top Tips (10TT) trial: economic evaluation based on a randomised controlled trial	Economic Evaluation alongside Randomised Control Trial	UK based study taking a UK National Health Service (NHS) and Personal Social Services perspective. Economic evaluation alongside an RCT (n=537, 24-month follow up) comparing the cost-effectiveness of habit-based advice for weight loss versus usual care for patients with obesity. Over a two-year time-horizon, the mean costs per patient were £1,889 for the intervention and £1,925 for usual care. The mean QALYs were 1.51 for both the intervention and usual care. At a willingness to pay threshold of £20,000, the incremental Net Monetary Benefit for the intervention verses usual care was £49.The authors concluded that the intervention was as cost-effective as usual care.
Perri et al. (2014)	Comparative Effectiveness of Three Doses of Weight-Loss Counseling: Two-Year Findings from the Rural LITE Trial	Economic Evaluation alongside Randomised Control Trial	US based study evaluating the effects and costs of three doses of behavioural weight-loss treatment. Those in the control received nutrition education without instruction in behavior modification strategies conditions. The authors computed the average cost per kg decrease in weight under each of the treatments considered (usual care, low dose moderate dose and high dose). Results showed the control group had the lowest costs ($13,233) followed by the low does ($16,351), moderate dose ($19,426), and high dose ($26,630) groups. Cost per kg lost per participant, were $22 for the moderate group, $25 for high dose group, $33 for the low dose group and $28 for the control group.
Ritzwoller et al. (2013)	Economic Analyses of the Be Fit Be Well Program: A	Cost Analysis	US based cost analysis comparing the Be Fit Be Well intervention with usual care. The intervention consisted of eHealth technology

Author (year)	Title	Study Type	Narrative Summary
	Weight Loss Program for Community Health Centers		monitoring and support, print support materials, mailing supplies, and the personnel needed for counselling calls and group session. Usual care participants received the “Aim for a Healthy Weight” self-help booklet. Outcome measures included total recruitment costs and intervention costs, cost per participant, and incremental costs per unit reduction in weight and blood pressure. The overall costs for the 2-year long intervention program were $424,624 or an average of $2,354 per intervention participant. The incremental cost of the intervention per kg lost at 24 months was $2,040 per kg and $574 per mmHg of systolic blood pressure reduction.
Rollo et al. (2018)	Cost evaluation of providing evidence-based dietetic services for weight management in adults: In-person versus eHealth delivery	Cost Analysis	Australian cost evaluation study comparing the theoretical cost of best-practice weight management in an in-person setting compared with remote consultations using eHealth technologies for adults requiring active weight management in an Australian context. Establishment costs were higher for eHealth compared with in-person costs ($1394.21 vs $90.05). Excluding establishment costs, the total (combined dietitian and patient) cost for one patient receiving best-practice weight management for 12 months was $560.59 for in-person delivery, compared with $389.78 for eHealth delivery. Authors concluded that although it is initially more expensive to establish an eHealth service mode, the overall reoccurring costs per patient for delivery of best-practice weight management were lower compared with the in-person mode.
Sandhu et al. (2023)	Once-Weekly Subcutaneous Semaglutide 2.4 mg Injection is Cost-Effective for Weight Management in the United Kingdom	Economic Decision Model	UK based study taking a National Health Service (NHS) and Personal Social Services perspective. Economic decision model estimating the cost-effectiveness of semaglutide alongside diet and exercise compared with diet and exercise alone for patients suffering from obesity in a UK context. The Core Obesity Model (COM) was

Author (year)	Title	Study Type	Narrative Summary
			supplemented with clinical data from the STEP 1 and STEP 2 clinical trials. The COM is a closed cohort Markov model. Semaglutide showed higher total costs and health benefits as compared with diet and exercise alone, with an ICER of £14,827 per QALY gained in the base case analysis.
Simpson et al. (2020)	An app-, web- and social support-based weight loss intervention for adults with obesity: the HelpMeDoIt! feasibility RCT	Economic Evaluation alongside Randomised Control Trial	UK based study taking a National Health Service (NHS) and Personal Social Services perspective. Study investigating the feasibility and acceptability of an app, web- and social support-based intervention in supporting adults with obesity to achieve weight loss goals. Data collected on health-related quality of life, NHS resource use, participant-borne costs and intervention costs. Health and social care resource use, food and drink and lifestyle activity spend patterns were broadly similar between the groups. The EQ-5D and ICECAP-A instruments were both found to be acceptable in this population group.
Simpson et al. (2021)	Healthy eating and lifestyle in pregnancy (HELP): a cluster randomised trial to evaluate the effectiveness of a weight management intervention for pregnant women with obesity on weight at 12 months postpartum	Economic Evaluation alongside Randomised Control Trial	UK based study taking a National Health Service (NHS) and Personal Social Services perspective. A broader societal perspective was also considered. Economic evaluation alongside an RCT (n=598, 12-month follow up) comparing the cost-effectiveness of a weight management intervention for pregnant women with obesity compared with usual care. The mean total cost per patient (including healthcare, out-of-pocket and intervention costs) was £404.50 lower for the intervention arm although not statistically significant. Mean QALYs were 0.0024 lower for the intervention arm compared with standard care. The authors concluded that the probability of intervention being cost-effective was above 60% at policy-relevant thresholds.
Trueman et al. (2010)	Long-term cost-effectiveness of weight	Economic Decision Model	UK based study taking an NHS and Personal Services perspective.

Author (year)	Title	Study Type	Narrative Summary
	management in primary care		The intervention was the Counterweight Programme, an evidence and theory-based intervention for weight management delivered in family practice and other settings by practice nurses or other healthcare workers, with initial guidance and facilitation by 'weight management advisers'.The control group was no active intervention.The cost utility analysis model on a cohort of 10,000 individuals, reported lifetime costs and outcomes with and without the counterweight intervention. Outcomes were represented as QALYs. Cost-outcome findings were presented as an ICER. Counterweight delivery cost was £59.83 per patient. Counterweight was cost-saving under 'base-case scenario', where 12-month achieved weight loss was entirely regained over the next 2 years, returning to the expected background weight gain of 1 kg/year. The incremental cost per QALY was £2017 where background weight gain was limited to 0.5 kg/year, and £2651 at 0.3 kg/year.
Tsai et al. (2005)	Cost-Effectiveness of a Low-Carbohydrate Diet and a Standard Diet in Severe Obesity	Economic Evaluation alongside Randomised Control Trial	Us based study with a societal perspective. The intervention (n=64) was a low carbohydrate diet, and the comparator (n=65) was a standard diet. Within-trial analysis reported costs, QALYs, and ICERs. Results found no statistically significant difference in costs between groups (incremental cost, $-49; 95% CI, -1388 to 1274;p =0.95). There was also no significant difference in QALYs during the 1 year of the study (incremental QALYs,0.04; 95% CI, -0.01 to 0.08; p = 0.17 The point estimate for the ICER was $-1225, with the lower costs and higher QALYs making the intervention dominant.
Wilson et al. (2016)	Cost-Effectiveness of a Community-Based Weight	Economic Decision Model	US based study using a societal perspective and 20-year time horizon. The intervention (n=509) was 'Beyond Sabor', a 12-week

Author (year)	Title	Study Type	Narrative Summary
	Control Intervention Targeting a Low-Socioeconomic-Status Mexican-Origin Population		community-based weight which promotes weight control through healthy dietary and physical activity behaviors using social cognitive theory constructs.Simulated controls demographically and physiologically matched to the baseline characteristics of 'Beyond Sabor' participants were used. The ICERs were $57,430 and $61,893, respectively, per QALY gained when compared with usual care for the 2% and 5% weight loss scenarios.
Xia et al. (2019)	Bariatric surgery is a cost-saving treatment for obesity—A comprehensive meta-analysis and updated systematic review of health economic evaluations of bariatric surgery	Systematic Review	Systematic review of health economic evidence regarding bariatric surgery from 1995 – 2018, including a meta-analysis to calculate the annual cost changes before-and-after surgery. Authors concluded that compared with no/conventional treatment surgery was cost saving over a lifetime scenario even without considering indirect costs.
Xin et al. (2020)	Type 2 diabetes remission: 2 year within-trial and lifetime-horizon cost-effectiveness of the Diabetes Remission Clinical Trial(DiRECT)/Counterweight-Plus weight management programme	Economic Decision Model	UK based study taking a National Health Service (NHS) perspective. Economic decision model estimating the cost-effectiveness of a weight management programme for patients with diabetes in the UK. Markov model structure with three states (remission, diabetes and death), with costs sourced from a within trial cost analysis from the DiRECT trial. Over the lifetime time horizon, the intervention was modelled to achieve a mean QALY gain of 0.06 and a mean lifetime cost saving of £1,337. The authors concluded that there is strong evidence for the intervention being cost-effective.

Appendix E: Correspondence with Companies

Appendix E1 – Initial questions from EAG

No.	Company (Technology)	Responded
1	DDM (Gro Health/W8Buddy)	26/05/2023
2	Oviva (Oviva)	26/05/2023
3	Liva (Liva)	30/05/2023
4	CheqUp (CheqUp)	06/06/2023
5	Xyla Health (Wellbeing Way)	19/06/2023
6	Second Nature (Second Nature)	19/06/2023
7	Reset Health (Roczen)	19/06/2023

	Question	Response
1	Is your technology CE or UKCA marked? a. If yes, which risk class does your device come under? b. If no, are there plans to obtain certification?	Company #1: Yes, the technology is CE marked. UKCA mark will be granted once a notified body has reviewed it in December 2023. The technology is a Class I Medical Device.
		Company #2: Please see response to NICE Request for Information Question 2- Oviva's technology is CE marked and is a class IIa certified medical device
		Company #3: Liva has a Class 1 CE-marked device indicated for Type-2 Diabetes under the EU's Medical Device Directives (MDD). As part of our transition to the EU's Medical Device Regulation (MDR), we have decided to keep the CE-marked device off the market whilst we expand our indication beyond Type-2 Diabetes and include the treatment of diet-related conditions. We are updating our Quality Management System and medical device technical file to support this expansion and the transition to MDR. We expect to finalise this process and transition to the MDR in 2024. [Note the Company at fact check (06 July 2023) clarified that whilst the Liva platform itself remains the same (it is the same data capturing and communication tool being used), that the CE certification is valid only to the Liva Diabetes version of the Liva Platform.]
		Company #4: Initial note for clarity: Chequp Health Limited sets itself apart from many other weight management companies by providing a personalised approach delivered through secure video consultations, which is facilitated through our proprietary online platform. We do not offer an app. We are committed to delivering a physician-led, person-to-person service that mirrors the NHS Tier 3 weight management services. Our virtual health platform ensures secure video consultations, seamless health record management, and enhanced customer communication. This reflects the way the global

		clinical trials for liraglutide and semaglutide were conducted, the NICE Technical Assessments (TA875 and TA664), and the May 2023 Final Scope document for the Early Value Assessment. When we use the word "virtual," we mean genuine, direct human interactions facilitated by video technology (people are meeting, virtually). All behaviour changing strategies such as physical activity / dietetic support and motivation are provided by real people, not bots! We have received advice that the CheqUp digital health platform does not need to be CE / UKCA marked as it is not a medical device. As mentioned above, we do not provide a pre-programmed app, rather a portal/platform which links our clinicians / physicians to our patients. All prescriptions, dietetic advice, psychological support,motivational advice etc are provided by people and the software performs no other functions than data storage, archiving, communications and search. It does not provide medical advice nor seek to replace or replicate the information which is provided by experts.
		Company #5: No, this is not planned as it is not intended to be used as a medical device.
		Company #6: As a clinical service providing regulated activities, we are regulated by the Care Quality Commissioners (CQC). [redacted] Roczen is the name of our proprietary care model and clinical service which, powered by digital technology, delivers care virtually. Within Roczen, we deliver two clinical programmes. • The Roczen programme is a digital weight management programme focused on lifestyle modification to improve metabolic health • The Roczen plus programme is a digital weight management programme that incorporates the lifestyle component and the prescription of GLP-1 medications. Roczen is not classed as a medical device as the technology involved underpins the clinical care delivered by the Roczen clinical team. As such, Roczen is not subjected to medical device regulatory approval.
		Company #7: As a nationally available provider of the NHS Healthier You: Diabetes Prevention Programme and the NHS Digital Weight Management programmes, we have undergone numerous assessments to ensure the safety and effectiveness of our programmes. These include: 1. The Digital Technology Assessment Criteria (DTAC) assessment 2. The Data Security and Protection Toolkit (DSPT) assessment 3. The National Information Board, Our Mobile Health and RSM UK review for the Digital Diabetes Prevention Programme Pilot 4. The NHS Apps Library assessment 5. The Quality Institute for Self-management Quality Training assessment 6. The NHS Digital DCB0129: Clinical Risk Management standard Based on previous contact with the Medicines and Healthcare products Regulatory Agency (MHRA), and our understanding of the regulations for the service we provide, the Second Nature smartphone application

		doesn't hold a CE marking and hasn't undergone approval by the MHRA in the UK. As a lifestyle change programme, Second Nature isn't considered a medical device, and as such, isn't subject to these specific regulatory approvals. For our programmes involving medication prescription, we collaborate with MDS Healthcare, an MHRA-approved and General Pharmaceutical Council (GPhC) regulated prescribing and dispensing partner. Should our service type necessitate a CE marking or MHRA approval in the future, we're prepared to undertake the required procedures to secure these accreditations, ensuring we continue to deliver a safe and effective service.
2	Does your technology meet the standards of Digital Technology Assessment Criteria (DTAC)? If yes, has your technology been through DTAC assessment? Or are there plans to within the next 12 months?	Company #1: Yes, the technology has been certified/passed DTAC.
		Company #2: Please see response to NICE Request for Information Question 3: The Oviva technology platform, called the Oviva Coaching Suite, including the Oviva app was DTAC assessed and passed. [redacted] The most recent DTAC appraisal was in 2023 [redacted] Again the Oviva Coaching Suite successfully passed this assessment. The Oviva Coaching Suite includes: ● Oviva App for patients ● Oviva Learn, a web-browser accessed learning portal for patients ● Oviva Patient Manager, an electronic patient record system for our Clinical Team. ● Oviva Administration Console, a patient administration system for our Patient Support Team.
		Company #3: The Liva app complies with the DTAC and has been assessed and deemed compliant by NHS England.
		Company #4: We believe that our technology meets the Digital Technology Assessment Criteria (DTAC) standard and we are currently undertaking the assessment. We expect this to be completed by the end of July 2023 and would be delighted to provide you with an update on work-in-progress or the completed documentation when completed.
		Company #5: Yes, it meets these standards and has been through the assessment.

		Company #6: We are in the process of finalising our DTAC assessment, and we have a high degree of confidence that we will be DTAC certified within the early part of Q3, in advance of the September 20th publication date to the NHS. Since 2022, we have been working with the Organisation for the Review of Care and Health Apps (ORCHA). We have completed an ORCHA Baseline Review (OBR) of our information technology in which Roczen scored positively. The satisfactory outcomes of the OBR assessment, which covers many of the measures included in DTAC, provides us with the quality assurance that Roczen will comply with standards set out in DTAC. We have developed our health information technology in line with the NHS Digital DCB Standards 0129 and 0160, and with a clinical risk management system in place.
		Company #7: Yes, Second Nature received DTAC approval in October 2022. Second Nature also holds the Cyber Essentials Plus accreditation, and regularly completes the Data Security and Protection Toolkit self-assessment, demonstrating our commitment to clinical effectiveness, data protection, and technical security. We continually align our practices with the latest standards in digital health technology to ensure safety, efficacy, and security for our users.
3	Is your technology currently used in the NHS? If yes, can you provide the total number of centres using your technology across England?	Company #1: Yes. The technology is used across 8 centres to provide weight management services.
		Company #2: Please see response to NICE Request for Information Question 10 for full list of English NHS Integrated Care Systems (ICS) and Scottish Health Boards where Oviva is delivering Specialist (Tier 3) weight management services, supported by the Oviva App: RFI 10): Oviva is currently commissioned to deliver our T3 WMP in [redacted] NHS regions. In all of these services Oviva provides a vertically integrated service including all HCPs and the Oviva technology platform. **English Integrated Care Systems (ICS)** [redacted] **Scottish Health Boards** [redacted] Oviva can provide assessments for patients being considered for Tier 4 Weight Management and onward

		referral to these specialist centres. [redacted]
		Company #3: Yes. The Liva app is used across England as part of the NHS Digital Weight Management Programme, and then is available across the following sixteen ICBs in our other programmes: Tier 3 Weight Management Programme: • NHS Somerset (available to patients across the whole South West) NHS Type 2 Diabetes Path to Remission: • Lancashire and South Cumbria NHS Diabetes Prevention Programme: • Birmingham and Solihull • Bristol, North Somerset and South Gloucestershire • Buckinghamshire, Oxfordshire and Berkshire West • Derbyshire • Dorset • Herefordshire and Worcestershire • Northamptonshire • Nottinghamshire • Shropshire, Telford and Wrekin • Hertfordshire and West Essex • Kent and Medway • North Central London • Surrey Heartlands • The Black Country
		Company #4: No, our service is not currently used within the NHS, although we have designed our weight management service to replicate the NHS Tier 3 weight management provisions.
		Company #5: The App is used as part of the NHS Digital Weight Management that is available all across England.
		Company #6: Roczen has been recently approved for use in NHS patients at ICS level to provide digital weight management services.

		It was launched in the UK in 2021 and currently operates via business-to-business-to-consumer and direct-to-consumer cohorts. Roczen has supported NHS staff members through employee wellbeing initiatives at Dartford and Gravesham Trust, and Chelsea and Westminster NHS Foundation Trust. Roczen provides large scale employer programmes for the likes of TFL, His Majesty's Prison Service and Network Rail.
		Company #7: Second Nature is currently commissioned by NHS England to provide the NHS Healthier You: Diabetes Prevention Programme (NDPP) and the NHS Digital Weight Management Programme (DWMP). The NHS DWMP we provide is designed to be a fully digital 12-week weight management intervention, while the NDPP programme is a more intensive 9-month intervention where we also send participants wireless weighing scales, a nutritional handbook, and a recipe book to help participants reduce their risk of developing type 2 diabetes through lifestyle changes. We also work directly with individual NHS Integrated Care Systems (ICSs) to provide type 2 diabetes structured education combined with behavioural change support. Since 2016, we have delivered our NHS-commissioned programmes to over 60,000 publicly funded participants through 2 national public health initiatives, more than 21 Integrated Care Systems and Local Authorities in England, and 9 health boards in Scotland and Wales. Second Nature is currently not commissioned by the NHS to provide tier 3 and tier 4 weight management services. However, we have extensive experience and a proven track record in delivering high-quality tier 2 weight management programmes and the more intensive NHS Healthier You: Diabetes Prevention Programme. More recently, we have expanded our capabilities with the launch of our medication-assisted programme. This new offering allows us to prescribe medications and provide access to specialised clinicians, equipping us with the necessary tools to deliver a safe and effective tier 3 weight management service. Building on our success and experience, we are now actively exploring opportunities to pilot a tier 3 weight management service with different health economies, including NHS Highlands in Scotland. We are confident in our ability to deliver this service effectively, given our extensive experience, proven outcomes, and newly expanded capabilities.
4	What is the process for patients to be referred in to use your app (self-referral, via GP, via secondary care or other)?	Company #1: Patient referral into the app can occur via self-referral, GP and through secondary care providers. It can also come from local authority-run Wellbeing/Lifestyle Hubs.
		Company #2: Please see response to NICE Request for Information Question 4 d): Given the complex medical needs of the patient population in a Tier 3 Weight Management Service and the NICE and NHS England eligibility criteria for such a service, it is essential any medical teams assessing the patient within a T3 WMP have full access to their medical history and medications with a minimum referral dataset to check their eligibility and ensure safe delivery of care.

		Therefore, Oviva requires patients accessing the Oviva T3 WMP to have a GP referral form completed with this minimum dataset. Oviva's Patient Support Team checks the referral form to ensure it is fully completed, and contacts patients to onboard them onto our T3 WMP. Patients are not given access to the Oviva app until this eligibility and minimum dataset assessment has been completed. We have noticed a rise in private self-pay services offering GLP-1RA medications where patients are not referred by their GP. These providers will not have the appropriate medical information in order to safely assess them and provide specialist HCP support, or to assess whether it is safe to commence GLP-1RA medications. Indeed there was recently an investigation by the Guardian on this topic (https://www.theguardian.com/society/2023/may/10/online-uk-pharmacies-prescribing-weight-loss-jabs-to-people-with-healthy-bmi-investigation), with the summary: *'Online pharmacies operating in the UK are approving and dispatching prescriptions of controversial slimming jabs for people of a healthy weight, a Guardian investigation has found.'* To maximise patient safety within NHS Tier 3 Weight Management Services, we feel it is essential all digitally-enabled weight management programme providers must be Care Quality Commission registered and regulated, and to have appropriate access to minimum datasets from GPs in a referral form format, in order to provide safe care.
		Company #3: Our referral process varies depending on the programme we provide and the customer/commissioner we are working with. Most of our programmes (including our Tier 3 Weight Management Programme) are accessed by GP referral. However, we do accept referrals from secondary care (should inclusion criteria allow), and some of our programmes, including the NHS Diabetes Prevention Programme, have introduced self-referral pathways. We also offer a direct-to-consumer extension product that can be accessed post-programme completion.
		Company #4: At present, the service is based on self-referral or by private doctors who can refer to an email address. We anticipate that our platform will be adapted to connect directly to the NHS through an API or similar connectivity.
		Company #5: Service users would need a GP/ NHS referral, it could also be configured for self-referral but is not currently used in this way.
		Company #6: Patients can self-refer into the programme using a digital assessment available on the website or the mobile app. Eligible patients identified by GPs or other healthcare professionals can be referred by sign-posting patients to the website or mobile app.

		We performed multiple stages of eligibility and suitability checks before initiating a patient on the programme. 1. Initial eligibility screen - This is done via a digital assessment on the patient web app. Patients are required to answer multiple questions to ascertain their initial suitability of the programme based on the exclusion criteria detailed in Appendix: List 1. These criteria are routinely reviewed by our MDT. Patients will be informed of their initial eligibility for the programme. Only those who are eligible will be allowed to proceed to the next stage to complete their registration on the system. For example, those that disclose type 1 diabetes (an autoimmune condition), will not be given the option to subscribe. 2. Clinician assessment - A GMC-registered doctor will review the initial screening responses and further validate this via a virtual consultation. The doctor will also review the patient's Summary Care Record and validate relevant information with the patient as part of the process. A patient's eligibility to commence the digital weight management plan is confirmed by a clinician in this virtual consultation.
		Company #7: We operate a number of referral models across the UK: 1. Clinicians (e.g. GPs, nurses, dietitians) can refer patients directly to the Second Nature programme based on local eligibility criteria. 2. Via the NDPP and NHS DWMP, users are referred to a central hub before being triaged to our services based on a number of criteria including patient choice, demographics and health profile. 3. Patients can also self-refer to Second Nature. Individuals are screened prior to sign up to ensure they meet eligibility criteria. Upon receiving an NHS referral, participants receive a unique signup link via email and text, ensuring secure access and accurate data tracking. They are then guided to our app, introduced to their health coach, and given access to resources. If signup is delayed, we initiate a follow-up process with reminders and phone calls to encourage participation. In addition to the NHS referral pathway, the public can directly access our service. They simply need to visit our website, answer a health assessment form which then recommends an appropriate programme based on their answers. For our medication-assisted programme, we have a rigorous process in place to ensure that medication is the best path forward for them. We ask the user questions on their weight and health history, check their Summary Care Record, and also perform a know-your-customer check to confirm that they are a real person. With their permission, we also share this information with their GP to ensure they are given the best care possible. Both of these pathways are designed to provide wide access to our programme, allowing as many individuals as possible to benefit from our comprehensive and personalised weight management plan.
5		Company #1:

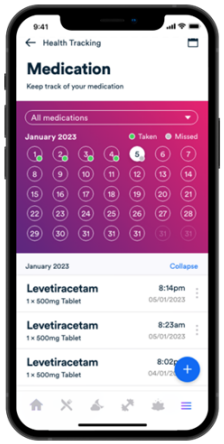
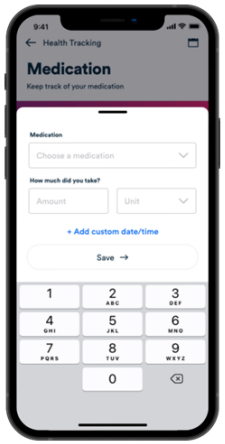
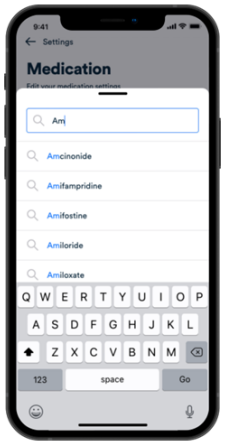
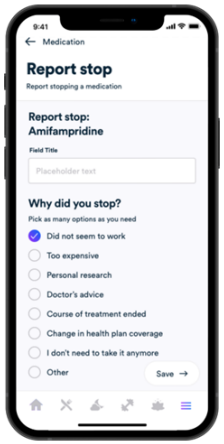
	Is your technology available in a language other than English?	Yes. The technology is available in: English, Welsh, Arabic, Hindi, Bengali, Gujarati, Punjabi, Tamil, Urdu, French, German currently; and will be available in Polish, Spanish and Portuguese in November 2023.
		Company #2: Please see response to NICE Request for Information Question 8: Where English is not the patients first language: [redacted] we match patients with HCPs who are able to speak their first language and who understand their specific cultural background and cultural drivers of behaviour. Where we don't have staff that speak that language, we use NHS approved ClearVoice translators. All learning materials can be translated into the appropriate language for those whom English is not their first language.
		Company #3: Yes – it is available in twelve languages: English, Bengali, Danish, Dutch, Finnish, French, German, Norwegian, Polish, Punjabi, Spanish and Swedish. In addition, our Health Coaching team speak over 20 languages.
		Company #4: Elements of our service can be provided in Spanish and Italian and other languages could be made available at short notice if required. One element of our service – a live one-to-one chat service with members of our team, called "WaitLess by CheqUp" - is provided through WhatsApp. Online translation services allow us to offer this in almost any language.
		Company #5: The base language of the App is English. Online learning resources are also available in Hindi and Polish.
		Company #6: Not at present. However, there are plans in our product roadmap to release multiple languages in the Roczen platform.
		Company #7: Second Nature offers the programme in 10 different languages, including English, Polish, Urdu, Hindi, Arabic, Gujarati, Bengali, Tamil, Chinese, and Punjabi. These languages were chosen to represent the highest proportion of non-native English speakers in the UK. Additional languages spoken in specific locales, such as Portuguese, French, or Spanish, can also be implemented upon request by commissioners.
6	Have any users reported access issues (e.g. patients with learning disabilities, or non-English language speakers)?	Company #1: There have been no reported user access issues. We have conducted significant PPIE (please see our pending-publication paper here) with tier 3 and tier 4 service users to ensure accessibility. The platform is available 24/7 as an app, website, smart app via TVs and speakers, smart assistants (Google Assistant,

		Amazon Alexa) and has a digital exclusion provision also. We have seen a preference for patients having both a digital exclusion pack and app to feel further supported (for instance, using the Meal Plans in the kitchen, using the app to speak to a coach or track weight). An Easy Read version of the programme is also available for people with learning difficulties.
		Company #2: Please see response to NICE Request for Information Question 8. We support all patients to access our services where at all possible, and have no patient reported access issues: Oviva has a dedicated team, our Programmes Team, who are responsible for continuously maximising the patient benefit of our T3 WMP, and this includes maximising access to care. Oviva has co-developed our T3 WMP with people living with obesity, and we recruit Champions who have been through the programme to engage in focus groups around how to maximise access and outcomes. Furthermore, the Programmes Team monitors any differences in referrals, uptake and retention by protected characteristic compared to the local population so we ensure no patient group is disadvantaged. We have the following solutions to maximise access and overcome barriers: A) Where English is not the patients first language: [redacted] we match patients with HCPs who are able to speak their first language and who understand their specific cultural background and cultural drivers of behaviour. Where we don't have staff that speak that language, we use NHS approved ClearVoice translators. All learning materials can be translated into the appropriate language for those whom English is not their first language. In 2022 Oviva won a Health Service Journal award for tackling health inequalities. This was awarded to recognise work in our diabetes service in a highly diverse area (Barking and Dagenham) - people living with Type 2 diabetes were linked remotely with dietitians and health coaches outside of the area to deliver care through the Oviva App in the patient's first language (in total care was delivered in 10 languages). B) People with cognitive disabilities: We screen for significant cognitive disabilities in our onboarding journey. If they are identified we support people to access the programme via a carer or family member, and that carer/family member helps the patient decide what is the best way of engaging, e.g. via app, video-calls, telephone calls or in-person. All learning materials are specifically designed for the UK population average reading age (8), and HCPs can signpost to visual content sources if needed C) Visual impairment: We screen for any impairments or disabilities in onboarding. People with visual impairment are supported to access the programme via a carer or family member, or they can complete it

		themselves via phone calls only. Our content is available in web text to speech formal so it can all be covered audibly. D) No or limited digital literacy: We screen for digital literacy and offer options of 1) signposting to local digital literacy courses, 2) accessing the programme via a carer or family member, or 3) accessing the programme as phone calls or in-person with a printed hardcopy Guidebook. E) Who do not have access to the internet or a smart device: We screen for access to the internet or a smartphone during onboarding and provide alternative options including telephone or in-person appointments supplemented by a printed hardcopy Guidebook
		Company #3: We work closely with individuals to identify and address access barriers and ensure our programmes are both suitable and accessible. We provide patients with detailed information on the Liva programme to allow them to make an informed choice. Our 30-45-minute onboarding session allows both coaches and patients to determine if the programme is suitable. Our health coaching team speak over 20 languages, and we are always recruiting coaches with additional languages as the need arises. Patients must have a smartphone and access to the internet in order to participate in the Liva programme, but our coaching team provide step-by-step guidance to those that are less digitally literate and require additional support. The app may not be suitable for those with severe learning disabilities, but we work with carers and family members to provide additional support.
		Company #4: No. We have designed the system to be very easy to use regardless of language, access, disabilities etc
		Company #5: The App can be configured to support those with learning disabilities to increase/reduce font size and bi-colour contrast options are available to aid with visual impairment and reading disabilities. The App is not used in isolation but is used alongside health coaching support and guidance.
		Company #6: We haven't had reported issues to date related to the accessibility of the web and mobile apps. We believe we are close to WCAG 2.0 level AA with an active project to close the gap on ensuring we meet all accessibility criteria.
		Company #7: We have continually developed the accessibility of our digital programmes through our extensive experience supporting participants with a wide range of needs, both commercially and in partnership with the NHS. We have a deep understanding of how to tailor our advice to certain groups, including those with cognitive or physical disabilities or limited digital literacy, who may face challenges when accessing our

		digital programmes. However, we are committed to inclusivity and have implemented several strategies to enhance accessibility: 1. Cognitive Disabilities: We provide personalised and sensitive support to individuals with cognitive disabilities. Our health and nutrition guidance is delivered in simple, jargon-free language. Our health coaches work closely with each participant, and their carers if applicable, to assess the level of support required and tailor the programme to their needs. We have had many successful participants with learning disabilities and work in partnership with Darlington council to deliver a learning disability tier 2 weight management service. 2. Digital Literacy: We recognise that digital literacy can vary across different demographics and that areas of high deprivation can suffer from digital exclusion. To address this, we have trained our customer support team to assist patients with using our technology and have developed walkthrough guides. Our application is designed to mimic popular applications for a familiar user interface, and it can be accessed via any computer through a web app. We have successfully supported people in the past to access the programme with the support of carers or at their local library. 3. Physical Disabilities: We offer tailored physical activity recommendations and specialised programmes for individuals with mobility issues, such as a knee injury programme and chair-based exercise videos for people living with osteoarthritis and other physical disabilities. For our medication assisted programme and complex patients, the exercise specialist within our MDT can provide more personalised recommendations. 4. Visual Impairment: For users with a visual impairment, we provide audio versions of our content in-app and ensure compatibility with screen reading software. A video case study from a visually impaired OurPath/Second Nature participant can be viewed here. 5. Multilingual support: As mentioned in question 5 we currently offer the programme in 10 different languages. Additional languages can be implemented upon request. We acknowledge that these patient groups might initially face difficulties in accessing our technology. As a result, we have put extensive measures in place to support these individuals and ensure the broadest possible access to Second Nature. Our aim is to provide an accessible and beneficial service to all patients, irrespective of their individual challenges.
7	Can you please check that the tabulated information in the Appendix is correct for your technology? (please track any suggested changes).	Company #1: Yes, please see tracked changes in red.
		Company #2: We have updated this directly into the Appendix
		Company #3: Please see the changes to the table (with tracked changes applied).
		Company #4: The information is now correct in the version below.

