NICE National Institute for Health and Care Excellence

Medical technologies advisory committee (MTAC)

6th October 2023

Information pack for draft guidance considerations on

GID-HTE10023 Digitally enabled weight management programmes to support treatment in specialist weight management services: early value assessment

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 03 November 2023 and 17 November 2023.

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Papers included in pack:

1. Front sheet
2. Final scope
3. Assessment report (AR)
4. Assessment report addendum

4a. Assessment report 2nd addendum

5. Assessment Report Overview (ARO)
6. Patient submission from the British Dietetic Association
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NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Digitally enabled weight management programmes to support treatment in specialist weight management services: early value assessment

Final scope

September 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.

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 the descriptions.

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 (MDT) 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. 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. 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 of obesity in adults. Following referral, these technologies 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.

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 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.

Twelve digitally enabled weight management programmes are included in the scope[1].

ChequUp

CheqUp (CheqUp Health) is a weight management app that provides a multidisciplinary weight management programme. 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 meeting with a doctor and a 30-minute session with a weight loss coach and dietician. The programme includes weekly meetings with a health coach, personalised progress meetings with a weight loss coach every 2 weeks, 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. Data is provided to a person's clinician via the clinician dashboard. Gro Health W8Buddy is available in 11 different languages.

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

[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.

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. The Liva online dashboard can be used by healthcare professionals to track user data 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. 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.

Wellbeing Way

Wellbeing Way (Xyla Health and Wellbeing) provides a tier 3 specialist weight management service for adults. This is delivered by a MDT 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.

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. Ongoing follow up is provided by the clinical team at 12 and 24 weeks.

Juniper

Juniper (Juniper Technologies UK Ltd) is an app that provides a weight management programme. 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.

Second Nature

Second Nature delivers a tier 3 specialist weight management programme through a web and mobile app. Users can access instant messaging with digital weight management technologies to support treatment with weight management health coaches and their peers, educational resources, goal setting and health tracking. Video calls can be arranged with members of the MDT.

Habitual

Habitual (Habitual Health Ltd) delivers a tier 3 specialist weight management programme, which includes behavioural intervention and guidance on healthy diet and exercise. Clinical consultation is offered initially to assess patient eligibility. The programme can be accessed via the Habitual app on mobile phone or tablet. The app features daily content that unlocks sequentially over the course of the programme and uses daily tracking of weight, nutritional choices, mental health, and physical activity to monitor progress. During the programme, additional support is accessible for users from a clinical support team.

Gloji

Gloji (Thrive Tribe) is a digital health app that delivers a specialist weight management programme. Users can receive personalised support from an MDT of healthcare professionals, which may include nutritionists, physical activity specialists and behavioural psychologists. An initial consultation helps to determine the most appropriate weight management options, then tailored advice and support is provided around nutrition, exercise and other factors such as sleep and mental wellbeing. Users also have access to one-to-one sessions with health coaches and an online physical activity platform.

Counterweight

Counterweight Refer Out model (Counterweight) delivers a tier 3 specialist weight management programme. The service is delivered either one-to-one or in groups by an MDT of healthcare professionals. This MDT includes dietitians, psychologists, specialist exercise therapists and medical doctors with an interest in weight management and type 2 diabetes. The app allows for goal setting, dietary support and provides educational content. The app

has a messaging function to receive support from the MDT or coach facilitated peer support. The app is accessible through a smartphone, tablet or computer. A hardcopy workbook is also available for those who are digitally excluded or those who prefer to access educational content as a workbook. Users are screened for additional support requirements. This includes consideration of disability, digital literacy, socioeconomic status, dietary requirements, cultural backgrounds as well as screening and support for disordered or emotional eating. Healthcare professionals can review progress via a healthcare professional platform.

Weight Loss Clinic

Weight Loss Clinic (Virtual Health Partners) is a digital health programme that delivers a tier 3 or 4 specialist weight management programme for adults via an app or web browser. The technology offers one-to-one coaching and instant messaging communication with dietitians. They also have psychologists, social workers and health coaches who lead virtual support groups. The technology contains educational content and exercise classes and has the functionality to track fitness, keep a food diary and personalised goal setting. Healthcare professionals can review progress via a healthcare professional platform.

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 the treatment of obesity in adults. NICE's clinical guideline on assessment and management of obesity in adults recommends that people should be considered for referral to tier 3 services if the underlying cases need to be assessed, the person has complex needs that cannot be managed adequately in tier 2, conventional treatment has been unsuccessful or if specialist interventions may be needed.

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.

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.

Potential place of digital weight management support in the care pathway

Digitally enabled weight management programmes would be offered as an option for people having treatment in specialist weight management services. 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.

Digitally enabled weight management programmes can be offered to provide support from an 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. 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, reducing health inequalities. In areas with established specialist weight management services, digitally enabled programmes could improve access to services and 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 programmes 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. 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. 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 who are eligible for treatment in specialist weight management services (tier 3 or tier 4), including people eligible for weight management medication.
Interventions (proposed technologies)	Digitally enabled weight management programmes providing specialist weight management services (such as tier 3 or tier 4) for adults with obesity. This includes: • CheqUp (CheqUp) • Gro Health W8Buddy (DDM Health Ltd) • Liva UK (Liva UK) • Oviva (Oviva) • Xyla Health and Wellbeing (Xyla Health and Wellbeing) • Roczen (Reset Health) • Second Nature (Second Nature) • Juniper (Juniper Technologies UK Ltd) • Habitual (Habitual Health Ltd) • Gloji (Thrive Tribe) • Counterweight (Counterweight) • Weight Loss Clinic (Virtual Health Partners)
Comparator	Standard care which could include: • specialist weight management services (including tier 3 and 4; face-to-face, remote or hybrid) • no treatment or waiting list
Healthcare setting	Specialist weight management services (including but not limited to tier 3 and tier 4)
Outcomes	Outcome measured to be prioritised are: • Change in weight • Intervention adherence, rates of attrition (dropouts) and completion • Intervention-related adverse events (including how they are monitored and reported within each programme) • Resource use (including the number and type of healthcare appointments) • Inaccessibility to intervention (digital inequalities)

	Other important outcomes include: • Change in body mass index (BMI) • Programme engagement • Health-related quality of life • Patient experience and acceptability • Psychological outcomes

	Costs will be considered from and NHS and Personal 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
	  ○ 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.

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.

Risk of disordered eating

Digitally enabled weight management programmes used to monitor eating behaviours may increase the risk of developing an eating disorder. Education about nutrition is important whilst using these technologies 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.

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Document cover sheet

Assessment report: GID-HTE10023 Digitally enabled weight management programmes

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EAG sign-off: Hayden Holmes

Version number	Brief description of changes	Author/reviewer (e.g. J Smith)	Date (DD/MM/YY)	Date sent to NICE (if applicable)
1.0	Draft report submitted to NICE	H Holmes J Patterson R McCool S Woods A Varghese	04/09/23	04/09/23
2.0	Amendments in light of NICE comments	J Patterson S Woods A Varghese R McCool	18/09/23	18/09/23

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Early Value Assessment

GID-HTE10023 Digitally enabled weight management programmes

External Assessment Group report

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Contains confidential information: Yes

Number of attached appendices: 3

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 and/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.

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Responsibility for report

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

Any 'commercial in confidence' (CiC) information in the submission document is underlined and highlighted in turquoise.

Any 'academic in confidence' (AiC) information in the submission document is underlined and highlighted in yellow.

Any 'personal identifiers' in the submission document are underlined and highlighted in pink.

Contents

Abbreviations

Term	Definition
AiC	Academic in Confidence
BMI	Body mass index
BP	Blood pressure
CI	Confidence interval
CiC	Commercial in Confidence
CLED	Continuous low-energy diet
DHSC	Department of Health and Social Care
DTAC	Digital Technology Assessment Criteria
EAG	External assessment group
EVA	Early Value Assessment
F2F	Face-to-face
GAD-7	7-item Generalized Anxiety Disorder scale
HbA1c	Glycated haemoglobin
ICER	Incremental cost effectiveness ratio
ILED	Intermittent low-energy diet
IQR	Interquartile range
MAUDE	Manufacturer and User Facility Device Experience
MDT	Multidisciplinary team
MHRA	Medicines & Healthcare products Regulatory Agency
MTEP	Medical Technologies Evaluation Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICE CG	NICE clinical guideline
NICE MTG	NICE medical technology guidance
NICE QS	NICE quality standard
PHQ-9	9-item Patient Health Questionnaire
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY	Quality-adjusted life year
QoL	Quality of life
QUORUM	Quality of Reporting of Meta-analyses
RCT	Randomised controlled trial
SD	Standard deviation
T2D or T2DM	Type 2 diabetes

VAS	Visual analogue scale
Vs	Versus

Executive summary

Quality and relevance of the clinical evidence

More than half of the publications assessed (33/58) were published as abstracts, and there was possible overlap between the studied populations. For the one study which matched the scope in all areas, limitations included follow-up only at 12 weeks after the core programme. Most studies were small, lacked randomisation or a comparator, and included populations not all of whom were living with obesity. There was a high likelihood of selection bias (uptake/engagement ranged from 31.2% to 89%) and high rates of drop-out (e.g., 40% at 12 months and 60% at 24 months). There was generally an inadequate duration of follow up, given the chronic nature of the condition. The studies reported outcome data only on a minority of participants (completers), which is also likely to introduce a bias.

Quality and relevance of the economic evidence

A search for existing economic models for this decision problem was not conducted. The EAG developed a cost-utility model to address the decision problem. The results from the model demonstrate that, based on the available evidence, it is plausible that a digitally enabled weight management program could be cost-effective when compared with both a prompt Tier 3 weight management services as well as a delayed service, but not against no treatment. However, a key limitation of this analysis is the short-term time horizon. For a more accurate estimate of cost-effectiveness a lifetime analysis is required which links short-term benefits to long-term outcomes. The model was informed by a published study and stakeholder feedback. For future modelling, further evidence is required to inform the long-term impact of short-term changes in clinical outcomes.

Evidence gap analysis

The available evidence does not present an unbiased estimate of the technology's treatment effect, because most studies were uncontrolled and reported outcomes on a small subset of participants, due to high drop-out and outcomes only being reported for

completers. Only one of the 38 studies matched the scope in all areas of population, intervention and comparator, with, in particular, very few studies focused exclusively on people living with obesity in tier 3/4 services. People using apps who are treated with total diet replacement food products (TDR) or weight loss medication may lose more weight than those treated with dietary modification plus app use. Uncertainties also remain about the long-term outcomes in this lifelong condition. One ongoing study has been identified that may help fill this evidence gap, but it only uses one technology (Oviva).

Ideally, RCTs (or real world comparative evidence) would be conducted in the appropriate population (people living with obesity in a tier 3/4 service), using an intervention which includes access to an MDT via the app, and reporting the relevant prioritised and important outcomes (weight, adherence/completion of programme, adverse events, resource use, BMI, engagement, discontinuation and reasons, quality of life, psychological outcomes) with a sufficiently long timescale to be a fair representation of a lifelong condition, where weight fluctuates over time and early losses may not be maintained. In addition, it would be important to follow up a higher proportion of study participants.

1 Decision problem

The decision problem is described in the scope.

Table 1.1.1: Summary of decision problem

Decision problem	Scope	EAG comment
Population	Adults with obesity who are eligible for treatment in specialist weight management services (tier 3 or tier 4)	Studies including people without overweight/obesity (e.g., those with type 2 diabetes) and not stated to be in Tier 3/4 included for listed interventions but coded **AMBER**
Intervention	Digitally enabled weight management programmes providing specialist weight management services (such as tier 3 or tier 4) for adults with obesity. This includes: • CheqUp (CheqUp) • Gro Health W8Buddy (DDM Health Ltd) • Liva UK (Liva UK) • Oviva (Oviva) • Second Nature (Second Nature) • Roczen (Reset Health) • Xyla Health and Wellbeing (Xyla Health and Wellbeing) Additional technologies identified August 2023: • Gloji (Thrive Tribe) • Habitual (Habitual Health Ltd) • Juniper (Juniper Technologies UK Ltd)	Scope required interventions to facilitate communication with an MDT; studies where intervention did not specify an MDT were included but coded **AMBER**
Comparator(s)	Standard care which could include: • specialist weight management services (including tier 3 and 4; face-to-face, remote or hybrid) • no treatment or waiting list	Single arm studies without comparators included but coded **AMBER**
Outcomes	Outcome measured to be prioritised are: • Change in weight • Intervention adherence, rates of attrition (dropouts) and completion • Intervention-related adverse events (including how they are monitored and reported within each programme) • Resource use (including the number and type of healthcare appointments)	If only important outcomes reported but no prioritised ones, the studies were coded **AMBER.** If neither prioritised nor important outcomes were reported, studies were coded **RED**

	• Inaccessibility to intervention (digital inequalities) Other important outcomes include: • Change in body mass index (BMI) • Programme engagement • Health-related quality of life • Patient experience and acceptability • Psychological outcomes •	
Cost analysis	Costs will be considered from an 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): o GP or secondary care appointments o 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.	

2 Overview of the technology

The technologies are digitally enabled weight management programmes to support treatment of obesity in adults; used to facilitate access to specialist weight management programmes; and 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. Please see the Scope for more details (NICE, 2023b).

2.1 Included technologies

Eight technologies were originally included in the scope of this EVA (as for the previous one: GID-HTE10007 (NICE, 2023), in which they are described): CheqUp (CheqUp), Gro Health W8Buddy (DDM Health Ltd), Juniper (Juniper Technologies UK Ltd), Liva

(Liva UK), Oviva (Oviva), Roczen (Reset Health), Second Nature (previously known as OurPath (Second Nature), Wellbeing Way (Xyla Health and Wellbeing).

An additional two (Gloji [Thrive Tribe] and Habitual [Habitual Health Ltd]) were identified in August 2023. No information was received from the company for Juniper for GID-HTE10007(NICE, 2023), but it was received during the current process for GID-HTE10023 Digitally enabled weight management programmes. Thrive Tribe notified NICE on 23 August 2023 that they no longer want to engage with the process and no information was received from them, so information included here is only from publicly available sources. On 29 August 2023, no information had been received from Xyla Health and Wellbeing for inclusion, so information included here is only from publicly available sources.

The included technologies are shown in Table 2.1, along with their regulatory status.

Table 2.1.1: Included technologies

Technology (Company)	Regulatory Status
CheqUp (CheqUp)	The MHRA has confirmed that Chequp's technology does not meet the requirements of a medical device, so CE / UKCA marking is not required. Our DTAC application is almost complete and we are working with a DTAC Delivery Manager to ensure accreditation is granted by the end of October (DCB0129 section complete, Cyber Essentials certificate received, DSPT complete)
Gro Health (DDM Health Ltd)	CE marked as a medical device (Class I); assessed and approved by DTAC
Liva (Liva)	Assessed and approved by DTAC
Oviva (Oviva)	CE marked as a medical device (Class IIa); assessed and approved by DTAC
Roczen (Reset Health Ltd) (details in Appendix A)	Working towards DTAC assessment: "Our latest DTAC assessment was submitted to NHS England for review on 26 July 2023. 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."
Second Nature (previously Our Path) (Second Nature)	Assessed and approved by DTAC

Wellbeing Way (Xyla Health and Wellbeing)	Assessed and approved by DTAC
ThriveTribe	Working towards DTAC assessment
Habitual (details in Appendix A)	Started the process of applying for an MHRA Class 1 Medical Device CE mark and expect the process to be complete in 1-2 months. DTAC ready as of 14/08/2023
Juniper	"Juniper does not currently have a CE/UKCA mark certificate as it does not meet the definition of a medical device. This is because the platform acts as a decision support tool for Juniper's practitioners who provide clinical care to patients. We are confident that our technology aligns with the Digital Technology Assessment Criteria (DTAC) standards. We have conducted an internal assessment process, and will submit our application for DTAC compliance. We anticipate that we will be compliant by the end of December 2023."