		You have rightly identified that, within the private sector, the service depends on the support package which is paid for (https://chequp.com/pages/weight-loss). However, within the NHS we would prefer to offer our Empower support package which provides the most accurate method of recording patients' weight, which aids compliance and patient motivation.
		Company #5: No additional response (appendix updated)
		Company #6: Please see the updated table in the Appendix.
		Company #7: We have added the information into the Appendix
8	In terms of medication: a. Does your service include in-house prescribing of weight loss medication(s)? b. If so, which medications do you prescribe? How frequently are user prescription plans reviewed? c. Does your platform measure adherence to weight loss	Company #1: a. Yes. In W8Buddy this is the local MDT team; and in W8Buddy+ is DDM's in-house prescribing team. b. Frequency of reviews are at baseline, 2-weeks, and then every 3 months from baseline; and if any anomalies/concerns appear on-demand. c. Weight loss medication adherence is reported digitally through a medication tracking tool, and virtually with health coaches and scheduled appointments with pharmacist/physician appointments. Symptom tracking monitors adverse effects, and any medication-related adverse effects are reported to MHRA. Questionnaires further track/confirm medication adherence and adverse events. The MDT team meets bi-weekly.

		medication and record any adverse effects? Is this done virtually through the app (self-reported) or are there regular meetings with a member of your MDT team?	 **Medication tracking**  **Save medication, dosage and time**  **Search/track a range of medications**  **Report stopping a medication**
			Company #2: a. Please see response to NICE Request for Information Questions 4 e) and 15. Yes Oviva's service includes in-house-prescribing of weight loss medication(s), this is led by qualified practitioners under our Care Quality Commission Registration. b. Please see response to NICE Request for Information Questions 4 e) and 15. We currently prescribe Liraglutide (Saxenda), and the option to prescribe Orlistat via the person's GP. We are able to prescribe Semaglutide (Wegovy), however this medicine is not yet available in the UK. **Patients prescribed a medication go onto our medication pathway**: Service users receive a nutrition and physical activity focussed pathway in addition to the prescription of a GLP-1RA medication (including, but not limited to Saxenda/Liraglutide and Wegovy/Semaglutide) and associated support. The pathway lasts 24 months and consists of 20 sessions of support from specialist weight management dieticians, health coaches and specialist nurses. The pathway will include the following: The Provider's change phase (months 0-3): ● 3 follow-up care appointments with specialist weight management dietitians to help with dietary weight loss and GLP-1 medication side effect management.

		● 4 sessions or reviews with specialist nurses to prescribe, titrate and monitor the GLP-1 medication effectiveness and side effects. The Provider's sustain phase (months 3-24): ● 6 coaching appointments with specialist weight management dietitians to make necessary adjustments to diet habits and plan for the future (e.g. avoiding weight gain following GLP-1 Medication cessation). ● 7 sessions or reviews with specialist nurses to monitor and prescribe the GLP-1 medication. GLP-1 medication pathway governance Oviva will monitor service users taking GLP-1 medication during their regular consultations with specialist weight management dieticians and specialist nurses. In addition, service users can upload their weight, medication dosing and side effects (including nausea and vomiting), in the Oviva App, or in paper diaries. The medically-led multidisciplinary team will provide oversight of and support the monitoring process, continually assessing the appropriateness of ongoing GLP-1 medication prescriptions in line with their licences, as well as advice and guidance on side effect management. If a service user meets the criteria for discontinuation of GLP-1 medication, for example, not achieving 5% weight loss at the requisite time from initiation of maximum dose (12 weeks for Saxenda and 6 months of Wegovy), a specialist nurse team will provide the appropriate support and advice to do so. See Attachment 8 which includes a summary of weight loss and dose tracking data from our GLP-1RA cohort in Switzerland. c. Please see response to NICE Request for Information Questions 4e) and 15. Please also see response 8b above. RFI 4e): All referrals into the Oviva T3 WMP are from the patient's GP, which includes a comprehensive medical history and minimum dataset in the referral form. Patients are screened for eligibility for the Tier 3 Weight Management service before being accepted. All patients accepted into the service have a Bariatric Physician Assessment to consider safety for the programme, as well as eligibility for weight management medication. The Bariatric Physician is a SCOPE Certified Consultant Endocrinologist ([redacted]), supported by a SCOPE Certified GP with Special Interest in Obesity and Diabetes ([redacted]

		[redacted]). SCOPE Certification (https://www.worldobesity.org/training-and-events/scope) is the only internationally recognised obesity management qualification. We use bespoke guided data capture forms to ensure best practice standardised screening assessments made as per NICE guidelines. Patients are screened against the eligibility criteria for weight management medication prescription in line with NICE and medication guidance. To ensure safe and appropriate prescribing screening this includes: All referral information received via the GP and the Summary Care Record is reviewed for: ● Eligibility for treatment (e.g. for Saxenda HbA1c, CVD risk factor, BMI≥35) ● Contraindications or cautions present to treatment ● Current medication ● Any recorded allergies ● Any communication difficulties or disabilities ● Any suggestion the patient may have a condition that could impair their capacity ● Any safeguarding concerns on record The Dietitian Initial Consultation is used to review for: ● Change in medical status since referred ● Change in medications since referred ● Relevant social history ● Any other concerns or patient preferences recorded We specifically screen for and seek information around any potential disordered eating or medication misuse, and if this is identified. If risk of an eating disorder is identified at this stage patients are discharged back to their GP with a request for an eating disorder assessment. For patients who are appropriate for GLP-1RA therapy, and choose to go onto this pathway, they have a comprehensive Onboarding Appointment with an Obesity Specialist Nurse [redacted]. This includes: ● The Nurse uses bespoke guided consultation templates aligned to the GMCs 'Remote prescribing high level principles' to ensure best practice embedded throughout the team. ● Issuing the prescription via our pharmacy partner [redacted], who then dispenses the medication sending it to their home address within 48 hours [redacted]. Patients are given direct access contact details for pharmacy partners to coordinate deliveries or address issues where needed.

		● A bespoke, secure prescribing platform is used to generate the prescriptions, which meets all NHS Cyber Security requirements and all statutory electronic prescribing legislation Following initiation: ● The patient has an intensive scheduled follow-up regimen with the Obesity Specialist Nurse during the titration period to individualise their onboarding journey based on tolerance, side effects and achieving appropriate adherence. ● Patient initiated Nurse prescriber contact also available at any time. ● The patient is requested to monitor their weight management medication dosing in the Oviva app, as well as weight loss progress which the Nurse can monitor remotely at each stage of treatment. If the patient is not using the Oviva app, the patient must still record this information and provide it to the Nurse during phone appointments. Required weight loss assessment for ongoing prescription in line with the NICE TA is completed at the prescribed time points. ● For any concomitant medications that need adjustment, the Nurse provides guidance in writing to the patient and their GP with recommended amendments. ● Weight loss outcomes are audited regularly and benchmarked against published outcome data, and we also submit data to the NHS National Obesity Audit as per the requirements of our NHS Tier 3 Weight Management Contracts. RFI 15): During our T3WMP, patients who are identified as eligible and appropriate for weight management medication, who commence this medication, are supported to track both medication, medication dosing, as well as weight and potential side effects related to the medicine. The Oviva app has specific tracking features for medicines, dosing, and weight, as well as potential side effects, with prompts/reminders that patients can set up to ensure these are captured regularly. For patients not using the Oviva app, we provide guidance about how to record medication, dosing and weight, as well as potential side effects. In terms of the frequency of tracking: ● Active medication is recorded when started ● Dosing: when taking the medication, e.g. daily for liraglutide. Note the patient is guided through their titration protocol by the Oviva Obesity Specialist Nurse ● Weight: approximately once weekly for the first 12 weeks, and then at least fortnightly from there ● Side effects: for the patient to log when encountered The Oviva T3WMP supports implementation of the NICE TAs for liraglutide and semaglutide, as both medications have a period of titration, as well as a review point for ongoing prescription based on achieved weight loss.

		The Oviva T3WMP and combined app supports a frequency of interaction to allow much more precise titration of dose than a face to face service, reduced side effects and complications, better patient experience and reduced waste of medicines. Our current UK performance data is shown in Attachment 3. Unpublished Internal Data: Eligibility, uptake and outcomes relating to Liraglutide (Saxenda) in Oviva's digitally enabled UK Tier 3 weight management services. Furthermore, we have data from our T3WMP in Switzerland in Attachment 8 Unpublished Internal Data: Clinical and service outcomes relating to Liraglutide (Saxenda) in Oviva's digitally enabled specialist weight management services in Switzerland
		Company #3: a. Not at present, but we have an in-house GP and are considering expanding the team to include additional clinician prescribers. We are exploring CQC registration to allow us to add in-house prescribing and medicines management to our service in future. b. We do not currently prescribe weight loss medications in-house. We have previously, however, in cooperation with prescribing partners, supported patients who are using weight loss medication - specifically: measured adherence, monitored and reported side effects, and provided personalised healthy lifestyle coaching focusing on physical activity and nutrition as an adjunct to medication. c. Yes, the Live app has the functionality to measure medication adherence. This has formed an important component of our partnership with a prescribing partner supporting individuals taking Saxenda. Adverse events are identified by several means: • Face-to-face (remote) communication between member and health coach during a live video interaction • Asynchronous video or text message from member to health coach • In a goal-tracking note inputted by a member onto the Liva platform. • In a group chat inputted by a member onto the Liva platform On our NHS Type 2 Diabetes Path to Remission Programme, we also have an adverse event keyword alarm system which automates an alert to a clinical inbox in the event of a potential adverse event being reported by a patient. This inbox is monitored daily by a Service Manager. Our health coaches regularly monitor all patient communications from their caseload.

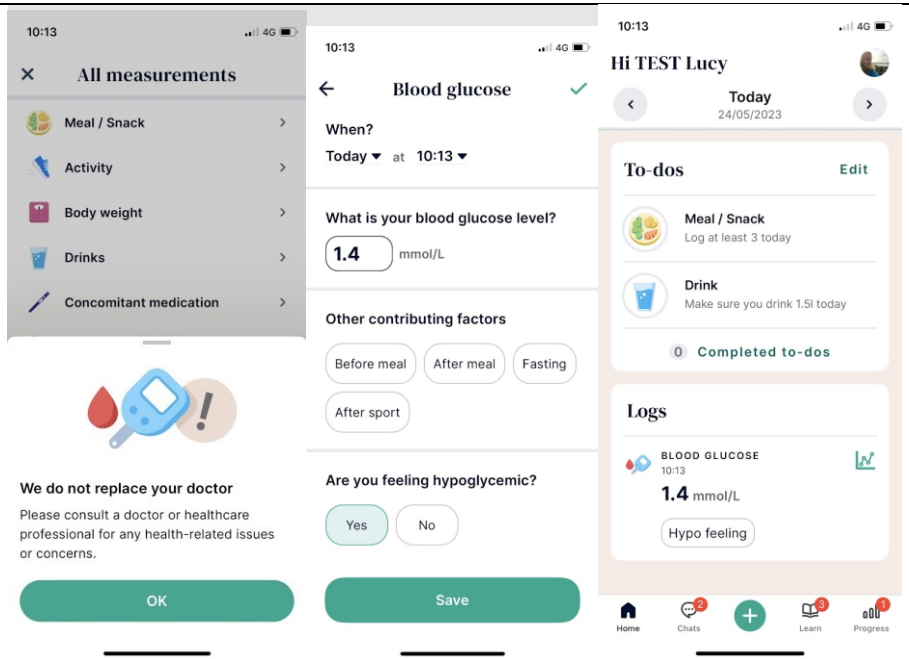
		Liva has an Adverse Event Policy as well as an Escalation Framework, developed by our in-house clinicians, to ensure that any clinical concern is appropriately and promptly escalated internally and/or to the patient's GP as indicated.
		Company #4: a. Yes b. We currently prescribe liraglutide, semaglutide (oral form), and dulaglutide. We anticipate offering semaglutide 2.4mg (Wegovy) and Tirzepatide 15mg (Mounjaro) when these are available within the UK. Our user prescriptions plans vary subject to the medication – for example, the dose titration stage for Saxenda (liraglutide 3mg) is five weeks but for Rybelsus (oral semaglutide 15mg) it is two months and for Wegovy it would be four months. We have direct person-to-person contact at least once per week with our patients and their titration and progress is discussed at our monthly MDT. c. We recognise the importance of monitoring weight for good medical practice, licence adherence and to identify non-responders. We perform this through two mechanisms: We have weekly virtual person- to-person conversations with all our patients at which we monitor their weight. Secondly, we can offer a service where we provide people with a set of digital scales (and wearable device, if required) which allows us to monitor weight remotely. Subject to cost, this is our preferred way of working with NHS-referred patients.
		Company #5 a. Not currently for weight loss although we have a relationship with Pharmacy2U for the prescription of medication. b. regular meeting with MDT c. This is done via the appointments with the MDT.
		Company #6: a. Yes b. Medications we prescribe are as below: Saxenda Ozempic Rybelsus Wegovy (when available in the UK) Prescriptions are reviewed every 3 months but patients are followed up by a metabolic health nurse monthly. c. Yes. We measure adherence to medications and record adverse effects. This is done by our trained metabolic health doctors and nurses through the clinic web app. Patients are also able to report any side effects to our clinicians via messaging and/or through regular consultations.
		Company #7:

		a. We currently prescribe through our partner, MDS Healthcare, who are MHRA-approved and GPhC regulated for prescribing and dispensing. b. [redacted]. c. We have monitoring systems in place for adherence to weight loss medication and also record any adverse effects. This is done virtually through the app, but can also be shared with the MDT team through the chat functionality of the app.
9	In terms of the MDT: a. Is each member of the MDT exclusively employed by the NHS, or do they work within the private sector? b. How frequently does your MDT meet? c. Is this done via telephone, video call, messaging via the app? d. Is information communicated to users via group support or 1:1 meetings? e. Does your MDT have clinical governance, or does responsibility for the patient's weight management continue under the referrer?	Company #1: a. In W8Buddy, each member is exclusively employed by the NHS. In W8Buddy+, they work within the private sector and employed by DDM. b. Daily. c. The MDT meet each other virtually over teleconferencing or face-to-face meetings. They communicate with patients via telephone, video call and in-app messaging. d. Yes. The app provides i) private in-app coaching; ii) group in-app coaching; iii) schedule 1-to-1 appointments with MDT/psychotherapist/health coach; iv) virtual meetups/sessions (held over teleconference); v) digitally via video delivered through the digital platform. e. The MDT has clinical governance oversight. Company #2: a. Oviva employs all of the HCPs delivering our Tier 3 Weight Management Programme (T3WMP). Those HCPs are often full time with Oviva, though some of those clinicians also maintain an NHS role. b. MDT meetings are at least weekly, or more often if needed. Members of the MDT include: ● Bariatric Physician, a Consultant Endocrinologist ● Bariatric Physician, a GP with Special Interest in Obesity ● Obesity Specialist Nurse ● Obesity Specialist Dietitian ● Clinical Psychologist ● Psychological Wellbeing Practitioner ● Registered Nutritionist ● Physical Activity Specialist c. MDT meetings are undertaken by video conference. d. All information and decisions from MDT meetings are communicated with patients in 1-to-1 meetings, ensuring appropriate patient confidentiality. e. Please see response to NICE Request for Information Questions 7 and 14.

		Oviva's MDT team are responsible for weight management of the patient whilst enrolled in our T3WMP and we have appropriate Clinical Governance to ensure safe care. Other conditions remain under the care of the patient's GP. RFI 7): As a CQC Registered Provider of T3 WMP, robust Clinical Governance is critical to Oviva's ways of working. Our Head of Clinical Quality oversees our approach to training, working in partnership with our People Team to ensure it is implemented. We have an in-house Learning Management System (LMS) with in-built quizzes of minimum knowledge levels to support effective training and monitoring. There are 3 key groups that are trained on delivering the Oviva T3 WMP and using the associated Oviva app: ● Oviva HCPs delivering the service ● Oviva Patient Support Team who onboard patients onto the service and deal with any technical support questions ● Patients referred and enrolled in the programme Detailed training is required to safely deliver specialist weight management care to a cohort of patients with complex medical needs. Our training is developed as follows: ● Our Head of Quality oversees our Clinical Governance training, supported by our Compliance Manager who provides Information Governance training and our Safeguarding Lead who has developed our safeguarding training. ● Our Programmes Team and Clinical Leads (Bariatric Physician, Obesity Specialist Nurse, Obesity Specialist Dietitian, Clinical Psychologist) develop the training on the T3 WMP curriculum, clinical knowledge and skills and content. ● Our Programmes and Product Team develop our training on the Oviva Coaching Suite, including the Oviva app, Patient Manager and Admin Console. They have developed specific training for our HCPs, Patient Support Team and patients. ○ HCP training covers the Patient Manager and the Oviva app, including best practice in supporting patients to use the app and delivering care via video call as well as asynchronous messaging. This includes ensuring HCPs are competent at using behaviour change techniques through the combination of app functionality and coaching (e.g. goal setting, self-monitoring and education). ○ Patient Support training covers the Admin Console and the Oviva app, including best practice in supporting patients to onboard to the app and how to deal with technical questions ○ Patient app Guide (including highlighting features, explaining its use and how to get the best benefits out of it) is embedded within the T3 WMP onboarding materials, and when first logging into the app it guides you through all of the features. Furthermore, patients are

		supported in using the app by their HCP Team and can reach out to the Patient Support Team at any time with technical questions. Disordered eating and the potential for medication misuse is a critical topic for safe delivery of T3WMP. Oviva's mandatory training includes emotional eating, disordered eating and linked contraindications for weight loss, as well as our screening approach to identify disordered eating. This is all delivered and monitored via LMS and the HCPs' Clinical Team Manager. Our Training Coordinator and T3 WMP Patient Support and Clinical Team Managers ensure all Patient Support and Clinical Staff receive training. All staff receive 2 weeks mandatory onboarding training, with clinical supervision and refresher training provided at least monthly and led by the respective team. The majority of training is remote via video call, with quarterly in-person training. Patients can also contact our Technical Support Team via email, [redacted]Our experience is that patients find the app intuitive, especially the messaging functionality, and that follows us doing extensive user testing to ensure the app is intuitive. Importantly, HCPs are delivering care using a different methodology (asynchronous app chats and video calls) than their original training (typically in-person) and it is critical that providers take a rigorous training approach. Lastly, our Clinical Lead Dietitian, Bariatric Physician and Service Managers train referring GPs and referring primary care staff (e.g. care coordinators) on the Oviva T3 WMP as they will identify eligible patients and refer them, and these GPs/primary care staff need to accurately describe its benefits and approach. We supplement this with patient-facing resources e.g. our website https://oviva.com/uk/en/programmes/tier-3-weight-management/ RFI 14): When accessing the Oviva T3 WMP, there are general risks associated with weight management services, including a high incidence of need for diabetes and hypertension medication titration following significant dietary changes and weight loss. Furthermore, due to people in weight management services having Class III obesity, they are at high risk of complications from their condition e.g. cardiovascular events, cancers and gallstones. As a core part of the Oviva Clinical Governance Processes, Oviva has an Adverse Events and Incident Management Policy for any arising clinical issues associated with risk of patient harm. [redacted]HCPs delivering the programme report all incidents via Oviva's internal reporting system. All incidents are reviewed by trained members of the senior clinical, safeguarding and compliance team. Assessment of incidents follows a standardised process to help ascertain if the incident was caused by Oviva care (including preventability), if duty of candour is required, level of severity and likelihood, and if the incident was a serious incident or never event. In the event of a serious incident or never event, Oviva reports to

		commissioners as per contractual requirements, ensuring internal investigations and learnings are shared to support patient safety and reduce future risk. Incident trends are audited quarterly by the Medical Lead, with learnings and patient safety improvement initiatives reviewed in the Clinical Governance meeting. HCPs delivering the programme are appropriately supported by our Bariatric Physician if there are any potential medical emergencies. Safeguarding support is provided via a senior clinician rota which all HCPs have access to. Quarterly Clinical Governance meetings discuss any arising Adverse events as part of a continuous learning culture. Specifically on the medicated aspect of the pathway and use of GLP-1RA medications within a Tier 3 service, there are known side effects of these medications, which are closely monitored for and managed by the Oviva Obesity Nurse supported by the wider HCP team. In all T3 WMP communications, we clearly state what patients should do in an emergency in line with standard NHS guidance. When specifically considering the Oviva app which is a Class IIa medical device: ● Please see Attachment 17 Oviva's Instructions for Use document. ● During the onboarding to the Oviva app, we clearly state the chat feature should not be used in an emergency, and rather they should contact emergency services. ● The Oviva app does not provide alerts for out of range readings (e.g. of blood glucose and blood pressure). Patients are instructed to discuss their results with the Oviva HCP or their GP if concerned, as shown in the screenshots below. If an out of range reading (e.g. blood glucose or blood pressure) is identified by the Oviva HCP delivering the T3 WMP, the incident is reported via Oviva's internal reporting system for senior clinician support and assessment.



Company #3:

a. Liva is a private provider whose services are commissioned by the NHS. Our MDT is employed by Liva. Many MDT members (including health coaches and our in-house clinicians), also work within the NHS in varied capacities (e.g., dietician, GP, nurse etc).
b. Our MDT members are in daily communication (or can be) during the working week, in addition to scheduled clinical team meetings held at least monthly either remotely or face-to-face.
c. This communication may occur via email, secure messaging service (Slack) or video call.
d. Information is communicated to patients securely via the app. This could be in the format of live 1:1 video calls, private video messages from the health coach, or private text messages from the health coach. All three of these methods are carried out via the Liva app. Some programmes also have a group-based component via our health coach-moderated group.
e. Currently, patients on a Liva weight management programme remain under the principal care of their GP/referring clinician. The GP/referring clinician retains responsibility for medicines management.

		As good practice, however, Liva does have a Clinical Governance Framework (which includes our Adverse Events and Escalation Policy and our activities to ensure clinical effectiveness and quality improvement), overseen by our in-house clinicians.
		Company 4#: a. Our MDT members are employed within the NHS and the private sector b. Monthly c. Via video call d. All information is provided to users / patients in one-to-one meetings which take place virtually e. Our MDT has clinical governance
		Company #5: a. The MDT are employed by the Acacium Group. The Clinical Medical Director works part time for Xyla Health and Wellbeing and is also employed by the NHS. b. Depends on programme it can be weekly, bi-weekly or monthly. c. This is dependent on patient choice d. The App facilitates both methods of communication e. Yes, the MDT is overseen by Clinical Governance.
		Company #6: All our GMC- and NMC-registered metabolic health doctors and nurses are permanently employed by Roczen on a full time or part time basis. The service is supported by a multidisciplinary team (MDT) of consultant endocrinologists, diabetologists, nephrologists, specialist weight management dieticians, and behaviour change specialists. These work predominantly in the NHS, with some seeing private patients outside of the NHS. The MDT meets weekly, or as needed, to discuss complex cases brought forward by the clinical team as part of the robust governance structure surrounding the Roczen model. It is conducted virtually via video to allow for a flexible and responsive service to meet the needs of the patients Outcomes of any MDT meeting are communicated to the respective patient 1:1 by their dedicated Roczen clinician, with any further management plans set and agreed with the patient As a CQC-registered service provider, Roczen has robust clinical governance processes in place. As long as the patient remains eligible on the programme, we assume responsibility for the patient's weight management. With the patient's consent, we communicate relevant clinical information with their routine care provider (eg. GP) or the referrer.
		Company #7: a. The members of our MDT work within the private sector. While some may have part-time employment with the NHS, this is not their exclusive employment.

		[redacted] c. The MDT meets via video call and also uses messaging to communicate. With users, the majority of the communication with the MDT is done via in-app messaging. When need arises, users can also communicate with their MDT via video call. d. Information is communicated in both group and 1:1 settings. Each user is assigned to a group of users with similar needs to them. This group is available to them throughout their entire journey with Second Nature and a health coach is present within the group. The user also has access to a 1:1 chat with a health coach, who works with the other members of the MDT to deliver the best support. When needed, 1:1 video meetings with MDT members are available. e. Our medication-assisted programme pathway is designed to have the highest level of clinical oversight. Prescriptions are reviewed every 4-weeks before the maintenance phase and prescribers have the opportunity to proactively reach out to the participants with any questions after their medication review. Our prescribing partner MDS Healthcare is regulated by the MHRA and regularly audited by the GPhC, ensuring that our prescribing activities are safe, effective, and in line with best practice guidelines. While we take on the responsibility of delivering a comprehensive and effective weight management service to the patient, we maintain a collaborative relationship with the patient's NHS General Practitioner (GP). This partnership ensures that the GP is kept informed about the patient's progress and any changes in their treatment plan, providing necessary context for their routine care.

<table>
<tr><td></td><td></td><td>When a patient is discharged from our care or that of our prescribing partner, we ensure a smooth transition by communicating all relevant information to the patient's GP. This approach ensures continuity of care and maintains the high standards of clinical governance required by both our team and the patient's primary healthcare provider.

In essence, while the patient is under our care, we assume responsibility for their weight management. However, we work closely with the referrer to ensure that the patient's overall health management is not compromised, and that the responsibility seamlessly transitions back to the referrer once our intervention is completed</td></tr>
<tr><td rowspan="2">10</td><td rowspan="2">What is the cost of the digital technology (please include initial purchase and any ongoing costs)?</td><td>Company #1:
We provide Tiered pricing, exclusive of VAT:<table><tr><td>Price per participant, per programme, per year</td><td>Less than 1,000</td><td>1,000+</td></tr><tr><td>W8Buddy</td><td>£390</td><td>£300</td></tr><tr><td>W8Buddy+</td><td>£840</td><td>£705</td></tr></table>Each additional programme extension (3 months) costs 25% of the per-licence cost.</td></tr>
<tr><td>Company #2:
Please see response to NICE Request for Information questions 16, 17, 18

RFI 16):
The pricing of the Oviva T3WMP is dependent on the volume of patients that we treat, and also the requirements of Oviva, for example how much support does primary care need with referral driving, and what the is the level of reporting back to NHS Commissioners that is needed (based on local contract KPIs).

For an ICB commissioning Oviva for [redacted] patients per year for a fully remote service, our current NHS price is [redacted] per patient (this is exclusive of VAT and we do not charge VAT as we provide a Healthcare Professional Service and under HMRC rules you do not charge VAT). This includes all HCP time, the Oviva app, and follow up for up to 24 months for those on the GLP-1RA pathway. We can offer price decreases for higher volumes of patients, and if referral driving is done by the local ICS.

Importantly, the Oviva price does not include any of the GLP-1RA costs including the medication, any pharmacy dispensing fee or consumables. Our pharmacy partner issued invoices directly to the local ICS</td></tr>
</table>

		medicines management team. This is because the price of Saxenda is confidential and providers are not given this information. [redacted] RFI 17): We do not provide a breakdown of the cost of the Oviva T3WMP. The total cost is in question 16 above and is our current NHS price. There are no additional costs to the NHS of the Oviva app, maintenance, or other costs to the healthcare system. RFI 18): a) What resource requirements are there to roll-out and integrate the technology into existing NHS systems? How much do you charge for consultancy fees to support this? Oviva provides a vertically integrated service only whereby both the technology and the specialist multidisciplinary workforce are provided by Oviva, furthermore all NHS reporting and referral driving from primary care are included within our price. There are no additional resource requirements of local systems to deploy this model of care. No consultancy fees are charged and the cost of mobilising the technology and the service in a local health system is covered in the overall service cost. When thinking about the total cost to the NHS of offering Tier 3 Weight Management services, there are some costs compared to usual care of 'do nothing': ● GP or other HCP making the referral

		• GP or other HCP ordering blood tests to rule out medical causes of obesity (e.g. Cushing, Hypothyroid) as well as reviewing these results The time to undertake this and the costs of the bloods is standard care for any patient with obesity being referred to an NHS Tier 3 Weight Management service. This is not unique to Oviva, though if rolling out Tier 3 Weight Management services nationally these costs would need to be considered. b) What resource requirements are there to support patients during use of the technology and subsequent follow-up? Please indicate the number of consultations required, type of consultation, duration of consultation required and expected Band and type of staff involved. Oviva have a standard service specification for our T3WMP which is included in [redacted] As Oviva provides a vertically integrated service, all staff costs are included within our total cost.
		Company #3: We are awaiting clarification from NICE on how to respond to this question.
		Company #4: [redacted]
		Company #5: To follow
		Company #6: The cost of the Roczen programme per patient is £50 per month. The service is VAT exempt. Our pricing does not include the cost for GLP-1 medications. All costs of the Roczen software are included within the monthly per patient cost, there are no additional costs beyond the monthly subscription to provide the software solution to the NHS.