3 Clinical context

NICE's clinical guideline on assessment and management of obesity in adults recommends that people should be considered for referral to tier 3 services (typically hospital-based) if the underlying causes need to be assessed, the person has complex needs that cannot be managed adequately in tier 2 (community-based), conventional treatment has been unsuccessful, or specialist interventions may be needed.

The technologies should allow remote access to a specialist multidisciplinary team (MDT), either alone or as a hybrid with face to face (F2F) contacts.

Special considerations including issues related to equality

As mentioned in the scope, the technology could facilitate more frequent contacts with the MDT and also enable access to services for people unable to attend secondary care (e.g. due to health, mobility or transport issues) or in areas where services are not available at all or are over-subscribed resulting in waiting lists. This could be important for equality in terms of the "postcode lottery" of unequal distribution of services, and areas of social deprivation where need may be high but waiting lists may] be long. However, people with visual, hearing, cognitive or dexterity problems, or speaking languages other than English, or without access to or experience in digital technologies may require additional resources and support.

4 Clinical evidence selection

4.1 Evidence search strategy and study selection

The search strategy has been described in the previous "Assessment report: GID-HTE10007 Diet and activity apps". That strategy was developed to identify apps that facilitate weight management medication monitoring or prescribing, in addition to the requirements of the apps reported here to facilitate communication with the MDT and behaviour change. For the current EVA, the EAG rescreened the records identified in that search to identify any that met the current criteria but would have been excluded from the previous work. Additional searches were conducted for the two newly-identified technologies (Gloji and Habitual).

Included studies lists of systematic reviews identified in the searches were hand-searched for any additional publications for relevant interventions.

4.2 Included and excluded studies

Included studies found in the searches are shown in Appendix B Table 4.1a.

Thirty-eight published studies were included in total, described in a total of 59 publications (26 full texts and 33 abstracts). However, there is an unknown likelihood of overlap between some of these publications, e.g., the three Roczen studies presented as abstracts (Brown et al 2022, Falvey et al. 2023 and Phung et al. 2023) likely all overlap with each other

[redacted]

One of these publications was a protocol (Murray et al. 2019) identified in the search, which linked to a full text publication (Ross et al. 2022) provided by two of the companies (Liva and Second Nature/OurPath); this study compared Liva, OurPath and Oviva and is reported separately in Appendix B Table 4.1b.

One additional publication (Hanson et al. 2021) was identified at the search stage but originally excluded as it appeared to be describing the standard Low Carb program. However, the Company stated that the intervention in this paper was a precursor of the

Gro Health W8Buddy and therefore eligible: “Our study, Hanson et al. 2021 "Low Carb Program Health App Within a Hospital-Based Obesity Setting: Observational Service Evaluation" details the use of the Low Carb Program app’s architecture (i.e., the platform, not the content, which was bespoke-created for Tier 3 Weight Management Services with UHCW [University Hospitals Coventry & Warwickshire]). Please note, even though the app is called “Low Carb Program”, the app itself delivered a Tier 3 Weight Management service - it did not deliver a “low carb tier 2” service.” This publication is therefore included in Appendix B Table 4.2.

One study (Huntriss et al. 2021b) completely matched the scope (all three areas [Participants, Interventions and Outcomes] scoring **GREEN**). Thirty-three only partially matched the scope (**AMBER**) in at least one of these areas. Four studies (Nicinska et al. 2022, Papathanail et al. 2022b, Sutter et al. 2020 and Thomson et al. 2022) did not match the scope at all (**RED**) in at least one area.

Twelve were stated to be exclusively in participants with obesity; the remainder had a mixed population (not exclusively those with obesity), participants other than those with obesity, or obesity was not stated. Five studies stated that it was a tier 3 or 4 service; the remainder did not. Six stated that the app included an MDT; the remainder did not. One study (Hanson et al. 2021) stated that participants had access to an MDT but not via the app.

Ten had a comparator group; the remainder did not.

Thirty-four reported at least one of the listed outcomes; the remainder did not.

Of the 38 studies, 25 studies were conducted in the UK, 4 in Germany, 3 in Denmark, 3 in Switzerland, 1 in the UK and Germany, 1 in the UK, Germany and Switzerland, and 1 was unknown.

[redacted]

[redacted]

Thus, the total literature found, by source of material, technology and study design, is shown in Table 4.4 below.

Table 4.4 Summary of literature

Technology	Published studies (participants not on weight loss medication)	Unpublished In Confidence material
CheqUp	0	[redacted]
Gro Health	4 single arm (one non-randomised comparative study but data only shown for intervention arm)	[redacted]
Liva	4: 1 RCT (versus face to face) and 3 single arm	[redacted]
Oviva	19: 1 RCT (but both arms had Oviva); 4 non-randomised comparative (versus phone or face to face); 14 single arm	[redacted]
Roczen	3 single arm	[redacted]
Second Nature (previously Our Path)	7 single arm	0
Wellbeing Way	0	0
Gloji	0	0
Habitual	0	[redacted]
Juniper	0	[redacted]
Comparing Liva, Our Path and Oviva	1 non-randomised comparative study	
Total	38	21

Excluded studies with reasons for exclusion are shown in Appendix B, Table 4.5.

5 Clinical evidence review

5.1 Overview of methodologies of all included studies

Two studies (Christensen 2022a, McDiarmid 2022) were RCTs, of which one study (Christensen 2022a) had a randomised comparator to the intervention app (the comparator was a face to face intervention) and one study (McDiarmid 2022) had the intervention app in both randomised arms (i.e. both groups had Oviva and the randomisation was between two different diets).

Eight studies (Hanson et al. 2021, Hanson et al. 2023, Tsai et al. 2023, Finnie et al. 2022, Huntriss et al. 2021b, Ross et al. 2022, Sutter et al. 2020, Sutter et al. 2021) were non-randomised comparative studies, of which two (Hanson et al. 2023, Tsai et al. 2023) only reported outcomes for the intervention group.

Twenty-eight were non-comparative studies ("no comparator" was outside the scope, which stated that a comparator was required; however, these studies have been included as potentially relevant to the problem).

5.2 Critical appraisal of studies

More than half of the publications assessed (33) were published as abstracts, with a consequent lack of information on which to appraise study quality. Twenty-five were fully published papers.

Due to the lack of detail for most of the publications, and an unknown possibility of overlap between the populations included in the publications, formal critical appraisal checklists were not performed for each publication, but limitations of each publication are included in Appendix B Tables 4.1a and 4.1b.

For the one study which matched the scope in all areas (Huntriss et al. 2021b), limitations included follow up only at 12 weeks after the core programme (of 12–16 weeks); this follow up was only offered to participants completing the core programme (and was only attended by 67/169 [40%] of participants who started the core programme).

Limitations of the other studies included:

- Lack of randomisation and lack of comparator in most studies, leading to the intrinsic limitations of non-randomised and non-comparative studies in the evidence hierarchy, i.e. the lack of a control group and randomisation means causality cannot be established (e.g. cannot rule out the possibility of a placebo effect, or potential bias and confounding)
- Small sample sizes (minimum 9 people; maximum 25,706 but not all of these were living with obesity; for all studies: median 169 [IQR 63 to 1036]; for studies including only participants with obesity: median 169 [IQR 94.5 to 623.5])
- Selection bias if only people with motivation agree to participate in interventions (uptake/engagement ranged from 31.2% to 89%)
- Large drop-out even in the RCTs: Christensen et al. 2022a reported a high drop-out rate at 12 months: 138 of 338 (40.8%) and at 24 months: 59% for the intervention group and 61% for the control group; McDiarmid et al. 2022 reported of the initial app users (n=70; 88.6% of the 79 enrolled) who completed the trial (n=51; 72.9% of initial users; 64.6% of enrolled), 44/51 (86% of completers; 62.9% of initial users; 55.7% of enrolled) still used the app at 52 weeks.
- Inadequate duration of follow up (ranging from 1 month to 5 years; mostly ≤12 months), given the chronic nature of the condition
- Some outcomes self-reported which can lead to low precision and reporting bias
- Reporting data only on a minority of participants (completers) that introduces a bias.

5.3 Results from the evidence base

No evidence was found in the searches for CheqUp, Wellbeing Way, Gloji or Juniper. No studies (from searches or unpublished In Confidence material) reported resource use.

Prioritised outcomes (except Adverse events; see Section 6) are shown in Appendix B: in Table 5.1 for studies from the main searches and Table 5.2 for the unpublished In Confidence studies; and important outcomes (except Discontinuation and reasons; see Section 6) in Appendix B in Tables 5.3 and 5.4, respectively.

Table 5.5 below summarises the outcome data available by technology and source (published [P] or unpublished Academic or Commercial In Confidence [AiC or CiC, respectively]); x represents no data for this outcome from either source.

[redacted]

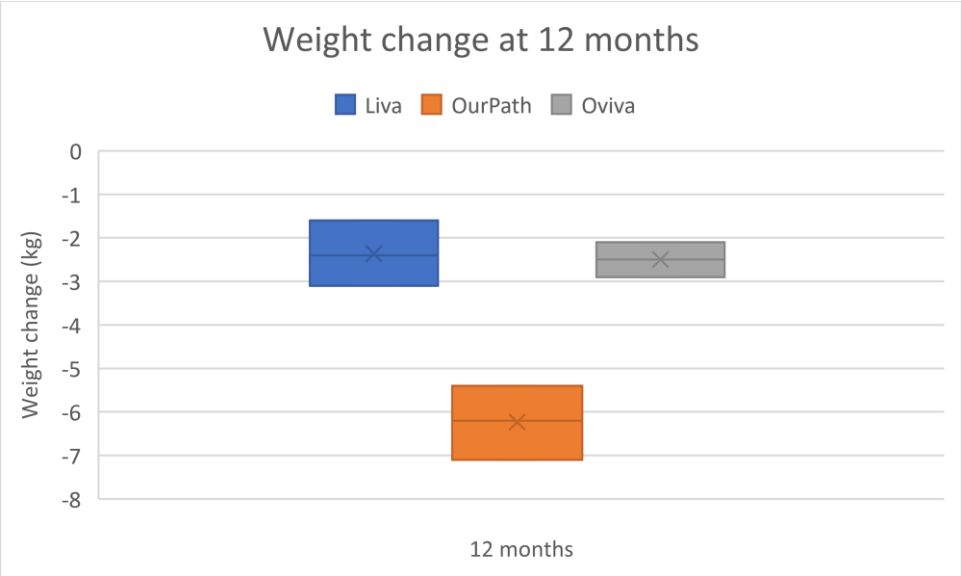
Table 5.5. Outcomes by technology

	Prioritised outcomes		**Important outcomes**			
Technology	**Weight loss**	**Adherence**	**BMI**	**Engagement**	**HRQoL**	**Psychological outcomes**
CheqUp	CiC	x	x	CiC	x	x
Gro Health	P; AiC	P	x	P; AiC	P	P
Liva	P; CiC	P; CiC	P; CiC	x	P	P
Oviva	P; CiC	P; CiC	P	P; CiC	P	P
Roczen	P; AiC	P	AiC	x	x	P; AiC
Second Nature (previously Our Path)	P	P	x	P	x	x
Wellbeing Way	x	x	x	x	x	x
Gloji	x	x	x	x	x	x
Habitual	AiC	x	x	x	x	x
Juniper	CiC (participants on medication)	x	CiC (participants on medication)	CiC (participants on medication)	x	x

For the prioritized outcomes in published studies: In the app versus non-app comparative studies, weight change and completion of 50% of the intervention were similar between the interventions (Liva and Oviva) and non-app control groups.

In the comparative study (Ross et al. 2022) between Liva, Oviva and OurPath (Second Nature), the mean (95% CI) weight loss reported at 12 months is shown in Figure 1 below.

Figure 1. Weight change at 12 months



In other studies, completion (reported at 3-12 months) ranged from 18% to 94%. Weight change is hard to compare across studies due to differing time points for reporting, potential overlap between populations and the majority of data presented in abstracts. Weight changes reported ranged from -1.89 kg at 1 month to -11 kg at 6 months (percentage weight change ranged from -1.65% at week 4 to -9.2% at 6 months).

Regarding the unpublished material:

The Academic In Confidence information supplied by Gro Health reported [redacted]. The Commercial In Confidence information supplied by Liva reported [redacted]. The Commercial In Confidence information

supplied by Oviva reported [redacted]. The Academic In Confidence information supplied by Roczen reported [redacted] The Commercial In Confidence information supplied by Juniper reported [redacted]

For the important outcomes, the only comparative study that reported a greater change in BMI in the intervention (Liva) than the control group at 12 months (Hesseldal et al. 2022a) was limited by the large drop-out rates (around 41% dropped out by 12 months). In other single arm studies, reductions in BMI of 2.2 kg/m^2 were reported at 12 weeks and 1.5 to 1.8 kg/m^2 at 12 months. One study reported an improvement in HRQoL at 6 months (with Gro Health) while 2 studies reported HRQoL was unchanged at 12 months (with Liva and Oviva). Of the four single arm studies reporting mental health outcomes, one reported improvements in depression, anxiety and stress scores (with Gro Health); one reported improvements in depression and anxiety (Roczen), and one reported improvements in depression (Oviva); the fourth reported that mental health was unchanged (Liva).

[redacted]

[redacted]

6 Adverse events and clinical risk

6.1 Adverse events

In the RCT by McDiarmid et al. 2022, nine serious adverse events were reported by four participants in the ILED and four in the CLED groups. This included hospital admissions for gallstones (two in CLED) and cholecystectomy (one in ILED), potentially related to the dietary intervention. Moderate adverse events potentially related to the LED were reported in 31% (12 of 39) of the ILED participants and 50% (20 of 40) of CLED participants. The most frequently reported adverse events included diarrhoea, fatigue, headaches, constipation, feeling cold, and dizziness. None were reported relating specifically to Oviva app use.

In the unpublished CiC information supplied by Oviva

[redacted]

In the unpublished CiC information supplied by Juniper

[redacted]

6.2 Discontinuation and reasons

These were reported in one unpublished CiC report

[redacted]

[redacted]

7 Evidence synthesis

Meta-analyses was not appropriate due to heterogeneity in populations and interventions between the studies, plus the possibility of overlap between populations in different publications.

8 Economic evidence

8.1 Economic evidence

A search for existing economic models for this decision problem was not conducted because this was considered to be appropriately reflected in the GID-HTE10007 (NICE, 2023) EVA, where no relevant economic evaluations were identified to the decision problem.

8.2 Conceptual model

8.2.1 Decision problem

An early model was developed to estimate the potential health and cost impact of introducing a digital weight management technology. The cost-utility analysis was developed to address the decision problem outlined in Table 8.1. The model captured digital technologies as a 'class' and did not model individual technologies and their impact.

Table 8.1: Decision problem

Element	Description
Population	People who are eligible for Tier 3 or 4 weight management
Intervention	Digital technology (e.g., Liva)
Comparator(s)	• Tier 3 weight management • No treatment

	• Delayed treatment
Outcomes	• Incremental costs • Incremental QALYs
Perspective for costs	NHS and personal social services (PSS)

8.2.2 Model structure

The current model is an adaption of the model that was developed for the GID-HTE10007 (NICE, 2023) EVA by Newcastle upon Tyne Hospital EAG. The model was adapted to include additional comparators as relevant to this decision problem.