		Our costs are not dependent on the number of patients or the length of the contract they remain as detailed in Question 8.
		Company #7: Final pricing will depend on the level of services desired by individual commissioning bodies, as well as the type of medication provided (e.g. Saxenda/Wegovy/Mounjaro), but indicative pricing is provided below. Please note: all prices are per person, exclusive of VAT, and are mutually exclusive i.e. it is possible to combine different packages together depending on desired specification (e.g. dietitian coaching + MDT team, but no GLP-1 medication; or dietitian coaching + GLP-1 medication, but no MDT team). Also note that prices are per engaged user i.e. we do not expect to charge for users that churn off the service after a certain amount of time. ● Each month of Second Nature's digital dietitian-based health coaching programme, including app access, digital weighing scales, and recipe book: £24.99 ● Each month of additional support from an MDT team (which can include a GP, psychologist, exercise specialist, and prescribing pharmacist): £16.99 ● Each month of once-weekly injectable Wegovy semaglutide GLP-1 medication, based on 2023 listing rates and titrated over time up to maximum dosage: ○ 0.25 / 0.5 / 1mg: £129 ○ 1.7mg: £179 ○ 2.4mg: £229 ○ This includes prescribing, dispensing, cold chain storage, and postage Second Nature can be delivered for 6, 12, 18, or 24 months using the above monthly costs. There is no difference between the initial purchase and ongoing costs - as fees are charged on a monthly basis. For the additional MDT support, the cost is based on a proportion of the users requiring additional regular MDT support (i.e. 100 users billed at £16.99 per month and a proportion of these 100 users requiring MDT support). Should commissioning bodies require 100% of users having MDT support, the monthly cost would increase. Finally, Second Nature does not have differential pricing based on volume, although we do require a minimum volume of 100 users per month to be economically viable.
11	Is the initial and/or ongoing cost calculation based on a fixed cost per patient?	Company #1: The cost for the programme is a fixed cost per patient. Participants are provided access for life to the app after their programme ends.
		Company #2: Please see response to NICE Request for Information questions 16, 17, 18 (above).

		We offer a fixed cost per patient.
		Company #3: Yes. Our programmes are priced on a cost-per-patient basis.
		Company #4: Yes, the price is per-patient and could decrease marginally subject to volume
		Company #5: Yes
		Company #6: Yes
		Company #7: Yes - based on a fixed monthly cost per patient that is customisable from a services level and time level i.e. ● Time level: whether the service is provided for 6, 12, 18, or 24 months (or longer) ● Services level: whether the digital programme + MDT team is delivered with or without accompanying weight-loss medication (e.g. injectable GLP-1s)
12	Does your technology include in-built functionality to identify patients at risk of eating disorders or medication misuse, or with other medical or safeguarding issues? For example, is weight loss trajectory monitored and compared routinely with expected trajectory to highlight any concerns? How are these patients managed within the team?	Company #1: We take safeguarding very seriously. As a sophisticated weight management app, there are a number of tools we have built to enable this: ● **Onboarding**: sign-up data is analysed and passed through an AI model that predicts the risk of stress, anxiety, depression and disordered eating based on patient data. The AI model was trained on referral data from DDM Tier 2, 3 and 4 weight management services (as eating disorders are an item that exclude participants, and captured by landing pages/customer service/signup health data). This provides an indication of the likelihood of disordered eating and is given to the clinician as a proxy. ● **Community interactions and in-app coaching conversations**: data is analysed and passed through an AI model that provides sentiment analysis and predicts the risk of stress, anxiety, depression, medication misuse and disordered eating based on patient data based on the comment(s) observed. This provides an indication of the likelihood of disordered eating and is given to the clinician as a proxy, and this is escalated for intervention by a health coach. ● **Scheduled consultations**: data science has been used to identify the best times to engage with patients to ensure safeguarding is maximised and issues are spotted. Scheduled consultations with psychologists who have access to patient data enables human-led identification of eating disorders or medication misuse. ● **Medication adherence**: medication tracking is used as part of the programme and verified through medication tracking in the app, health coach and physician/pharmacist conversations. Any concerns (missed medication, too much medication) is highlighted in the GroCARE Clinician Dashboard and given a Red RAG priority rating on the dashboard.

		● **Weight loss**: the weight loss trajectory is measured against medication taken and compared with expected data trends. Any concerns are highlighted in the GroCARE Clinician Dashboard and given a Red RAG priority rating on the dashboard. ● **Food diary monitoring**: AI monitors the food diary tracking feature of the app and should patients' data show very low carlorie intake, very high calorie intake or other anomalous trends, this is highlighted in the GroCARE Clinician Dashboard and given a Red RAG priority rating on the dashboard. ● **Symptom tracking**: the app provides symptom tracking (an InnovateUK funded feature) which provides collection of symptom data, severity, frequency and is used to identify any emerging symptoms. Preventative measures are taken where patients appear to be becoming more "at-risk", and high-risk patients escalate immediately to the GroCARE Clinician Dashboard, and contact made by customer services for forward triage. **Managing concerns**: Once a profile is flagged, it is brought to the attention of our in-app support team which includes registered dietitians and health coaches. They review the case, and if necessary, they reach out to the user to discuss the potential concern and suggest healthier alternatives or adjustments to their weight management plan. At-risk patients (e.g., eating disorders) are notified by email, in-app, SMS and/or telephone and scheduled an appointment with a psychologist within 2 working days of observation. The initial contact is made immediately on observation. A human is responsible for overseeing the escalation to completion.
		Company #2: Please see response to NICE Request for Information questions 4e and 7. As a clinically-led CQC registered provider of Tier 3 weight management services, Oviva takes the identification of patients at risk of eating disorders or medication misuse, as well as potential other medical or safeguarding issues incredibly seriously. We address this through our robust Clinical Governance processes overseen by our Registered Manager, a Bariatric Physician [redacted] To address this: ● All referrals in our T3WMP are triaged according to their eating disorder risk using a validated scale (BED-7). ● Any eating disorder risk is assessed with separate consultations by a Weight Management Specialist Dietitian and a member of the psychology team. ● If risk is identified, patients are red flagged at our weekly multidisciplinary Eating Disorder review meeting (in addition to the general MDT meeting), run by the Clinical Lead for T3 and the Clinical Lead for Psychology. This informs which pathway a patient continues on and the nutritional approach that is deemed most clinically appropriate. If risk of an eating disorder is identified at this

		stage patients are discharged back to their GP with a request for a specialist eating disorder assessment. ● Patients with subthreshold disordered eating (e.g. emotional eating, occasional binges, over restriction) are offered the option to remain on the programme. [redacted] ● During the programme, all our highly qualified specialist dietitians and nutritionists are trained to identify signs of an eating disorder and refer patients they are concerned about to the multidisciplinary eating disorder team and/or discuss with their manager. Weight loss trajectory is monitored (either in the Oviva app, or self-reported to the Oviva clinical team at appointments and tracked in the patient's electronic health record) and compared routinely with expected trajectory to highlight any concern. ● Our approach encourages regular self-monitoring via the food diary app but the app does not offer the option for calorie counting, again in line with best practice with regards eating disorders. ● The dietary approach is always tailored to the individual, including their eating behaviours. ● There is extensive content about binge eating disorder, emotional eating, etc embedded into the app in the form of written content, audio, self-report quizzes and activities RFI 4e): all referrals into the Oviva T3 WMP are from the patient's GP, which includes a comprehensive medical history and minimum dataset in the referral form. Patients are screened for eligibility for the Tier 3 Weight Management service before being accepted. All patients accepted into the service have a Bariatric Physician Assessment to consider safety for the programme, as well as eligibility for weight management medication. The Bariatric Physician is a SCOPE Certified Consultant Endocrinologist ([redacted]), supported by a SCOPE Certified GP with Special Interest in Obesity and Diabetes ([redacted]). SCOPE Certification (https://www.worldobesity.org/training-and-events/scope) is the only internationally recognised obesity management qualification. We use bespoke guided data capture forms to ensure best practice standardised screening assessments made as per NICE guidelines. Patients are screened against the eligibility criteria for weight management medication prescription in line with NICE and medication guidance. To ensure safe and appropriate prescribing screening this includes: All referral information received via the GP and the Summary Care Record is reviewed for: ● Eligibility for treatment (e.g. for Saxenda HbA1c, CVD risk factor, BMI≥35)

		● Contraindications or cautions present to treatment ● Current medication ● Any recorded allergies ● Any communication difficulties or disabilities ● Any suggestion the patient may have a condition that could impair their capacity ● Any safeguarding concerns on record The Dietitian Initial Consultation is used to review for: ● Change in medical status since referred ● Change in medications since referred ● Relevant social history ● Any other concerns or patient preferences recorded We specifically screen for and seek information around any potential disordered eating or medication misuse, and if this is identified. If risk of an eating disorder is identified at this stage patients are discharged back to their GP with a request for an eating disorder assessment. For patients who are appropriate for GLP-1RA therapy, and choose to go onto this pathway, they have a comprehensive Onboarding Appointment with an Obesity Specialist Nurse [redacted]. This includes: ● The Nurse uses bespoke guided consultation templates aligned to the GMCs 'Remote prescribing high level principles' to ensure best practice embedded throughout the team. ● Issuing the prescription via our pharmacy partner [redacted], who then dispenses the medication sending it to their home address within 48 hours [redacted]. Patients are given direct access contact details for pharmacy partners to coordinate deliveries or address issues where needed. ● A bespoke, secure prescribing platform is used to generate the prescriptions, which meets all NHS Cyber Security requirements and all statutory electronic prescribing legislation Following initiation: ● The patient has an intensive scheduled follow-up regimen with the Obesity Specialist Nurse during the titration period to individualise their onboarding journey based on tolerance, side effects and achieving appropriate adherence. ● Patient initiated Nurse prescriber contact also available at any time. ● The patient is requested to monitor their weight management medication dosing in the Oviva app, as well as weight loss progress which the Nurse can monitor remotely at each stage of treatment. If the patient is not using the Oviva app, the patient must still record this information and provide it

		to the Nurse during phone appointments. Required weight loss assessment for ongoing prescription in line with the NICE TA is completed at the prescribed time points. ● For any concomitant medications that need adjustment, the Nurse provides guidance in writing to the patient and their GP with recommended amendments. ● Weight loss outcomes are audited regularly and benchmarked against published outcome data, and we also submit data to the NHS National Obesity Audit as per the requirements of our NHS Tier 3 Weight Management Contracts. RFI 7): As a CQC Registered Provider of T3 WMP, robust Clinical Governance is critical to Oviva's ways of working. Our Head of Clinical Quality oversees our approach to training, working in partnership with our People Team to ensure it is implemented. We have an in-house Learning Management System (LMS) with in-built quizzes of minimum knowledge levels to support effective training and monitoring. There are 3 key groups that are trained on delivering the Oviva T3 WMP and using the associated Oviva app: ● Oviva HCPs delivering the service ● Oviva Patient Support Team who onboard patients onto the service and deal with any technical support questions ● Patients referred and enrolled in the programme Detailed training is required to safely deliver specialist weight management care to a cohort of patients with complex medical needs. Our training is developed as follows: ● Our Head of Quality oversees our Clinical Governance training, supported by our Compliance Manager who provides Information Governance training and our Safeguarding Lead who has developed our safeguarding training. ● Our Programmes Team and Clinical Leads (Bariatric Physician, Obesity Specialist Nurse, Obesity Specialist Dietitian, Clinical Psychologist) develop the training on the T3 WMP curriculum, clinical knowledge and skills and content. ● Our Programmes and Product Team develop our training on the Oviva Coaching Suite, including the Oviva app, Patient Manager and Admin Console. They have developed specific training for our HCPs, Patient Support Team and patients. ○ HCP training covers the Patient Manager and the Oviva app, including best practice in supporting patients to use the app and delivering care via video call as well as asynchronous messaging. This includes ensuring HCPs are competent at using behaviour change techniques through the combination of app functionality and coaching (e.g. goal setting, self-monitoring and education). ○ Patient Support training covers the Admin Console and the Oviva app, including best practice in supporting patients to onboard to the app and how to deal with technical questions

		○ Patient app Guide (including highlighting features, explaining its use and how to get the best benefits out of it) is embedded within the T3 WMP onboarding materials, and when first logging into the app it guides you through all of the features. Furthermore, patients are supported in using the app by their HCP Team and can reach out to the Patient Support Team at any time with technical questions. Disordered eating and the potential for medication misuse is a critical topic for safe delivery of T3WMP. Oviva's mandatory training includes emotional eating, disordered eating and linked contraindications for weight loss, as well as our screening approach to identify disordered eating. This is all delivered and monitored via LMS and the HCPs' Clinical Team Manager. Our Training Coordinator and T3 WMP Patient Support and Clinical Team Managers ensure all Patient Support and Clinical Staff receive training. All staff receive 2 weeks mandatory onboarding training, with clinical supervision and refresher training provided at least monthly and led by the respective team. The majority of training is remote via video call, with quarterly in-person training. Patients can also contact our Technical Support Team via email, [redacted] Our experience is that patients find the app intuitive, especially the messaging functionality, and that follows us doing extensive user testing to ensure the app is intuitive. Importantly, HCPs are delivering care using a different methodology (asynchronous app chats and video calls) than their original training (typically in-person) and it is critical that providers take a rigorous training approach. Lastly, our Clinical Lead Dietitian, Bariatric Physician and Service Managers train referring GPs and referring primary care staff (e.g. care coordinators) on the Oviva T3 WMP as they will identify eligible patients and refer them, and these GPs/primary care staff need to accurately describe its benefits and approach. We supplement this with patient-facing resources e.g. our website https://oviva.com/uk/en/programmes/tier-3-weight-management/
		Company #3: Liva has a Disordered Eating/Eating Disorder Policy, which includes guidance for health coaches on when to suspect disordered eating or eating disorders and how to act upon any concerns. This also feeds into our Adverse Event and Escalation Policies. Liva also has a comprehensive Safeguarding Policy, which all staff are trained in, and an in-house Safeguarding Lead. Weight is tracked within the Liva app, and our health coaches regularly monitor this. Any clinical concern is initially escalated internally according to the Escalation Policy. The patient may be signposted to their GP and/or other appropriate support. In the event of significant or urgent clinical concern, Liva would (with patient consent) contact the GP directly in a time-appropriate manner.
		Company #4: Yes. There are a number of ways in which we examine the risk of eating disorders. Firstly, all patients are required to undertake an online consultation which rejects them in the event that their BMI is too low; if they

		have a history of eating disorders; or if the evidence provided to us at the identification stage (including a full-body selfie) is insufficient. We also have a number of questions related to eating disorders which are not binary accept/reject but provide additional information for the prescribing physicians. During the provision of our service, we monitor weight in two ways. Preferably, users take advantage of our service to obtain Fitbit digital scales so we can monitor weight progression accurately ad remotely. Alternatively, we monitor weight through our weekly virtual meetings with users / patients – it's one of the first questions we always ask. We use the weight loss trajectory from the STEP and SCALE clinical trials to define the 'norm" against which we assess our patients' progress. One tirzepatide is launched (and assuming it is granted its own TA) we would measure patient progress against the SURMOUNT trial data, in the absence of alternative data.
		Company #5: The system flags adverse events but makes no decisions. All adverse health events go to the MDT.
		Company #6: Our service has multi-stage processes in place to identify patients at risk of eating disorders. Screening begins in the initial digital assessment at the beginning of the pathway. If patients progress, they will give consent for clinicians to access their NHS Summary Care Record (via virtual smart cards and the NHS Spine). Previous diagnoses, problems, medications are checked against the provided details by the member to ensure no documented history of eating disorders, medication misuse or safeguarding issues. All patients are sent a baseline mental health and eating behaviour questionnaire containing the Binge Eating Scale and Three Factor Eating Questionnaire, among others. This allows the clinicians to screen for disordered eating and adds further quantitative information to the overall baseline assessment. The clinical team is trained to conduct a clinical interview in line with the DSM IV Criteria for Binge Eating Disorder should the questionnaire imply disordered and/or binge eating, or if any other red flags arise in the consultation as part of the weight and diet history. Patients with diagnosed eating disorders unfortunately are unsuitable for the programme and will be excluded as part of the multi-stage eligibility screening process, with a final decision made by the clinician. Where it is deemed that the patient needs further assessment, or review by their routine care provider, a GP letter is sent to ensure effective handover of care, with the patient's consent. At Roczen, we are acutely aware of the prevalence of binge eating among people living with obesity and have standardised processes in place to counsel patients regarding suitability, recommended steps and, if appropriate, signposting or referring to other services for Binge Eating Disorder (a lesser known eating disorder). As with all of our programmes, our approach is non-stigmatising and empathetic to the stigma that people living with obesity often face.

		Medical oversight and monitoring underpins the programmes, prioritising patient safety, effectiveness and clinical team responsiveness. Follow up includes a monthly consultation with our GMC- and NMC-registered healthcare professionals, where patients' response to medications will be assessed in detail. Clinicians routinely review the patient's weight trajectory and any side effects reported. Additionally, the licensing for GLP-1 medications clearly states time points at which to re-evaluate effectiveness and suitability to continue the medication. All clinicians are trained on the available clinical trial data and licensing of GLP-1s by Professor Barbara McGowan, including expected weight loss (%) outcomes, side effect profiles and effective monitoring. They are also trained on red flags around sudden or unexpected weight loss.
		Company #7: Throughout our programme, the user's main day-to-day contact is with their health coach. This health coach works with the user and the other members of the MDT to ensure the best healthcare possible. Our application provides a full programme of proactive monitoring for patient health and safeguarding. Our health coaching team is trained on recognising and processing patients who are at risk of an eating disorder. We have a screening tool they use to best understand these situations and move along the correct pathway. We also have general procedures in place to help our staff act quickly in safeguarding situations. This also includes a designated safeguarding lead who is employed by Second Nature and can serve as a resource to our coaches. In addition to our medication adherence tools, we have built out monitoring systems to ensure that users who are losing too much weight are escalated to other members of the MDT. In some scenarios, this may mean stopping medication and referring the patient back to their main GP.
13	Do you have any published evidence of your technology demonstrating its use in an UK NHS setting, which meets the Final Scope (published by NICE on the 16 May)?	Company #1: Yes. A previous version of the technology is published and meets the Final Scope. **Author**: Petra Hanson et al. 2021. **Study details**: Digital health app Within a Hospital-Based Obesity Setting: Observational Service Evaluation; UK; Case-Control Study; Intervention: Digital app providing dietary support + virtual consultations from Tier 3 MDT compared against a control group. **Results**: Statistically significant mean loss of body weight of 2.7 kg (P=.001) and improvement in HbA1c of 3.3 mmol/mol (P=.01). Data comparisons between the app user group and the pre–Covid-19 retrospective control group revealed equivalence for loss of body weight and change in HbA1c between the two groups. 84% engagement at follow-up (7.4months)

		A draft of a paper prepared/submitted for publication that meets the final scope for the W8Buddy technology specifically is available to share, but not accepted for publication yet.
		Company #2: Please see response to NICE Request for Information questions 19 and 20. RFI 19): **Please see the detail in Question 19 tables provided below.** We have a variation of our T3WMP for people with Type 2 Diabetes (which does or does not include a Bariatric Physician based on the specification of the contract). We refer to this programme as Oviva Diabetes 800, Oviva Diabetes Remission, or the NHS England Low Calorie Diet programme depending on the environment in which the data is collected. This is a subcomponent of our wider T3WMP, hence we believe it is highly relevant. Oviva is contributing demographic data, service data and outcome data from our Tier 3 specialist weight management services to the recently initiated NHS National Obesity Audit in England. https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/national-obesity-audit As yet, the national audit team is yet to publish any output data relating to Tier 3 services (existing publications relate solely to bariatric surgery). RFI 20): Please see the detail in Question 20 tables provided below
		Company #3: No. We have published evidence of the Liva programme being successfully used in a healthcare setting (which meets the final scope) across Denmark. There is also an ongoing study on our NHS Somerset programme, which meets the Final Scope. However, the data from this study will not be published until 2024.
		Company #4: As the CheqUp technology is not in use in an NHS setting we do not have any published evidence of this type but have found that the responsiveness matches or exceeds those from the global clinical trials.
		Company #5: No, we do not have published evidence but the evaluation of the DWMP programme is due June / July 2023.

		Company #6: Roczen has been recently approved for use in NHS patients at ICS level to provide digital weight management services. Roczen has supported NHS staff members through employee wellbeing initiatives at Dartford and Gravesham Trust, and Chelsea and Westminster NHS Foundation Trust. Roczen provides large scale employer programmes for the likes of TFL, His Majesty's Prison Service and Network Rail. We have presented outcomes of the Roczen programme on NHS employees and large scale employers in conferences. Please refer to Supporting Evidence Document 3-8. Note that Document 3 and 4 consist of information that is academic in confidence.
		Company #7: While we don't yet have published evidence specifically related to our newly launched medication-assisted specialist weight management programme, we have a wealth of experience and published studies demonstrating the effectiveness of our weight management services in an NHS setting. These studies, which include long-term weight loss outcomes and significant health improvements, provide a strong foundation for our current work. As we continue to roll out our medication-assisted programme, we are actively collecting both qualitative and quantitative data to evaluate its effectiveness and impact. We look forward to sharing these findings in the future to further demonstrate our commitment to delivering high-quality, effective weight management services within the NHS. We started building the evidence base for Second Nature in 2016 with the publication of a small pilot study demonstrating a mean 3-month weight loss of 6.7% for the Second Nature commercial weight management programme.[4] Follow-up analyses published in Diabetes Technology & Therapeutics and Diabetic Medicine reinforced our initial pilot study. The first study showed participants achieving a mean weight loss of 7.1% and 7.5% at 3 months in the commercial and NHS-referred programmes, respectively. This increased to 8.6% and 9.2% at 6 months.[5] The second study observed a type 2 diabetes programme cohort and reported a mean weight loss of 6.6% at 3 months, with 40% of participants achieving an HbA1c level of less than 48mmol/mol. At 6 months, the mean weight loss rose to 8.3%. These findings suggested sustained weight loss over time, warranting further research.[6] Following these articles, we published a much larger study in the Journal of Medical Internet Research (JMIR) in 2019, showing a 6-month weight loss of 7.5% and a 12-month weight loss of 6.5%.[3] Then we published an original article in Practical Diabetes to provide longer-term real-world outcomes for a type 2 diabetes programme cohort. Of the participants with data available, they achieved a mean weight loss of

		7.8kg, 60.6% achieved over 5% total body weight loss, and 28.7% achieved over 10% total body weight loss.[2] To provide further insight into the sustained weight loss outcomes of our programmes, we have also published follow up analyses demonstrating weight loss after 2 years, 3 years and 5 years. At the 2-year mark, participants averaged a weight loss of 5.7kg (6.0%), with self-funded participants losing 4.8kg (5.0%) and those with type 2 diabetes losing 7.5kg (7.9%).[7] This trend continued at 3 years, with an overall average weight loss of 5.68kg (5.83%), and self-funded and type 2 diabetes participants losing 5.51kg (5.65%) and 5.87kg (6.05%) respectively.[8] Even at 5 years, participants maintained an average weight loss of 5.71kg (5.65%), with self-funded participants losing 4.85kg (4.71%) and NHS-referred participants losing 7.42kg (7.52%).[9] Working in partnership with the University of Glasgow, they published an independent study looking at the qualitative experience of Second Nature commercial weight management participants during the Covid-19 pandemic.[10] We are committed to continuously developing our evidence base, and currently have an Randomised Controlled Trial (RCT) in progress with the Nuffield Department of Primary Health Care Sciences at the University of Oxford - REmote SUpport for Low-Carbohydrate Treatment of Type 2 Diabetes (RESULT) trial. These studies and data underscore the benefits of Second Nature to patients, healthcare professionals, and the health system. References: 1. Ross JAD, Barron E, McGough B, et al. Uptake and impact of the English National Health Service digital diabetes prevention programme: observational study. BMJ Open Diabetes Research and Care 2022;10:e002736. doi: 10.1136/bmjdrc-2021-002736 2. Kar P, Goward C, Whitman M, Davies M, Willner T, Shaw K. Engagement and effectiveness of digitally enabled behavioural change support for people living with type 2 diabetes. Practical Diabetes 2020;37(5): 167–172 3. Idris I, Hampton J, Moncrieff F, Whitman M. Effectiveness of a Digital Lifestyle Change Program in Obese and Type 2 Diabetes Populations: Service Evaluation of Real-World Data. JMIR Diabetes 2020;5(1):e15189 4. Hampton, J., Allen, E. and Edson, C., 2017. Service evaluation of a digital behavioural change programme. Future Hospital Journal, 4(3), pp.173-177 5. Hampton, J., Dee S., Whitman M. 2019, Clinical care and other categories posters: Education and self-management. Diabet. Med., 36: 94-119. doi:10.1111/dme.26_13883 6. Hampton, J., Kar P., Whitman M. Diabetes Technology & Therapeutics. Feb 2019.A-1-A-164. http://doi.org/10.1089/dia.2019.2525.abstracts

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14	What are the lengths of the weight management programmes you offer? Please specify whether these have different costs associated.	Company #1: ● Tier 3: 12 month to 15 month programme dependent on extensions ● Tier 4: with surgical approval and meeting of requirements, 6 to 24 month programme. The exact duration will depend on the clinical team's opinion.
		Company #2: Oviva's T3WMP is 12 months for the standard programme. For people on the GLP-1RA pathway it is 24 months in length. We price at a fixed level per patient based on our knowledge of the split of patients between these different pathways, though yes we could offer these pathways at different price points. [redacted] Oviva also offers a Tier 2 Weight Management programme which is 12 weeks, however this does not include prescribing of GLP-1RAs as it is not a specialist Tier 3 Weight Management service.
		Company #3: Our weight management programmes are available in the following durations: • 12 weeks • 6 months • 9 months • 12 months • 18 months • 24 months Each programme duration has a different cost associated as longer programmes include more coaching time.
		Company #4: Within the private sector, our preference is that our patients remain with us for at least 12 months, but this is impossible to enforce. Within the NHS, our preference is that our weight management services would be contracted for a minimum 24 months to meet the NICE TAs for liraglutide 3.0mg and semaglutide 2.4mg (and the corresponding TA for tirzepatide 15mg when launched).

		Company #5: NHS Digital Weight Management Programme is 12 weeks, T2DR is 12 months, Newham Weight Management Programme is 12 weeks. Yes, there are different costs for each programme as it depends on need and programme specifications.
		Company #6: We offer a monthly subscription but encourage patients to remain on the programme for a minimum of one year. We agree terms of 1 year most frequently with our corporate partnerships when providing employee medical schemes. We do not discharge patients, in keeping with the chronicity of obesity. We encourage members to continue lifestyle modifications life-long.
		Company #7: We can offer 6, 12, 18, and 24 month long programmes. These are priced on a per-month basis and are detailed in the cost section.
15	Are you aware of your app compliance/adherence rate?	Company #1: Yes. App/platform adherence is 93% at 3-months and 84% at 12-months
		Company #2: Yes, Oviva has live data recording covering all of the below categories [redacted] If the evaluators would like a specific analysis, please let us know. ● Time spent in Oviva learn content ● Clinical appointments with Oviva ● Asynchronous messages exchanged ● Self-tracking, including meals, weights and activity ● To-do setting and completion ● Dose tracking of GLP-1s
		Company #3: [redacted]

		[redacted]
		Company #4: The adherence/compliance rate for our service is 100% - everyone takes part. Our patients undergo a prescription meeting with a physician and within a day or so of joining CheqUp, we expect them to attend a meeting with a health coach to familiarise themselves with the service. They will also meet with their dietitian and physical activity advisor. These meetings continue on a monthly cycle throughout the period the patient is with us. It is our observation that the person-to-person element provides a stronger incentive to adhere than an app-based model – people respond better to people whereas apps are easy to ignore. We have not yet had any non-responders
		Company #5: **Retention rates for T2DR** For North Central London LCD programme, There was a 68% completer rate and a 95% retention rate during the first twelve weeks. For West Yorkshire, the retention rate in the first twelve weeks was 97% **Retention rates DWMP** Top provider for service user retention at Level 2 intervention level. Average Programme Uptake May 2023: 79%. Average Programme Retention: 55%
		Company #6: The Roczen programme (without medications) has a retention rate of 43% at 1 year. This data was recently presented in the 30th European Congress on Obesity (ECO 2023). Note that this does not reflect the rate of medication adherence.
		Company #7: Second Nature has a robust system in place to monitor and encourage app compliance and adherence, drawing on our extensive experience in delivering digital health programmes. Our system is designed to actively track various forms of user engagement, such as weight readings submission and interactions with health coaches, which are key indicators of adherence. [redacted]

		[redacted]As part of our commitment to transparency and accountability, we also have extensive experience providing granular engagement reports to NHS England as part of the NHS Digital Weight Management Programme and The NHS Healthier You: Diabetes Prevention Programme. This experience has further refined our system's ability to monitor and encourage participant interactions, making it a reliable tool for delivering safe and effective digital weight management programmes.
16	Are you aware of what proportion of patients proceed to bariatric surgery?	Company #1: Recent data is not available.
		Company #2: During delivery of our Wakefield T3WMP in 2017-2020, we know that ~10% of completers went on to bariatric surgery[redacted]Due to Covid-19, there has been a significant reduction in the proportion of people completing bariatric surgery (from nearly 6k/year to <2k/year, source: https://app.powerbi.com/view?r=eyJrIjoiYmIyZWRmYjUtYTQ1ZS00YWEwLWIxOGUtYTkyZTM2ZDlmNDQ0IiwidCI6IjUwZjYwNzFmLWJiZmUtNDAxYS04ODAzLTY3Mzc0OGU2MjllMiIsImMiOjh9) . This makes any assessment of the proportion going onto bariatric surgery in this post-Covid-19 recovery period challenging. If a patient is exiting the current service, we discuss whether bariatric surgery is appropriate and make an onward referral. We are unable to track the proportion that go onto receive bariatric surgery as the criteria are always subject to change and Tier 4 centres have their own assessments as well as long waiting lists (often over 1 year).
		Company #3: No – we do not have access to this information.