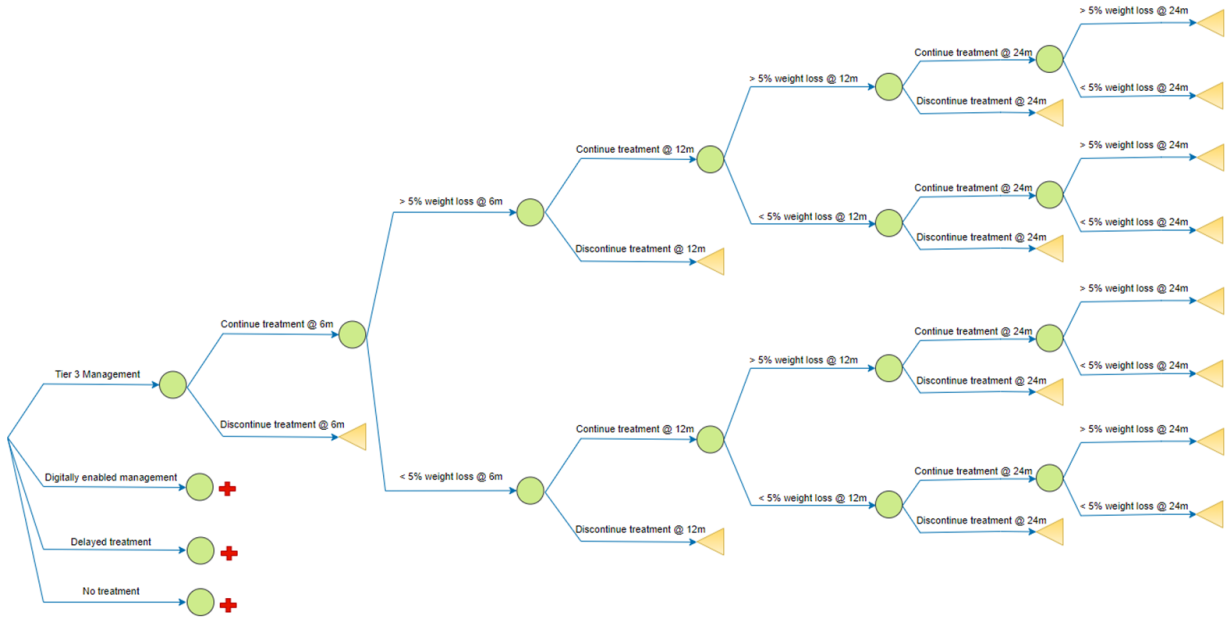
The model structure consisted of a decision tree to capture short-term treatment outcomes at 6, 12, and 24 months. The key clinical outcome was weight loss greater than or less than 5% of the body weight. At each time point the patient could either continue or discontinue treatment, and those who continue either lost more than 5% body weight or less than 5% body weight.

The model had a 24-month time horizon to represent the typical Tier 3 follow-up period, which was previously specified by clinical experts for GID-HTE10007 EVA (NICE, 2023). In addition to the Tier 3 weight management (standard care) arm in the original model, no treatment and delayed treatment arms were included as comparators. For the delayed treatment arm, two scenarios were included whereby treatment can be delayed for 6 months or 12 months. This was due to varying waiting times for Tier 3 services in the NHS (NHS Devon, 2023; NHS Maidstone and Tunbridge, 2023; NHS Derbyshire, 2023).

The intervention of interest is a weight management digital technology. Data on clinical outcomes and costs was sourced for the Liva intervention. However, in the model digital technologies were considered as a class.

Figure 8.1 outlines the decision tree structure. All costs and health benefits that were observed after 12 months were discounted at a rate of 3.5%, in line with the NICE methods guidance (NICE, 2017)

Figure 8.1: Decision tree structure



The key assumptions applied in the model are:

- Less than 5% reduction in body weight may capture people who had both less than 5% body weight loss and no change in weight.
    - For the standard treatment and digital technology arms, everyone was assumed to lose weight (i.e., no one remained the same or gained weight) due to limited evidence.
    - For the no treatment and delayed treatment, up to the point of commencing treatment, everyone was assumed to remain at the same weight (i.e., no one lost weight) due to limited evidence.
- An increase in body weight was not modelled due to lack of data available. This would likely be important in future modelling where payoffs could be applied. For example, evidence suggest that higher BMI is strongly associated with events such as type 2 diabetes, osteoarthritis, and cardiovascular disease such as occurring related to body weight.
- Those who discontinue treatment are assumed to have done so due to no improvement in weight and not because of target weight being achieved.

8.2.3 Model inputs

8.2.3.1 Clinical parameters

In line with the GID-HTE10007 EVA (NICE, 2023) and consistent with the available evidence, a 5% of body weight loss was used as the clinically significant level of weight loss. The Liva RCT (Hesseldal et al., 2022) was used to inform the standard care and digital technology treatment effect. This study was conducted in Denmark whereby the digital technology provided online sessions to support weight management, without the use of weight loss medication. However, because it is a Danish study the results may not be truly generalisable to the UK NHS setting.

The proportion of patients losing more than 5% of body weight at each time point is displayed in Table 8.2. The proportions at each time point must equal to 1 (i.e., at 6 months in the standard care arm 8.5% had a weight loss more than 5% of body weight, therefore, 91.5% have a weight loss less than 5% of body weight, (100% minus 8.5%)). For the delayed patients the same proportions as standard care was applied from the point of commencing treatment.

Table 8.2: Proportion losing >5% body weight

Variable	Value	Source
Standard care		
6 months	8.5%	Hesseldal et al. (2022)
12 months	19.2%	Hesseldal et al. (2022)
24 months	19.2%	Assumed to be the same as 12 months
Intervention		
6 months	38.9%	Hesseldal et al. (2022)
12 months	37.8%	Hesseldal et al. (2022)
24 months	37.8%	Assumed to be the same as 12 months

To account for variation in drop out throughout the model, drop out was assessed at each time point. Participants can drop out of the treatment for both positive and negative reasons. However, the proportion dropping out were not reported stratified by the proportion that lost more or less than 5% body weight nor by the cause of drop out.

An assumption that drop out was due to unsuccessful treatment was applied in the model.

Table 8.3 shows the proportion dropping out used in the model, as sourced from the study. For delayed treatment, a new 18-month dropout value was calculated from the same source based on people who discontinued at 24 months. This was done by adding the number dropped out at 12 months and the number dropped out at 24 months divided by 2 to obtain the number dropped out at 18 months. A limitation with this approach is that it must be assumed that the dropout rate between 12 and 24 months is linear (or constant). However, in the absence of data to inform otherwise this was applied as a simplifying assumption.

Table 8.3: Drop out rate

Variable	Value	Source
Standard care		
6 months	40.0%	Christensen et al. (2022)
12 months	13.1%	Christensen et al. (2022)
24 months	30.1%	Christensen et al. (2022)
Intervention		
6 months	25.3%	Christensen et al. (2022)
12 months	14.2%	Christensen et al. (2022)
24 months	36.2%	Christensen et al. (2022)
Delayed treatment		
18 months	26.2%	Calculated from Christensen et al. (2022)

8.2.3.2 Costs

All costs were provided by the companies and are displayed in Table 8.4. Wellbeing Way did not respond with an updated cost, therefore the cost provided for GID-HTE10007 EVA (NICE, 2023) was included and considered relevant to the current decision problem. In addition to the license cost for the technology, those who are in the intervention arm also incur a cost for a tablet computer and a monthly cost of mobile internet (Table 8.4). This is currently applied for the whole population in the intervention arm.

Table 8.4: Digital technology costs

	Cheq up	W8Buddy (Gro Health)	W8Buddy + (Gro Health)	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Juniper	Habitual	Gloji
Licence cost per participant per year based on number of participants				Not provided	Not provided	£540	£504	£2,456*	£540**	[redacted]	Not provided
500											
1,000											
1,500											
<1,000	£1,200	£390	£840								
>1,000	£1,140	£300	£705								
Licence cost based on programme duration	Not provided	Not provided	Not provided		Not provided	Not provided	Not provided	Not provided	Not provided	Not provided	Not provided

	Cheq Up	W8Buddy (Gro Health)	W8Buddy + (Gro Health)	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Juniper	Habitual	Gloji
6 months				£1,000							
12 months				£1,200							
18 months				£1,400							
24 months				£1,600	£900						
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	None stated	None stated	None stated

*Not an updated cost. Assumed to be an annual cost, includes total diet replacement products, all monitoring equipment and coaching time, however unclear whether this is with or without weight loss medication.

** Second nature – based on a monthly cost £42; Juniper – based on a monthly cost of £45

The cost of Tier 3 services was calculated using advice provided by clinical experts regarding the staff utilised, and the frequency and duration of appointments for each patient. These data were combined with unit costs obtained from the 2022 Personal Social Services Research Unit (Jones et al., 2022). The cost applied in the model was directly sourced from GID-HTE10007 EVA (NICE, 2023). These costs are shown in Table 8.5**Error! Reference source not found.**. Clinical opinion stated that there is uncertainty in the cost of providing current weight management care with variability likely between different centres. For the North Bristol NHS centre, the cost was estimated to be lower than currently used at approximately £1,000 annually according to one clinical expert.

Table 8.5: Key additional cost parameters

Parameter	Value	Source
Tablet computer	£100	Clinical input
Monthly cost of mobile internet	£21	Clinical input
Tier 3 service secondary care (per year)	£1,796	Clinical input

8.2.3.3 Health state utilities

To establish a baseline utility, 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) was used. These BMI categories are eligible for Tier 3 weight management services and, therefore, were included for baseline utility calculations. In line with the modelling assumptions applied in GID-HTE10007 EVA (NICE, 2023), improvements in utility were estimated based on an improvement in weight loss. For the less than 5% weight loss category, a 2.5% body weight loss was applied while for the more than 5% weight loss category, a 7.5% body weight loss was applied. These values were then used alongside the Breeze et al. (2022) values to

calculate the utility increments associated with weight loss. The utility values included are shown in Table 8.6.

Table 8.6: Utility values

Parameter	Value	Source
Baseline	0.78	Breeze et al. (2022)
Discontinued	0.78	Assumed to be the same as baseline utility
Less than 5% weight loss	0.79	Assumed to be a 0.008 utility increment
More than 5% weight loss	0.80	Assumed to be a 0.023 utility increment

8.3 Results from the economic modelling

Base case results are displayed in Table 8.7. When comparing digital technologies to standard care, digital technologies are estimated to be cost saving with improved QALYs, making it the dominant strategy. Alternatively, when compared to no treatment, digital technologies are cost incurring yet result in increased QALYs with an ICER of approximately £125,000. However, the QALYs for the no treatment and treatment arms are over and underestimated, respectively. This is because long-term outcomes such as comorbidities associated with weight gain is not included in this analysis. Therefore, the ICER for the not treatment comparison is likely over inflated and should be interpreted with caution.

When comparing digital technologies to delayed standard care, the technology is estimated to be cost-effective against both a 6- and 12-month standard care delay. However, with a delay of 6 months, digital technologies are estimated to the dominant intervention with cost savings and increased QALYs. With a longer delay in treatment (12 months), digital technologies become cost incurring but still lead to increased QALYs (£17,000 per QALY gained). However, there is uncertainty in the current standard weight management process. Additionally, as mentioned above the impact of

comorbidities and potentially preventing the development of these may have an impact on both the cost and QALY outcomes.

Threshold analysis was conducted on the cost for the digitally enabled weight management services and Tier 3 weight management services (see Figure 8.2). The results demonstrate that the incremental cost is largely impacted by the cost of the two treatments. The cost for Tier 3 weight management services is uncertain due to the lack of a robust national estimate and varied local estimates. There is variation in the cost of the digital intervention, depending on which digital system is used (see Table 8.5).

Results for the 12-month scenario analysis are displayed in Table 8.8. For each of the comparators, digital weight management is estimated to be cost incurring but with increased QALYs. However, it was estimated to be not cost-effective at a threshold of £30,000 per QALY gain against all four comparators. It should be noted that the estimate of cost-effectiveness is limited by the short time horizon considered in this analysis. However, the results show that there is potential for such digital tools to be cost-effective.

Figure 8.2: Cost threshold graph

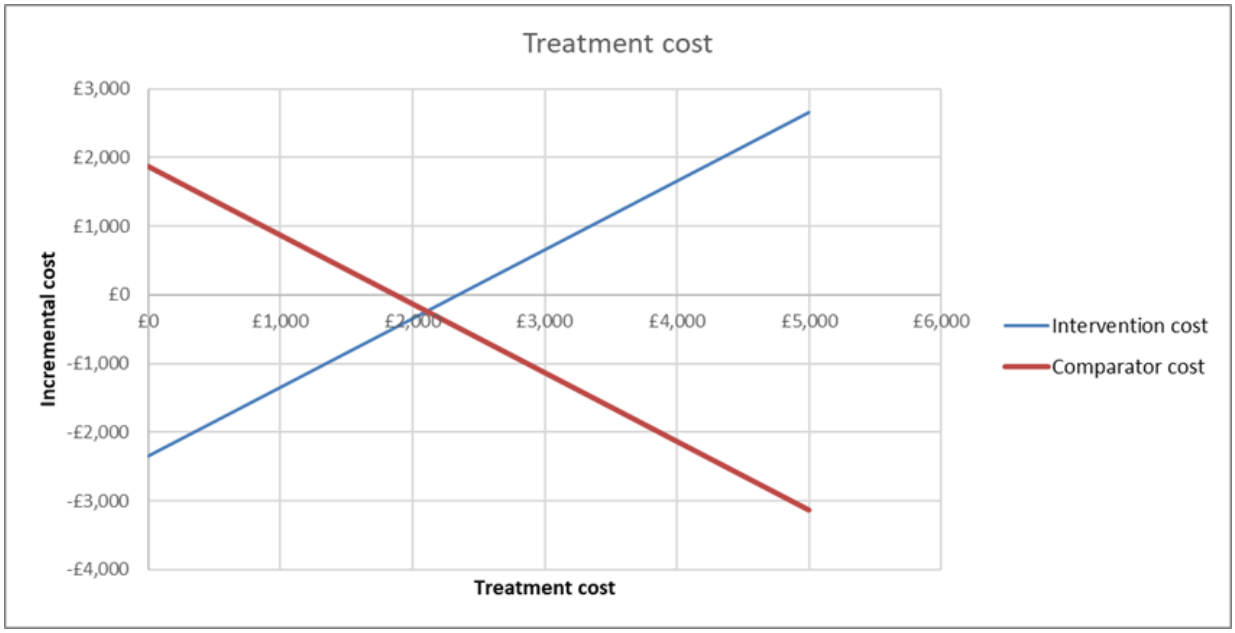


Table 8.7: Base case results (24 months)

	Total (per person)		Incremental (per person)		NHB	ICER
	Costs	QALYs	Costs	QALYs		
Digital intervention	£1,874	1.543	-	-	-	-
Standard care	£2,342	1.537	-£468	0.006	0.029	Dominant
Delayed standard care (6 months)	£2,298	1.535	-£425	0.008	0.029	Dominant
Delayed standard care (12 months)	£1,735	1.534	£139	0.008	0.001	£16,862
No treatment	£0	1.528	£1,874	0.015	-0.079	£125,259

Table 8.8: 12-month scenario results

	Total (per person)		Incremental (per person)		NHB	ICER
	Costs	QALYs	Costs	QALYs		
Digital intervention	£1,470	0.787	-	-	-	-
Standard care	£1,437	0.783	£33	0.004	0.002	£8,354
Delayed standard care (6 months)	£1,257	0.780	£212	0.007	-0.004	£31,372
Delayed standard care (12 months)	£0	0.777	£1,470	0.010	-0.064	£153,805
No treatment	£0	0.777	£1,470	0.010	-0.064	£153,805

8.4 Summary and interpretation of the economic modelling

Based on the available evidence, the results demonstrate that it is plausible that a digitally enabled weight management program could be cost-effective when compared with current standard of care and 6- and 12-month delayed treatment. However, the intervention is not shown to be cost-effective against no treatment. However, due to

time horizon considered in the model, QALYs associated with developing or worsening comorbidities and the costs of managing these are not considered. Therefore, the QALY benefits associated with the providing digital weight management over no treatment is likely underestimated.

Therefore, the ICER with such a short time-horizon is flawed as benefits are likely to accrue over time. However, this analysis shows that there is potential for this to be a cost-effective treatment in the NHS. Further evidence should be collected to inform clinical outcomes, specifically those outcomes which can be linked to long-term outcomes to enable benefits that develop beyond the short-term to be evaluated.

As this is an early model with limited and uncertain evidence, the results should be treated with caution. Due to the evidence used in the model, it is associated with limitations which must be addressed with further evidence collection. One of these limitations is that the inputs for the digital technology was only sourced from a single technology (Liva), meaning that the results may not be representative of all digital technologies for weight management. Future models built for this decision problem should include evidence for each individual digital technology to generate more representative results. Future analyses should consider the impact variability in service delivery on clinical and cost outcomes and, potentially, what the optimal make up of a digital technology (e.g., mode of access, frequency of interaction) would have to be to maximise benefits.

Another limitation of the model is that it does not account for differences in dropout rate during the early stages of the time horizon. The model assumes that dropout rates are the same for both the more than 5% and less than 5% weight loss groups at each time point. However, it may be the case that more people will drop out in those with lower weight loss (i.e., less than 5% of body weight lost) because they are discouraged by the treatment not working to expectations.

Furthermore, the model does not capture those patients who gain weight during the time horizon. It is unlikely that every person loses weight or remains the same, therefore including those who gain weight would paint a more representative picture.

Capturing changes in weight in either direction along with modelling the increased risk of certain events, such as heart disease or stroke would be important to capture the true health and cost outcomes associated with any weight management program.

The utility increments 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. However, several strong assumptions were used to incorporate these estimated increments into the model. This means that there is a lot of uncertainty surrounding these inputs.

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. A more robust economic evaluation would be attained in the future by implementing a clearer definition of the services alongside a detailed outline of the resources needed for their delivery.

The economic model does not account for issues related to access and uptake. It assumes that both treatment options (digitally enabled services and current standard care) are available to all patients where the provision of a service exists. However, 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. The Newcastle EAG consulted clinical experts who estimated that up to 20% of patients may not be able to access digital services.

9 Interpretation of the evidence

9.1 Interpretation of the clinical and economic evidence

The clinical evidence is limited, with only one non-randomised comparative study matching the scope in all areas. The comparative studies (most only partially matching the scope) showed little difference between apps and non-app face to face interventions, and interpretation of outcomes was hampered by high drop-out rates.

The comparative study of Liva, Oviva and OurPath (Second Nature) suggested a greater weight loss over 12 months with OurPath (Second Nature). Non-comparative studies reported relevant outcomes e.g. weight loss but are subject to the intrinsic problems of interpretation which may be hampered by confounding. Potential sources of bias included data only being collected for completers. However, since no major adverse events were reported and single arm studies suggested benefits in terms of weight loss, based on the evidence identified, it is plausible that the use of apps may be a safe alternative to face to face management that would enable access to weight management services for users who may not have services in their local area, or who may have difficulty in accessing in-person services due to transport, mobility or comorbidity issues.

9.2 Integration into the NHS

The technology is considered an adjunct to care for patients receiving referrals to specialist weight management programmes. Patients in the studies could refer themselves, or were referred by NHS professionals; only 4 studies included people in a tier 3/4 service. Training for clinicians (e.g. online or via videos) may include app structure and function including a walkthrough of the patient experience and communication tools, examples, best practice tips and common queries. Clinical risk should be mitigated by the MDTs having appropriate regulation, clinical oversight, audit, and reviews of practice. Use of the technology may be limited by sight, dexterity, ability to use an iPhone or tablet, or language proficiency.

9.3 Ongoing studies

9.3.1 Ongoing studies identified through searches of registries

Registries (Clinicaltrials.org, DRKS, Chinese registry) were searched for relevant ongoing clinical trials. Six were identified, which are shown in Tables 9.1 and 9.2. Ongoing studies from Company websites are shown in Table 9.3.

Table 9.1 Numbers of ongoing studies from registries

	Clinicaltrials.org	DRKS	Chinese registry
CheqUp (CheqUp)	0	0	0
Gro Health (DDM Health Ltd)	0	0	0
Liva (Liva)	1	0	0
Oviva (Oviva)	3	1	0
Roczen (Reset Health Ltd)	0	0	0
Second Nature (previously Our Path) (Second Nature)	1	0	0
Wellbeing Way (Xyla Health and Wellbeing)	0	0	0
Gloji	0	0	0
Habitual	1	0	0
Juniper	0	0	0

Table 9.1: Ongoing studies list from EAG searches

Ongoing study (EAG searches)	Alignment with scope	Outcome data for economic model	Indicated trial end date
CheqUp (CheqUp)			
None			
Gro Health (DDM Health Ltd)			
None			
Liva (Liva)			
Digital Individualized and Collaborative Treatment of T2D in General Practice Based on Decision Aid (DICTA) RCT: NCT04880005 Last Update Posted: May 10, 2021 Sponsor: University of Southern Denmark Denmark	**Participants**: T2DM **AMBER (not stated to have overweight/obesity)** **Intervention**: Liva for participants plus decision support tool for doctors and integrating patient registered outcomes to GP record **AMBER (not stated to have MDT)** **Comparator:** Usual care **GREEN** **Outcomes:** Composite endpoint of HbA1c, systolic blood pressure, low-density lipoprotein cholesterol, no smoking, and normal albuminuria; components of composite endpoint separately; antihypertensive medication; QoL; weight; abdominal circumference to hip circumference; physical activity **GREEN** **Setting**: General practice **AMBER (not tier 3/4)**	None	December 30, 2024
Oviva (Oviva)			
The DR-EAM Type 2 Diabetes Study Single arm study: NCT05626842 Last Update Posted: November 25, 2022	**Participants**: Minimum BMI of 27kg/m^2 (adjusted to 25kg/m^2 in people of South Asian or Chinese origin); BMI <45kg/m^2; T2DM **GREEN** **Intervention**: Total Diet Replacement (800kcal/day). The intervention will be led by Diabetes Specialist Dietitians	None	September 30, 2023

Sponsor: Oviva UK Ltd UK	(DSD) via the Oviva app, telephone, or video calls. **AMBER (not stated to have MDT)** **Comparator:** None **AMBER (no comparator)** **Outcomes:** HbA1c, weight, lipids, BP, physical activity, QoL, participant experience **GREEN** **Setting**: GP Practices **AMBER (not tier 3/4)**		
The Transform Type 2 Diabetes Study (Transform) Non-randomised controlled trial: NCT05648903 Last Update Posted: December 13, 2022 Sponsor: Oviva UK Ltd UK	**Participants**: T2DM, BMI ≥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) **AMBER (not exclusively overweight/obesity)** **Intervention**: One to one; choice of total diet replacement, low-carbohydrate diet or intermittent fasting; support via the Oviva app, telephone or video calls **AMBER (not stated to have MDT)** **Comparator:** As above but group not one to one; support through video group sessions not Oviva app **GREEN** **Outcomes:** HbA1c, weight, lipids, BP, NHS resource use including medication cost; QoL; diabetes remission; acceptability, motivations and preferences; engagement with the programme **GREEN** **Setting**: GP Practices **AMBER (not tier 3/4)**	NHS resource use including medication cost	July 30, 2024
Manchester Intermittent and Daily Diet Type 1 Diabetes App Study (MIDDAS-Type 1) (MIDDAS T1) RCT: NCT04674384 Last Update Posted: May 10, 2023 Sponsor: Manchester University NHS Foundation Trust	**Participants**: 12 patients with type 1 diabetes and obesity **GREEN** **Intervention**: Both groups had Oviva **GREEN** **Comparator:** Intermittent Low Energy Diet (ILED) versus Continuous Low Energy Diet (CLED) **AMBER (no non-Oviva comparator)** **Outcomes:** Glucose monitoring; adverse events; adherence; diet; engagement; satisfaction; MDT and dietitian resource use **GREEN** **Setting**: Not stated **AMBER (not stated to be tier 3/4)**	MDT and dietitian resource use	April 30, 2024

UK			
Weight management with a digital lifestyle intervention in persons with obesity RCT: DRKS00025291 Last update in DRKS: 18 August 2022 Sponsor: Oviva Germany	**Participants**: 168 people with BMI 30–40 kg/m^2 **GREEN** **Intervention**: Oviva (app-based lifestyle intervention for 12 weeks, followed by 12 weeks of follow-up) **GREEN** **Comparator:** delayed start of Oviva (current lifestyle for 12 weeks, followed by 12 weeks of app-based lifestyle intervention) **GREEN** **Outcomes:** Weight, QoL **GREEN** **Setting**: Secondary care possibly tier 3 **GREEN**	None	Not stated
Roczen (Reset Health Ltd)			
None			
Second Nature (previously Our Path) (Second Nature)			
REmote SUpport for Low-Carbohydrate Treatment of Type 2 Diabetes (RESULT) RCT: NCT04916314 Last Update Posted: May 11, 2023 Sponsors and Collaborators: University of Oxford Second Nature UK	**Participants**: 115 people from GP diabetes registers; diagnosed with type 2 diabetes within the past six years and who want to and are able to follow an app-based behavioural support programme to change their diet and have a BMI of at least 27kg/m^2 (≥30kg/m^2 if of white European ethnicity). **GREEN** **Intervention**: Second Nature **GREEN** **Comparator:** Standard NHS type 2 diabetes care **GREEN** **Outcomes:** HbA1c, diabetes remission, weight, BP, lipids, ALT, QoL, diet, engagement, satisfaction **GREEN** **Setting**: Tier 2 (GP) **AMBER (not tier 3/4)**	None	December 31, 2023
Wellbeing Way (Xyla Health and Wellbeing)			
None			
Gloji			
None			

Habitual			
Digital Diabetes Remission Trial (DIGEST) RCT: NCT05647226 Last update posted: December 12, 2022 Sponsors and Collaborators: Habitual Health Ltd; Lindus Health UK	**Participants:** 100 adults with type 2 diabetes and BMI ≥28 kg/m^2 **AMBER (not exclusively overweight/obesity)** **Intervention:** Habitual Remission Programme (digital therapeutics + 12-week 800kcal/day low-energy diet, delivered remotely) **GREEN** **Comparator:** standard care as delivered by the NHS **GREEN** **Outcomes:** HbA1c, weight, waist circumference, blood pressure, side-effects and any changes in medication **GREEN** **Setting:** Tier 2 (GP) **AMBER (not tier 3/4)**	None	January 2024

9.3.2 Ongoing studies identified through company website

These are shown in Table 9.3 but have insufficient information to code as green, amber or red.

Table 9.3. Ongoing studies identified from company websites:

CheqUp (CheqUp)	None
Gro Health (DDM Health Ltd)	**Evaluation of the Effectiveness of Gro Health App in London Hospitals:** Our study with King's College London, funded by the The Association for the Study of Obesity, is evaluating the feasibility of the Gro Health app and obesity program in a Tier 3 and Tier 4 obesity setting in London. **Evaluation of the Effectiveness of Gro Health App in London Hospitals:** Our study with Imperial College London is evaluating the feasibility of the Gro Health app and obesity program in a Tier 3 and Tier 4 obesity setting in London. **Evaluation of the Feasibility of Gro Health to Provide Personalized Nutrition:** An international study in partnership with the University of British Columbia and Institute of Personalized Nutrition will look at the feasibility of using Gro to deliver personalized nutrition to patients across Canada. The study, led by Professor Jonathan Little, will assess the use of the Gro app on a number of parameters and will collect physician and patient data throughout the course of the study
Liva (Liva)	None
Oviva (Oviva)	SAFE-LCD | Oviva UK **Type 2 diabetes remission and SAFE-LCD** Oviva has been awarded a grant from Innovate UK to conduct a research project, SAFE-LCD. In this world-first trial, we will research whether the combination of continuous glucose monitoring and a digital low calorie diet programme makes Type 2 diabetes remission achievable and safe in people on insulin therapy. Research on SAFE-LCD will begin this year, in partnership with Hull University Teaching Hospital, University College London and Insight Health Improvement. The RCT to show that patients on insulin therapy can safely achieve Type 2 diabetes remission via a digitally delivered low calorie diet intervention. This study has the potential to achieve significant reductions in insulin use, transforming the lives of tens of thousands of people living with Type 2 diabetes. If it's rolled out to just 62,000 patients annually, it will positively impact medications, monitoring, and hospital and GP usage, saving the NHS more than £229 million a year.
Roczen (Reset Health Ltd)	None

Second Nature (previously Our Path) (Second Nature)	None
Wellbeing Way (Xyla Health and Wellbeing)	None
ThriveTribe	None
Habitual	None

9.3.3 Studies identified through company submissions

We are aware of 10 ongoing studies from Gro Health listed in the EVA1 (GID-HTE10007(NICE, 2023)), with estimated completion dates between December 2023 and January 2025, but their populations were not reported.

Juniper reported three ongoing studies, shown in Table 9.4.

Table 9.4 Juniper ongoing studies

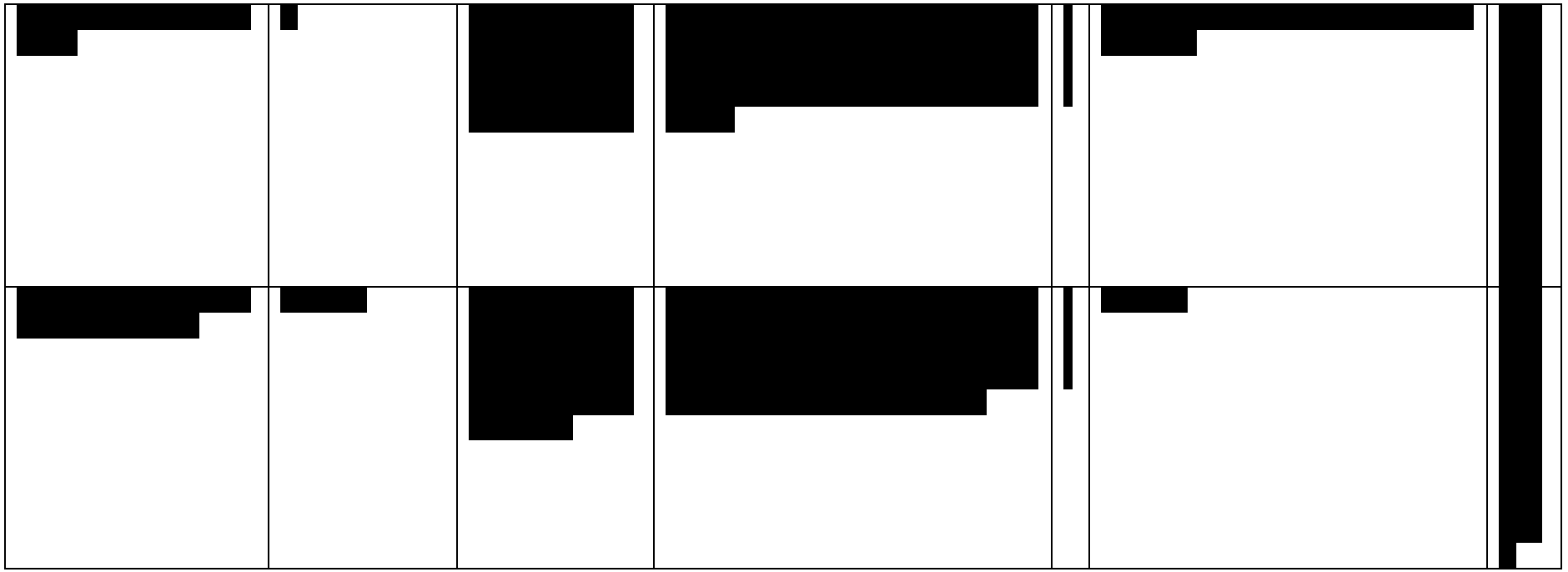
Study name	Country	Study type	Intervention	Comparator	Outcomes	Expected quarter and year for data availability
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Second Nature reported three ongoing studies, shown in Table 9.5.