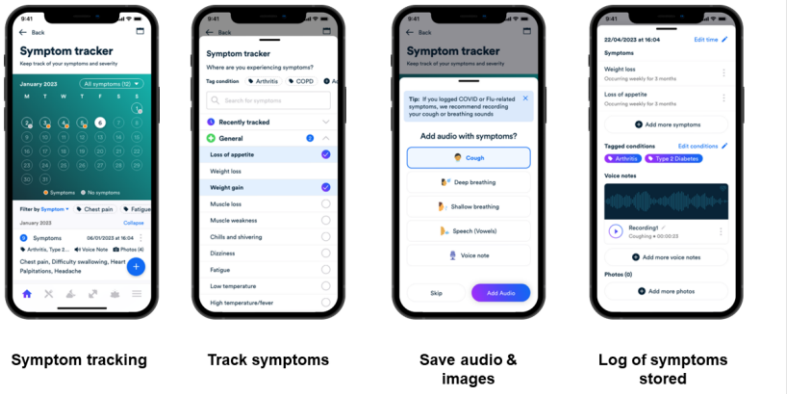
		Company #4: [redacted].
		Company #5: Not known
		Company #6: We do not have this data, however, we do facilitate referral for patients to Tier 4 services for counselling on bariatric surgery via the GP, where appropriate. Furthermore, we advocate for our patients in these scenarios, where we may convey the patient's involvement, commitment and progress on a structured medical weight management programme - a common prerequisite to being listed for elective surgery.
		Company #7: While we don't directly track the number of our participants who proceed to bariatric surgery, and our programmes aim to reduce the need for such procedures, we estimate the proportion of our participants undergoing bariatric surgery to be minimal.

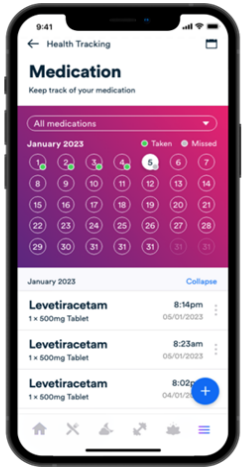
Appendix E2 – Follow-up questions from EAG (sent 16/06/2023)

	Question	DDM (Gro Health) Response (23/06/2023)
1	DDM (Gro Health) stated that they have digital exclusion provision and has an Easy Read version of the programme available for those with neurodiversity. Can you expand or give examples of what “digital exclusion provision” includes?	*Digital exclusion provision:* Our digital exclusion provision supports digitally excluded users with a booklet/manual containing education, recipes and meal plans; DVD of behavioural change resources (e.g., exercise classes, guided mindfulness) and consultations and coaching delivered over the telephone. These are made available to those who may lack internet access or digital proficiency and are designed to enable individuals to engage in our weight management program offline. These are available in all of the supported languages. People who need additional support (e.g. BSL-interpreter) are provided a virtual, tailored programme which is delivered virtually in-app and through telecommunications software, and/or over the telephone. Our digital exclusion provision therefore ensures that our weight management service remains accessible, comprehensive, and effective for all users, regardless of their digital capabilities. A photo of the pack is shown below: 

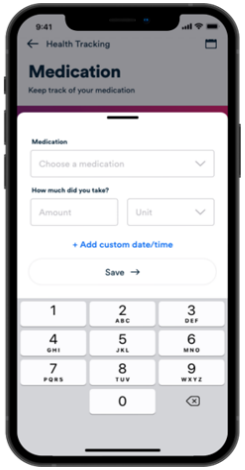
		Easy read provision: "Easy Read" is an accessible communication method designed for people who have difficulty reading and understanding information, often used to support individuals with learning disabilities, neurodiversity, or anyone who prefers information in a simplified format. This version is designed with the key principles of Easy Read in mind. We use straightforward language, short sentences, and simple grammar to convey our message clearly. Important points are highlighted and reiterated to ensure understanding. To assist visual learning, we include supportive imagery alongside the text. Images are carefully selected to be representative and clear, directly relating to the text they accompany. This helps users to visualise and better comprehend the information being presented. We also use larger text sizes and considerate layouts to make the information easier to read. Our Easy Read materials are designed to be intuitive and engaging, breaking down the complex concepts of weight management into digestible information. Beyond the materials, our staff are trained to communicate effectively with individuals who prefer or require Easy Read resources. Whether it's during in-person consultations or telephone coaching sessions, they are equipped to explain concepts in an accessible, patient and understanding manner.
2	DDM (Gro Health) stated that there was no recent data available for progression to bariatric surgery. Does your programme have the capability to at least measure/record this information if necessary?	Apologies, we were waiting for data from our clinical sites but were not able to get this in time for the original submission. Progression to bariatric surgery stands at 24.4% (2022). This data is collected through the platform and we confirm the solution has the capability of recording this.
3	For the eligibility criteria, DDM stated 'other long term health conditions such as Type 2 diabetes'. Does this also include patients with hypertension? What other health conditions?	Health conditions: Type 2 diabetes, hypertension, obstructive sleep apnoea, high cholesterol, non-alcoholic fatty liver disease, polycystic ovarian syndrome.
4	Does PT session stand for physiotherapy training, or personal training session? Please clarify.	PT stands for Personal Training sessions. The PTs deliver "exercise plans" under the guidance of a physiotherapist at one-to-one and group level.
5	DDM stated 'health tracking' and 'menopause' as one of the programme's features. What exactly do you mean by this?	*Health tracking:* Users can track weight, activity, exercise, sleep, mood, blood glucose, and medications with data-led feedback to support positive behaviours. This can be self-reported via the Health Tracking area, or automatically brought in from synced wearables and devices including FitBit, Apple Health, Google Fit, Samsung and Withings. On signup, users choose SMART goals, which they reflect upon at regular intervals with their dedicated coach. Coach/facilitators can log weight readings through the clinical portal during online consultations. Coaches also assist virtual weigh-ins to ensure correct weight readings are received (e.g. patient sends picture of scales, or conducts weight in with coach). Users can connect with NHS login. IM1 integration will go live in Q4 2023 to pull/push from the patient's GP record. The app also provides symptom tracking, where patients and their clinicians can record/monitor health symptoms.

		Additionally, patients can provide a voice sample for analysis to identify mental health/wellbeing concerns. All data is made available to clinicians in the GroCARE Analytics Dashboard, including the source of data (clinical, self-reported, wearable).  **Health dashboard** **Weight data** **App syncing** **Wellness Score** The above screenshots show the Health Dashboard which displays aggregated tracked health data. The Weight data screen shows an individuals's tracked weight data, App syncing screen shows how services can be integrated to provide real-time data, and Wellness Score shows how this data is quantified to provide ongoing tailored behavioural change support, insights and nudges to users. Patients and their clinicians can record/monitor health symptoms through an Innovate UK-funded AI tool created with clinical experts at Royal Holloway, University of London as below:

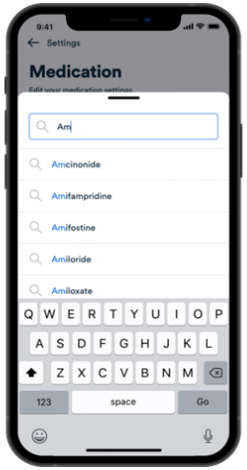
		 Medication management monitoring is conducted in-app through the tracking of all medications taken by the patient including weight management medication (medication, dosage, time) and at regular consultations with a Pharmacist if taking weight loss medications. Questionnaires further track/confirm medication adherence and side effects/adverse events.



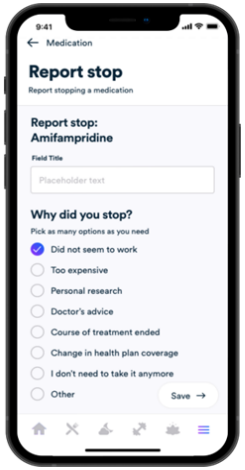
Medication tracking



Save medication, dosage and time

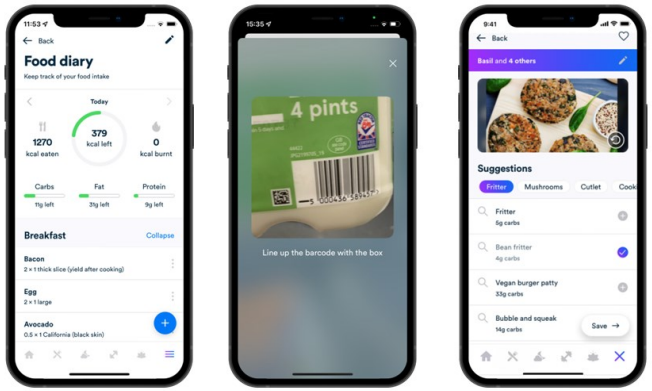


Search/track a range of medications



Report stopping a medication

Meal and food logging is conducted by scanning barcodes, searching for foods or taking a photo and use the AI-powered food recognition tool to take the burden out of food logging. Additionally, patients can save or add recipes from the in-app Recipes library.

		 **Food diary** **Search for food by barcode/search** **Take a photo of a meal and save** The platform facilitates co-morbid complex care. ***Menopause*** refers to the platform also providing a 12-module menopause support course for patients experiencing menopause during their weight management journey. This is provided through structured education modules (addressing physical and emotional effects of menopause), health coaching and behavioural change resources.
6	For in-house prescriptions, what GLP-1RA medications are prescribed? Does this include Orlistat?	We do prescribe Orlistat. The GLP1 analogues that can be prescribed in our service are liraglutide (various strengths), Semaglutide (various preparations), and dulaglutide.
7	With regards to eligibility, do you have an exclusion criteria?	Yes, patients have to be BMI 35 with a comorbidity such as T2DM, hypertension, obstructive sleep apnoea, high cholesterol, NAFLD, PCOS or a BMI of 33 or over if they are of South Asian descent such as Bangladeshi, Indian or Pakistani or BMI 40 and above with no comorbidities.

8	How do you define and measure engagement with the programme?	Engagement with the program is measured through a series of metrics: • **Completion of the programme:** number of participants completing all programme modules and attending all consultations • **Engagement:** measured as a participant accessing and engaging with the virtual platform at any time within the last 7 days • **Outcomes:** we measure engagement impact through outcomes including clinical markers and standardised questionnaires with the capacity to personalise these based on implementation.
9	What is the difference between W8Buddy and Gro Health? Are they comparable in terms of being able to deliver a Tier 3 or Tier 4 weight management programme?	Gro Health is a precision health app that provides health pathways, remote monitoring and virtual support to patients across a variety of health conditions and is able to provide complex care/co-morbid support. The **Tier 3 Weight Management Service** is one of 11 health pathways the app is used to support. **W8Buddy** is the *name of the programme/pathway/stream* for Tier 3 Weight Management to distinguish it from the app (i.e. W8Buddy is the name of the T3WMS delivered through the Gro Health app). [redacted] We use the following metaphor: The precision health app (Gro Health) is like the general hospital, a comprehensive healthcare facility designed to address a multitude of medical conditions. From health tracking, managing chronic illnesses, to emergency escalation – it encompasses a broad spectrum of health services to cater to a wide range of patient needs. On the other hand, W8Buddy, the tier 3 obesity stream, can be likened to a specialist obesity clinic within this general hospital. This clinic has a team of dedicated experts focusing solely on obesity-related issues. Their role is to provide specialised care and treatment for patients dealing with obesity, including tailored diet plans, exercise regimens, and potentially medical or surgical interventions. In essence, while the precision health app serves as a comprehensive umbrella for a variety of health conditions, much like a general hospital, W8Buddy operates as a specialised stream within this system, comparable to a dedicated obesity clinic, providing a focused and personalised health pathway for those managing obesity.

	Question	**Oviva Response (22/06/2023)**
1	With regards to the frequency of reviews with HCPs, please could you clarify the following information a. Baseline: Bariatric physician assessment High intensity (0-3 months)	Baseline 1. Bariatric Physician Assessment (x1) 2. Pathway Selection Appointment with Specialist Dietitian (x1) 0-3 months 1. Dietitian appointments (once per month) 2. Nurse specialist remote review (x4 within these 3 months)

	b. Reviews with dietitians (once a month) c. Medication reviews with specialist nurse (x4 within 3 months) Monthly (3-24 months) d. Coaching appointments with dietitians (x6) – is this once per month? e. Further monitoring with specialist nurse (x7) – is this once per month? f. HCP available at all times for issues Weekly MDT meetings	3-24 months 1. Coaching appointments with Dietitian (x6, including every 6-9 weeks to 12 months, then as needed months 12-24) 2. Further monitoring with Specialist Nurse (x7, once every 3 months) 3. Psychological Support: Frequency of support/number of appointments is based on information collected at triage 4. Dietitian and specialist Nurse available at all times as escalation point for issues Weekly Consultant Bariatric Physician led MDT meetings to discuss/review complex cases.
2	For the eligibility criteria, do you mean South East Asian descent, not South Asian descent?	We follow NICE (CG189 and recent Semaglutide TA 875) which suggests using lower BMI cut-offs for "people with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background"
3	For the eligibility criteria, Oviva stated 'other long term health conditions such as Type 2 diabetes'. Does this also include patients with hypertension? What other health conditions?	As per question 9 of Oviva's response to NICE's Request for Information this does include hypertension: ● All Service Users referred must meet the national criteria for accessing tier 3 weight management services, as per the NICE QS127 for bariatric surgery and https://cks.nice.org.uk/topics/obesity/management/management/: ○ BMI 40 kg/m^2 without the presence of diabetes and/or other significant comorbid conditions; or ○ BMI of ≥35 kg/m^2, in the presence of diabetes and/or other significant comorbid conditions e.g metabolic syndrome, hypertension, obstructive sleep apnoea, functional disability, infertility, and depression. ○ BMI ≥30 kg/m^2 with recent-onset type 2 diabetes (diagnosed within a 10-year time frame) If further clarification is needed, Oviva follows: ● NICE CG 189 which mentions the following in relation to assessing risk in obesity: assess for "any comorbidities, for example type 2 diabetes, hypertension, cardiovascular disease, osteoarthritis, dyslipidaemia and sleep apnoea."

		• NICE TA's where relevant including for liraglutide (TA 664): BMI criteria + Non Diabetic Hyperglycaemia + elevated CVD risk based on risk factors such as hypertension or dyslipidaemia, and for Semaglutide (TA 875): BMI criteria + "one weight related comorbidity."
4	What exactly is a psychological wellbeing practitioner? Is this the same as a psychotherapist?	Psychological wellbeing practitioners (PWP) are a distinct group of healthcare professionals and are different from clinical psychologists or psychotherapists. The NHS careers site defines PWPs as follows: "Psychological wellbeing practitioners (PWPs) are trained to assess and support people with common mental health problems – mainly anxiety disorders and depression – to manage their recovery." See more: https://www.healthcareers.nhs.uk/explore-roles/psychological-therapies/roles/psychological-wellbeing-practitioner Our PWPs have all graduated from a British Psychological Society (BPS) Accredited PWP training course or apprenticeship. See more: https://portal.bps.org.uk/Accredited-Courses
5	How do you define and measure engagement with the programme?	We measure engagement using: • Attendance at appointments with the HCP team, including provision of required monitoring information such as weight measurements. • Engagement with the Oviva Tier 3 Weight Management Programme learning content (via app or web browser) • App engagement metrics, e.g. setting to-dos, self-tracking of meals, weight, activity • Medication tracking of GLP-1s for those who are on this medication. All interactions between the patient and Oviva are tracked using the Oviva Coaching Suite, our Electronic Health Record. These interactions are monitored in our Business Intelligence Team dashboards, and used for NHS commissioner reporting.
6	For those with no or limited digital literacy, you have specified that the programme can be accessed in-person, please can you describe how this is done (for example, where and any additional associated costs)?	For people with no or limited digital literacy, our first step is to offer a remote telephone pathway plus a hardcopy printed guidebook (for them to access the learning content). This pathway is identical to our smartphone app pathway in terms of sessions with HCPs. There is no difference in cost for this pathway. We offer this telephone pathway in all of our Tier 3 Weight Management NHS contracts. Where it is specifically requested by the commissioner, we can also offer in-person access to our Tier 3 Weight Management programme. Again the pathway is identical to our smartphone app pathway in terms

		of sessions with HCPs. Costs vary significantly based on the contract requirements, e.g. number of venues offered across an ICS geography.

	Question	Liva Response (21/06/2023)
1	With regards to reviews with healthcare professionals, how often does a member of your team meet with the patient? The Doctor, dietitian, health coach – how frequently do they meet with the patient?	All our programmes start with a one-to-one 30–60-minute consultation with a health coach (always a dietitian on our Tier 3 programmes), who will remain the patient's coach for the programme duration. For the programme's first phase, patients receive at least weekly contact from their coach. As patients build resilience, this moves to biweekly and then monthly contact during the final stage of the programme. Contact includes asynchronous video messages, text messaging, and one-to-one in-app video calls. For patients requiring additional support, we can book sessions with doctors and health psychologists, in addition to health coach support.
2	LIVA stated that there was no data available for progression to bariatric surgery. Does your programme had the capability to at least measure/record this information if necessary?	Yes – with the appropriate data-sharing agreements with the patient and their GP, we should be able to obtain this information and record it within our system. We can also add post-programme follow-up engagement events and nudges to prompt patients to add updates to the app.
3	LIVE states that the BMI threshold will be lowered for patients from ethnic minority backgrounds, or people from south east Asian descent only?	NICE CG189 1.2.8 states, "People *with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background are prone to central adiposity and their cardiometabolic risk occurs at lower BMI, so use lower BMI thresholds as a practical measure of overweight and obesity:* · *overweight: BMI 23 kg/m2 to 27.4 kg/m2* · *obesity: BMI 27.5 kg/m2 or above.* *For people in these groups, obesity classes 2 and 3 are usually identified by reducing the thresholds highlighted in recommendation 1.2.7 by 2.5 kg/m2*." Therefore, we apply this guidance to our Tier 3 programme unless otherwise stipulated by commissioner/customer eligibility criteria.
4	How do you define and measure engagement with the programme?	Different customers/commissioners require us to measure programme engagement in different ways. Ultimately, we measure patient engagement through interaction with the health coach (e.g., attending video consultations, responding to messages), setting and measuring against goals (e.g., inputting weight measurements), interaction with in-app learning materials and the amount of time spent in the app.

	Question	CheqUp Response (23/06/2023)
1	With regards to accessibility, please could you expand on how the programme is 'easy to use'. Are patients with cognitive disabilities screened for? Is there an easy read version of the programme available? Are hard copies or web-to-text speech available?	The CheqUp weight management platform has been developed by professional UI/UX specialists to make it very easy to use an online technology. As we are a person-led service, interactions can take place through a variety of different mechanisms – phone, email, WhatsApp (our WaitLess service) and our bespoke video consultation system. We also produce and distribute printed versions (hard copies) of numerous different types of material. We do not yet screen for patients with cognitive disabilities, nor do we have web-to-text speech available although both of these could easily be added to the platform if required.
2	CheqUp stated that there were no known patients that progressed to bariatric surgery following completion of the programme. Does your programme have the capability to at least measure/record this information if necessary?	We understand the importance of recording the incidence of patients proceeding to bariatric surgery so we have the capability to record and measure this information. Our suggestion would be that any company taking part in the pilot programmes is provided with the ability to enter information on all participants into the National Obesity Audit. In this case, we would need to collect a patient's NHS number.
3	Would it be possible to be more specific regarding the BMI for the eligibility criteria please? What BMI do you use? Do you have lowered thresholds for people with south east Asian descent, or who have T2DM or hypertension? Please clarify.	We prescribe for medications in accordance with their licence. Our online consultation will automatically reject patients if their BMI is too low as outlined below: Our eligibility criteria are for adults (18 and over) with a body mass index (BMI) of 30kg/m² or greater, or a BMI of 27 kg/ m² or greater with at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes). In September 2022, NICE updated their guidance regarding lowering BMI thresholds for people from different ethnic groups (Recommendations | Obesity: identification, assessment and management | Guidance | NICE). We adopt these guidelines but would prescribe below a BMI of 27 as per the licensed indication of the medication.
4	With regards to eligibility, do you have an exclusion criteria?	We follow the SmPC for each medication in terms of exclusion criteria and exclude people accordingly. Examples include: • Age under 18 years • BMI. As detailed above • Eating disorders. Anyone with a history of anorexia nervosa, bulimia • Identification. Anyone who fails our identification process • History of certain conditions or current conditions in accordance with the SmPc e.g. Pancreatitis • Other GLP-1 medication. Patients must not take more than one form of GLP-1 medication simultaneously • Pregnant, planning a pregnancy or breastfeeding

	Question	CheqUp Response (23/06/2023)
		Additionally, we apply the stopping criteria as follows • Patients who have not reached 5% weight loss after 12 weeks of reaching maximum dose titration (3.0mg for liraglutide, 2.4mg for Semaglutide) Additionally, we screen for certain co-morbidities, which are part of the physician review process, which are governed by CheqUp Standard Operating Procedures. Examples include: • Renal function. If the prescribing doctor has concerns relating to renal function they will request a renal function test with the objective of determining if the eGFR is <30; if so, liraglutide / Semaglutide will not be prescribed. This is applied to people who have a history of renal issues, or are >50 years of age, have type 2 diabetes, and/or high blood pressure. • Certain medications, We ask the patient to list all prescription medication which they are taking to make the prescribing doctor aware. On the basis of this information and the combination of information within the entire consultation, the prescribing doctor will decide whether a prescription is acceptable and subsequently determine the specific type of medication.
5	Within the technology table sent, can you confirm that the MDT component of psychology is correct “referral to psychological/counselling services only”?	Correct. We currently have an arrangement with a company called HelloSelf (Private Clinical Therapy | HelloSelf), which is governed through a contract dated 05 June 2023, which we are happy to share with you, in confidence, if required. We see this as a pragmatic option until we have reached sufficient scale to provide this service ourselves. To this end, the psychological component of the service would be brought in-house if we were to be part of the pilot programme. All other elements of the weight management programme are provided in-house.
6	How do you define and measure engagement with the programme?	CheqUp offers a very substantial number of meetings each and every month for the entire duration of the programme. These meetings are with physicians, dietitians, physical activity advisors, psychological counsellors (if required) and trained health coaches. The exact schedule of contact over a 24-monthe period can be provided if requested. We believe that early and full engagement is fundamental for a successful weight loss outcome, so we define compliance throughout the programme as participation as a % of the total meetings offered and measure that compliance through our bespoke online portal. We would be delighted to share more information on this as required.

Appendix F: Correspondence with Clinical Experts

#	Name	Response received
1	Arut Vijayaraman, Clinical Director and Consultant Endocrinologist	25/05/2023
2	Karen Coulman, Research Fellow	26/05/2023
3	Anu Sinha-Reid, Clinical Psychologist	02/06/2023
4	Jennifer James, Physiotherapy Lecturer and Researcher	07/06/2023
5	Nicola Carruthers, Lead Specialist Dietitian	07/06/2023
6	Will Smith, Healthier Weight and Treating Obesity Strategic Manager	19/06/2023
7	Imad Mekhail, GP	07/06/2023
8	John Wilding, Professor of Medicine and Honorary Consultant Physician	22/06/2023
9	James O'Connell, Lead Specialist Dietitian	22/06/2023
10	Chetan Parmar, Consultant Bariatric and General Surgeon	24/06/2023
11	Nuala Davison, Clinical Nurse Specialist in Bariatric Surgery	30/06/2023
12	Rob Andrews, Associate Professor of Diabetes	02/07/2023

Question		Responses
1	For current Tier 3 weight management services in the NHS, can you estimate the proportions for the different methods of delivery for <u>initial appointments</u> following referral: a. Face-to-face (0-100%) b. Virtual/telephone (0-100%)]	Expert #1: a. Face-to-face (0-100%) 90% b. Virtual/telephone (0-100%)] 10%
		Expert #2: I suspect this varies by services, this reflects my own service. a. Face-to-face (0-100%) 30% b. Virtual/telephone (0-100%)] 70%
		Expert #3: a. Face-to-face (0-100%) 20% b. Virtual/telephone (0-100%)] 80%
		Expert #4: a. 90% b. 10%
		Expert #5: a. 80% b. 20% Covid changed this significantly, before would have said almost all initial assessments in person.

		While virtual uptake has increased this is not wholly related to patient preference (other factors may include service provider preference, lack of rooms for consultations etc).
		Expert #6: a. 90% b. 10%
		Expert #7: Of those I am aware of locally, 100% had an initial F2F consultation.
		Expert #8: a. 70% (for our service we are now back at 95% F2F for first appointments) b. 30%
		Expert #9: a. Face-to-face *Medical clinic 100% F2F* *Dietetic clinic and DAP clinic 53%* *Physiotherapy clinic* *Physiotherapy group* *Dietetic group 0%* b. Virtual/telephone *Medical clinic 0%* *Dietetic clinic and DAP 47%* *Physiotherapy clinic* *Psychology 100%*
		Expert #10 a. 80% b. 20%
		Expert #11: Initial appointment 100% face to face
		Expert #12: a. 90% -most patient want to see us face to face as until now no one has been particularly interested in helping them to lose weight or talk to them about the cause of their weight gain, which can be very personal. It also enables us to get an accurate weight (for 30% of people who attend our service the weight given by GP is inaccurate by 10-30% as weighed on scales that do not go up to their weight) and to do investigations (bloods, Xrays and ECGs) b. 10%
2	Of those referred to Tier 3 weight management services in the NHS, can you estimate the proportions who attend their first appointment?	Expert #1: In my experience, and in my clinic more than 90% attend the 1st appointment.
		Expert #2:

		Unsure, but DNA rates are definitely better since using virtual/telephone
		Expert #3: a. Face-to-face: (0-100%) 70%
		Expert #4: 70%*
		Expert #5: 85%
		Expert #6: Across the NENC ICS its between 60 to 90% Expert #7: Of those I am aware of locally, approx. 75% attended their first appointment.
		Expert #8 75% (we have increased this to nearly 90% in our Wigan service, by using an 'opt-in' service; that means that all referred patients have to telephone to confirm that they are interested in attending and then make the final decision about whether they want to be referred after being provided information about what the service does and what it can (and cannot) provide for them.
		Expert #9 *Aintree medical led clinic 66.5%* *Dietetic clinic 88%* *Physiotherapy clinic 76%* *Non-Merseyside MDT clinic 70%*
		Expert #10 70%
		Expert #11: 75-80%
		Expert #12: 85% but we have a wait time of 16 months so could have forgotten had been referred.
3	For current Tier 3 weight management services in the NHS, can you estimate the proportions for the different methods of delivery for <u>follow-up appointments</u>: a. Face-to-face: (0-100%) b. Virtual/telephone: (0-100%)	Expert #1: a. Face-to-face: (0-100%) 70% b. Virtual/telephone: (0-100%) 30%
		Expert #2: a. Face-to-face: (0-100%) 10% b. Virtual/telephone: (0-100%) 90%
		Expert #3: a. Face-to-face: (0-100%) 70% b. Virtual/telephone: (0-100%) 30%
		Expert #4: a. 80%* b. 10%*
		Expert #5: a. 80% b. 20%
		Expert #6: a. Face-to-face: (0-100%) 70% b. Virtual/telephone: (0-100%) 30%

		Expert #7: I'm unfortunately unable to answer this. Locally referral numbers were generally quite low, and so not many patients were referred or had been there enough to require follow-up.
		Expert #8: a. 60% b. 40%
		Expert #9: a. Face-to-face: (0-100%) *Medical clinic 100%* *Dietetic clinic and DAP clinic 55%* *Physiotherapy clinic* *Physiotherapy group* *Dietetic group -50%* b. Virtual/telephone: (0-100%) *Medical clinic 0%* *Dietetic clinic and DAP clinics 45%* *Physiotherapy clinic* *Psychology 100%* *Dietetic group 50%*
		Expert #10: a. 20% b. 80%
		Expert #11: Definitely an estimate – dietitian/psychologist F2F 30%, surgeons / CNS F2F more like 80%
		Expert #12: a. 40 %– patient like to see the doctor and psychologist in person b. 60% - almost all our dietitian and nurse appointments are done virtually.
4	Can you estimate what proportion of patients are referred for Tier 3 weight management services but have no weight management service involvement because there are no services available where they live?	Expert #1: I would guess 60% but it is only a guess
		Expert #2: Unsure. I suspect they might not even get a referral if there is nothing in their area.
		Expert #3: Unable to comment on this as our patients (within Newcastle) are offered our partial tier 3 service.
		Expert #4: A significant amount – John Wass at the Royal College of Physicians did some work on this and so he has data regarding this.
		Expert #5: 25% Huge parts of the UK with no appropriate service or services funded on and off. Local referrers tend to become aware if a service not available so wouldn't be making referrals.
		Expert #6:

		Over the last few years, it would have been between 30 to 50%, but going forward in the NENC ICS this figure will increase as only 3 out of 13 Local Authorities will have a Tier 2 service and NHSE Digital Weight Management Programme is restricted to patients with BMI greater than 30 plus Diabetes and/or Hypertension.
		Expert #7: I'm unable to answer this at a national level.
		Expert #8: Impossible to say, as if no service then no referral is likely to be made. In our services we used to accept 'out of area' referrals but are now unable to do so due to very long waiting lists for those areas where we actually have a contract. From previous surveys and work done by the RCP and NHS England about 35% of population have no access to tier 3 services. I expect the true proportion is lower as many 'tier 3 services' do not have full MDT (eg no medical input, no psychology, no pre-surgical MDT)
		Expert #9: We provide a service for Cumbria and Lancashire who have no tier 3 provision, so have to make an extended journey to come here.
		Expert #10 70%
		Expert #11: Approx 70/75% of patient referred to us have no access to Tier 3
		Expert #12: At the moment about 70% of people who attend our service have not seen a dietitian, been to any commercial service, or tried digital app or diabetes remission or prevention programme (if applicable), There is though a group of obese people who there is nothing other than commercial programmes to offer them as they do not fit into any of the categories that can be offered anything.
5	Can you estimate the proportion of patients who do have Tier 3 weight management services available locally, but unable to attend face-to-face appointments (i.e., may prefer digital access)?	Expert #1: 10%
		Expert #2: Unsure
		Expert #3: Approx 30%. Three main reasons given to us by patients are due to: childcare, work commitments, mental health (e.g. anxiety preventing them from attending, although we do try and encourage as much as possible as we realise the positive impact a group can bring).
		Expert #4:

		Being unable to attend and preferring digital access aren't the same thing. Some patients will prefer face to face but insecure working might mean this is not possible. It's not necessarily a preference issue. Ask the patients directly.
		Expert #5: 10%
		Expert #6: 10%
		Expert #7: In my experience, patients who are unable to attend face-to-face appointments would also have difficulty with a digital app. Of those eligible and referred, 100% preferred face-to-face.
		Expert #8: Difficult to say. In our experience the majority prefer F2F but would use digital access for some aspects of their care (ie hybrid model). It might be useful for some people who find it difficult to leave their homes (we have a small domiciliary service to support these people but only see 2 or 3 people (out of over 1000 annual referrals) per year in their homes.
		Expert #9: Not yet answered
		Expert #10 25% - 30%
		Expert #11: Not sure about this
		Expert #12: We have very few people who cannot attend in person if that is required and these people, we offer a home visit. Across the service (so all appointment) about 25% want all their appointments digitally.
6	Can you estimate the proportion of current Tier 3 weight management service users where a digital app would be unsuitable (i.e., manual dexterity, learning difficulties, digital element)?	Expert #1: 100% unsuitable as the digital systems will not assess and treat obesity as a disease. It will be useless and might be harmful to patients at a T3 level. Treating obesity is not just managing the weight but to have a holistic approach to assess and treat all aspects of health including physical health mental health social health and financial health.
		Expert #2: 30%
		Expert #3: 20%
		Expert #4: Most patients are in their mid 40's so likely to be ok with digital apps. However, there will be special groups e.g people with learning difficulties, older people and younger people who will require

		traditional appts. I would estimate this is about 20-30%.
		Expert #5: 20%
		Expert #6: All patients as a digital system would not assess the patients to understand circumstances, co morbidities, psychological health and personal circumstances. These patients often come with a number of issues that need assessing by an MDT team to determine the most appropriate treatment and support required.
		Expert #7: In my experience, approx. 20% of patients who would be eligible for Tier 3 for referral would have difficulty managing a digital app. This was frequently seen when counselling patients eligible for lower tier digital weight management services
		Expert #8: <20% (some have limited access to good internet connection or old / unsuitable devices that make it difficult)
		Expert #9: 4%
		Expert #10 Would depend on the region. Eg: In London we have multicultural society with language barrier as the main issues. Hence 30%. I expect less in other parts of the country
		Expert #11: 15% for those reasons, need to think about language as well
		Expert #12: About 2-3% of our patients have learning difficulties, another 5% do not have phones that are high enough specs for the apps. When we have offered apps to the complex people that come to tier 3 the response has not been great. Many of them have never had anyone who has given them time to help identify the causes of their weight and to compassionately help them to lose weight and if needed given them therapy to overcome past events that have caused the weight gain (30% of people in our service have been abused). An app is not able to provide the person touch needed. This means unlikely people in Tier 1 and 2 weight management systems having their care given through an app or going off to have a fixed time using an app with not contact with our team is not helpful. Patients do find them useful in conjunction with appointments to reinforce messages and to have more contact with the team. They can mean we see them slightly less

		in person. We are currently looking at using stand-alone app contact for our people on the waiting list to get them ready to see us .
7	Follow-up appointments: a. What is the typical frequency of follow-up with the patient within the Tier 3 weight management service? b. Does the frequency of follow-up vary by staff (e.g., 6-month follow-up with consultant, monthly follow-up with dietitian)? i. Can you estimate the average attendance rates at follow-up appointments in Tier 3 weight management services?	Expert #1: a. Fortnightly with healthcare wellbeing profession, monthly to every 2 months with either physician dietitian psychologist physiotherapist b. Yes i. Our attendance rates are 90%
		Expert #2: a. This will vary depending on the service, and staffing levels. Also if they're taking part in a group programme or 1:1. For 1:1 dietitian appointments, 4-6-weekly in our service. For group programmes, weekly for 8 weeks followed by a couple of 1:1 sessions if needed. b. Yes. 1:1 appointments with dietitian and psychologist might be 4-6 weekly, consultant 6 monthly or less. i. 70%??
		Expert #3: a. Varies depending on what intervention is being offered. For dietetic and psychology groups the frequency is weekly. For 1:1 psychology, frequency is every 2-3 weeks. For 1:1 dietetics, frequency is every 3-6 weeks. b. Yes, as stated above. i. 60%.
		Expert #4: a. From a physio' perspective. A patient who needs more input might be seen 1 month after their initial appt. Otherwise likely 2-3 months to give the patient time to implement changes. b. Yes – in my experience, physicians might need to see the patient less, and psychologists more. I would estimate physio and diet' 2-3 months, physician, 4-6 months, psychologists 2 months with potential for fortnightly or weekly support if required.
		Expert #5: a. This tends to be more frequent for an initial period e.g. weekly or fortnightly for 2-3 months then reduce to monthly thereafter. b. Yes it varies. Dietitians often have the most frequent follow up (e.g. weekly initially then reducing to monthly. Most patients have some Dietetic input. Patients will see

		Psychology where clinically indicated rather than as a matter of routine. May be fortnightly over 4-6 months. Consultant/medic review might be every 3 months if needing medication review. Medic input into patient review in certain situations, tends to be every 3 months for review but will need more regular input in clinical discussions and non patient facing activities like reviewing bloods, medications and offering guidance. Clinicians often offer follow up permitted by service restraints rather than what they view to be clinically best practice. i. 65%
		Expert #6: a. Fortnightly with healthcare wellbeing profession, monthly to every 2 months with either physician dietitian psychologist physiotherapist b. Yes i. Attendance rates across the NENC rates are between 70 and 90%
		Expert #7: Unable to answer
		Expert #8: a. We aim for intensive follow up initially eg in groupd every 1-2 weeks, gradually reducing to 3-4 monthly. This has been significantly impacted post pandemic.
		Expert #9: a. Between 3-6 months b. Yes: Medical weight management clinic follow up 6 monthly AHP follow up 3 months with the exception of group based follow up which offers weekly follow for a 6 week period Psychology is offered in a weekly format for a 6 week group program. i. Aintree Medical weight management clinic 72% Dietetic clinic 78% Physiotherapy 75% Non-Merseyside weight management clinic 74%
		Expert #10 a. 3 months b. Yes. More frequently with dietitian (4-6 weeks). 6 monthly with consultant. i. 70%

		Expert #11: a. After surgery: 2 weeks, 8 weeks, 3/12, 6/12, 1 year 18/12, 24/12. Pre-surgery depend on the patient a bit. Most online seminars etc b. i. Differs per clinician. More DNA with dietitians/psych than with Surgeons/ CNS
		Expert #12: a. Varies from who sees – Doctor every 6-8 months but once seen by a doctor many people do not need to see again, Nurse and Dietitian on average every 3 months but sometimes front loaded so seen more often at start. Psychologist -see patient in blocks of therapy eg 10 and then seen every 1-2 weeks for this therapy. b. i. This varies by person seeing – Doctor 90%, Psychologist 90%, Nurse 70-80%, dietitian 60-70%.
8.	MDT: a. What proportion of the MDT meetings does the patient attend (0-100%)? b. What staff/band would be involved in the MDT for this patient? i. GP ii. Consultant iii. Surgeon iv. Dietitian v. Physiotherapist vi. Psychologist vii. Other (please specify) c. Typically, how long would each MDT take (in minutes) per patient? d. Can you estimate the proportions for the different methods of MDT delivery: i. Face-to-face: (0-100%) ii. Virtual/telephone: (0-100%) iii. Combination (some MDT attendees attending in-person and others attending virtually at the same meeting): (0-100%)	Expert #1: a. Not answered b. i. 50 ii. 50 iii. 0 in tier 3 iv. 100 v. 75 vi. 75 vii. Healthcare wellbeing professionals 100 c. 45 minutes to 60 minutes d. i. 90 ii. 10 iii. 10
		Expert #2: a. 0% b. • Consultant • Surgeon – very occasionally in tier 3 • Dietitian • Psychologist • Other (please specify). Pharmacist very occasionally c. 5 d. Combination (some MDT attendees attending in-person and others attending virtually at the same meeting): (0-100%) 100%
		Expert #3: a. 0% b. Dietitian, Psychologist c. 15 minutes d. i. 60% ii. 10% iii. 30%
		Expert #4:

		a. 0% b. Depends on the service. GPwSI/Consultant, physio, dietitian, psychologist (medical MDT) Potentially surgeon and member of the medical MDT if the medical MDT had agreed the patient was suitable for surgery from their perspective. All clinicians involved in the patients care should attend. c. Depends on the complexity of the patient. A 'straightforward' patient might be 20 minutes. Patients who are more complex could be upto 40 minutes and there might need to be additional actions, e.g updated psychology review/ sleep referral. d. Face to face – was 100% pre covid. Virtual during Covid. Likely to be the same (e.g all online), due to the challenges with some people dialling in to an in person meeting.
		Expert #5: a. 5% - <u>If multiple staff involved in clinical consultation at the same time patient will attend.</u> Where teams tend to review patients separately then hold clinical discussions, I wouldn't usually see patients in that discussion. b. Dietitians & Psychologists usually as a minimum. This varies hugely based on resources available in different regions, where medics/consultants available they may be involved for part of the MDT where relevant. If teams have physio /nursing they would be involved. c. 15 minutes average d. i. 85% ii. 10% iii. 5%
		Expert #6: a. No response b. i. 50 ii. 50 iii. 0 in tier 3 iv. 100 v. 75 vi. 75 vii. healthcare wellbeing professionals 100 c. 45 minutes to 60 minutes d. i. 90 ii. 10 iii. 10

		Expert #7: Unable to answer
		Expert #8: Not really sure what you mean here a. Services are highly variable in how they do this. We do MDT (without patient) for all potential surgical referrals to tier 4 and complex patients. b. i. depends on service usually no ii. Yes iii. Only for tier 4 iv. yes v. Yes vi.Yes vii. Nurse therapies assistants c. 10 min d. We do some F2F, some virtual and some combined depending on the service / MDT. I expect this is the case across the country. I can't really give a figure for this.
		Expert #9 a. 0% b. i.No response ii. Yes iii. No response iv. Yes v. Yes vi. Yes vii. No response c. 15 min d. i. 98% ii. 2% (Psychology) iii. 0%
		Expert #10 a. No response b. All the below expected to be involved. Invariably as expected you might have 1 or 2 apologies for the meeting c. 10 minutes d. i. No response ii. No response iii. 70% f2f and 30% virtual iv.
		Expert #11:

		a. None – all just staff b. For all MDT meetings: i. No ii. Yes iii. Yes iv. Yes v. Don't have one vi. Yes vii. CNS (leads MDT), anaesthetist, hepatologist, plastic surgeon c. Very variable – 2 mins to 10/15 mins at times if complex post-op d. Combination - all like this
		Expert #12: a. % only on rare occasions do we have MDT with patient. b. i. occasionally ii. yes iii. yes iv. yes v. no vi. yes vii. nurse c. 20 minutes d. i. Currently 100%
9	What proportion of patients within Tier 3 weight management service are currently taking weight loss medication?	Expert #1: 20% on Saxenda. This is suspected to be at 70% when wegovy becomes available
		Expert #2: Unsure. Data systems are not as good as we'd like them to be to be able to find out this information. A significant proportion are on Saxenda. Many are also on semaglutide for diabetes.
		Expert #3: 0% - we have no medical staff or prescriber within our team
		Expert #4: Unable to comment – the meds were approved after I left clinical practice. However, in my experience, some patients were accessing these online prior to them being approved by NICE.
		Expert #5: Many Tier 3 services will be 0% as have no weight loss medications available at all (with the exception of orlistat which is available but often provided via GPs). Where services have weight loss injectables available, the proportion may be 4-5%. A big increase on this is expected when medication such as Wegovy and lily become available in the UK (expected late 2023/early 2024). Drug companies can provide expected impact on proportion on medications.
		Expert #6:

		Only available within two services currently within the NENC ICS and it is 20% on Saxenda
		Expert #7: N/A
		Expert #8: Currently we are rolling out Saxenda (liraglutide) as per NICE guidance. We probably have about 3-5% of people on this; across the country it is highly variable and zero in many places. Other treatments (orlistat) are rarely used (<1%). This is likely to increase +++ once Semaglutide is available.
		Expert #9: Saxenda 4%. I can not estimate this for orlistat.
		Expert #10: Difficult to predict as new medications have been licenced recently. Also there has been recent increase in awareness among patients. But would assume 30%
		Expert #11: We are Tier 4 only
		Expert #12: 10%
10	What is the difference between Tier 3 weight management service and Tier 4 in terms of the following: a. Frequency of follow-up b. Staff band/time involved in MDT c. Average length of MDT review (minutes) per patient d. Method of delivery of patient review (face-to-face/virtual split)	Expert #1: Not Much difference but will vary depending on the individual patient
		Expert #2: a. Follow-up pathway is more standardised. Seen at 6 weeks, 3,6,9,12,18,24 months. b. The same except surgeons are involved regularly rather than very occasionally. c. 3-5 d. Follow-ups are predominantly done face to face due to the need for bariatric blood tests.
		Expert #3: I do not know the differences and this would be difficult to generalise as we are aware that all tier 3 and tier 4 services are set up differently.
		Expert #4: Patients get much more support in tier three. They are likely to have appointments with someone from the team every month/ six weeks, be it dietitians/physios/physicians/psych. I can't comment more than this as I did not deliver tier 4 services. Anecdotally from working with patients' post-surgery for my PhD, lots was done via the telephone, and patients reported they didn't feel as well supported. This was part of the rationale for my study.
		Expert #5: a. Tier 3 more frequent, intensive input every 1-2 weeks initially, reducing to monthly. Tier 4 will mostly follow up initially 3 months post

		op then at 6-month intervals for 2 years although more frequent if psychological concerns or post operative complications. b. Tier 3 and 4 services need similar staffing although Tier 4 needs an additional consultant surgeon and may have pharmacy input. Tier 3 often has an endocrinologist or other medic input instead of surgeon as in Tier 4. Tier 4 will need more consultant time in the MDT, less time required at Tier 3. Psychology required in both Tiers although a larger percentage of patients may require psychology in Tier 3 so more time needed. Dietitians will be heavily involved in Tier 3 and Tier 4 although review more frequent in Tier 3 so more input per patient. Physio more likely needed in Tier 3. c. Can't really answer this easily. Not all MDTs work in joint clinics in Tier 3 & Tier 4. For example, a patient may be involved with Psychology & Dietetics in Tier 3 (plus surgeon review in Tier 4) but see each clinician separately (e.g. 30 – 45 minutes with Dietitian, 60 minutes with Psychology, 15 minutes with surgeon). Clinical discussions then take place in separate MDT meetings where appropriate. Some services will have MDT clinical reviews in both Tier 3 & Tier 4 (multiple staff in room at same time with patient for 60 – 90 minutes) although not at every appointment. d. Tier 4 90% face to face, 10% virtual, Tier 3 75% face to face, 25% virtual
		Expert #6: This is dependent on the patient needs
		Expert #7: N/A
		Expert #8: a. I presume you mean post-op – this is usually 2-3 x in year 1 and twice in year 2. Pre-op patients are usually seen once. b. Highly variable. Will include surgeon, physician, anaesthetist, dietitian, psychology. c. For initial assessment 40 mins approx.. d. Tier 4 is 100% F2F as = bariatric surgery. Some of the follow up is virtual.
		Expert #9: We refer on to a number of different tier 4 services. I can not estimate this information.
		Expert #10: a. More follow up in Tier 4 b. More involvement in Tier 4

		c. More in Tier 3 d. More f2f in Tier 4
		Expert #11: Only provide Tier 4
		Expert #12: a. bit more frequents as just see them before and immediately after surgery unless problem b. about the same c. about the same d. Almost all face-face as need to examine or do procedure.
11	What proportion of patients within Tier 4 management service are currently taking weight loss medication?	Expert #1: Less than 5%
		Expert #2: Unsure. It would be good to have this data
		Expert #3: Not known as we are not a tier 4 service
		Expert #4: Unable to comment on this, as above.
		Expert #5: My experience has been even less than in Tier 3 (see Q9)
		Expert #6: Less than 5%
		Expert #7: N/A
		Expert #8: Almost none; there may be a few post-op patients who meet NICE criteria for Saxenda (liraglutide 3mg), but these will almost certainly have been discharged from tier 4 at this stage, and may have been referred back to tier 3 for further medical management due to weight regain.
		Expert #9: We don't run a tier 4 service.
		Expert #10: 10%
		Expert #11: would estimate maybe 10% might be lower
		Expert #12: 1%
12	Semaglutide NICE guidance states that patients may be taken off the medication at 6 months if they have not lost 5% of their initial weight. Can you estimate the proportion of patients taking Semaglutide who have medication withdrawn at 6 months for this reason?	Expert #1: Semaglutide is still not made available in UK hence the question is irrelevant. However I would guess 10- 20% of the patients may have to be withdrawn for this reason.
		Expert #2: NHS Tier 3 services are not yet set up for semaglutide for weight loss so we don't know. There are definitely some who have had Saxenda

		withdrawn due to inadequate weight loss but I'm unsure of the proportion.
		Expert #3: Not known as we do not prescribe weight loss medications.
		Expert #4: Unable to comment on this, as above
		Expert #5: 10%
		Expert #6: This is a difficult question to answer, but it could be anywhere between 10 to 20%
		Expert #7: I have not encountered a patient having Semaglutide withdrawn due to this reason, with it usually being stopped due to s/e or cost if taking privately.
		Expert #8: Semaglutide is not yet available. In the trials over 80% of people achieved 5% weight loss. There is no reason to think this will be different in clinical practice.
		Expert #9: N/A as Semaglutide is not currently available.
		Expert #10: No experience of this yet. But I will assume majority will have medication withdrawn at 6 months for this reason. Minority will benefit.
		Expert #11: Dont know proportions. We are using Saxenda more due to availability if they meet criteria. Weight review every 3 months and it is sopped if not losing weight
		Expert #12: As yet Semaglutide has not been made available by the drug companies due to shortage of supplies. There is a drug called Saxenda prescribed by Tier 3 clinics that has to be stopped if 5% weight loss is not seen in about 20%-30% we have to withdraw the drug for this or side-effects.

#	Question to Arut Vijayaraman	Response received 06/06/2023
1	At the scoping workshop on Wednesday 10 May, it was mentioned that NENC carried out a cost assessment which reported [redacted] per patient cost for tier 3 weight management services [redacted]. The EAG has not been able to	[redacted]

#	Question to Arut Vijayaraman	Response received 06/06/2023
	locate this report in their literature searches. a. Would it be possible to have access to this report? b. If this report is not in the public domain, are you able to share some detail as to how [redacted] was derived (as this could help us in determine the comparator costs in the economic evaluation).	[redacted]
2	For the "typical" patient accessing current NHS Tier 3 weight management services in your area, can you estimate on average: a. How often (e.g. weekly, fortnightly, monthly) do patients have appointments with: i. GP ii. Psychologist iii. Physiotherapist iv. Dietitian v. Other (please specify) b. For how long do patients have access to Tier 3 services (e.g. 6 months, 12 months)? c. Do patients have access to all the clinicians specified in your response to 2a. for the full duration of their time in Tier 3 services?	It's not GP, but a consultant physician with special interest in obesity. As an average physician, psychologist, physiotherapist will see 4 times a year. It will vary individually Dietitian will see more than 4 times a year. All patients will be offered a 2 weekly weight and a motivational consultation with a band 4 or 3, specially trained healthcare well-being professional (working directly under the physician, dietitian and psychologist). These are face to face consultations. Yes. Patients will have access to all the clinicians throughout the year as per individual needs. Also the clinicians will cross refer (example the dietitian will arrange a follow up with physician if and when needed in addition) The service is offered for a minimum period of 12 months. Most patients continue up to 18 months to 2 years.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health technology evaluation

Assessment report overview

Digitally enabled for delivering specialist weight-management services to manage weight-management medication

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the external assessment group (EAG) report. It includes **brief** descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the committee may wish to discuss. It should be read along with the external assessment report. The overview forms part of the information received by the medical technologies advisory committee when it develops its recommendations on the technology.

Key issues for consideration by the committee are described in section 9, following the brief summaries of the clinical and cost evidence, and evidence gaps.

This report contains information that has been supplied in confidence and will be redacted before publication. This information is underlined and highlighted in either yellow (for academic in confidence information) or in blue (for commercial in confidence information). Any depersonalised data in the submission document is underlined and highlighted in pink.

This overview also contains:

- Appendix A: Sources of evidence

1 The technology

Weight management medication should be used within a specialist weight management service. Digitally enabled weight management technologies can be used to deliver specialist weight management programmes, following referral, by the technology itself and by healthcare professionals using the technology. They can be accessed online or via an app, providing a multidisciplinary programme and in-app support from a multidisciplinary team (MDT) of healthcare professionals. This could include dieticians, nutritionists, specialist nurses, psychologists, psychiatrists, physiotherapists, pharmacists and obesity physicians. Digitally enabled programmes should include behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake.

Some digitally enabled weight management programmes offer in-programme medication reviews with a prescribing clinician alongside regular reviews with health coaches such as nutritionists or dieticians. Other digitally enabled programmes can be used to support weight management medication prescribing by sharing medication adherence data with local healthcare professionals. The frequency of reviews may vary depending on the technology, user preference and the stage of the programme.

Eight digitally enabled weight management programmes designed to support treatment with weight management medication, that include specialist weight management services and prescribing or monitoring capabilities, are included in the evaluation. Detailed descriptions of the technologies are provided in the scope.

- CheqUp (CheqUp Health)
- Gro Health W8Buddy (DDM Health Ltd)
- Juniper (Juniper Technologies UK Ltd)

- Liva (Liva)
- Oviva (Oviva)
- Roczen (Reset Health)
- Second Nature (Second Nature)
- Wellbeing way (Xyla Health and Wellbeing)

2 Proposed use of the technology

2.1 Disease or condition

Obesity is a chronic condition characterised by excess body fat. People living with obesity are at an increased risk of developing other health conditions such as cardiovascular disease, type 2 diabetes, atherosclerosis (the presence of fatty deposits in the arteries), hypertension, dyslipidaemia (abnormal levels of fats in the blood), stroke and some types of cancer (for example, breast cancer and bowel cancer). In 2019 to 2020, 10,780 hospital admissions were directly attributed to obesity, and obesity was a factor in over 1 million admissions (NHS Digital, 2021).

Obesity is typically measured by calculating a person's body mass index (BMI). It is defined as 30.0 kg/m^2 and above and severe obesity is defined as 40.0 kg/m^2 and above (NHS England, 2023). Slightly lower thresholds for obesity (usually reduced by 2.5 kg/m^2) are used for people with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background. The Health Survey for England 2021 estimated that 25.9% of adults (25.4% of men and 26.5% of women) are living with obesity in England. The same survey found that people aged 45 to 74 and those living in the most deprived areas are more likely to have obesity.

2.2 Patient group

Adults who are eligible and referred for treatment with weight management medication for the management of overweight and obesity, in line with NICE's guidance that includes but is not limited to:

- NICE's technology appraisal guidance for semaglutide for managing overweight and obesity
- NICE's technology appraisal guidance for liraglutide for managing overweight and obesity

2.3 Unmet need and current management

There is an unequal distribution of specialist weight management services across the country, creating a postcode lottery. In some areas there is no access to specialist weight management services. In areas with established specialist weight management services, there is an increasing number of people on waiting lists because of limited resources and funding. Services offered can vary widely across the country.

Limited access to these services also limits access to weight management medications for people who are eligible. Providing specialist weight management services using digitally enabled programmes could improve access to these services. These technologies could also reduce the number of in-person appointments and increase the capacity of service delivery in areas that have established services.

NICE's technology appraisal guidance for semaglutide recommends that it is used as an option for weight management only if it is used within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4). NICE's technology appraisal guidance for liraglutide recommends it as an option for managing overweight and obesity only if it is prescribed in secondary care by a specialist multidisciplinary tier 3 weight management service.

Tier 3 and 4 specialist weight management services for people with overweight and obesity are defined in the guidance for Clinical Commissioning Groups (CCGs): Service Specification Guidance for Obesity Surgery (2016).

The intensity, frequency and variety of support from an MDT of healthcare professionals varies between specialist weight management programmes. They may be offered in person, remotely via telephone or video call, or a combination of in person and remote support. Programmes can last between 6 and 24 months and eligibility to access these services may vary depending on area and local funding.

2.3 Proposed management with new technology

Digitally enabled weight management programmes would be offered as an option to adults with obesity that are referred for weight management medication. Patient preference and engagement should be considered when helping people make decisions about the care that they want to receive.

3 The decision problem

Details of the decision problem are described in the scope. The EAG has provided further clarification to some elements of the decision problem (see section 1 of the external assessment report [EAR]). However, the EAG made no changes to the decision problem.

4 The evidence

4.1 Summary of evidence of clinical benefit

Evidence for 5 out of the 8 technologies was identified (Oviva [n=11], Liva [n=10], Roczen [n=5], and Gro Health [n=1], Second Nature [n=4]). A total of 22 studies reported across 27 publications were considered relevant to the decision problem by the EAG. A further 4 studies for Second Nature were excluded from the EAG evidence review but may be considered relevant to this assessment. Of the studies included, 8 were unpublished and provided by

the companies. For further details about study inclusion and exclusion see sections 4.1 and 4.2 of the EAR.

The number of studies for each technology and study design are summarised in Table 1.

Table 1: Summary of included studies for each technology

Technology	Publication and study design
CheqUp	No relevant published or unpublished evidence identified
Gro Health W8Buddy	1 publication • Prospective cohort study (Hanson et al. 2023)
Juniper	No relevant published or unpublished evidence identified
Liva	10 publications, of which 3 are unpublished • 1 RCT (reported across 4 publications) (Christensen et al. 2022a; Christensen et al. 2022b; Hesseldal et al. 2022; Imeraj et al. 2022) • 1 non-randomised comparative study (Tsai et al. 2023) • 2 cohort studies (Komkova et al. 2019; Pedersen et al. 2019) • [redacted] (Liva CiC-1; Liva CiC-2; Liva CiC-3)
Oviva	11 publications, of which 3 are unpublished • Pilot RCT (does not compare Oviva with standard care) (McDiarmid et al. 2022) • 3 retrospective comparative studies (Huntriss et al. 2021; Sutter et al. 2021; Sutter et al. 2020)

	• 3 before and after studies (Haas et al. 2019; Huntriss et al. 2020; Lawson et al. 2022) • 1 feasibility study (Papathanail et al. 2022) • [redacted](Oviva CiC-2; Oviva CiC-3)[redacted] (Oviva CiC-1)
Roczen	5 publications, of which 2 are unpublished • 3 single-arm cohort studies (Brown et al. 2022; Falvey et al. 2023; Phung et al. 2023) • [redacted](Roczen AiC-1; Roczen AiC-2)
Second nature	4 publications • 1 prospective cohort study (reported across 2 publications) (Hampton et al. 2017) • 3 retrospective cohort studies (Idris et al. 2020; Kar et al. 2020; Thomson et al. 2022)
Wellbeing way	No relevant published or unpublished evidence identified

Summary of the clinical outcomes

Evidence for 20 out of 24 outcomes across 5 of the 8 included technologies (Gro Health, Liva, Oviva, Roczen and Second Nature) was identified and considered relevant to the decision problem.. The evidence base generally reports weight loss when compared to baseline when using digitally enabled weight management programmes. It also reports greater weight loss for people using digitally enabled programmes compared with standard care

(non-digitally enabled programmes). For more detail on the outcomes reported in the evidence base see section 5.3 and Table 3 of the EAR.

Gro Health W8Buddy

One study for Gro Health was considered relevant to the decision problem. The single-arm prospective cohort study (Hanson et al., 2023) reported that 51.3% of people offered free access to the technology were interested in using the technology (102 of 199). Of those who were interested, 34.2% engaged with the technology (68 of 102). The study reported that 4% of people (n=4) were unable to engage with the digitally enabled weight management programme because of the lack of a smart phone or internet connection. For more detail about engagement and adherence outcome see Table 4 of the EAR. There is a lack of weight loss data for Gro Health and limited engagement and adherence data.

Liva

Ten publications including 1 RCT and 1 non-randomised comparative study for Liva were considered relevant to the decision problem. The RCT reported a statistically significant difference in absolute weight reduction (Christensen et al., 2022a) and BMI (Hesseldal et al., 2022) for people using Liva compared with face-to-face weight management services at 6 and 12 months (P<0.001). There was also a reported difference in weight loss between the groups at 24 months, but this was not statistically significant. Non-comparative evidence generally showed a reduction in weight compared to baseline. For more details about weight loss outcomes see Tables 6b and 7a to 7d in the EAR.

In the RCT (Christensen et al., 2022a), greater levels of adherence were reported for people using Liva compared with face-to-face weight management services at 6 months (74.0% compared to 60.0%), 12 months (63.5% compared to 52.1%) and 24 months (40.5% compared to 36.4%). Published adherence rates for single arm studies ranged from 3.0% to 97.6%. However, the EAG noted that adherence was not consistently defined between studies.

Hesseldal et al. (2022) reported no statistically significant change in EQ-5D-5L or Short Warwick-Edinburgh Mental Wellbeing scale between patients receiving Liva compared with standard care at 6 or 12 months, or when compared with baseline.

Oviva

11 publications, including 1 pilot RCT (comparing Oviva plus an intermittent low-energy diet to Oviva with a continuous low-energy diet) and 3 retrospective comparative studies for Oviva were considered relevant to the decision problem.

Comparative evidence suggests that there is no difference between Oviva and face-to-face weight management services for weight loss outcomes. A retrospective comparative study (Huntriss et al., 2021) reported no statistically significant difference in absolute weight reduction or change in BMI between people using Oviva compared with face-to-face weight management services at 12 to 16 weeks and 24 to 28 weeks. All of the remaining studies reporting weight loss outcomes for Oviva reported a mean or median reduction in weight when compared to baseline. For more detail about weight loss outcomes see Tables 6a, 6b and 7a to 7d in the EAR.

A before-and-after study (Haas et al., 2019) reported no change in mental or physical component summary scores (from SF-12) at 3 months when compared with baseline. However, another before-and-after study (Lawson et al., 2023) reported a statistically significant change in PHQ-9 at 3 months (P=0.0026) and 6 months (P=0.0022) when compared with baseline. For more details on health-related quality of life outcomes (including psychological outcomes) see Table 15 of the EAR.

There is limited engagement and adherence data for Oviva. A retrospective non-randomised comparative study (Huntriss et a., 2021) reported a higher uptake of Oviva (64.5%) compared with face to face (28.4%) and telephone based (7.1%) weight management services. For more details about engagement and adherence see Table 4 and Table 5 of the EAR.

Roczen

Three single-arm cohort studies and [redacted] for Roczen were considered relevant to the decision problem. Studies reported a consistent reduction in absolute weight loss was when compared to baseline. One published abstract (Brown et al., 2022) reported this change as statistically significant (*P*<0.001) at both 12 and 24 weeks. Another abstract (Falvey et al. 2023) reported 71% of participants achieved a clinically significant weight loss (>5%) at 12 months. [redacted] (Roczen AiC-2)[redacted] For more details about weight loss outcomes reported for Roczen see Table 6a, 7b and 7d of the EAR.

There is limited data on engagement and adherence for Roczen. Retention was reported as 69% at 6 months and 43% at 12 months in 1 abstract (Falvey et al., 2023). Another abstract (Brown et al., 2022) reported programme completion of 37.4% (244 out of 653) at 6 months. [redacted](Roczen AiC-1)[redacted] For more detail about programme adherence outcomes see Table 5 in the EAR.