Table 9.5 Second Nature ongoing studies

Study name	Country	Study type	Intervention	Comparator	Outcomes	Expected quarter and year for data availability
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]



Roczen reported one ongoing study, shown in Table 9.6.

New **Table 9.6 Roczen ongoing studies**

Study name	Country	Study type	Intervention	Comparator	Outcomes	Expected quarter

						and year for data availability
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

10 Evidence gap analysis

Gaps in the current published evidence include:

- population: only a small minority of publications include exclusively people living with obesity attending a tier 3/4 service
- intervention: most do not specify access to an MDT through the app
- comparator: almost all do not have a comparator group not receiving the app.
- outcomes: a few of the trials do not report any of the listed prioritised or important outcomes (i.e. do not report weight or BMI among others)
- study design: almost all low level of evidence.

Only one publication matched the scope in all areas but this was not an RCT, so does not provide the highest level of evidence.

[redacted]

Among the ongoing studies, one (using Oviva) matched the scope in all areas (Weight management with a digital lifestyle intervention in persons with obesity; RCT: DRKS00025291) but did not specify an expected trial end date. This study and three further ongoing RCTs coded amber (Liva: NCT04880005; Second Nature: NCT04916314; Habitual: NCT05647226) compare the apps with a usual care control group.

[redacted]

The evidence gap analysis is shown in Table 10.1 (only studies among patients not stated to be on weight management medication).

Table 10.1: Evidence gap analysis

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper
Prioritised outcomes										
Weight	No studies **RED**	1 comparative study **AMBER** [redacted] **AMBER**	1 RCT; 1 comparative study and 1 single arm study **AMBER** [redacted] **AMBER**	1 comparative study **GREEN** 1 RCT but all had Oviva; 3 comparative studies and 12 single arm studies	3 single arm studies **AMBER** [redacted] **AMBER**	1 comparative study and 6 single arm studies	No studies **RED**	No studies **RED**	[redacted] **AMBER**	No studies **RED**

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper
				AMBER [redacted] AMBER		AMBER				
Adherence	No studies RED	1 comparative study AMBER	1 RCT and 1 single arm study AMBER [redacted] AMBER	1 comparative study GREEN 1 RCT but all had Oviva; 1 comparative study and 6 single arm studies AMBER [redacted] AMBER	2 single arm studies AMBER	1 single arm study AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Important outcomes										
BMI	No studies RED	No studies RED	1 RCT and 1 single arm study AMBER [redacted] AMBER	1 comparative study GREEN 1 single arm study AMBER	[redacted] AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Engagement	[redacted]	2 single arm studies AMBER	No studies RED	1 RCT but all had Oviva and 3 single arm studies AMBER	No studies RED	1 single arm study	No studies RED	No studies	No studies RED	No studies RED

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper
	AMBER	[redacted] AMBER		[redacted] AMBER		AMBER		RED		
HRQoL	No studies RED	1 single arm study AMBER	1 RCT AMBER	1 single arm study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Psychological outcomes	No studies RED	1 single arm study AMBER	1 RCT AMBER	1 single arm study AMBER	1 single arm study AMBER [redacted] AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED

Table 10.2: Evidence gaps that could be addressed by the ongoing research

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper
Prioritised outcomes										
Weight	No studies RED	No studies RED	1 RCT AMBER	**1 RCT** GREEN	No studies RED	1 RCT AMBER [redacted]	No studies RED	No studies RED	1 RCT AMBER	3 single arm studies AMBER

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper
				1 comparative study; 1 single arm **AMBER**		**AMBER**				
Adherence	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Resource use	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT; 1 comparative study **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Important outcomes										
BMI	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	3 single arm studies **AMBER**
Engagement	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT; 1 comparative study **AMBER**	No studies **RED**	1 RCT **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	2 single arm studies **AMBER**
HRQoL	No studies **RED**	No studies **RED**	1 RCT **AMBER**	**1 RCT** **GREEN** **1 comparative study; 1 single arm** **AMBER**	No studies **RED**	1 RCT **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper
Psychological outcomes	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	[redacted] [redacted] **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**

10.1 Summary and conclusions of evidence gap analysis

The key evidence gap is the lack of high quality RCT evidence (or even non-randomised comparative data) that matches the scope; almost all the evidence is non-comparative, does not target people living with obesity being treated in tier 3/4 and does not provide access to an MDT via the app. One ongoing study may help fill this evidence gap (an RCT coded GREEN as matching all areas of scope) but only uses one technology (Oviva). Four more ongoing RCTs coded AMBER (Liva, Oviva, Second Nature, Habitual) may add data on weight outcomes, with some also reporting engagement, adherence and resource use. One non-randomised comparative study (Oviva) is due to report on weight, engagement, quality of life and resource use. Three single arm studies for Juniper are due to report weight and one single arm study for Oviva is due to report weight and quality of life.

There are key evidence gaps which needs to be addressed to provide a robust economic output for this decision problem. Further evidence collection should consider the following:

- Comparative impact of the intervention against current standard of care, particularly for waiting lists and no treatment.
- Impact of short-term health outcomes and how this can affect longer-term health is unclear from existing evidence. This includes considerations such as the development of or worsening of comorbidities associated with obesity. This can potentially be associated with substantial cost and QALY implications and capturing this would be important to truly estimate the value of a digital intervention within the current decision problem.
- Costs associated with standard care is highly variable, particularly across different centres. An assessment of what these costs are and how it varies between centres would be important to appropriately cost the comparator arm in a future economic model.

10.2 Key areas for evidence generation

Ideally, RCTs (or real-world comparative studies) would be conducted in the appropriate population (people living with obesity in a tier 3/4 service), using an intervention which includes access to an MDT via the app, and reporting the relevant prioritised outcomes (weight, adherence/completion, adverse events, resource use) and other important outcomes (BMI, engagement, discontinuation and reasons, quality of life, psychological outcomes) with a sufficiently long timescale to be a fair representation of a lifelong condition, where weight fluctuates over time and early losses may not be maintained. In addition, it would be important to follow up a higher proportion of study participants.

Future modelling must take into consideration the long-term health outcomes associated with the chronic condition and the additional adverse events that could occur as a consequence of unmanaged obesity. In addition to long-term modelling, the model would also need to capture the impact these various risks can have on future weight management.

11 Conclusions

11.1 Conclusions from the clinical evidence

The available evidence does not present an unbiased estimate of the technology's treatment effect, since most studies were uncontrolled and reported outcomes on a small subset of participants, due to high drop-out and outcomes only being reported for completers. Only one of the 38 studies matched the scope in all areas of population, intervention and comparator, with, in particular, very few studies focused exclusively on people living with obesity in tier 3/4 services. Uncertainties also remain about the long-term outcomes in this lifelong condition.

11.2 Conclusions from the economic evidence

An early economic model was developed, based on existing evidence and assumptions due to a lack of available data. The modelling results suggest that digitally enabled weight management programmes are potentially cost saving and more effective than

current standard of care, even when this treatment is delayed. Sensitivity and threshold analysis showed that the results were sensitive to the cost used for specialist weight management services. Therefore, the development of a robust cost estimate should be prioritised. A further economic evaluation, with a more comprehensive modelling approach over a lifetime time horizon, is required to fully evaluate the potential of digitally enabled weight management services to be cost-effective. This model should consider the differential rates of developing or worsening comorbidities that changes in weight can have. This could take the form of a cohort-based or patient-level simulation approach depending on available data to inform the relationship between patient history, changes in weight and occurrence of events.

11.3 Conclusions on the gap analysis

The available evidence does not present an unbiased estimate of the technology's treatment effect, since most studies were uncontrolled and reported outcomes on a small subset of participants, due to high drop-out and outcomes only being reported for completers. Only one of the 38 studies matched the scope in all areas of population, intervention and comparator, with, in particular, very few studies focused exclusively on people living with obesity in tier 3/4 services. Uncertainties also remain about the long-term outcomes in this lifelong condition.

One ongoing study may help fill this evidence gap (an RCT coded GREEN as matching all areas of scope) but only uses one technology (Oviva). Four more ongoing RCTs coded AMBER (Liva, Oviva, Second Nature, Habitual) may add data on weight outcomes, with some also reporting engagement, adherence and resource use. One non-randomised comparative study (Oviva) is due to report on weight, engagement, quality of life and resource use. Three single arm studies for Juniper are due to report weight and one single arm study for Oviva is due to report weight and quality of life.

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13 Appendices

Use the appendices to describe additional data and information as needed – we've given some examples as a guide.

List the titles of the appendices here.

Appendix A: Information from the companies

Habitual from the file named "Habitual request for information":

The technology
1) Please can you confirm the name of the technology. *Habitual*
2) What is the regulatory status of this technology in the UK? a) If the technology does not currently have regulatory approval, has this process started and when do you expect to receive it? [redacted] **Please submit a copy of (i) the CE/UKCA mark certificate and (ii) the instructions for use document**.
3) What is the national and local digital technology assessment criteria (DTAC) status of this technology? If you do not have DTAC and are not planning to apply, please explain why not. *DTAC ready as of 14/08/2023.*
What is the main purpose of this technology? Please describe: a) the main features of the technology b) how it is delivered (e.g., computer, smart phone, tablet) c) whether the technology is supported by a healthcare professional (within the platform or in the NHS). If so, please describe the type of healthcare professional(s) involved, their role and qualifications d) how is the technology accessed (e.g., referral from a healthcare professional required or can it be access widely by the public) e) how weight management services are incorporated into the use of the technology f) if there is a system in place if people need additional support *a. The Habitual app includes the following features:*

- *Asynchronous clinical consultation for initial eligibility screening*
- *Full body photo used for eligibility validation*
- *Identity verification which matches patient name and DOB from government-issued photo ID with consultation inputs*
- *Clinical consultation, full body photo, and ID verification are used together to validate 1) patient identity and 2) eligibility*
- *Monthly asynchronous repeat consultation and medication review*
- *Daily content that unlocks sequentially over the course of a programme and includes advice on nutrition, physical activity, mental health, and sleep habits. The Habitual behavioural change program is a unique delivery of lifestyle change-related health communication based on an interdisciplinary approach to breaking, building, and maintaining habits. The curriculum integrates behavioural science, neuroscience, developmental and identity psychology, and trauma-informed health communication. The Habitual behaviour change curriculum is theory- and evidence-based and contributes original content to the cumulative behavioural science, designed to hold up to academic scrutiny.*
- *Daily tracking of weight, nutritional choices, mental health, and physical activity. The app also has the ability to record blood pressure and blood glucose measurements.*
- *Daily journaling feature.*
- *Progress reporting including changes in weight, blood pressure, blood glucose, and habits.*
- *Gamification to encourage patients to engage with the app by earning points and working towards unlocking digital rewards.*
- *Low-calorie, balanced recipes which can be saved and compiled into a shopping list.*
- *Chat functionality to enable a patient to speak to a clinician or access customer/technical support.*
- *Data reporting for aggregate data analysis and service/contractual monitoring*

b. *The Habitual app is available on mobile phones and tablets.*

c. *The Habitual app is used in a number of different modalities and can facilitate multidisciplinary team care remotely. Examples of this use include:*
NHS Type 2 Diabetes Path to Remission - Our technology has been licensed to facilitate multidisciplinary patient care with health coaches, specialised dietitians, and registered nutritionists.
GLP-1 Programme -Our technology facilitates prescribing and clinical care provided
by specialist pharmacists (overseen by GP clinical lead).

d. *At present our technology is either accessed by the general public when they sign up to a paid plan with Habitual, or via an NHS primary care referral for patients eligible for the Type 2 Diabetes Path to Remission.*

e. *Weight management services are the only services provided by Habitual Health Ltd and our technology. We provide a range of research-backed weight management programmes to patients - type 2 diabetes remission programmes, low-calorie weight management programmes, and medication-assisted weight management programmes.*

f. *During any of the above programmes additional support is accessible through the app which facilitates communication with the clinical or customer support team, depending on the structure of the service and patient need.*

4) Have there been any previous versions or names of the technology? If so, please describe in detail how any previous version(s) differ from the current technology and provide any data comparing performance between the different versions.

Whilst we are constantly improving the technology including bug fixing and minor UX improvements to improve the patient experience, there are no significantly different previous versions of the technology to note.

5) Do you plan on releasing updated versions or making significant changes to the technology in the next 6-12 months? If so, please provide details on how the updated versions will compare with the current version. Also, are there any plans to withdraw or supersede any of the versions currently available to the NHS?

We will continue to provide bug fixes and UX improvements.

We have no plans to withdraw or supersede any of the versions available to the NHS.

Is there any training needed or offered to use the technology?

a) If so, please describe how the training is done, what is covered, and who is offered training (e.g., patients, clinicians)?
b) If not, please explain why training is not needed.

All patient training occurs on an automated basis as the patient is onboarded to the app. This includes videos and on-screen walkthroughs as a patient starts using the app.

Clinicians have been trained remotely via video call and recorded training sessions. Curriculum covers:

- *App structure and function including walkthrough of patient experience*
- *Internal tool training including facilitating app access and common support queries*

- *Patient communication tool - software walkthrough, communication example, macros, best practice tips including considerations for data collection*

Are there any patient groups who may struggle to access this type of technology and if so what measures are in place (if any) to support these patients needs e.g. for whom English is not their first language, people with cognitive disabilities, visual impairment, no or limited digital literacy or who do not have access to the internet or a smart device

All images in the Habitual app have pinch and zoom functionality, and the content size is scalable for patients with visual impairment. Our content can also be delivered in an audio-only format for this patient group.

At present our technology is only available in English, however the underlying content management system is designed in such a way that it is simple to add in translation of resources and long-form content.

Our technology has been tested on a variety of mobile and tablet devices, including much older models, to accommodate a wide range of patients. Our minimum supported OS versions are Android 5 (2014) and iOS 13.0, supporting devices as old as iPhone 7 (release date 2016).

Use in current care

What is the intended population for this technology?

c) Are there any subgroups of patients who may benefit most from using this technology?
   i) *Patients who could benefit from a weight management service but are unable or unwilling to access in-person services.*
   ii) *Noting significant geographical variation in tier 3 weight management service availability, Habitual could be used to deliver these services for patients who do not have access, or for whom it is unfeasible to travel to existing services. These patients represent a significant unmet need and often coexist in low-income areas where obesity prevalence is higher than in other areas*

d) Are there any subgroups for which this technology is considered unsuitable?
   i) *Those who are unable to use a mobile phone or tablet.*
   ii) *At present, basic English proficiency is a requirement to use the app, however translation could be facilitated at a later date (see technology section) and the app could facilitate care with staff fluent in required languages.*

e) How is eligibility for the technology screened (for example, by the referring clinician or by the technology itself)?

i) *Depending on the weight management service that a user is engaging with, the technology assesses eligibility against an established clinical protocol. In the case that validation is required, patients are requested to securely upload a full body photo of themselves to provide clinical correlation, which is also then checked against a government issued ID document, before the patient is allowed to proceed.*

Is this technology currently used in the NHS to provide specialist weight management service (such as tier 3 and tier 4 programmes)?

f) If yes, please provide information on where and how it is being used in the NHS?

g) If not, has the technology been launched in the UK or when do you expect this to happen?