Second Nature

Four non-comparative studies were excluded from the EAG review but may be considered relevant to the assessment. The EAG stated that the studies were excluded as they include a programme without MDT support. However, the company contested this during a factual inaccuracy review and stated that the excluded studies do include an MDT approach similar to that of other studies included in the assessment.

Studies consistently reported weight loss for people using Second Nature when compared to baseline. The largest study (Idris et al. 2020 [n=3,649]) reported a mean weight loss of 7.1kg (7.5%) at 6 months and 6.1kg (6.5%) at 12 months compared with baseline. The remaining evidence base also generally reported a reduction in weight compared with baseline.

The same study reported that 24.6% of users had data available at baseline, 6 months and 12 months. The study reported higher rates of adherence (47.5%) for users referred directly from the NHS. A prospective cohort study (Hampton et al. 2017) reported that retention rates ranged from 78.6% at 6 weeks to 29.6% at 6 months. For further details about studies evaluating Second Nature, see Appendix B3 of the EAR.

EAG comments on the quality of the clinical evidence

- **Population –** study eligibility criteria was reported in 7 publications (including 6 abstracts), and the EAG noted that 'obesity' was not explicitly defined. However, the mean BMI was greater than 30 in 6 publications and greater than 27 in the remaining publications.

- **Intervention**

    - **Intervention alongside weight management medication** - two publications specifically excluded people taking weight management medication. Two published studies explicitly mentioned including patients taking weight loss medications (including Orlistat, GLP-1 analogues and sodium-glucose co-transporter-2 inhibitors) and [redacted] The EAG stated that the use of weight management medication alongside digitally enabled weight management programmes reflects real-world interventions but noted that this may confound results and requires careful reporting.

  - **Intervention alongside specific diets –** Five publications used digitally enabled weight management programmes alongside a specified diet. Three abstracts reported the use of Roczen alongside a time-restricted eating, low carbohydrate moderate protein plan and 2 studies reported the use of Oviva alongside a low-energy low-calorie Optifast, with or without a mediterranean diet. The EAG noted that this reflects real-world interventions but may also confound results.

- **Study duration** - Study duration varied between technologies. The EAG also noted that outcomes were poorly described and inconsistently reported across the evidence base.

- **UK setting –** the EAG noted that about half of the evidence base is set within the UK and largely within the NHS. However, the main RCT for Liva took place in a different country (Denmark) and healthcare system and therefore the results may not be generalisable to the UK NHS setting.

For more detail about the EAG comments on the clinical the evidence, see section 5.2 of the EAR.

4.2 Summary of economic evidence

No studies were identified that were directly related to the decision problem. The EAG identified a total of 39 studies that were considered to be potentially relevant to the decision problem. The EAG's search for economic evidence identified 22 potentially relevant economic evaluations or related studies. A further 17 studies were identified through reference trawling, clinical searches, information supplied by companies and related NICE guidance.

Most identified studies were an economic evaluation alongside an RCT of a weight management intervention (n=16) or an economic decision model (n=19). A small number of studies were identified (n=4) that evaluated the

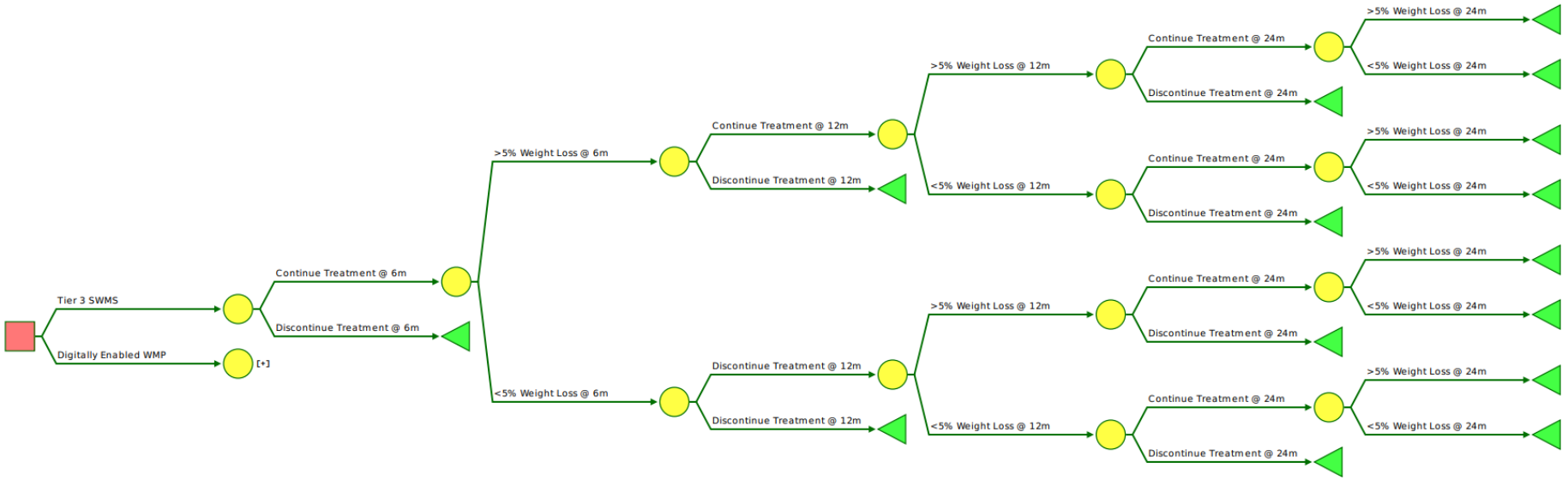
cost-effectiveness of remotely delivered weight management programmes, with the results being mixed. For further information about the economic evidence, see sections 7.1 and 8.2 of the EAR.

Early economic modelling

The EAG undertook a cost-utility analysis of digitally enabled weight management programmes compared to current tier 3 specialist weight management services. The model structure is a highly simplified early analytic model (see figure 1). The EAG noted that developing a comprehensive de novo Markov or microsimulation model, or adapting an existing model was not feasible. It also noted that a long-term state-transition model would likely be needed to predict the incidence and mortality associated with long-term conditions such as obesity.

The EAG reported the costs, quality of life years (QALYs) and the mean net benefit using the willingness to pay threshold of £20,000 per QALY gained. For costs and outcomes beyond 12 months, the EAG applied a discount rate of 3.5% in line with NICE's Health Technology Evaluations manual (PMG36, 2022).

Figure 1: Structure of the EAG's conceptual model



Note: [+] indicates that the sub-tree is identical to the sub-tree above but has been collapsed for clarity.

The model allows people eligible and referred for tier 3 specialist weight management services to receive current standard care (face-to-face tier 3 specialist weight management service) or a digitally enabled weight management programme. A time horizon of 24 months was chosen to reflect the maximum recommended prescription length for semaglutide and liraglutide. At each time point (6 months, 12 months and 24 months) people can continue using the service or drop out of the service. People continuing to use the service can lose less than 5% of their body weight or more than 5% of their body weight. The EAG noted that weight loss is reported in several different ways in the literature, but that this value was the most commonly reported. It also noted that losing less than 5% of body weight is also considered a stopping criteria for semaglutide. The model does not incorporate weight management medication adherence and impact on weight loss.

Due to lack of data on costs and outcomes, the EAG's model assumed a class effect using the data provided by Liva. For further information about the model structure, see section 8.3 of the EAR.

Key parameters

Key parameters in the model were rates of weight loss and discontinuation of treatment. Due to the lack of data for included technologies, the rate of weight loss and treatment discontinuation for Liva, reported across 2 publications (Hesseldal et al. 2022 & Christensen et al. 2022a), were used in the model and assumed to apply for all included technologies. The rate of discontinuation for standard care was also taken from the clinical evidence relating to attendance at follow up (Christensen et al. 2022a). The rate of weight loss for standard care was taken from a systematic review related to specialist weight management services for adults with obesity in the UK (Alkharaiji et al. 2019). The EAG noted that the populations in the studies used to derive values for weight loss are not directly comparable. It also noted that discontinuation of treatment may be due to positive or negative reasons, and so the model assumes that drop-out rates are equal for both those who

have lost 5% of weight or more and those who had lost less than 5% of weight. For further information about key model parameters, see section 7.4 and Tables 21 and 22 in the EAR.

Costs and resource use

Technology costs

A total of 7 out of the 8 companies provided a per person license cost for the technologies which are summarised in the following table (Table 2). Due to the heterogeneity of the costs, the EAG used cost estimates for Liva in the base case. The EAG also included additional costs in the model for a tablet computer (£100) and for the monthly cost of a mobile internet connection (£21) to address potential barriers of digital exclusion. The cost of weight loss medication and any costs associated with system-set up and integration with NHS system were not included in the model. The EAG noted that system set up costs are unclear and could be substantial.

Table 2: Summary of technology costs provided by companies

	CheqUp	W8Buddy (Gro Health)	W8Buddy+ (Gro Health)	Liva	Oviva	Roczen	Second Nature	Wellbeing Way
Licence costs per participant per year based on number of participants, with medication	Not provided	Not provided	Not provided	Not provided	Not provided	Not provided	£2,051.76 to £3,251.76*	£2,456***
Licence costs per participant per year based on number of participants, without medication				Not provided		£600	£503.76**	
500					£1,000			
1,000					£960			
1,500					£940			
<1,000	£1,200	£390	£840					
>1,000	£1,140	£300	£705					
Licence costs based on programme duration, without medication	Not provided	Not provided	Not provided		Not provided	Not provided	Not provided	Not provided
Per month								
6 months				£1,100				
12 months				£1,320				
18 months				£1,550				
24 months				£1,720				

Additional resources from company information	Price with fitbit scales adds £15 per patient per month to cost	Price with weight scale adds £75 per patient to cost	Price with weight scale adds £75 per patient to cost	None stated	None stated	None stated	None stated	None stated
Key: * depending on semaglutide dose, includes digital scales and recipe book; **minimum volume of 100 users per month, ***assumed to be annual cost, includes total diet replacement products, all monitoring equipment and coaching time, however unclear whether with or without weight loss medication.								

Health state utilities

The EAG identified limited evidence on utility that was considered appropriate for the model. The EAG estimated the utility for people at baseline and subsequent increments when losing less than 5% body weight and losing more than 5% body weight using information from a study investigating the impact changes to weight and BMI on EQ-5D-3L utilities using evidence from a behavioural group-based weight loss intervention trial (Breeze et al., 2022). The utility values used in the model are summarised in Table 24 of the EAR.

Results

EAG base case results are summarised in the following table (Table 3). The base case results suggest that digitally enabled weight management programmes are cost saving and cost effective compared with standard care (face-to-face specialist weight management services). The EAG noted that the evidence base for digitally enabled weight management programmes is limited and uncertain, and the results from the early economic analysis should be treated with caution.

Table 3: EAG base case results

	Standard Care (Tier 3 weight management services)	Digitally enabled weight management services (Liva)
Cost	£2,342	£1,982
QALYs	1.537	1.543
Mean NB @ £20,000	£43,774	£44,294
Interpretation		Dominant
Abbreviations: NB, Net Benefit; QALY, Quality Adjusted Life Year		

Additional analyses

The EAG did a number of targeted deterministic sensitivity analyses to explore the uncertainty of key parameters in the model which are summarised in the following table (Table 4). Sensitivity analysis 2 shows that when the dropout rate for digitally enabled weight management service is assumed to

be equal to the standard tier 3 services, digitally enabled weight management services could be less costly and more effective.

In sensitivity analysis 5, using the upper limit of alternate costs for standard care based in primary care, digitally enabled programmes were not cost saving but were still cost-effective. But, when using the lower limit costs in primary care (sensitivity analysis 6), standard care was found to be cost-effective. For more details about the results of the EAG sensitivity analysis see table 30 in the EAR.

The EAG also conducted a threshold analysis related to the costs of digitally enabled programmes and standard care. Results showed that if standard care costs reduced to £1,350 (by approximately 25%), or digitally enabled programme costs increased by 35%, then standard care would be cost-effective

Table 4: Results of EAG sensitivity analysis

Scenario		Standard care			Digitally enabled weight management services (Liva)			Interpretation
#	Description	Cost	QALYs	Mean Net Benefit at £20,000	Cost	QALYs	Mean Net Benefit at £20,000	
	Base case	£2,342	1.537	£43,774	£1,982	1.543	£44,294	Digitally enabled services dominant
1	Dropout rates and weight loss % for standard care from Alkharaiji et al. (2019)	£2,456	1.540	£43,737	£1,982	1.543	£44,294	Digitally enabled services dominant
2	Assumed dropout rate of digitally enabled services equal to standard care	£2,342	1.537	£43,774	£1,862	1.540	£44,346	Digitally enabled services dominant
3	No utility increment for those losing <5% weight	£2,342	1.531	£43,589	£1,982	1.537	£44,134	Digitally enabled services dominant
4	Increase utility increments by 100%	£2,342	1.547	£44,057	£1,982	1.557	£44,738	Digitally enabled services dominant
5	Standard care cost from Jennings et al. (2014) - Lower	£1,378	1.537	£44,737	£1,982	1.543	£44,294	Standard care cost-effective
6	Standard care cost from Jennings et al. (2014) - Upper	£1,915	1.537	£44,200	£1,982	1.543	£44,294	Digitally enabled services cost-effective
7	Standard care cost from Public Health England Audit	£611	1.537	£45,504	£1,982	1.543	£44,294	Standard care cost-effective
8	Standard care cost - Hybrid Services	£1,421	1.537	£44,695	£1,982	1.543	£44,294	Standard care cost-effective
9	Threshold analysis – standard care costs reduced to £1,350	£1,760	1.537	£44,355	£1,982	1.543	£44,294	Standard care cost-effective
10	Threshold analysis – digitally enabled services cost increased by 35%	£2,342	1.537	£43,774	£2,510	1.543	£43,766	Standard care cost-effective

Abbreviations: QALY, Quality Adjusted Life Year

5 Ongoing research

The EAG identified 20 ongoing studies related to 4 out of the 8 included technologies (Gro Health [n=10], Liva [n=4], Oviva [n=4], and Second Nature [n=2]). During fact check, a company stated that there were 2 ongoing studies for Roczen. But the EAG noted there was a lack of detail for the studies. No ongoing trials were identified for CheqUp, Juniper or Wellbeing Way. The EAG could not determine if the ongoing studies were related to the decision problem due to poor reporting and lack of available published information. For more detail about ongoing studies see section 5.4 and Table 21 in the EAR.

6 Evidence gap analysis

The EAG presented a summary of the evidence gaps for intermediate, clinical, patient-reported and economic outcomes. The EAG considered the relevance of the evidence to the decision problem, the generalisability of findings and evidence quality. Table 5 contains the evidence gaps for the outcomes prioritised by the EAG. For more detail on the EAG's evidence gap analysis see section 8.4, Table 31 and Table 32 of the EAR.

Table 5: Evidence gap analysis for key outcome in current evidence

Outcome measure		CheqUp (N=0)	Gro Health (N=1)	Juniper (N=0)	Liva (N=7)	Oviva (N=9)	Roczen (N=3)	Second Nature (N=0)	Wellbeing Way (N=0)
Intermediate measures	Engagement with the programme	RED None	AMBER One non-comparative study	RED None	RED None	GREEN Multiple studies	RED None	RED None	RED None
	Intervention adherence, rates of attrition and completion	RED None	RED None	RED None	GREEN Multiple studies	GREEN Multiple studies	AMBER Two non-comparative studies	RED None	RED None
	Intervention-related adverse events	RED None	RED None	RED None	RED None	RED None	RED None	RED None	RED None
	Weight management medication adherence and medication-related adverse events	RED None	RED None	RED None	RED None	AMBER One unpublished study	RED None	RED None	RED None
Clinical outcomes	BMI	RED None	RED None	RED None	GREEN Multiple studies	AMBER One comparative and 1 non-comparative study	AMBER 1 unpublished study	RED None	RED None
	Weight loss	RED None	RED None	RED None	GREEN Multiple studies	GREEN Multiple studies	AMBER Multiple non-comparative studies	RED None	RED None
PROMs	Health-related quality of life (including psychological outcomes	RED None	RED None	RED None	AMBER One RCT	AMBER Two non-comparative studies	AMBER Multiple non-comparative studies	RED None	RED None
E c o	Healthcare appointments	RED None	RED None	RED None	RED None	AMBER	RED None	RED None	RED None

Outcome measure		CheqUp (N=0)	Gro Health (N=1)	Juniper (N=0)	Liva (N=7)	Oviva (N=9)	Roczen (N=3)	Second Nature (N=0)	Wellbeing Way (N=0)
						One non-randomised comparative study			
	Medication use and adverse events	**RED** None	**RED** None	**RED** None	**AMBER** One RCT	**AMBER** One unpublished study	**AMBER** One non-comparative study	**RED** None	**RED** None
Key: **GREEN**, evidence available; **AMBER**, partial evidence available; **RED**, no evidence available Abbreviations**:** BMI, body mass index; RCT, randomised controlled trial									

Summary and conclusions of evidence gap analysis

The EAG identified several evidence gaps. The evidence gaps most related to the early value assessment are as follows:

Study design and duration

- Lack of randomised evidence with standard care as a comparator for all included technologies, other than Liva (RCT done in Denmark). The EAG noted that differences in intervention engagement and standard care practices may impact the generalisability of RCT results. There is limited evidence beyond 2 years for Liva, 1 year for Oviva, mean 1 year for Roczen and 8 months for Gro Health.

Population

- Only 1 published study reported the proportion of people taking weight management medication (in baseline characteristics only). [redacted] This is relevant to evaluating weight management medication adherence.
- Lack of evidence for how different populations engage with digitally enabled weight management programmes.

Intervention

- Limited (Gro Health) or no available evidence (CheqUp, Juniper & Wellbeing Way) related to the decision problem for some of the included technologies.

Comparator

- Unknown number of specialist weight management service providers in the NHS as well as the number of people accessing these services.

The NHS Obesity Audit will enable monitoring of accessibility to these services over time.

Outcomes

- Only 1 unpublished study reported data on weight management medication adherence. There is a lack of evidence reporting intervention-related adverse events, cardiovascular events, mortality and rate of referral for weight loss surgery.

Decision modelling

- Lack of direct economic evaluations related to all of the included technologies.

Key areas for evidence generation

The EAG noted that there are a large number of outcomes in the decision problem. It emphasised the importance of identifying key outcomes to be able to inform future evidence generation. The EAG has suggested categorical prioritisation for outcomes in the decision problem (see Table 6). The EAG also suggested that future studies on digitally enabled weight management programmes should explicitly report the technology name in the title or abstract to aid future literature searches and the proportion of participants taking weight management medications.

Table 6: EAG suggested categorical outcome prioritisation

		Essential	Important	Supportive
Intermediate measures	Engagement *[Defined as: initial uptake of digitally enabled weight management services]*	✓		
	Intervention adherence, attrition, completion *[Separated as continued engagement with the digital technology and continued engagement with the service]*	✓		
	Intervention-related adverse events *[Defined as all adverse events during the course of service delivery]*	✓		
	Weight management medication adherence	✓		

	[Defined as uptake and ongoing adherence of named medication]			
	Inaccessibility to intervention		✓	
Clinical outcomes	BMI	✓		
	Weight loss	✓		
	Body fat			✓
	Waist circumference			✓
	Hip circumference			✓
	Waist-to-hip ratio			✓
	HbA1c		✓	
	Cardiovascular events			✓
	Mortality			✓
	Physical activity		✓	
	Rate of referral for weight loss surgery		✓	
	Eating habits			✓
PROMs	Health related quality of life	✓		
	Satisfaction		✓	
Health resource use	Healthcare appointments	✓		
	Medication use	✓		
	Healthcare professional grade and time		✓	

Abbreviations: BMI, body mass index; HbA1c, glycated haemoglobin; PROMs, patient reported outcome measures

The EAG noted that the following evidence will need to be generated for future economic evaluations:

- Comparative data on costs and outcomes associated with long term use of digitally enabled weight management programmes
- Comparative data on medication adherence
- Additional information about standard care (including the frequency, duration and number of follow up appointments)
- Cost data for comorbidities associated with long term conditions such as obesity to allow for a longer time horizon
- Data for transitions to tier 4 services and bariatric surgery

The EAG acknowledged that UK audits or real-world studies related to the included technologies within specialist weight management services could be a source of data for current evidence gaps.

For more detail on the evidence gap analysis and evidence generation recommendations see sections 8.5 and 8.6 of the EAR.

7 Comments from patient and carer organisations

Advice and information was sought from patient and carer organisations. The following patient and carer organisations responded:

- Diabetes UK

Advice was summarised in 4 key points:

- Digitisation will provide greater access to weight management services
- Digital methods should not completely replace face-to-face due to this being potentially detrimental to those in certain groups
- Providing a choice of delivery method will likely increase adherence
- Weight management services should be consistently accessible across the country, person centred and stigma

8 Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Several potential equality issues have been identified. Key aspects include:

- Obesity rates increase with age and people aged 45 and over have an increased risk of obesity.
- Obesity rates differ between socio-economic groups. People living in the most deprived areas are more likely to be living with obesity than those in the least deprived areas.
- People with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background are prone to central adiposity and have an increased risk of chronic health conditions at a lower BMI.

- Digitally enabled weight management programmes are accessed via a mobile phone, tablet, or computer. People will need regular access to a device with internet access to use the technologies. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies or people who do not have access to smart devices or the internet.
- People with visual, hearing, or cognitive impairment; problems with manual dexterity; a learning disability; or who are unable to read or understand health-related information (including people who cannot read English) or neurodivergent people may need additional support to use digitally enabled programmes.
- Some people would benefit from digitally enabled weight management programmes in languages other than English. People's ethnic, religious, and cultural background may affect their views of digitally enabled weight management interventions. Healthcare professionals should discuss the language and cultural content of digitally enabled programmes with patients before use.
- Age, disability, race, and religion or belief are protected characteristics under the Equality Act 2010.

9 Implementation

Variations and uncertainties in the care pathway

Access to specialist weight management services varies across England and Wales. In areas with established services the referral criteria, programme length and programme content also vary depending on resources and available funding. Implementation of digitally enabled weight management programmes could vary depending on the technology and how services are currently delivered and funded.

Costs

The costs of implementing different technologies varies. Implementation of digitally enabled weight management programmes could initially increase staff workload and costs to set up new pathways and change service delivery. Smaller service areas may have higher costs per user due to not needing as many licenses for the technology. Digitally enabled programmes may be chosen based on the balance between costs and expected outcomes.

10 Issues for consideration by the committee

10.1 Unmet need

- The committee may wish to consider that digitally enabled weight management programmes can be used to improve access to specialist weight management services and weight management medication. In some areas there is no access to weight management services and in areas where there are services, there is an increasing number of people on waiting lists because of limited resources and funding, creating a postcode lottery. Clinical experts estimated that 30 to 70% of people do not have access to local specialist weight management services. They also estimated that 10 to 30% of people are unable to attend face–to-face appointments because of time commitments or mental health reasons. Limited access to these services may also limit access to weight management medication for people who may be eligible.

10.2 Clinical evidence

- Overall, the evidence base for people using digitally enabled programmes reports greater weight loss when compared with standard care (comparative studies) and baseline (single arm studies). The clinical evidence included by the EAG consists of 22 studies reported across 27 publications. Four studies excluded by the EAG for Second Nature may also be considered relevant to the assessment. These were excluded by the EAG but the company have stated that the studies reflect an MDT service.

  - The RCT evaluating Liva in Denmark reported a statistically significant difference in absolute weight reduction and BMI for people using Liva compared with standard care at 6 and 12 months (*P*<0.001). The reduction in weight was higher for Liva (-4.4kg) compared with standard care (-2.5kg) at 24 months but this was not statistically significant (*P*=0.101). Single arm studies support this and suggest a reduction in weight loss compared with baseline
  - A non-randomised comparative study for Oviva suggests that there are no significant differences in weight loss between people receiving Oviva and those receiving face-to-face treatment, demonstrating equivalence. This is supported by single arm studies which suggest a reduction in weight loss compared with baseline
  - Single arm studies for Roczen (n = 4) and Second Nature (n = 4) suggest a reduction in weight loss compared with baseline.
  - There is a lack of weight loss evidence for Gro Health W8buddy.
  - At present there are no peer-reviewed or unpublished studies for 3 out of the 8 technologies (CheqUp, Juniper and Wellbeing Way)

- The committee may wish to consider the impact that offering digitally enabled weight management technologies has on engagement with the services
  - Comparative evidence suggests that adherence and engagement may be similar (Huntriss et al., 2021) or higher (Chirstensen et al., 2022a) for digitally enabled programmes when compared with face-to-face services. When the intervention is delivered via telephone, adherence rates were higher for digitally enabled interventions (Huntriss et al., 2021)

10.3 Cost evidence

- The results of the early decision modelling suggest that digitally enabled weight management programmes may be cost-effective compared with current standard care (face-to-face specialist weight management services). But, the EAG noted that the evidence base for digitally enabled weight management programmes is limited and uncertain, and the results from the early economic analysis should be treated with caution
- Based on the sensitivity and threshold analysis, the biggest factor affecting the results is the estimate of cost used for current Tier 3 services
    - Threshold analysis results showed that if standard care costs reduced to £1,350 (by approximately 25%), or digitally enabled programme costs increased by 35%, then standard care would become the cost-effective option

10.4 Evidence gap analysis

- Outcomes that potentially need to be prioritised for future evidence generation include engagement, intervention adherence, attrition and completion, intervention related adverse events, weight management medication adherence, BMI, weight loss, health-related quality of life (including psychological outcomes), healthcare appointments and medication use
- The EAG identified several ongoing studies for most interventions. However, only a small number of these studies may partly address the research gaps

11 Authors

Amy Barr and Lirije Hyseni, technical leads

Lizzy Latimer, technical adviser

NICE Medical Technologies Evaluation Programme

July 2023

Appendix A: Sources of evidence considered in the preparation of the overview

Details of assessment report:

- Keltie K et al., Digitally enabled weight management programmes to support weight management medication [GID-HTE1007] External Assessment Group report, July 2023

  For a list of the organisations that accepted the invitation to participate in this assessment as stakeholders and the Expert Adviser Specialist Committee members, see the published project documents. They were invited to attend the scoping workshop and to comment on the external assessment report.

Manufacturers and developers of technologies included in the final scope:

- CheqUp
- Gro Health W8Buddy
- Juniper
- Liva
- Oviva
- Roczen
- Second Nature
- Wellbeing way

Related NICE guidance:

- Semaglutide for managing overweight and obesity. NICE technology appraisal guidance 875 (2023). Available from www.nice.org.uk/guidance/TA875
- Obesity: identification, assessment and management. NICE clinical guideline 189 (2022). Available from www.nice.org.uk/guidance/CG189

- Liraglutide for managing overweight and obesity. NICE technology appraisal guidance 664 (2020). Available from http://www.nice.org.uk/guidance/TA664

References

Please see external assessment report for full list of references.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

GID-HTE10007 Digitally enabled weight management programmes to support treatment with weight management medication

External Assessment Group Report Addendum 1

Produced by: Newcastle External Assessment Group (EAG)

Authors: Kim Keltie, Lead Healthcare Scientist, The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH);

Rosalyn Parker, Evaluation Healthcare Scientist, NuTH;

Paula Leslie, Pre-registrant Clinical Scientist, NuTH

Date completed: 31 August 2023

Contains confidential information: Yes

Responsibility for report:
The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Any 'commercial in confidence' information in the submission document (or corresponding appendices) are highlighted in turquoise.

Background of additional EAG work

During the evaluation of the technologies included within the Final Scope for 'GID-HTE10007 Digitally enabled technologies to support treatment with weight-management medication in specialist-weight management services: early value assessment', no published evidence relating to one of the technologies (Juniper) was identified by the EAG searches (conducted May 2023), nor was any information

provided by the Company. During public consultation for the topic, Juniper submitted evidence in confidence for consideration by the Committee. The Newcastle EAG have summarised the evidence submitted, including details relating to the technology.

Summary of the technology

Juniper is a web-based platform available on computers and as a smartphone app. Patients can access educational content, communicate with professionals from the Juniper multidisciplinary team (MDT) and record data. Data collected in the platform includes self-reported measurements of weight, waist circumference, eating habits, sleep, water consumption, medication (use and dose) and mood. The technology uses an algorithm to flag patients who may require MDT support.

Accessibility and equality

Juniper is currently only available in English for the UK market. Further multi-language capability is planned as part of the EQuIP6 accreditation quality improvement program. The technology currently supports larger text sizes and alternate text for all sections of the app that are interactable, for example, hyperlinks, and buttons, which may be compatible with screen readers. However, the Company's RFI response notes that the technology is not suitable for visually impaired or blind patients. No further detail was provided relating to accessibility for people with learning disabilities, non-English speakers, or other groups.

Regulatory status

Juniper is not currently CE or UKCA marked as the Company note that the platform is a "decision support tool" for practitioners rather than a medical device. An application for assessment against the Digital Technology Assessment Criteria (DTAC) is planned for December 2023.

Referrals and integration into the NHS

Currently, access to Juniper is restricted to private services sought by the public (self-referral). Juniper is not currently being used within the NHS. The Company report that their service is accessible to patients throughout the UK, regardless of their eligibility for NHS services.

MDT staff and frequency of reviews

The MDT communicates daily and meets regularly (frequency not provided) to discuss patient safety events, incidents and other areas or issues within the clinical governance framework. The MDT has clinical governance over weight management, although can collaborate with the patient's regular GP or specialist if required.

The UK MDT comprises pharmacist-independent prescribers, registered pharmacists, dispensing pharmacists, dietitians, clinical nutritionists, and health coaches. Juniper advise that they are currently seeking to recruit a psychologist, physical activity specialists, and a physiotherapist.

In-house prescribing and adherence monitoring

Juniper includes in-house prescribing of weight loss medication for suitable patients in the UK by Pharmacist Independent Prescribers (PIPs) (GPhC registered) who prescribe and manage a patient's treatment.

Juniper has integral decision support in the platform to identify clinical flags with the prescriber before a prescribing action has been confirmed. Prescription plans are for a maximum of 6 months treatment before mandatory routine review. There is continual access to the platform if a person wishes to raise an issue, and response is given within 24 hours (personnel and method unspecified). If patients require a follow up consultation before 6 months due to side effects or clinical queries the treatment is placed on hold until consultation with a member of the clinical team.

Juniper report that patients have fortnightly check-ins to track weight and raise concerns about side effects, however do not include detail for how this is conducted (such as, via telephone, virtual messaging, video calls, or whether communication is in real time or asynchronous). Patients can raise concerns to a dedicated health coach who is trained to escalate matters to an appropriate member of the MDT. The platform includes a 'Trends Engine' which tracks "Active" data submitted by the patient or member of the MDT, such as medication adherence. 'Passive' data is also logged by internal systems accessed by MDT members, including monthly dosage information.

Adverse events

See Section 6 of the EAG report for previous safety searches conducted by the EAG. The Company report that adverse events are captured from patient-reported data relating to side effects, either directly in the app or to a member of the MDT. Juniper advises that they have policies to identify and manage high-risk patients, including specific protocols and MDT training for eating disorders and mental health, and escalation or sign-posting to external services where appropriate. The Company report a 'verification process' to prevent medication misuse, however provide no additional details. A clinical analytics query is run every 48 to 72 hours comparing clinical patient information against clinical events.

Training

When patients join the platform there are several resources, which include an onboarding education module addressing programme overview and first-dose support videos. There is a self-service training library accessible throughout the programme.

All members of the MDT receive an individual compulsory technology onboarding by members of the Juniper team, including clinical training by the leads for each MDT field and clinical governance processes, which are overseen by a global advisory board. Clinical audits on all members of the MDT are continuous with quarterly performance reviews. This includes aspects such as the rate at which patient suitability is determined and first response time connecting with patients.

Bariatric surgery

Juniper do not currently record data relating to progression to bariatric surgery, however do collect data for patients who have undergone previous weight loss surgery prior to undertaking the programme.

Summary of evidence

Juniper provided details of 3 ongoing or planned studies (Table 1), including 2 with interim data (Table 2):

- **Study 1 (Juniper CiC-1):** [redacted]

[redacted]

Study 2 (Juniper CiC-2): [redacted]

Study 3 (Juniper CiC-3): [redacted]

The inclusion criteria and baseline characteristics of the population were poorly reported, however the EAG has assumed all patients are eligible for weight loss medication as part of the eligibility to the medication-assisted programme and note that the mean baseline BMI is above 30 kg/m2 where reported. Interim follow-up data is available up to 11 months although the number of participants at each follow-up time point is not reported.

Key findings from interim data

Weight loss

[redacted]

Adverse events

[redacted]

Retention and Adherence

[redacted]

Satisfaction

[redacted]

Key findings summary

All the evidence relating to Juniper includes patients taking concomitant weight loss medication, which is in line with the Final Scope. [redacted]

[redacted]

he EAG consider the existing summary of the evidence gaps and recommendations for evidence generation reported in Sections 8.4 to 8.6 of the EAG report would also be applicable to Juniper.

Table 1: Summary of ongoing studies for Juniper (N=3)

Study title [ref]	Study design (number of patients); [estimated completion date] Country	Population	Intervention	Comparator	Intermediate measures: Engagement with the programme	Intermediate measures: Intervention adherence, attrition, completion	Intermediate measures: Intervention-related adverse events	Intermediate measures: Weight management medication adherence	Intermediate measures: Inaccessibility to intervention	Clinical outcomes: BMI	Clinical outcomes: Weight loss	Clinical outcomes: Body fat	Clinical outcomes: Waist circumference	Clinical outcomes: Hip circumference	Clinical outcomes: Waist-to-hip ratio	Clinical outcomes: Glycated haemoglobin (HbA1c)	Clinical outcomes: Cardiovascular events	Clinical outcomes: Mortality	Clinical outcomes: Physical activity	Clinical outcomes: Rate of referral for weight loss surgery	Clinical outcomes: Eating habits	PROMs: Patient reported outcomes	PROMs: Satisfaction	Health resource use: Healthcare appointments	Health resource use: Medication use	Health resource use: Healthcare professional grade and time
Juniper CiC-1: [redacted]	[redacted]	**GREEN**	**GREEN**	N/A			✓			✓	✓												✓			
Juniper CiC-2: [redacted]	[redacted]	**GREEN**	**GREEN**	N/A			✓			✓	✓												✓			
Juniper CiC-3: [redacted]	[redacted]	NR	**GREEN** (Juniper and semaglutide vs Juniper, semaglutide and strength training)	**GREEN** (in-person weight management and semaglutide)		✓	✓				✓															

Key: **GREEN** aspect of study in scope
Abbreviations: N/A, not applicable; NR, not reported; vs, versus

Table 2: Summary of ongoing studies with interim results (N=2)

#	Study (year) [design, n]	Population	Intervention and comparator	Key results	EAG Comments
1.	Juniper CiC-1: [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2.	Juniper CiC-2: [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Abbreviations: N/A, not applicable; NR, not reported

Table 3: Evidence Gap Analysis for Juniper

Outcome measure		Juniper (N=2)
Intermediate measures	Engagement with the programme	**RED** None
	Intervention adherence, rates of attrition and completion	**AMBER** Juniper CiC-1, Juniper CiC-2
	Intervention-related adverse events	**RED** None
	Weight management medication adherence and medication-related adverse events	**AMBER** Juniper CiC-1, Juniper CiC-2
	Inaccessibility to intervention (digital inequalities)	**RED** None
Clinical outcomes	BMI	**AMBER** Juniper CiC-1, Juniper CiC-2
	Weight loss	**AMBER** Juniper CiC-1, Juniper CiC-2
	Body fat	**RED** None
	Waist circumference	**RED** None
	Waist-to-hip ratio	**RED** None
	Hip circumference	**RED** None
	HbA1c	**RED** None
	Cardiovascular events	**RED** None
	Mortality	**RED** None
	Physical activity	**RED** None
	Rate of referral for weight loss surgery	**RED** None
	Eating habits	**RED** None
PROMs	Health-related quality of life	**RED** None
	Patient satisfaction	**AMBER** Juniper CiC-1, Juniper CiC-2
Economics	Healthcare appointments	**RED** None
	Medication use and adverse events	**AMBER** Juniper CiC-1, Juniper CiC-2
	Healthcare professional grade and time	**RED** None

Summary of economic considerations

Cost of the technology

The Company provided a cost of Juniper as £45 per month exclusive of VAT and weight loss medication. The monthly subscription includes digital Bluetooth scales.

EAG economic modelling

Early economic modelling was undertaken by the EAG as part of this EVA, please see Section 7 of the EAG report.

The EAG have not conducted any additional modelling specific to Juniper. The EAG note that no quality of life outcomes were reported in the evidence that would enable the EAG to derive utilities and QALYs for modelling. The EAG would also highlight that the cost of the technology is comparable to the range of costs of the other technologies in Scope of this evaluation so may plausibly be cost-effective if the range of outcomes included in the modelling can be generalised to Juniper.

NICE National Institute for Health and Care Excellence

Medical Technologies Advisory Committee Interests Register

Topic: Digital technologies for delivering specialist weight-management services to manage weight-management medicine

NICE's declaration of interest policy can be accessed here

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Dr Andrew Currie	Specialist committee member	Financial Interest	Nothing to declare				
Dr Andrew Currie	Specialist committee member	Non-Financial Professional and Personal Interest	NICE Scholar in Metabolic Surgery – Investigating the adoption of CG 189 Quality Standard on referral of patients with obesity and type 2 diabetes for metabolic surgery.	April 2019		April 2020	
Dr Andrew Currie	Specialist committee member	Indirect Interest	Nothing to declare				
Dr Imad Mekhail	Specialist committee member	Financial Interest	Nothing to declare				
Dr Imad Mekhail	Specialist committee member	Non-Financial Professional and Personal Interest	Nothing to declare				
Dr Imad Mekhail	Specialist committee member	Indirect Interest	Voluntary and non-representative role as a Committee Member on the Society of Endocrinology's	29/03/23			

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			National Obesity Database Steering Group.				
Mrs Irena Cruickshank	Specialist committee member	Financial Interest	Nothing to declare				
Mrs Irena Cruickshank	Specialist committee member	Non-Financial Professional and Personal Interest	Nothing to declare				
Mrs Irena Cruickshank	Specialist committee member	Indirect Interest	Nothing to declare				
Dr Jennifer James	Specialist committee member	Financial Interest	Nothing to declare				
Dr Jennifer James	Specialist committee member	Non-Financial Professional and Personal Interest	Nothing to declare				
Dr Jennifer James	Specialist committee member	Indirect Interest	Nothing to declare				
Dr Karen Coulman	Specialist committee member	Financial Interest	Consultancy – provided research and dietetic advice for Oxford Medical Products (https://oxfordmedicalproducts.com/about-us/) for a trial they were developing for a new weight loss technology. This consultancy work was undertaken through my academic role at the University of Bristol. The fee	March 2021		December 2021 (paid for the work in March 2023)	

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			for this work (approx. £500 was charged and paid to me through the University of Bristol)				
Dr Karen Coulman	Specialist committee member	Non-Financial Professional and Personal Interest	International Consortium for Health Outcomes Measurement (ICHOM) Working Group member – patient-centred outcome measures for patients living with obesity. I am part of an international multi-disciplinary working group tasked with developing a a set of patient-centred outcome measures that matter most to adult patients living with obesity. (https://www.ichom.org/patient-centered-outcome-measures/)	March 2023			
Dr Karen Coulman	Specialist committee member	Non-Financial Professional and Personal Interest	UK National Obesity Database Steering Committee Member, Society for Endocrinology. Part of a committee that is overseeing the set-up of a national Tier 3 weight management database.	March 2021			

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			(https://www.endocrinology.org/clinical-practice/research-projects/national-obesity-database/)				
Dr Karen Coulman	Specialist committee member	Non-Financial Professional and Personal Interest	I undertake research funded through a Health Education England/National Institute for Health Research (HEE/NIHR) Clinical Lectureship Award: "Understanding barriers to referral for specialist weight management services and bariatric surgery and identifying ways to improve access".	April 2019			
Dr Karen Coulman	Specialist committee member	Non-Financial Professional and Personal Interest	British Obesity and Metabolic Surgery Society (BOMSS) Research co-lead for Dietetics. Encouraging and undertaking national dietetic research related to bariatric surgery – e.g. a national audit of pre-operative diets for bariatric surgery.	January 2019			
Dr Karen Coulman	Specialist committee member	Indirect Interest	Nothing to declare				

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Mrs Rebecca Fahey	Specialist committee member	Financial Interest	I work part-time for Cambridge University Hospitals NHS Foundation Trust. I am a permanent member of staff and am paid on a monthly basis by the trust. I work in the Obesity Service – this specialty is relevant to the proposed role.	2010		Ongoing	
Mrs Rebecca Fahey	Specialist committee member	Non-Financial Professional and Personal Interest	Nothing to declare				
Mrs Rebecca Fahey	Specialist committee member	Indirect Interest	Nothing to declare				
Ms Sarah Le Brocq	Patient Expert	Financial Interest	Honorarium for presentations – Novo Nordisk	2018		2023	
Ms Sarah Le Brocq	Patient Expert	Financial Interest	Hosting of podcast series – J&J	2020		2020	
Ms Sarah Le Brocq	Patient Expert	Non-Financial Professional and Personal Interest	Director of All About Obesity	2020			
Ms Sarah Le Brocq	Patient Expert	Non-Financial Professional and Personal Interest	Trustee of ASO	2021			
Ms Sarah Le Brocq	Patient Expert	Non-Financial Professional and Personal Interest	Member of National Obesity Audit	2022			

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Ms Sarah Le Brocq	Patient Expert	Non-Financial Professional and Personal Interest	Strategic Council Member – APPG Obesity	2020			
Ms Sarah Le Brocq	Patient Expert	Indirect Interest	Nothing to declare				

NICE National Institute for Health and Care Excellence

Assessment Report Fact Check

GID-HTE10007: Digitally enabled weight management programmes to support weight management medication

Expert 1	Karen Coulman HEE/NIHR Clinical Lecturer (Research Fellow) Bristol Medical School, University of Bristol
Expert 2	Helen Parretti, Consultant Clinical Associate Professor in Primary Care. Faculty of Medicine and Health, University of East Anglia
Expert 3	Imad Mekhail, registered general practitioner
Expert 4	Nicola Carruthers, Specialist Dietitian , Newcastle hospitals NHS foundation trust

Issue 1

Expert	Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
Karen Coulman	'overweight or obese patients' throughout the document	Use person first language 'people living with overweight or obesity' instead	Weight stigma, need for person first language	Thank you for your comment. The EAG have amended language in the report to reflect patients living with obesity or are overweight.
Helen Parretti	Table 2 – for GroHealth duration is listed as 12 to 5 months for Tier 3	Should this be 5 to 12 months?	Query only and based on logic	Thank you for highlighting this typographical error. This has been changed to "12 to 15 months".
Imad Mekhail	Weight management medication, such as semaglutide and liraglutide, can only be accessed with specialist weight management services, potentially leading to unequal access to treatment (TA664, 2020; TA875, 2023).	Add a clarification that expansion of this is currently being explored, such as through the 2-year £40mill trial which includes expanding prescribing into primary care settings through GPs.	While digitally enabled weight management programmes may be a viable option, it is important to clarify that other non-digital options to deal with access inequality is also being explored. Particularly given access inequality is listed as a special consideration, and concerns about the appropriateness of digital delivery of this service has been previously raised.	Thank you for your comment. Currently, NICE guidance recommends weight management medication alongside specialist weight management services. The EAG note the following press release states: *"The £40 million pilots will explore how approved drugs can be made safely available to more people by expanding specialist weight management services outside of hospital settings. This includes looking at how GPs*

				could safely prescribe these drugs and how the NHS can provide support in the community or digitally - contributing to the government's wider ambition to reduce pressure on hospitals and give people access to the care they need where it is most convenient for them." The impact of this is that the setting of the digitally enabled weight loss services could change over the next 2 years, and hybrid approaches may be adopted. The EAG consider accessibility concerns relating to digitally enabled technologies remain regardless of setting.
Nicola Carruthers	Semaglutide and liraglutide are recommended for use for a maximum of 2 years due to the limited length of Tier 3 specialist weight management services	Consider removing the reason for recommended 2-year maximum on these medications being due to limited length of tier 3 service engagement.	Semaglutide is recommended for max 2 years within specialist weight management service including but not limited to Tier 3 & 4 therefore the reason for weight loss medications stopping at 2 years can't be solely due to limited Tier 3 time.	Thank you for your response. This relates to the NICE final scope and the EAG are unable to alter this wording.

Issue 2

Expert	Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
Karen Coulman	'Specialist weight management services support the management and maintenance of weight loss through behavioural and lifestyle changes.'	'Specialist weight management services support the management and maintenance of weight loss through behavioural and lifestyle changes supported with medication where appropriate? in	The definition given of specialist WM services doesn't really differentiate between a tier 2 WM service. In the next few sentences, it talks about digital enabled specialist WM programmes providing	Thank you for your comment. The EAG have amended the report to reflect this change.

		people with severe and complex obesity' Access to these is also via referral (same as digital WM services)	medication, but 'standard' T3 services also can. Also need to specify that T3 services are for people with severe and complex obesity (to differentiate with T2 services)	
Helen Parretti	The aim of the current NICE guidelines (CG189, 2022) is to help people lose weight and become more physically active to reduce the risk of diseases associated with obesity.	The aim of the current NICE guidelines (CG189, 2022) is to give recommendations on the identification, assessment and management of obesity.	Based on expert opinion and what CG189 states it covers	Thank you for highlighting this. This change has been made.

Issue 3

Expert	Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAG response
Karen Coulman	4 technologies can be accessed through GPs (Oviva, Wellbeing Way, Second Nature, Liva, Gro Health)	5 technologies can be accessed through GPs (Oviva, Wellbeing Way, Second Nature, Liva, Gro Health)	5 are stated in brackets. Typo?	Thank you for your comment, this typographical error has been corrected in the EAG report.

Issue 4

Expert	**Description of factual inaccuracy**	**Description of proposed amendment**	**Justification for amendment**	**EAG response**
Karen Coulman	Table 2 Gro Health Tier 3: 12 to 5 months	Typo here? Should it be 12-15 months?	Typo?	Thank you for your comment, this typographical error has been corrected in the EAG report.

NICE National Institute for Health and Care Excellence

Assessment Report Fact Check

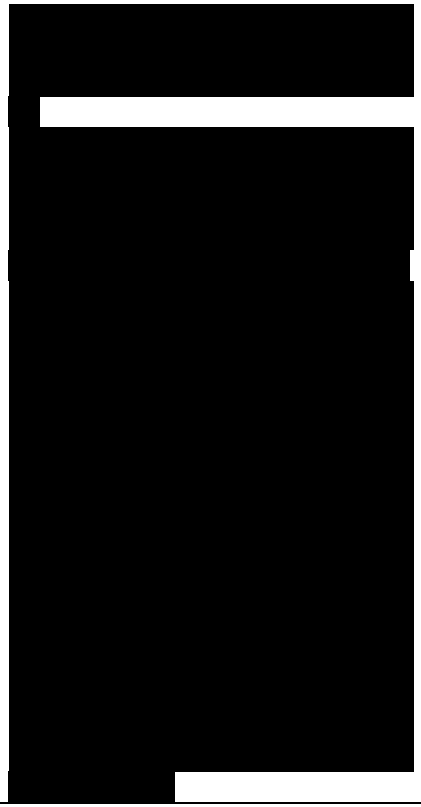
GID-HTE10007: Digitally enabled weight management programmes to support weight management medication

Company 1	LIVA Health, Hayleigh Findlay, Head of Commercial Operations
Company 2	Oviva, Neel Gupta, Medical Lead
Company 3	**R**eset Health Clinics Ltd, Oliver McGuinness, Chief Operating Officer
Company 4	Second Nature, Head of NHS Partnerships

The technologies and care pathway

Company	Question	Comments	Proposed changes	EAG response
LIVA	1 Are there any factual inaccuracies in the way the technologies have been described?	p.17 states that Liva is a CE-marked device	The Liva Platform used in the UK for specialist weight management delivery is not a CE-marked device. For background: during the first quarter of 2021, Liva certified a version of the Liva Platform as a medical device (Class 1 MDD) which is called “Liva Diabetes”. Whilst the Liva platform itself remains the same (i.e. it’s the same data capturing and communication tool being used that is not a medical device), the programme that is delivered using Liva Diabetes is intended to assist and supplement the treatment of Type 2 Diabetes. Liva was able to certify Liva Diabetes as a Class 1 medical device under the MDD after being able to show through various clinical studies that the regular use of the Liva Platform coupled with strong engagement in the programme being delivered	Thank you for this comment. This has been amended in the report (and a change noted in the Company correspondence to note this additional information provided by the Company).

			through it was able to reduce a patient's HbA1c (glucose level) and that the device coupled with the programme was safe.	
Oviva		1) p.20 summary Table 2, the Oviva row is missing a tick in the 1:1 appointments column. 1:1 appointments are definitely part of the Oviva functionality 2) p.27 in section 3.4 relating to languages - the information related to Oviva is incomplete and needs amending please	1) Add a tick in the 1:1 appointments column for Oviva in Table 2 p.20 2) replace "NHS translators are used in Oviva" with "NHS approved translators or in-house clinical staff (25 languages spoken) are used in Oviva"	1. Thank you for your comment, this has been updated in the EAG report. 2. Thank you for your comment. The EAG has removed the term NHS and added detail relating to the number of collective languages spoken within the in-house clinical team.
Reset Health Clinics Ltd		We are not aware of any factual inaccuracies in the technologies that have been described, however we have noted an omission from our original submission and some clarifications.	**Page 21, Table 2** - Device type for Roczen to include • Other (e.g. phone) - Whilst video calls are the preferred method for follow-up consultations with our clinicians, our clinical team also use phone as an alternative if required **Page 21, Table 2** - HCPs available within MDT for Roczen to include • Dietician - This was ticked in our submission but not reflected in the report	Thank you for your comment. To address this the EAG have added a tick to the "Device type (Other)" and to the "HCP available to MDT (Dietitian)" columns.
Second Nature		1 - Second Nature offered a breakdown of estimated costs with or without medication that could be included for a more consistent comparison between provider pricing options.	1 - Table 25, summary of technology costs should include a lower end estimated price for Second Nature, excluding medication. The costs to provide a specialist weight management	1.Thank you for your comment. The EAG has added the costs without medication to Table 25. 2.Thank you for your comment. The EAG have updated Table 2 removing the tick for health

		2 - We noticed that dietitian and nutritionist are unticked for Second Nature in table 2. 	programme with full MDT support are as follows: Licence costs per participant per year: Including medication cost - £2051.76 to £3251.76 Excluding medication cost - £503.76 * **Both include a set of digital scales and recipe book* 2 - All Second Nature health coaches are registered dietitians or nutritionists, so table 2 should be updated to reflect this. 3 - The section relating to Second Nature's tier 3 weight management delivery experience should be updated to reflect that we do deliver tier 3 weight management services in partnership with the NHS.	coach (undefined) and ticked the column for dietitian and also nutritionist. 3.Thank you for your comment and information provided in confidence. No factual inaccuracy however, the EAG have updated Section 8.3 to state that the technology has been used to deliver Tier 3 specialist weight management services in partnership with the NHS.
LIVA	2 Has the care pathway been correctly described?	p.20 duration of programme for Liva is listed as 12 weeks - 24 months	Can we add: *(depending on programme)* Our Tier 3 programmes are at least 6 months, but we do offer 12-week weight management programmes too.	Thank you for your comment. For consistency, we have amended the report to reflect your Tier 3 programme.
Oviva		p.18 "Referrals" – there is incorrect/incomplete information related to access/referrals to Oviva	Oviva can accept self-referrals, referrals via GPs, secondary care providers, and other healthcare professionals. We require additional information from the GP	1. Thank you for your comment, this has been updated in the EAG report.

			in order to onboard patients to the programme safely in line with Tier 3 best practice. Please amend this section accordingly.	2. Thank you for your comment. The EAG has removed the term NHS and added detail relating to the number of collective languages spoken within the in-house clinical team.
Reset Health Clinics Ltd		Page 18, Adherence monitoring section - The report stated that "Five technologies include an adverse event tracker (Gro Health, Liva, Oviva, Roczen, Second Nature) and…" We would like to clarify how adverse events are recorded for Roczen.	Page 18, Adherence monitoring section • Patients will be able to report adverse events via the messaging feature of the patient-facing app. These will be reviewed by a clinician and recorded in the patients' clinical records on the clinic app.	Thank you for your comment. The EAG report acknowledges that adverse events are captured, tracked and recorded across a number of technologies. For consistency across technologies, this additional detail received at fact check has not been incorporated in the report.
Second Nature		Yes		Thank you for your comment, no change required.
LIVA	3 Have all appropriate equality considerations been considered?	Yes		No change required.

Clinical evidence

		Comments	**Proposed changes**	**EAG response**
Oviva				No change.
Reset Health Clinics Ltd		We agree that appropriate equality considerations have been included in the report		Thank you for your comment, no change required.
Second Nature		Yes		Thank you for your comment, no change required.

LIVA	4 Is any key clinical evidence missing from this report?	In Table 12c you assess patients achieving a significant reduction in HbA1c. Due to the longer duration of the study, you include Hesseldal over Christensen. There is, however, a slight difference between the two studies. Christensen is on Type-2 Diabetes (T2D) patients who are also overweight, and Hesseldal is on overweight patients, where some also have T2D. This changes the numbers showing that in the 6 months outcome (Christensen 2022b) the results are: In the intervention group, 24 out of 62 (39%) patients with elevated HbA1c at baseline had normalised their HbA1c < 6.5% at six months, compared to 8 out of 40 (20%) patients in the control group with elevated HbA1c at baseline (p = 0.047) . In the section on Additional outcomes (page 68), these is no mention of Christensen 2022b on the selected outcomes. This study should be added to the same areas as Hesseldal.	Include the 39% significant reduction from Christensen 2022b	Thank you for your comment. The EAG included data from the same RCT available from Hesseldal et al. (2022) that reported results in patients Type 2 diabetes at 6 and 12 months. The EAG has not tabulated results from Christensen et al. (2022b) due to significant risk of double counting, which would introduce bias. Thank you for your comment, this has been added to the EAG report.
Oviva		1) Oviva provided NICE with an abstract presented at the 2022 UK Congress on Obesity (UKCO) entitled “Total Diet Replacement (TDR) results in superior weight loss outcomes as part of a	1) Incorporate evidence from this abstract into the report. This abstract is attachment 4 in the original response to NICE’s request for	1. Thank you for your comment. This conference abstract attachment was later shared by NICE with the EAG. Details for excluding this abstract are available in Appendix B2. The

		digital/remote Tier 3 weight management programme." (Finnie et al, 2022). This does not appear to have been used in the EAR. This is despite this evidence being presented at a major obesity conference and being real world evidence directly relevant to the scope of this EVA i.e. evidence from an English Tier 3 Weight Management Service utilising Oviva's digitally-enabled Tier 3 delivery model. The study provides further evidence around Engagement and Weight Loss within a digitally enabled UK Tier 3 service. 2) The EAR uses an Oviva abstract identified by the EAG themselves (Huntriss et al 2020) relating to the use of a digitally delivered low calorie diet (LCD) programme to achieve significant weight loss and HbA1c improvement in people with Type 2 Diabetes. However, two of the pieces of evidence Oviva provided to NICE in the response to their Request for Information also cover the same scope (and are published abstracts) but have not been used in the EAR evidence summary. However, they provide additional valuable evidence as they are based on: i) larger patient numbers and ii) longer follow up	information and is embedded below. 2) These two abstracts (Miller et al 2022b; Miller et al 2022c) are included in attachment 12 of the original submission to NICE in response to their request for information (embedded below). The two studies have been referenced in the EAR on p.82 but have been incorrectly referred to as relating to the NHS Diabetes Prevention Programme (DPP). In reality they are more representative of the UK Tier 3 weight management population and are not related to the NHS DPP. Please can these abstracts be utilised in the main evidence analysis rather than being referenced incorrectly in the NHS DPP section on p.82	EAG excluded the abstract as patients received the digitally enabled coaching from a dietitian or telephone coaching from a dietitian from an existing NHS Tier 3 specialist weight management service alongside one of two diets. Results were not reported exclusively for those selecting Oviva, therefore results could not be attributed to the intervention in Scope. 2. Thank you for your comment. The EAG have removed the reference to the NHS DPP setting from the description. The EAG note that Miller et al. (2022b) and Miller et al. (2022c) relate to patients with Type 2 Diabetes and do not report an obese or overweight population and do not report BMI, therefore the EAG have considered that this evidence is out of Scope for this EVA as not relating to digitally enabled specialist weight management programmes for patients with obesity, however has been summarised within Section 5.5 and Appendix B3 for completeness.

Reset Health Clinics Ltd		We have not identified any key clinical evidence that is missing from this report.		Thank you for your comment, no change required.
Second Nature		1- We noticed that the Ross et al (BMJ Open Diabetes Research Care, 2022) study was excluded from the report. While the primary recruitment focus of this study was diabetes prevention, it's important to note that the mean BMI of the cohort was 31.1kg/m², indicating that the majority of participants were in the obese category. Weight loss was also the primary outcome of the study, making it highly relevant to the scope of this evaluation. We understand that one of the reasons the study was excluded due to the inability to determine outcomes by intervention. However, the full PDF of the study, including supplementary materials (https://drc.bmj.com/content/bmjdrc/10/3/e002736.full.pdf?with-ds=yes) provides the outcomes are broken down by each intervention. In this breakdown, Second Nature's 12-month diabetes prevention intervention (9-months of daily 1:1 dietitian/nutritionist health coach support followed by ongoing access to asynchronous health	1 - We would like to suggest the inclusion of the study by Ross et al. (BMJ Open Diabetes Research Care, 2022) into the report. 2 - We would also like the external assessment group to consider including the internal analysis that is awaiting publication: A Retrospective Analysis on the Impact of Second Nature's Digital Lifestyle Intervention as a Specialist Weight Management Service in NHS-Referred Patients.	1. Thank you for your comment. The EAG confirm that the outcomes included within this publication, including the supplementary materials, are not reported explicitly for each technology provider. The EAG note that the publication relates to outcomes from patients being referred to the NHS Digital Diabetes Prevention Programme and so is not reflective of adults with obesity referred for treatment or a programme equivalent to a Tier 3 specialist weight management service so is not in Scope of this Early Value Assessment. No factual inaccuracy, no change made. 2.No factual inaccuracy. This information was not shared with the EAG at the time of the EAG Early Value Assessment and so was not considered in the report. The EAG note that the healthcare professionals listed (dietitian) and non-healthcare professionals (nutritionist, exercise specialist) alone would not be representative of a Tier 3 specialist weight management service.

		coaching support) is identified as provider 4, Oviva's intervention is identified as provider 5, and Liva's intervention is identified as provider 3. The study also analysed a large sample size of data after 12-months and was conducted independently of the providers, ensuring there was no bias or conflict of interest that could potentially influence the results. We believe that the Ross et al. study provides valuable, unbiased, and robust evidence regarding the effectiveness of digital weight management programmes and should be considered in this report. 2 - There is another piece of evidence that should be considered for inclusion in the report. We have attached a recently completed internal analysis that is awaiting publication: A Retrospective Analysis on the Impact of Second Nature's Digital Lifestyle Intervention as a Specialist Weight Management Service in NHS-Referred Patients. This study was not included in the original submission due to time constraints. The study analysed the impact of Second Nature's digital weight management intervention on 1,194 NHS-referred patients living		

		with obesity or obesity and type 2 diabetes with a minimum BMI of 35kg/m^2. The programme utilised a multidisciplinary team of dietitians, nutritionists, and exercise specialists to encourage behavioural changes and manage patients' care. The results demonstrated significant weight loss for a notable proportion of the participants over a two-year period.		
LIVA	5 Are there any factual inaccuracies in the results presented from the evidence base?			No change required.
Oviva		1) Section 5.4 ongoing studies, table 21 on page 80. One of the ongoing Oviva studies is the SAFE-LCD study. The information relating to the SAFE-LCD study is not complete and needs to be amended please.	1) The SAFE-LCD study will include the following elements which are not currently marked i) A comparator of “standard care” delivered in English General Practice as part of the RCT ii) Assessment of adherence with the digital tools iii) Measurement of “satisfaction” iv)NHS resource use and medication cost as per the Transform study above Please can you amend the table accordingly. This may mean that table 32 on p.128	1. Thank you for your comment. The EAG have updated Tables 21 and 32 to reflect the outcomes captured. The EAG note that the comparator described is not reflective of a Tier 3 specialist weight management service for patients with obesity.