No, however the product is currently used in the NHS Type 2 Diabetes Path to Remission. It has also been used privately by self-pay customers since 2021.

Please describe how this technology fits into the current care pathway in the NHS. Include how patients would be identified, which settings it may be used in, how treatment is delivered, and when treatment ends.

h) Is the technology considered a replacement for standard care or an adjunct to standard care?
    i) *At present the technology is considered an adjunct to care receiving referrals to specialist weight management programmes either directly or through NHS primary care referral.*

i) What is the most relevant comparator(s)?
    i) *Second Nature, Counterweight, Oviva.*

j) Would the treatment displace any element of standard care?
    i) *No*

k) Are there any changes in facilities or infrastructure needed to adopt the technology, or additional resources, including healthcare professional time or expertise?
    i) *No infrastructure or facilities required. Healthcare professionals would need to be trained in appropriate referral pathways (this excludes any healthcare professionals involved in delivering service through the Habitual technology as they would receive separate training).*

Benefits and outcomes

Please outline potential benefits to patients, healthcare professionals, and the health system associated with the use of this technology. Please send any studies or data that demonstrate these benefits specific to the technology.

GLP-1 Programme

- *Reduced major adverse cardiovascular events*
- *Reduced frequency of progression to type 2 diabetes*
- *Remission of prediabetes*
- *15% weight loss*
- *Reduced primary care workload*
- *Improved access to care*
- *Increased mobility, quality of life*

Low Calorie Intervention

- *15% mean weight loss*
- *Remission of type 2 diabetes and prediabetes*
- *Improved access to care*
- *Reduced medication use (specifically hypertensives and type 2 diabetes medication)*
- *Increased mobility, quality of life*

Does this technology have the potential to address an unmet clinical or system need in the NHS? If so, please describe.

Yes: Tier 3 weight management services often have long waiting lists, and as a result many eligible patients are unable to access care through existing pathways. In some areas, no tier 3 services are available at all, despite many patients standing to benefit. Still further, some patients may be unable or unwilling to travel for appointments, but could still benefit from specialist weight loss services. The Habitual technology has the potential to meet the needs of these patients, as well as helping to alleviate some of the existing burden on specialist weight management services unable to keep up with demand. We have built the clinical and prescribing pathways necessary to providing medication-assisted weight management programmes, including the wraparound behavioural care involving guidance on healthy diet and exercise.

6) Please describe potential risks, adverse events, or safety issues for people using this technology. Are you aware of any safety alerts for this technology?

As per DTAC, MHRA, and software development best practices we keep up to date hazard logs and are continually reviewing risks, adverse events, and safety issues. This is kept in conjunction with our clinical risk monitoring process and both are

reviewed regularly with our Head of Engineering, Clinical Lead, and executive team to improve and iterate on both our software and processes.

We are happy to provide examples of these documents separately, but for the purposes of this application we will list high level risks and mitigations:

- *Data security (Mitigation: DTAC, Pen testing, Cyber Essentials, DSPToolkit, DCB0129)*
- *Appropriate triaging of support/care queries (Mitigation: Staff training, automated query routing, and auditing of practice)*
- *Clinical risk (Mitigation: Multidisciplinary teams that deliver care through the Habitual app should have appropriate regulation, clinical oversight, audit, and reviews of practice. Technology built in line with DCB 0129. Habitual has clinical safety officer with appropriate NHS training)*
- *Technology risk (Mitigation: Error monitoring/logging, system monitoring)*
- *Deceitful or inappropriate use (Mitigation: Government-issued ID/facial recognition, correlatory clinical photograph, eligibility screening)*

7) What information does this technology collect for someone on a specialist weight management programme, how often and at which time points? Please list the key outcomes of this technology. Please include any UK performance data (quantitative and qualitative) in the current evidence section of this document.

a. Medical history

b. Medication history

c. Inclusion/exclusion criteria

d. Safety data - ID verification, full body photography, GP details

e. Prescription details

f. Initial and repeat consultation data

g. Weight (daily)

h. Blood glucose (daily/weekly)

i. Blood pressure (daily)

j. Nutritional habits (scale of 1-5, daily)

k. Physical activity habits (scale of 1-5, daily)

l. Psychological habits (scale of 1-5, daily)

m. Sleep (scale of 1-5, daily)

n. Engagement and time reading content

o. App access and time spent

p. Engagement data around use of support team or multidisciplinary team

q. Demographic details

Technology costs

8) Please provide the cost of this technology. Please state whether this cost is inclusive or exclusive of VAT.

[redacted] *(subject to service specification and contract particulars agreements), however we are open to discussing alternative pricing models that would be more suitable for individual contracts. This does not include prescribing services or clinical support.*

Please provide detailed costs of the technology itself (software and hardware), maintenance, and any other costs associated with the use of the technology relevant to the healthcare system. Please state whether these costs are inclusive or exclusive of VAT. Please state whether the price provided is the current NHS price or proposed price for this evaluation. Where pricing is dependent upon the number of units purchased, please clearly indicate this.

Costs - see above

No other specific costs to the healthcare system

Price above is a proposed price for this evaluation. Our other NHS contract is delivered jointly (split clinical and digital) and thus the pricing model is different.

Please provide details regarding the resource requirements from the NHS to roll-out use of this technology:

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?

i) *We do not charge consultancy fees for roll-out at present.*

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.

i) We do not require specific NHS input beyond referral and communications about patients.

Evidence

Please forward all references which are relevant for the assessment of this technology. These may include unpublished data, post-marketing surveillance, conference abstracts, published articles etc. Evidence that is specific to the UK is of particular interest. Please let us know if you are aware of any ongoing audits in the NHS that may provide results in the next few months. Please categorise the evidence as follows: 1) evidence specific to people with obesity in specialist weight management programmes and 2) other.

Please see the tables provided below to format the response to this question

Please provide a list of any ongoing studies on this technology including details such as study descriptions, study populations, outcomes, expected completion dates, etc.

Please see the tables provided below to format the response to this question

Study name / reference	Country	Study type (e.g. RCT)	Intervention	Comparator(s)	Outcomes	Expected month / year for data availability
DiGEST Trial ClinicalTrials.gov Identifier: NCT05647226	UK	RCT	Habitual Digital Diabetes Remission Programme (Low calorie + digital behaviour change)	Standard Care	1ry Outcome 1)Weight Loss > 15kg 2) T2DM Remission	November 2023

What do you consider to be the key limitations to the data available for your technology (e.g. generalisability to UK practice, small patient numbers, length of follow-up, using an old version of the device)

Significant reliance on patient-reported outcomes: Data entry errors, sporadic measurement, etc. We compensate for this by having introduced discrete, mandatory outcome measures at consistent intervals throughout treatment plans. This is further mitigated by design of input validation and exclusion of clearly anomalous data.

Potential variability in patient behaviour between self-pay and reimbursed—in our experience patients who do not pay are more likely to adhere to treatment.

What data would you consider it most valuable to collect to resolve uncertainties in the effectiveness and safety of the device as part of the EVA?

Weekly weight loss comparison to in-person care (already being done in DiGEST, we plan to undertake similar studies for medication-assisted programmes)

Adherence data for medication-assisted programmes

Quality of life score changes over the duration of an engagement with a patient

Customer satisfaction score for clinical and support engagements with patients

Thrive Tribe did not submit any information.

Liva submitted a file: “Liva Evidence Submission for Digitally enabled weight management programmes”

Roczen submitted a file: “Roczen clinical evidence”

Juniper submitted files: “[FOR SUBMISSION] Att 7 - Request for Information (1)” and “[FOR SUBMISSION] Att 8 - Checklist of confidential information.docx”

Oviva submitted 19 attachments.

CheqUp submitted information at fact check as follows:

CheqUp state that their care pathways have been designed by a world-leading obesity specialist to match those undertaken by patients in the STEP, SCALE and SURMOUNT global clinical trials and NICE TAs 875 and 644. They provide a full clinician-led service delivered virtually through their weight management programme and supported by a full MDT, including psychological support.Appendix B: Included and excluded studies

Included studies (design) are shown in Table 4.1a and 4.1b.

Table 4.1a: Studies selected by the EAG as the evidence base

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
CheqUp				
None identified				
Gro Health				
Abdelhameed et al. 2022 UK [abstract] Abdelhameed et al. 2022 full paper https://preprints.jmir.org/preprint/47224 Study: 1 Publications: 2 Full: 1 Abstracts: 1	Non-comparative study (case series/before and after study) Intervention: Gro Health MDT: Not stated Comparator: None (single arm study) Funding: Not stated but 3 authors employed by DDM Health Ltd **AMBER (no comparator)**	N=1767; people with diabetes/prediabetes Age: mean (SD) 49.2 (12.7) years Female: 1129 (63.8%). BMI: Not stated Tier: Not stated **AMBER (no information on BMI; no requirement for overweight/obesity; tier not stated)**	EuroQol-5D (EQ-5D) **AMBER (no prioritised outcomes, only important ones)**	Limitations: little information; not people with overweight/obesity; no comparator; no prioritised outcomes

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Hanson et al. 2023 UK Study: 2 Publications: 1 Full: 1 Abstracts: 0	Non-randomised comparative study (but data for intervention group only) Intervention: Gro Health MDT: No: evidence-based structured education, guided behavioral change activities, weekly virtual meetups and community support, health tracking, and data-driven insights to users based on their individualized data Comparator: Usual care Funding: Health Education England **AMBER (no MDT)**	N=199 people on a waiting list for tier 3 weight management services Age range 18-81; median (IQR) 40 (32-51) years Gender: 154 (77.4%) female BMI: median (IQR) 45.5 (41.9-51) kg/m^2 Tier: tier 3 **GREEN**	Engagement (intervention group only) **AMBER (no prioritised outcomes, only important ones)**	Limitations: only assessed initial interest in the app and the subgroup who actually activated the app in the intervention group only; no clinical/patient-reported/cost outcomes

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Summers et al. 2021 UK Study: 3 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study) Intervention: Gro Health MDT: No: coaching mentioned Comparator: None (single arm study) Funding: Not stated but 1 author employed by DDM Health **AMBER (no comparator; no MDT)**	N= 347 participants Age: range 22-70 years (mean 49.6, SD 9.24 years) Gender: 162 (59.3%) female BMI: Not stated but 80.2% (219/273) reported being obese Tier: Not stated **AMBER (not stated to be tier 3/4; not all participants with overweight/obesity)**	Engagement; psychological outcomes: self-reported symptoms of anxiety (7-item Generalized Anxiety Disorder scale [GAD-7]), depression (9-item Patient Health Questionnaire [PHQ-9]), and perceived stress (Perceived Stress Scale [PSS]) **AMBER (no prioritized outcomes)**	Limitations: No comparator; no MDT; not stated to be tier 3/4; not all participants with overweight/obesity; follow up only 12 weeks; no prioritized outcomes
LIVA				

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Christensen et al. 2022a (n=340; 24 months); Hesseldal et al. 2022a (n=340; 12 months); Imeraj et al. 2022 (n=104; 12 months); Christensen et al. 2022b (n=170; 6 months); Brandt et al. 2022 [abstract] (n=340; 12 months); Hesseldal et al 2022b [abstract] (n=235; 12 months); Brandt et al. 2020 (protocol) Denmark Study: 4 Publications: 7 Full: 5 Abstract: 2	RCT Intervention: LIVA MDT: not mentioned; telehealth lifestyle-coaching by a dietitian Comparator: standard face to face care (standard municipal secondary or tertiary preventive care service) Funding: This study acquired no external funding. However, one author is the cofounder of LIVA Healthcare A/S and another was financially supported by LIVA Healthcare A/S, which also paid for the coaching and instruments used in the study. **AMBER (no MDT)**	N=340 people with obesity Age: 18-70 years; mean around 52 years Gender: 213 (62.6%) female BMI: 30–45 kg/m^2 Tier: 3/4 (secondary or tertiary care service) **GREEN**	Adherence, BMI, weight loss, HbA1c, waist circumference, hip circumference, waist-hip ratio, quality of life **GREEN**	Limitations included high drop-out rate: At 12 months: 138 of 338 (40.8%) At 24 months: 59% for the intervention group and 61% for the control group

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Komkova et al. 2019; Study: 5 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study) Intervention: LIVA MDT: No: local healthcare professional coaching Comparator: None (single arm study) Company funded **AMBER (no comparator; no MDT)**	N=103 people with obesity and diabetes Age: Mean (SD) 55.6 (10.8) years Gender: 57 (55.3%) female BMI: mean (SD) 36.0 (5.2) kg/m^2 Tier: Tier 2 local healthcare setting **AMBER (not Tier 3/4)**	BMI, weight loss **GREEN**	Limitations: no comparator; no MDT; not Tier 3/4; follow up only 12 months

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Pedersen et al. 2019 Denmark Study: 6 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study): predictive models of risk of dropout Intervention: Liva MDT: Not stated Comparator: None (single arm study) Funding: Liva Healthcare provided the data and allocated resources to conduct and assist in the research and creation of this paper. The publishing of this paper was funded by the University of Southern Denmark, Health Informatics. **AMBER (no comparator; no MDT)**	N= 2684 patients using Liva: overweight (85%), diabetes (17%), heart diseases (12%), chronic obstructive pulmonary disease (5%), stress (15%), cancer (1%), alcoholism (1%), smoking (6%), or another secondary disease (20%) Age: mean (SD) 48.6 (13.2) years Gender: 1943 (72.39%) female BMI: mean (SD) 33.6 (6.0) kg/m^2 Tier: Not stated **AMBER (not all had overweight/obesity; not stated to be Tier 3/4)**	Adherence/ completion **GREEN**	Limitations: no comparator; no MDT; not all had overweight/ obesity; not stated to be Tier 3/4; dropouts in the first 14 days were excluded from this study

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Tsai et al. 2023 Germany [Abstract] Study: 7 Publications: 1 Full: 0 Abstract: 1	Non-randomised comparative study; outcome data for intervention group only Intervention: LIVA MDT: Not stated Comparator: Not stated Funding: Not stated **AMBER (comparator unclear; MDT not stated)**	N=63 people with overweight/obesity and type 2 diabetes Age: >18 years Gender: 51% female BMI: 25-40 kg/m^2; mean 33.4 kg/m^2 Tier: Not tier 3/4: recruited from social media campaigns **AMBER (not all participants with obesity; not tier 3/4)**	Adherence, HbA1c reduction **GREEN**	Limitations: 3-month pilot study; published as abstract only; comparator not stated so unclear; outcome data presented for intervention group only; MDT not stated; not tier 3/4
Oviva				
Finnie et al. 2022 UK [Abstract] Study: 8 Publications: 1 Full: 0 Abstract: 1	Non-randomised comparative study Intervention: behaviour change support from a specialist coach via Oviva MDT: No: specialist coach Comparator: behaviour change support from a specialist coach via phone coaching Funding: This work was carried out within Oviva UK **AMBER (not MDT)**	N= 2,578 participants of diabetes structured education Age: Not stated Gender: Not stated BMI: Not stated Tier: Not stated **AMBER (not stated to be tier 3/4; not stated to have overweight/obesity)**	Completion, weight loss, HbA1c **GREEN**	Limitations: Abstract only; little information; no MDT; not stated to be tier 3/4; 490 (19%) had weight data; 101 (3.9%) had HbA1c data