		2) There are errors/omissions in the Evidence Gap Analysis Table 31 on page 125. For Oviva's column the Mcdiarmid et al 2022 study seems to have been missed off erroneously from several sections and needs to be added in. Inclusion of this study to several evidence domains may affect the overall RAG rating for Oviva's technology in each of these domains as it will increase the total amount of existing evidence available for these domains.	Evidence Gap Analysis needs to be amended. 2) McDiarmid et al 2022 is erroneously missing from the following evidence domains: i) weight loss ii) Body fat iii) waist circumference iv) hip circumference v)HbA1c vi) Eating habits vii) Medication use and adverse events (Huntriss et al 2020, referenced in the main body of the text is also missing from this domain)	
Reset Health Clinics Ltd		We have not identified any factual inaccuracies. Due to word limitation for abstracts, we were unable to include all relevant data for comparison. Therefore, we would like to provide the relevant data for studies referenced in the report. 1. Page 31, Section 5.1 - We would like to clarify the type of studies relating to Brown et al 2022, Falvey et al 2023, and Phung et al 2023. 2. Page 38, Table 3 - We would like to clarify the	Proposed updates are as below. **1. Page 31, Section 5.1, second bullet point** ○ Brown et al 2022, Falvey et al 2023, and Phung et al 2023 are retrospective service evaluations. **2. Page 38, Table 3** ○ Of the two pieces of evidence (academic in	1.Thank you for clarifying the retrospective nature of these studies. For consistency with how other studies have been defined we have included these as retrospective cohorts. 2.Thank you for your comment, the EAG have removed grey shading from the row relating to AiC-2 and added a tick in the column relating to PROMs data. The EAG have also updated highlighting for tabulated results relating to AiC-1. 3.(3a) Thank you for your comment. This definition of retention has been added to Table 5 for the row relating to Falvey et al. (2023).

		clinical outcomes included in the evidence we submitted. 3. Page 44, Table 5 - We would like to clarify the definition of adherence for Falvey et al 2023 and Brown et al 2022. 4. Page 57, Table 9 - We would like to include data marked as NR for Brown et al 2022 and Falvey et al 2023. 5. Page 61, Table 12a - We would like to include data marked as NR for Falvey et al 2023. 6. Page 72, Table 15 - We would like to include data marked as NR for Brown et al 2022. 7. Page 129, Section 8.5 - We identified an inaccurate reference to Roczen's longitudinal evidence.	confidence) submitted, only one is an abstract. ○ As the report is redacted, we can only derive from the ticked clinical outcomes that Roczen AiC-1 is the abstract. ○ Therefore, Roczen AiC-2 shouldn't be shaded grey. ○ Additionally, Roczen AiC-2 does include PROMs data, such as PHQ-9, GAD-7, and BES. Therefore, this column should be ticked for Roczen AiC-2. **3. Page 44, Table 5, Falvey et al 2023** ○ Adherence is defined as patients who have been on the programme for 12 months or more at the point of reporting, and have been engaging with the clinical team by messaging on	4.(3b) Thank you for your comment. The EAG have updated the table to reflect this as 'completed 6 months of the programme with data'. 5.(3c) Thank you for your comment. The monthly subscription for Roczen is stated within "Resource Use and Cost" subsection. No changes to the report required. 6.(4a) Thank you for your comment. This is not a factual inaccuracy as the baseline value was not reported within the publication and the values within the EAG report have been taken directly from the source data. No change made. 7.(4b) Thank you for your comment. This is not a factual inaccuracy as the baseline value was not reported within the publication and the values within the EAG report have been taken directly from the source data. No change made. 8.(5) Thank you for your comment. This is not a factual inaccuracy as the baseline value was not reported within the publication and the values within the EAG report have been taken directly from the source data. No change made. 9.(6) Thank you for your comment. This is not a factual inaccuracy as the baseline value was not reported within the publication and the values within the EAG report have been taken directly from the source data. No change made.

			the app or attending follow up consultations. **3. Page 44, Table 5, Brown et al 2022** ○ Adherence is defined as patients who have been on the programme for 6 months or more at the point of reporting, and have provided data at 6-months. ○ For both of the above, there is no set length for the programmes we offer, but we do offer a monthly subscription model. We do not discharge patients, in keeping with the chronicity of obesity. We encourage members to continue lifestyle modifications life-long. **4. Page 57, Table 9, Brown et al 2022** ○ Baseline measurement is	10.(7) Thank you for your comment. The EAG note that results were available from Phung et al. (2023) for patients who had enrolled on their respective programmes for 49 (SD 24) weeks. We have stated a mean of 12 months for Roczen.

			107.2 cm, SD 17.9. o At 6 months, n = 116. 4. **Page 57, Table 9, Falvey et al 2023** o Baseline measurement is 106.8 cm, SD 14.0. o Note that not all 732 patients provided waist circumference data at the start, therefore n = 673. 5. **Page 61, Table 12a, Falvey et al 2023** o Baseline measurement is 59.6 mmol/mol, SD 9.5. 6. **Page 72, Table 15, Brown et al 2022** o Depression baseline score absolute is 5.7; Anxiety baseline score absolute is 4.6; Emotional eating score baseline absolute is 2.7; Binge eating score baseline absolute	

			is 15.3 7. **Page 129, Section 8.5, Study design gaps** - In the third paragraph "Longitudinal evidence is limited to 2 years for Liva, 1 year for Oviva, 8 months for Gro Health, and 18 months for Roczen." o We have only submitted evidence for up to 12 months for Roczen.	
Second Nature		1 - We noticed that the studies submitted by Second Nature were excluded based on a lack of a multidisciplinary team (MDT) and as more representative of a tier 2 service. We believe there may be a misunderstanding regarding the MDT approach and length of intervention used in the studies involving Second Nature's delivery to patients in the NHS living with type 2 diabetes, including Kar et al (Practical diabetes 2020) and Idris et al (JMIR 2020). For the programme delivery in all the submitted studies with type 2 diabetes cohorts referred by an NHS health care professional, our health coaches worked with the patients' NHS healthcare team (including GPs and nurses)	1 - We propose that the report be revised to acknowledge the MDT approach used in the studies involving Second Nature's delivery to patients in the NHS living with type 2 diabetes. This would involve recognising the collaborative work between our health coaches and the patients' NHS healthcare team, which effectively created an MDT of healthcare professionals and is a similar approach referenced for Gro Health's W8Buddy programme that was included in the scope. Based on this additional information, we believe it is crucial to include the studies by Kar et al (Practical	Thank you for your comment. The EAG note from the Company information shared with NICE and with the EAG that Second Nature offer a weight management programme with an MDT for patients using weight loss medication or those with complex obesity (Appendix E, EAG EVA report). The EAG note that Kar et al. (2020), Idris et al. (2020), Hampton et al. (2017), Davies et al. (2023a), Thomson et al. (2022) do not exclusively report outcomes relating to this population, for example, Hampton et al. (2017) includes patients with a BMI considered within the healthy range (23 kg/m2) and who paid to use the OurPath 6-week programme. Furthermore, the addition of a GP or a primary care diabetic nurse alongside the digitally enabled

		responsible for managing their medical care and medication. This collaborative approach created an MDT of healthcare professionals, which included monitoring clinical measures such as HbA1c and adjusting medication based on weight loss and dietary changes. This was particularly relevant for patients taking hypoglycemic-inducing medication such as sulphonylureas or insulin. All participants in Kar et al (Practical diabetes 2020) had a BMI over 29kg/m^2 and the mean baseline BMI of participants was 35.7kg/m^2. We believe this approach aligns with the MDT model, entry criteria, and length of a Tier 3 specialist weight management programme, and the studies should be included on this basis. We noticed that several other studies included in the scope followed a similar approach and were not excluded for this reason: ● Christensen et al. 2022a: dietitian support only, no mention of MDT. ● Tsai et al. 2023: no mention of MDT or support received during intervention. ● Hanson et al. 2023: no mention of MDT or support received during intervention. ● Haas et al. 2019: dietitian support only, no mention of MDT.	diabetes 2020) and Idris et al (JMIR 2020) in the report. The effective deployment of an MDT involving our dietitian or nutritionist health coaches working with GPs and nurses in these studies is noteworthy and should therefore be reconsidered in the evidence assessment. Additionally, we kindly request the inclusion of three specific studies we originally provided in the evidence base. We believe this is justified, considering the interventions utilised in these studies closely mirror those of several studies that have already been assessed. The studies in question are: ● Hampton et al. (Future Healthcare Journal; 2017; 4(3): 173-177) - 6 month intervention, delivered by a registered dietitian and a mean body mass index of 31kg/m^2 (n=98) ● Davies et al. (Diabetic Medicine. 2023a; 40(suppl.1): 116 - 6 month intervention with results reported at 5 years, delivered by a registered dietitian and a mean body mass index of 32.4kg/m^2 (although this was not in the publication) (n=344)	weight management programme led by a health coach (which may include a nutritionist only), each lasting between 6 to 12 weeks, is not reflective of a Tier 3 specialist weight management service for patients with obesity. The EAG also note that the 'Sustain' element of the programme is not reflective of a Tier 3 specialist weight management service as considered within the NICE Final Scope. Evidence relating to Second Nature programmes not representative of a Tier 3 specialist weight management service is out of Scope of this Early Value Assessment, however this evidence has been summarised in Section 5.5 and Appendix B3 of the report for completeness alongside other evidence for similar programmes offered by the other technologies within the NICE Final Scope. The generalisability of such evidence should be carefully considered and note that the EAG did not perform systematic searches for evidence relating to interventions or populations outwith the Final Scope. - Kar et al. (2020): 3 month programme with health coach only; - Idris et al. (2020): 3 month programme (OurPath) with health coach only; - Hampton et al. 2017: initial 'core' 6 week diabetes prevention programme, with dietitian only; - Davies et al. 2023a: 3 months 'core' Tier 2 weight

		• Sutter et al. 2020: dietitian support only, no mention of MDT. • Schirmann et al. 2022: dietitian support only, no mention of MDT. • Huntriss et al. (2020): dietitian support only, no mention of MDT. The interventions delivered in the studies provided by Second Nature were also divided into two distinct periods: the initial phase, named 'Core', and the maintenance phase, named 'Sustain'. While the 'Core' phase typically lasts for 3 months, it's important to note that this is not the total length of the Second Nature intervention, which is 12 months long. The 'Sustain' phase is designed to encourage weekly engagement and offer more sustainable advice, enabling people to maintain and monitor their reduced weight and healthier behaviours. During the 'Sustain' phase, participants are encouraged to continue engaging with the programme for over 12 months. They can still access support from a dietitian/nutritionist health coach through a support forum embedded within the application. This forum is moderated by health coaches and populated by other individuals who have completed the programme. Participants can	• Thomson et al. (Clinical Obesity, 2022; 12(3): e12512) - 3 month intervention, delivered by a registered dietitan and a mean body mass index of 31.6kg/m^2 (n=48) While we ideally would like the whole report, particularly sections 4 and 5, to reflect these additions, we do recognise the constraints on the EAG's time. If a comprehensive revision is not feasible, as a minimum, the key outcome data from our studies should be integrated into the key comparator tables. Specifically, tables 3 (included publications summary), 6a, 6b (BMI), 7a, 7b, 7c, 7d (Weight loss), 12a, 12b, 12c (HbA1c) should include this data. We also request an update to the evidence gap analysis in table 31. We also ask that the comment in section 5.1 detailing the exclusion of Second Nature's evidence be reconsidered and updated based on this additional information. We believe these revisions will accurately represent the evidence base for Second Nature's programmes and to ensure a fair comparison with other studies included in the	management programme (as stated in title); - Thomson et al. 2022: 12-week programme with health coach (dietitian) only. The EAG note that: • Liva (Christensen et al. 2022a: 12 month programme, Tsai et al. 2023: 6-month programme) supports existing weight management services and health coaches include dietitians, health psychologists, and physiotherapists. Therefore, all studies incorporate an MDT of healthcare professionals. This is reflective of a Tier 3 weight management service. • Gro Health (W8Buddy) (Hanson et al. 2023: minimum of 3 month programme duration) uses existing Tier 3 NHS MDT staff as part of this programme delivery. • Oviva offers Tier 2 and Tier 3 services, with the reported evidence including an intervention period between 3 and 12 months which is representative of a Tier 3 service (Haas et al. 2019: 12 months; Sutter et al. 2020: 3 to 12 months; Huntriss et al. 2020: 6 months). The EAG confirms that Schirmann et al. (2022) reported use of Oviva for 12 weeks only, representative of a Tier 2 service, and therefore this has been moved from the main body of the report to Section 5.5 alongside other

		also continue to use the tracking technology to self-monitor progress, and access educational content and recipes for as long as necessary. This extended support aligns with the longer and more comprehensive approach to tier 3 specialist weight management programmes. Therefore, it's crucial to consider the full duration of Second Nature's programmes, including the 'Sustain' phase, when evaluating the evidence base.	scope that followed a similar approach.	evidence relating solely to their Tier 2 programme.
LIVA	6 Do you know of any adverse events associated with the specific technologies or using digitally enabled therapies not already reported?			No change required.
Oviva				No change.
Reset Health Clinics Ltd		We are not aware of any adverse events associated specifically with the Roczen programme	N/A	Thank you for your comment, no change required.
Second Nature		No		Thank you for your comment, no change required.
LIVA	7 Do you know of any ongoing studies not listed in the report?			No change required.
Oviva				No change.
Reset Health Clinics Ltd		We are currently working on an ongoing real-world clinical service evaluation of outcomes at 1 year	**Page 129,Section 8.5, Study design gaps** - In the second paragraph,	

		in patients with pre-diabetes and type 2 diabetes on the Roczen Programme, to be published retrospectively. Primary outcome is change in HbA1c, secondary outcomes include % remission of diabetes and % reduced reliance on medication. We are also currently working on a study to follow up patients at 2 years to collect longitudinal data on maintenance of weight loss and other health benefits of the programme. We continue to evaluate the patients and their outcomes on our programme.	• Suggest "Ongoing UK-based real-world studies for Gro Health, Liva, Oviva, Second Nature **and Roczen** have been identified that may address some of the real-world evidence gaps. **Page 130, Intervention Gaps** • Remove Roczen in the sentence "No ongoing studies for CheqUp, Juniper, Roczen or Wellbeing Way have been identified"	
Second Nature		No		Thank you for your comment, no change required.

Economic evidence

		Comments	**Proposed changes**	**EAG response**
LIVA	8 Are there any additional economic studies that should be included?			No change required.
Oviva				No change.
Reset Health Clinics Ltd		There are not any additional economic studies that we are aware should be included.	N/A	Thank you for this additional information. We have clarified in the report, however have been unable to update Tables 21 or 32 due to lack of detail provided and information provided after submission of the EAG report.

Second Nature		No		Thank you for your comment, no change required.
LIVA	9 Are the key assumptions appropriate? Such as healthcare professional time and grade, training time, hospital **admissions**			No change required.
Oviva				No change.
Reset Health Clinics Ltd		We agree with the key assumptions included in the report.	N/A	Thank you for your comment, no change required.
Second Nature		Yes		Thank you for your comment, no change required.
LIVA	10 Are the cost parameters used in the model appropriate? Have any key costs been omitted?			No change required.
Oviva				No change.
Reset Health Clinics Ltd		We agree with the cost parameters included in the report, e.g. Digital inclusion costs.	N/A	Thank you for your comment, no change required.
Second Nature		Yes		Thank you for your comment, no change required.

Further comments

		Comments	**Proposed changes**	**EAG response**
LIVA	11 Please add any further comments relating to factual inaccuracies and key assumptions on the assessment report.	Liva is referred to both Liva UK and Liva Health in some sections of the report. p. 20 within the 'other' section of this table, there are some additional	Please just use 'Liva' to avoid any confusion. Please add 'mood tracking, blood pressure, blood glucose, blood pressure, HbA1c, alcohol consumption, smoking status, and pain)	Thank you for your comment. The EAG have used the term Liva where possible in the report to avoid confusion. Where studies explicitly report input from Liva Healthcare this has remained. The EAG also note that Liva UK is stated within the NICE Final Scope.

		metrics that need to be added.		Thank you for your comment, this information has been added to Table 2.
Oviva		1) A very important error/misconception to correct relates to the assumption/statement on p.88: “All companies confirmed inclusion of NHS staff within the technology”. The EAR then raises the issue of workforce capacity and whether these digital technologies are actually contributing towards increased capacity. *All the healthcare professionals providing Oviva’s Tier 3 Weight Management programmes are employed “in-house” by Oviva and are provided by Oviva. These healthcare professionals may not be based in the same geographic area as the patients they serve. *There is no requirement for any local NHS clinical staff when utilising Oviva’s digital Tier 3 Weight Management Service in an area. This facilitates rapid mobilisation, scaling of services and serving areas that struggle with	There is a full description of how Oviva’s remote and asynchronous care model can contribute to an overall expansion of the Tier 3 clinical workforce in our response to NICE’s Request for Information and our initial response to the EAG. However, we would be very happy to outline this again more explicitly if it would be helpful. This is a very important point as it is a crucial part of Oviva’s offer and a vital benefit associated with the use of digitally delivered specialist weight management care vs traditional care. In the EAR this issue needs to be addressed and rectified on the following pages p.88 as per above comment p.118 as per above comment p.123 “additional factors” section which also erroneously states that all technologies “include the involvement of NHS staff”	1. Thank you for your comment. We have edited Section 7.3 and the “Additional factors” section to highlight that the involvement of NHS staff varies across the technologies. The impact of the technologies on NHS resources remains uncertain and recommend that evidence relating to this impact is captured in future data collections.

		recruitment/retention of specialist clinical staff. Therefore, there is an important error on p.118 with the paragraph which begins: “Finally, the model does not take into account local capacity constraints…” This section needs to be significantly amended please. *Oviva recruits, employs and trains its clinical staff itself. Some clinical staff may have worked in the NHS previously and some may choose to continue to work part-time for Oviva alongside separate part-time NHS work. 2) Minor Correction p.120 “current use of technologies in the NHS section”. Oviva is also one of the providers of the NHS Weight Management Programme (as well as the Diabetes Prevention Programme) but we have been omitted from the list with only Liva, Second Nature and Wellbeing Way being mentioned currently.	2) Please add Oviva to the list of providers of the NHS Weight Management Programme.	

Reset Health Clinics Ltd		N/A	N/A	Thank you for your comment, no change required.
Second Nature		N/A		No change required.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies – Digital weight management technologies for managing obesity

Please read the guide to completing a submission fully before completing this template.

Information about your organisation	
Organisation name	Diabetes UK
Contact person's name	Eoin McGinley
Role or job title	Policy Officer
Email	[redacted]
Telephone	
Organisation type	Patient/carer organisation (e.g. a registered charity) ☒ Informal self-help group ☐ Unincorporated organisation ☐ Other, please state:
Organisation purpose (tick all that apply)	Advocacy ☒ Education ☒ Campaigning ☒ Service provider ☐ Research ☐ Other, please specify:
What is the membership of your organisation (number and type of members, region that your organisation represents, demographics, etc)?	

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies – Digital weight management technologies for managing obesity

If you haven't already, please register as a stakeholder by completing the stakeholder registration form and returning it to medtech@nice.org.uk

Further information about registering as a stakeholder is available on the NICE website.

Did you know NICE meetings are held in public? You can register on the NICE website to attend a meeting up to 20 working days before it takes place. Registration will usually close 10 days before the meeting takes place. Up to 20 places will be available, depending on the size of the venue. Where meetings are oversubscribed NICE may need to limit the number of places we can offer.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies – Digital weight management technologies for managing obesity

Sources of information

What is the source of the information about patients' and carers' experiences and needs that are presented in this submission?

This information is gathered from insights produced by our own organisation (Diabetes UK) and through research completed by others:

1. Barron E, Bradley D, Safazadeh S, et al. Effectiveness of digital and remote provision of the Healthier You: NHS Diabetes Prevention Programme during the COVID-19 pandemic. Diabet Med. 2023;40(5):e15028. doi:10.1111/dme.15028
2. Albury C, Strain WD, Brocq SL, et al. The importance of language in engagement between health-care professionals and people living with obesity: a joint consensus statement. Lancet Diabetes Endocrinol. 2020;8(5):447-455. doi:10.1016/S2213-8587(20)30102-9
3. Diabetes UK report on NHS Diabetes Prevention Programme (2021)
4. Jonathan Valabhji, Emma Barron, Dominique Bradley, Chirag Bakhai, Jamie Fagg, Simon O'Neill, Bob Young, Nick Wareham, Kamlesh Khunti, Susan Jebb, Jenifer Smith; Early Outcomes From the English National Health Service Diabetes Prevention Programme. Diabetes Care 1 January 2020; 43 (1): 152–160. https://doi.org/10.2337/dc19-1425
5. Chadwick, D., Ågren, K. A., Caton, S., Chiner, E., Danker, J., Gómez-Puerta, M., Heitplatz, V., Johansson, S., Normand, C. L., Murphy, E., Plichta, P., Strnadová, I. and Wallén, E. F. (2022) 'Digital inclusion and participation of people with intellectual disabilities duringCOVID-19: A rapid review and international bricolage', Journal of Policy and Practice in Intellectual Disabilities.
6. ONS (2019) Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/releases/exploringtheuksdigitaldivide (Accessed: 28th June 2023).
7. Reeves, D., Woodham, A. A., French, D., Bower, P., Holland, F., Kontopantelis, E., & Cotterill, S. (Accepted/In press). The influence of demographic, health and psychosocial factors on patient uptake of the English NHS Diabetes Prevention Programme. BMC Health Services Research.

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Patient Organisation Submissions for Medical Technologies – Digital weight management technologies for managing obesity

Impact of the symptoms, condition or disease	
	How do symptoms and/or the condition or disease affect people's lives or Living with obesity or overweight increases a person's risk of developing type 2 diabetes - it accounts for about 80-85% of their risk. For those who have been diagnosed with diabetes, getting support to lose weight can be very beneficial for managing the condition by improving glycaemic control and reducing risk of the long term complications of diabetes complications affecting the eyes, feet and kidneys. It can also increase the risk of heart attacks and strokes, complications which can affect a person's quality of life. We know from the research evidence some people with type 2 who lose significant weight loss can put their type 2 diabetes into remission. There are significant health benefits of weight loss even if remission does not occur. It reduces the risk of developing other conditions and reduction or stopping blood glucose lowering and blood pressure medications Two thirds of the UK population are currently classified as having obesity or overweight and many experience significant stigma as a result. Many of these people would benefit from being able to access support to help them to lose weight and maintain weight loss.
1.	**How do symptoms and/or the condition or disease affect carers and family?** Living with type 2 diabetes can impact emotional and mental wellbeing of both patients and their families/carers. Any intervention can have a positive impact on all.
2.	**Are there groups of people that have particular issues in managing their condition?** Losing weight and maintaining that weight loss is complex, individual and requires a supportive environment. We also recognise that there are significant health inequalities that lead to development of overweight and obesity, disproportionately impacting less affluent communities, which should be addressed. People with obesity should be supported to understand the complex causes of obesity. Stigma, including internalised stigma, can be damaging and act as a barrier to seeking support. They should be encouraged to seek support from healthcare professionals to manage their obesity, rather than managing it alone Higher prevalence of diabetes amongst people with learning disabilities and there are higher proportions in the more severe category of obese (37% of people with learning disabilities compared to 30.1% of people without learning disabilities). As noted in the PHE 2020 to 2025 strategy, poor diets and excess body weight deprive people in England of more than 2.4 million life years through premature mortality,

illness and disability each year. There are close links to broader social disadvantage, such as poverty, poor housing and social isolation, which is experienced disproportionately by people with learning disabilities.

Experiences with currently available technologies

3. How well do currently available technologies work?

The lack of consistent tier 3 services across the country means that most people living with obesity are not able to access the level of support that these technologies offer. Broader insight work into barriers to weight management services by Diabetes UK carried out recently highlights key issues impacting the success of these technologies. The insight work included perspectives of providers of tier 3 and 4 services and the perspectives of people living with type 2 diabetes. Diabetes UK found that:

- People with type 2 diabetes, who could benefit from the support offered by these technologies, report that they are not regularly offered advice about weight management or signposted to information on how they can be supported to manage their weight.
- For people with type 2 diabetes stigmatising exchanges with healthcare professionals can have a huge impact on both accessing and completing weight management services. For technologies to work it is important that people are referred without experiencing stigma within primary care.
- Many people with type 2 diabetes report that having access to peer support is a key component in achieving weight loss aims. Technologies that facilitate peer support for those that wish to access it are likely to achieve better results.
- The person-centred support that people experience within tier 3 services is an integral component. This is particularly the case for people weight related comorbidities such as type 2 diabetes. People who have accessed tier 3 services repeatedly report that the personalised focus and emotional support received was key to their successful weight management.

In addition, research comparing the effectiveness of digital/remote and F2F services found the mean baseline weight of those using digital weight management services was higher than those using remote or F2F, likely due to the weight stigma resulting in avoidance of group-based environments. Digital services were also reported to have a lower completion rate, particularly for those with a greater body weight, so it is vital that the issue of stigma is addressed so that the most appropriate and effective service delivery method can be used.

Barron E, Bradley D, Safazadeh S, et al. Effectiveness of digital and remote provision of the Healthier You: NHS Diabetes Prevention Programme during the COVID-19 pandemic. Diabet Med. 2023;40(5):e15028. doi:10.1111/dme.15028

Albury C, Strain WD, Brocq SL, et al. The importance of language in engagement between health-care professionals and people living with obesity: a joint consensus statement. Lancet Diabetes Endocrinol. 2020;8(5):447-455. doi:10.1016/S2213-8587(20)30102-9

4. Are there groups of people that have particular issues using the currently available technologies?

In terms of who is most likely to be actively engaged in tier 3 services, healthcare professionals reported to Diabetes UK that it is more likely to be affluent, younger, white women who they see. Further efforts need to be made to make services inclusive of the diversity of local communities.

There is also a postcode lottery in access to weight management services provided by ICSs that negatively affects those in more isolated, rural communities. A 2019 House of Lords select committee on the 'Rural Economy' highlighted the issues with access to local healthcare services, and so providing a service that can be accessed remotely will address one of the barriers faced by this group. However, both lack of connectivity and digital literacy are a problem in these communities and so digitisation of these services can only be beneficial if these are also addressed.

https://www.culturehive.co.uk/resources/fixing-the-digital-divide-facts-and-stats/

Chadwick, D., Ågren, K. A., Caton, S., Chiner, E., Danker, J., Gómez-Puerta, M., Heitplatz, V., Johansson, S., Normand, C. L., Murphy, E., Plichta, P., Strnadová, I. and Wallén, E. F. (2022) 'Digital inclusion and participation of people with intellectual disabilities duringCOVID-19: A rapid review and international bricolage', Journal of Policy and Practice in Intellectual Disabilities.

ONS (2019) Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/releases/exploringtheuksdigitaldivide (Accessed: 28th June 2023).

About the medical technology being assessed

6. For those <u>with</u> experience of this technology, what difference did it make to their lives?

The mode of delivery of the service itself has been shown to make a positive difference to people's lives. A review by Diabetes UK of the NHS Diabetes Prevention Programme (DPP), a weight management service run by organisations including Xyla Health and Wellbeing and Oviva that aims to reduce the risk of developing type 2 diabetes for high-risk individuals, used an online survey and structured focus groups to understand the experiences and preferences of those taking part on this programme. Individuals reported that the service was easier to fit around other commitments due to the lack of travel and

using apps meant that they could access resources as and when they needed them. This led to a positive difference to people's lives as they reported being able to commit to the service where without technology, they wouldn't have been able to fit it into their day.

People who have taken part on the NHS DPP and the NHS Pathway to Remission Programme, another digital weight management service, highlighted improvements in their symptoms of diabetes… Additionally, they have reported improvements in their ability to complete physical activity and exercise

7. **For those <u>without</u> experience of the technology being assessed, what are the expectations of using it?**

Based on the previously referenced review of the NHS Diabetes Prevention Programme (DPP), it was highlighted that patients expected to be able to have the ability to track/set goals, access online content whenever they need and have regular communication with a coach which they were receptive to.

8. **Which groups of people might benefit most from this technology?**

An evaluation of the NHS DPP showed that those of Asian and mixed ethnicities had greater retention rates when using remote/digital services compared to using F2F services. As referenced in section 5, those who live in isolated communities will benefit from this technology.

Additional information

9. **Please include any additional information you believe would be helpful in assessing the value of the medical technology (for example ethical or social issues, and/or socio-economic considerations)**

Research has found that people who are limited users of the internet are 1.5 times more likely to be from Black, Asian or other minority ethnic backgrounds, and many of these have English as a second language and will require further support. In addition, there is a higher prevalence of diabetes amongst people with learning disabilities and there are higher proportions in the more severe category of obese (37% of people with learning disabilities compared to 30.1% of people without learning disabilities). Both groups are, therefore, at risk of being digitally excluded.

Research by Manchester University saw greater weight loss for the remote and digital groups compared to the F2F groups which reenforces the effectiveness of digital weight management services. However, although remote delivery had greater completion rate than F2F, digital delivery had a lower completion rate. This supports the need for a combined approach that maximises both the accessibility and support needed for patients utilising these services.

The Diabetes UK NHS DPP report referenced previously shows that key to patients was to have a choice between digital or face to face services, reenforcing the importance of clinicians considering personal preference to increase adherence. Additionally, many said they would prefer face-to-face sessions over digital due to the ability to have conversations and discuss things more easily face-to-face and so, despite potential other benefits of digital services face-to-face groups should not be removed altogether.

Jonathan Valabhji, Emma Barron, Dominique Bradley, Chirag Bakhai, Jamie Fagg, Simon O'Neill, Bob Young, Nick Wareham, Kamlesh Khunti, Susan Jebb, Jenifer Smith; Early Outcomes From the English National Health Service Diabetes Prevention Programme. Diabetes Care 1 January 2020; 43 (1): 152–160. https://doi.org/10.2337/dc19-1425

Chadwick, D., Ågren, K. A., Caton, S., Chiner, E., Danker, J., Gómez-Puerta, M., Heitplatz, V., Johansson, S., Normand, C. L., Murphy, E., Plichta, P., Strnadová, I. and Wallén, E. F. (2022) 'Digital inclusion and participation of people with intellectual disabilities duringCOVID-19: A rapid review and international bricolage', Journal of Policy and Practice in Intellectual Disabilities.

ONS (2019) Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/releases/exploringtheuksdigitaldivide (Accessed: 28th June 2023).

Reeves, D., Woodham, A. A., French, D., Bower, P., Holland, F., Kontopantelis, E., & Cotterill, S. (Accepted/In press). The influence of demographic, health and psychosocial factors on patient uptake of the English NHS Diabetes Prevention Programme. BMC Health Services Research.

Key messages

10. In up to five statements, please list the most important points of your submission.

- Digitisation will provide greater access to weight management services
- Digital methods should not completely replace face-to-face due to this being potentially detrimental to those in certain groups
- Providing a choice of delivery method will likely increase adherence
- Weight management services should be consistently accessible across the country, person centred and stigma free
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Thank you for your time. Please return your completed submission to helen.crosbie@nice.org.uk and medtech@nice.org.uk