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Haas et al. 2019; Haas et al. 2020 [abstract]; Weishaupt et al. 2020 Switzerland Study: 9 Publications: 3 Full: 2 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: No (dietitian) Comparator: None (single arm study) Funding: Innosuisse-Suisse Innovation Agency and Oviva **AMBER (no comparator, no MDT)**	N=43 people with BMI between 26 and 33 kg/m^2 Age: range 20–67 years Gender: 36 (84%) female BMI: range 26.4–33 kg/m^2; median 30.2 kg/m^2 Tier: Not people referred to Tier 3/4. Subjects were invited to participate with flyers distributed through the Center for Obesity and Metabolism Medicine Winterthur (in Canton Zurich), via general practitioners, advertisements on the websites of the participating research institutions, local newspapers, and through word of mouth advertising. **AMBER (not all participants with obesity; not Tier 3/4)**	Weight, BMI, waist circumference, body fat, HbA1c, dietary assessment, physical activity, and health related quality of life; experiences with the app **GREEN**	Limitations: Single arm pilot study; small size; no comparator; follow up only 1 year; not all participants with obesity

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Huntriss et al. 2020 UK [Abstract] Study: 10 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: No: dietitian only Comparator: None (single arm study) Funding: Not stated but one author employed by Oviva **AMBER (no comparator, no MDT)**	N=9 people with type 2 diabetes Age: mean (SD) 47.6 (11.8) years Gender: Not stated BMI: mean (SD) 39.1 (6.7) kg/m^2 Tier: tier 2 (recruited from GP practice) **AMBER (not all participants with obesity; not Tier 3/4)**	Weight loss, HbA1c, completion **GREEN**	Limitations: Abstract only; little information; no comparator, no MDT; very small sample size; not tier 3/4; participants not stated to have overweight/obesity
Huntriss et al. 2021a UK/Germany [Abstract] Study: 11 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: Coach only mentioned Comparator: None (single arm study) Funding: Oviva **AMBER (no comparator, no MDT)**	N=907 people with obesity Age: Mean (SD) among those who achieved a relative weight loss of ≥3%: 45 (12) years and those who did not: 45 (13) years Gender: 72% and 74% female, respectively BMI: not stated Tier: Not stated **AMBER (tier not stated)**	Weight loss ≥3% **GREEN**	Limitations: abstract only; no baseline BMI; no comparator; weight loss dichotomised into ≥3% vs. not losing this amount; follow up only 12 weeks

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Huntriss et al. 2021b UK Study: 12 Publications: 1 Full: 1 Abstract: 0	Non-randomised comparative study Intervention: Oviva MDT: Monthly multi-disciplinary team meetings were held in person to discuss relevant patient cases and included the tier 3 dietitian and clinical psychologist, Consultant Physician, in addition to tier 4 dietitians and clinical psychologist. Comparator: Face to face or phone support Funding: Not stated but two authors employed by Oviva **GREEN**	N=169 people with BMI ≥ 45 kg/m^2 or ≥40 kg/m^2 with a complex comorbidity Age: mean (SD) 46.6 (13.8) years Gender: 79.3% female BMI: range 37.1–66.2 kg/m^2; mean (SD) 48.3 (6.2) kg/m^2 Tier: Tier 3 **GREEN**	Adherence, weight, BMI **GREEN**	Limitations: Follow up only at 12 weeks after core programme (of 12–16 weeks); only offered to participants completing the core programme (only attended by 67/169 [40%] of participants starting the core programme)

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Jones et al. 2018 UK [Abstract] Study: 13 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: No: coaching by registered dietitians only Comparator: None (single arm study) Funding: Authors affiliated to Oviva **AMBER (no comparator; no MDT)**	N=42 adults with Type 2 diabetes Age: mean 59 years Gender: 21 (50%) female BMI: 36.8 kg/m^2 Tier: Not stated **AMBER (not stated to be tier 3/4; not exclusively people with overweight/obesity)**	Engagement (programme uptake), HbA1c, weight loss **GREEN**	Limitations: Abstract only; little information; no comparator, no MDT; not stated to be tier 3/4; not exclusively people with overweight/obesity; small sample size; weight loss outcomes only presented for 22/42 (52.4%) participants

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Kanehl et al. 2022 Germany [Abstract] Study: 14 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: Not stated: "blended-care weight loss interventions at a specialized nutritional care provider" Comparator: None (single arm study) Funding: Authors affiliated to Oviva **AMBER (no comparator; no MDT)**	N=11758 obese patients Age: Not stated Gender: 8194 (69.7%) female BMI: mean (SD) 37.3 (6.1) kg/m^2 Tier: Not stated **AMBER (not stated to be tier 3/4)**	Weight loss **GREEN**	Limitations: Abstract only; little information; no comparator, no MDT; not stated to be tier 3/4
Lawson et al. 2022 UK Study: 15 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: Yes Comparator: None (single arm study) Funding: Not stated but 7 of 8 authors employed by Oviva **AMBER (no comparator)**	N=54 people with BMI of >35kg/m² with comorbidities Age: Not stated Gender: 78% female BMI: Not stated Tier: Tier 3 **GREEN**	Psychological outcome: depression score on PHQ-9 **AMBER (no prioritised outcomes; only important ones)**	Limitations: small sample size; no comparator; depression outcomes but not weight or BMI; follow up only 6 months

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
McDiarmid et al. 2022; Harvie et al. 2020 [abstract] Issa et al. 2020 [abstract] UK Study: 16 Publications: 3 Full: 1 Abstract: 2	RCT in which all had Oviva Intervention: groups randomised to intermittent low-energy diets (ILEDs) vs. continuous low-energy diets (CLEDs); all had frequent telephone or Oviva app support; Oviva use and outcomes reported for each group separately MDT: Yes for both groups Comparator: see above; all participants had Oviva so no non-Oviva comparator Funding: Néstle Health Science and Oviva UK Limited **AMBER (no non-Oviva comparator)**	N=79 people with overweight/obesity and type 2 diabetes Age: mean (SD): 55.5 (11.3) years Gender: 37 (47% female) BMI: mean (SD): 36.4 (5.8) kg/m^2 Tier: Not tier 3/4: Participants were recruited from three general practices, two NHS hospital trusts and a volunteer research register, via mailshot, face-to-face clinical contacts and poster displays **AMBER (not tier 3/4)**	Engagement, adherence, weight loss, diet quality, physical activity, adverse events, HbA1c, body fat, waist and hip circumference **GREEN**	Limitations: no non-Oviva control group; follow up only 1 year; drop-out: of the initial app users (n=70; 88.6% of the 79 enrolled) who completed the trial (n=51; 72.9% of initial users; 64.6% of enrolled), 44/51 (86% of completers; 62.9% of initial users; 55.7% of enrolled) still used the app at 52 weeks

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Miller et al. 2021a (Service evaluation of diabetes structured education in Kent and Medway) UK [Abstract] Study: 17 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: No: programme coach Comparator: None (single arm study) Funding: Not stated but author affiliated to Oviva **AMBER (no comparator; not stated to use MDT)**	N=598 adults with type 2 diabetes following a digitally-enabled diabetes structured education programme Age: Not stated Gender: Not stated BMI: Not stated Tier: Not stated **AMBER (not stated to be tier 3/4; not stated to have overweight/obesity)**	Weight loss, engagement, completion **GREEN**	Limitations: Abstract only; little information; only 12-week programme; weight loss at 12 weeks reported for 188 (31.4%); no comparator; not stated to use MDT; not stated to be tier 3/4
Miller et al. 2022a (Increasing access to Diabetes Structured Education (DSE)…) UK [Abstracts] Study: 18 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: No: programme coach Comparator: None (single arm study) Funding: Not stated but author affiliated to Oviva **AMBER (no comparator; not stated to use MDT)**	N=1384 adults with type 2 diabetes following a digitally-enabled diabetes structured education programme Age: Not stated Gender: Not stated BMI: Not stated Tier: Not stated **AMBER (not stated to be tier 3/4; not stated to have overweight/obesity)**	Weight loss, engagement, completion **GREEN**	Limitations: Abstract only; little information; only 12-week programme; weight loss at 12 weeks reported for 199 (14.4%); no comparator; not stated to use MDT; not stated to be tier 3/4

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Miller et al. 2022b (Uptake and retention …; n=37; Wolverhampton data); Miller et al. 2021b (n=29); Miller et al. 2022c (n=28; East Riding Yorkshire data); Miller et al. 2021c (n=25) UK [Abstracts] Study: 19 Publications: 4 Full: 0 Abstract: 4	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: No: coach support Comparator: None (single arm study) Funding: Not stated but author affiliated to Oviva **AMBER (no comparator; not stated to use MDT)**	N=37 adults with T2DM Age: Not stated Gender: Not stated BMI: Not stated Tier: Not stated **AMBER (not stated to be tier 3/4; not stated to have overweight/obesity)**	Completion, weight loss, HbA1c **GREEN**	Limitations: Abstract only; little information; no comparator; not stated to use MDT; not stated to be tier 3/4; data at 12 months for only 11 (29.7%) people
Nicinska et al. 2022 [Abstract] UK, Germany Study: 20 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: Not stated Comparator: None (single arm study) Funding: Not stated; all authors employed by Oviva **AMBER (no comparator; not stated to use MDT)**	N= 3166 patients who participated in blended-care weight-loss interventions with a specialised nutritional care provider for over a year Age: Not stated Gender: 2681 (84.7%) female BMI: Not stated Tier: Not stated **AMBER (not stated to be tier 3/4)**	Meal log data **RED (outcomes neither prioritised nor important ones)**	Limitations: No prioritised or important outcomes; abstract only; little information; no comparator; not stated to use MDT; duration of follow up not stated

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Papathanail et al. 2022a [Abstract]; Papathanail et al. 2022b; Vasiloglou et al. 2020 Switzerland Study: 21 Publications: 3 Full: 2 Abstract: 1	Non-comparative feasibility study (case series/before and after study) Intervention: Oviva MDT: No: dietitians only Comparator: None (single arm study) Funding: funded in part by Innosuisse under the framework of the project medipiatto (Project Nr. 33780.1 IP-LS). Two authors employed by Oviva **AMBER (no comparator; no MDT)**	N= 24 weight loss patients with BMI > 27 kg/m^2 Age: mean (SD) 46.9 (13.1) years Gender: 21 (87.5%) female BMI: mean (SD) 31.8 (4.4) kg/m^2 Tier: Unclear; recruited by dietitians who were treating participants **AMBER (tier not stated; not all people with obesity)**	Food frequency; satisfaction **RED (outcomes neither prioritised nor important ones)**	Limitations: No prioritised or important outcomes; no comparator; duration of follow up only 1 month

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Schirmann et al. 2022a UK, Germany, and Switzerland Study: 22 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: Only coaching by a healthcare professional (certified health coaches and/or dietitians) stated Comparator: None (single arm study) Funding: No external funding; all authors employed by Oviva **AMBER (no comparator; not stated to use MDT)**	N=25,706 patients who used Oviva for prevention or therapy of various nutrition-related conditions Age: mean (SD) 47.3 (10.96) years Gender: 17,749 (69.0%) female BMI: not stated but baseline mean (SD) weight 106.7 (21.4) kg for the 15,012 people with weight data at 1 month Tier: not stated (not exclusively tier 3/4 **AMBER (not exclusively people with overweight/obesity; not only tier 3/4)**	Weight **GREEN**	Limitations: Diverse sample (not all people with overweight/ obesity); not tier 3/4; no comparator; not stated to have an MDT. Only 58.3% of people had weight data at 1 month; 37.1% at 3 months; 16.4% at 6 months and 3.8% at 12 months and those with less weight loss more likely to drop out leading to bias.

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Schirmann et al. 2022b Germany [Abstract] Study: 23 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: No: starting call with a dietitian and chat interactions, if needed Comparator: None (single arm study) Funding: Not stated but authors affiliated to Oviva **AMBER (no comparator; not MDT)**	N=20 people with obesity that completed the 12-weeklong Oviva Direkt digital therapy Age: mean 48.25 years Gender: 17 (85%) female BMI: mean 35.31 kg/m^2 Tier: not stated to be tier 3/4 **AMBER (tier not stated)**	Weight loss **GREEN**	Limitations: Abstract only; little information; no comparator; small sample size; no MDT; only completers included; tier not stated

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Sutter et al. 2020 Switzerland [Abstract] Study: 24 Publications: 1 Full: 0 Abstract: 1	Non-randomised comparative study Intervention: Oviva plus face to face counselling MDT: No: individual nutritional counseling by registered dietitians Comparator: Face to face counseling Funding: Not stated but authors affiliated to Oviva **AMBER (no MDT)**	N=166 people with type 2 diabetes under individual nutritional counselling by registered dietitians integrated in Swiss GP practices Age: mean (SD) 60 (11) years Gender: 72 (43.4%) female BMI: mean (SD) 33 (6) kg/m² in Oviva group and 32.6 (5.3) kg/m² in comparator group Tier: Tier 2 GP practices **AMBER (not all participants with obesity; community tier 2 not tier 3 service)**	HbA1c **RED (outcomes neither prioritised nor important ones)**	Limitations: Not all participants with obesity; abstract only; not prioritised or important outcomes; HbA1c follow up measurement at 3-12 months not at a consistent time point

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Sutter et al. 2021 [Abstract] Study: 25 Publications: 1 Full: 0 Abstract: 1	Non-randomised comparative study Intervention: Oviva MDT: No: nutritionist Comparator: patients could choose whether they would like pure face-to-face advice or a combination of personal and digital advice (hybrid) via a smartphone app Funding: Not stated **AMBER (no MDT)**	N=86 with obesity Age: Mean (SD) 43.9 (13.3) years Gender: 59 (68.6%) female BMI: Mean (SD) 36.6 (6.3) kg/m^2 Tier: Not stated **AMBER (not stated to be a tier 3/4 service)**	Weight loss **GREEN**	Limitations: abstract only; little information; no MDT; not stated to be tier 3/4

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Watt et al. 2021 UK Study: 26 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study) Intervention: Oviva MDT: Not stated; telephone and text-based education Comparator: None (single arm study) Funding: Sustainability and Transformation Programme **AMBER (no comparator; not MDT)**	N=47 people recently diagnosed with type 2 diabetes; not stated to have overweight/obesity Age: mean (SD) 61.3 (13.7) years Gender: 18 (38.3%) female BMI: Not stated; baseline mean (SD) weight 99.4 (25) kg Tier: Tier 2 (GP/community) **AMBER (not all participants with obesity; community tier 2 not tier 3/4 service)**	Weight, HbA1c **GREEN**	Limitations: Small sample size; no comparator; not MDT; not all participants with obesity; community tier 2 not tier 3/4 service
Roczen				

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Brown et al. 2022 UK [Abstract] Study: 27 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Roczen MDT: Yes Comparator: None (single arm study) Funding: Not stated, all authors affiliated with Reset Health. **AMBER (no comparator)**	N=653 adults Age: Not stated Gender: Not stated BMI: Mean (SD) 35.2 (6.4) kg/m^2 Tier: Not stated **AMBER (not all participants with obesity; not stated to be tier 3/4 service)**	Weight loss, completion **GREEN**	Limitations: Conference poster only; (submitted by Company); no comparator; not all participants with obesity; not stated to be tier 3/4. Likely overlap with [redacted]
Falvey et al. 2023 UK [Abstract] Study: 28 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Roczen MDT: Clinicians and mentors Comparator: None (single arm study) Funding: All authors affiliated with Reset Health **AMBER (no comparator)**	N=732 adults completing programme Age: Not stated Gender: Not stated BMI: Mean (SD) 349 (6.3) kg/m^2 Tier: Not stated **AMBER (not all participants with obesity; not stated to be tier 3/4 service)**	Weight loss, waist circumference, HbA1c, systolic and diastolic blood pressure, PHQ-9 depression score, Binge-Eating Scale, retention **GREEN**	Limitations: Abstract only; (submitted by Company); no comparator; not all participants with obesity; not stated to be tier 3/4. Likely overlap with [redacted]

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Phung et al. 2023 UK [Abstract] Study: 29 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Roczen MDT: Yes Comparator: None (single arm) Funding: Not stated but 4 authors affiliated to Reset Health **AMBER (no comparator)**	N=82 people with type 2 diabetes Age: mean (SD) 53 (8.6) years Gender: 45 (54.9%) female BMI: mean (SD) 35 (6.7) kg/m^2 Tier: Not stated **AMBER (not all participants with obesity; tier not stated)**	Weight loss, HbA1c **GREEN**	Limitations: abstract only; no comparator; not all participants with obesity; mean (SD) time on the programme was 49 (24) weeks and outcome not reported for a consistent time point (49±24 weeks)
Second Nature (OurPath)				

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Davies et al. 2022 (3 years); Davies et al. 2023b (5 years, p115) Davies et al. 2023a (p116; referred subgroup at 3, 6 and 12 months) UK [Abstract] Study: 30 Publications: 3 Full: 0 Abstract: 3	Non-comparative study (case series/before and after study) Intervention: Second Nature MDT: Not stated Comparator: None (single arm) Funding: Not stated but all authors employed by Second Nature **AMBER (no comparator, MDT not stated)**	N=1072 people who submitted readings at 36 months (baseline number not stated); those referred by GPs were living with type 2 diabetes at initiation; self-referred not stated Subgroup of N=344 participants who registered readings at 5 years Subgroup of N=53 people referred by NHS healthcare professionals as part of their respective tier 2 weight management pathway who registered weight readings at 3, 6 and 12 months Age: Not stated Gender: Not stated BMI: Not stated Tier: Tier 2; private self-funded and referred by NHS GP. **AMBER (not Tier 3/4; not stated to have overweight/obesity)**	Weight change **GREEN**	Limitations: Abstract only; little information; no comparator; MDT not stated; not tier 3/4; not stated to have overweight/obesity

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Hampton et al. 2017; Edson et al. 2019 [Abstract] UK Study: 31 Publications: 2 Full: 1 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Our Path MDT: No; health coaching by dietitian Comparator: None (single arm) Funding: Not stated but one author co-founder and CEO of OurPath **AMBER (no comparator, not MDT)**	N=77 people with BMI ≥23 kg/m^2 Age: mean 46 years Gender: 74% female BMI: mean 31 kg/m^2 Tier: recruited online through digital advertising on Facebook and Google, using diet and weight loss-related keywords; not referred to Tier 3/4 service **AMBER (not Tier 3/4; not all participants with obesity)**	Adherence, weight loss **GREEN**	Limitations: No comparator; not all participants with obesity; large drop out: weight loss achieved after 3 months reported in 42 (55%) participants and after 6 months in 15 (19%) participants

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Hampton et al. 2019a UK [Abstract] Study: 32 Publications: 1 Full: 0 Abstract: 1	Non-comparative study (case series/before and after study) Intervention: Second Nature MDT: No: health-coaching from a registered dietitian Comparator: None (single arm) Funding: Solent Diabetes Association **AMBER (no comparator, not MDT)**	N=190 referred; 150 enrolled; people with type 2 diabetes Age: Not stated Gender: Not stated BMI: Mean (SD) 35.1 (6.7) kg/m^2 Tier: recruited by practice and specialist nurses working in the NHS; likely Tier 2 but not stated **AMBER (not stated to have overweight/obesity; not Tier 3/4)**	Weight loss, HbA1c **GREEN**	Limitations: abstract only; little information; no comparator; not MDT; not stated to have overweight/obesity; not Tier 3/4; 112 (74.7%) with 3-month outcome data; 51 (34.0%) with 6-month outcome data

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Hampton et al. 2019b; (3 and 6 months) Hampton et al. 2020 (24 months) UK [Abstracts] Study: 33 Publications: 2 Full: 0 Abstract: 2	Non-comparative study (case series/before and after study) Intervention: OurPath MDT: Not stated Comparator: None (single arm) Funding: Not stated but 3 of the 4 authors employed by OurPath **AMBER (no comparator, not stated to have MDT)**	N=1036 at 3 months; 341 at 6 months; 304 participants who submitted weight readings at baseline and 24 months after starting the programme. All participants referred by their GP were living with type 2 diabetes. Age: Not stated Gender: Not stated BMI: Not stated Tier: Not Tier 3/4: Participants either signed up to take part in the programme privately (self-funded participants) or were referred via their NHS GP. **AMBER (not stated to have overweight/obesity; not Tier 3/4)**	Weight loss **GREEN**	Limitations: abstract only; little information; no comparator; not MDT; not stated to have overweight/obesity; not Tier 3/4

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Idris et al. 2020 UK Study: 34 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study) Intervention: OurPath MDT: No; one-to-one health coaching from a registered dietitian Comparator: None (single arm) Funding: Not stated but 2 authors employed by OurPath **AMBER (no comparator, not MDT)**	N=3649 signed up; 896 people with overweight or obesity, with a BMI>25 kg/m^2 with data at 6 and 12 months Age: mean (SD) 49.4 (12.6) years Gender: 627 (70.0%) female BMI: mean (SD) 33.7 (6.1) kg/m^2 Tier: Participants either paid to access the program privately (self-funded clients) or were referred by their GP to participate in the program free of charge (funded by the NHS) **AMBER (not patients referred into tier 3/4)**	Weight change **GREEN**	Limitations: No control group; of the 3649 people who signed up for OurPath, data only presented for 896 people (less than 25%) with weight readings at 6 and 12 months; those who continued to register weight readings were more motivated and, therefore, more likely to have lost weight, introducing a self-selection bias to the data

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Kar et al. 2020 UK Study: 35 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study) Intervention: Second Nature MDT: No; mentoring from a registered dietitian or nutritionist (health coach) Comparator: None (single arm) Funding: Solent Diabetes Association **AMBER (no comparator, not MDT)**	N=144 people with Type 2 diabetes (overweight or obesity not specified) Age: mean (SD) 51.6 (11.0) years Gender: 80 (55.5%) female BMI: mean (SD) 35.9 (6.7) kg/m^2 Tier: Tier 2: Community diabetes specialist nurses recruited participants from GPs or Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) sessions. The offer to take part in the programme was part of their usual care for weight management and behavioural change support. **AMBER (not patients referred into tier 3/4; not all participants with obesity)**	Weight, HbA1c, engagement **GREEN**	Limitations: Only 94 (65.3%) participants submitted weight readings 12 months after starting the programme, meeting the criteria for the data analysis; those who submitted weights were more likely to be motivated, and more likely to lose weight, introducing a self-selection bias; HbA1c data were only available for 41 participants. The analysis did not explore long-term engagement, as the main elements of the programme only lasted for three months

Thomson et al. 2022 UK Study: 36 Publications: 1 Full: 1 Abstract: 0	Non-comparative study (case series/before and after study) Intervention: Second Nature MDT: No: dietitian acted as health coach Comparator: None (single arm) Funding: This research is funded as part of an MRC PhD studentship. Two authors were supported by UK Medical Research Council and Scottish Chief Scientist Office core funding as part of the MRC/CSO Social and Public Health Sciences Unit 'Complexity in Health Improvement' programme; one was supported by MRC Skills Development Fellowship Award **AMBER (no comparator; no MDT)**	N=48 people with BMI ≥25 Age: mean (range) 49.09 (26–74) years Gender: 40 (83%) female BMI: mean (range) 31.6 (24.2–44.4) kg/m^2 Tier: Not Tier 3/4: Participants were recruited via the Second Nature online behavioural weight management programme **AMBER (not Tier 3/4; not all with obesity)**	Qualitative study of how COVID-19 and perception of risk interacted with weight loss attempts **RED (outcomes neither prioritised nor important ones)**	Limitations: The participants in this study had all paid to take part in the weight loss programme and chose to contact the research team to take part, which may limit the range of views gathered; no comparator; no MDT; not tier 3/4; no prioritised or important outcomes

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Wellbeing Way				
None identified				
Gloji				
None identified				
Habitual				
None identified				
Juniper				
None identified				

One additional publication was provided by two companies (Liva and OurPath), in which three relevant technologies were compared: Liva, Oviva and OurPath, shown in Table 4.1b.

Table 4.2b: Additional study provided by the companies

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green = prioritised)	EAG comments
Liva, Oviva and OurPath				
Ross et al. 2022; Murray et al. 2019 UK Study: 37 Publications: 2 Full: 2 Abstract: 0	Non-randomised comparative study MDT: Not stated Comparators: Liva, Oviva and OurPath Funding: NHS England, as part of the Digital Diabetes Prevention Programme. EM is part funded by the NIHR School for Primary Care Research and the NIHR Collaboration for Leadership in Applied Health Research and Care, North Thames. AL is funded by the HEE Deanery (North Thames) **AMBER (no MDT)**	N=3623 adults with non-diabetic hyperglycaemia (NDH) (HbA1c 42–47 mmol/mol or fasting plasma glucose 5.5–6.9 mmol/L); of these, only 3 of the 5 interventions eligible for this analysis: N=813 for Liva; 494 for OurPath and 1002 for Oviva. Age, gender and BMI not stated by intervention type Tier: from GP practices **AMBER (not Tier 3/4; not all with overweight/obesity)**	Weight **GREEN**	In total: 2734 (75%) were eligible for inclusion in the analyses; for the 3 eligible interventions, weight outcomes available for N=213 for Liva (26.2%); 250 for OurPath (50.6%) and 697 (69.6%) for Oviva

Table 4.2: Additional study identified as precursor to W8 Buddy by the Company

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green = prioritised)	EAG comments
Precursor of Gro Health W8 Buddy				

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green = prioritised)	EAG comments
Hanson et al. 2021 UK Study: 38 Publications: 1 Full: 1 Abstract: 0	Non-randomised comparative observational study MDT: Yes although not via the app; participants had ongoing clinical input and follow-up with members of the hospital-based (tier 3) Obesity management team as part of usual care throughout the study period; no patient in the tier 3 weight management service received specialist dietary input from March 2020 onward. The clinical follow-up varied between patients but most received telephone review by a doctor 6 months after the previous appointment. The Low Carb Program app supported each participant with invited virtual meetups every Monday to provide an opportunity for social connection with other users for the sharing of personal experiences and establishment of peer support networks. Comparators: retrospective control group (n=126) that had received traditional face-to-face obesity management from our team without concomitant use of the Low Carb Program app in the pre–COVID-19 era Funding: Not stated; two authors employed by DDM Health **AMBER (MDT available as part of usual care, not via the app)**	N=105 patients who attended the authors' hospital-based obesity service; 126 historical controls Age: mean (SD): intervention: 48.8 (12.7) years; control: 44.4 (13.3) years; p=0.01 Gender: 59 (56.2%) and 74 (58.7%), respectively, p=0.02 BMI: Not stated; weight 130.2 (29.2) kg and 137.1 (27.0) kg, respectively; p=0.07 Tier: Tier 3 **GREEN**	Weight **GREEN**	Limitations: no randomisation; change in glycemic therapy could be a confounder, given the effects of SGLT2 inhibitors and GLP1 analogues on body weight; data on BMI was not available for all participants and therefore the authors did not include it; a lack of data collection on all the patients originally invited to use the Low Carb Program app, so no measure of uptake; due to the impact of the COVID-19 pandemic and the requisite remote management paradigm, participants self-measured and self-reported their body weight measurements throughout which may have introduced some inaccuracy; MDT as part of usual care, not via the app; retrospective control group differed on age and gender from intervention group.

Unpublished In Confidence information was provided from the Companies for CheqUp, Gro Health, Liva, Oviva, Roczen, Habitual, and Juniper; these are shown in Table 4.3. Second Nature/OurPath did not provide information In Confidence; all the publications

they provided were already included. Thrive Tribe did not provide any information and no information had been received from Wellbeing Way at close of play on 29 August 2023.

Table 4.3 Unpublished In Confidence studies (design)

Author, year	Study name	Country	Study type (e.g. RCT)	Population, Intervention	Comparator(s)
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]					

Author, year	Study name	Country	Study type (e.g. RCT)	Population, Intervention	Comparator(s)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Author, year	Study name	Country	Study type (e.g. RCT)	Population, Intervention	Comparator(s)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Author, year	Study name	Country	Study type (e.g. RCT)	Population, Intervention	Comparator(s)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Author, year	Study name	Country	Study type (e.g. RCT)	Population, Intervention	Comparator(s)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Author, year	Study name	Country	Study type (e.g. RCT)	Population, Intervention	Comparator(s)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Author, year	Study name	Country	Study type (e.g. RCT)	Population, Intervention	Comparator(s)
Second Nature					
Second Nature did not provide information In Confidence; all the publications they provided were already included.					
Wellbeing Way					
None supplied					
Gloji					
None supplied					
Habitual					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Author, year	Study name	Country	Study type (e.g. RCT)	Population, Intervention	Comparator(s)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 4.5 Excluded studies

Study	Exclusion reason
{Aceves-Martins, 2018 #539}Presentation Abstracts	Wrong study design
{Appleton, 2021 #401}Digitaaliset tyÃ¶vÃ¤lineet aikuisten lihavuuden hoidossa perusterveydenhuollossa	Wrong study design
{Arens, 2018 #128}Novel App- and Web-Supported Diabetes Prevention Program to Promote Weight Reduction, Physical Activity, and a Healthier Lifestyle: Observation of the Clinical Application	Wrong intervention
{Azar, 2018 #131}A framework for examining the function of digital health technologies for weight management	Wrong study design
{Berry, 2021 #326}Incorporating automated digital interventions into coach-delivered weight loss treatment: A meta-analysis	Wrong study design
{Berry, 2021 #44}Does self-monitoring diet and physical activity behaviors using digital technology support adults with obesity or overweight to lose weight? A systematic literature review with meta-analysis	Wrong study design
{Burke, 2020 #71}The SMARTER Trial: Design of a trial testing tailored mHealth feedback to impact self-monitoring of diet, physical activity, and weight	Wrong intervention
{Carpenter, 2019 #118}A Randomized Pilot Study of a Phone-Based Mindfulness and Weight Loss Program	Wrong intervention
{Cavero-Redondo, 2020 #332}Effect of Behavioral Weight Management Interventions Using Lifestyle mHealth Self-Monitoring on Weight Loss: A Systematic Review and Meta-Analysis	Wrong study design
{Crochiere, 2021 #41}Comparing ecological momentary assessment to sensor-based approaches in predicting dietary lapse	Wrong intervention
{Crochiere, 2022 #34}Momentary predictors of dietary lapse from a mobile health weight loss intervention	Wrong intervention
{Daud, 2023 #409}The effect of mobile health (mHealth) interventions on clinical outcomes and self-management behaviours in individuals with metabolic syndrome: a narrative review of evidence	Wrong study design
{Duarte, 2021 #57}Effect of adding a compassion-focused intervention on emotion, eating and weight outcomes in a commercial weight management programme	Wrong intervention
{Duncan, 2020 #67}Efficacy of a Multi-component m-Health Weight-loss Intervention in Overweight and Obese Adults: A Randomised Controlled Trial	Wrong intervention
{Dupuy-McCauley, 2020 #219}Treating Severe Obesity to Reduce Dyspnea in Patients With Chronic Lung Disease: A Pilot Mixed Methods Study	Wrong intervention

{Forman, 2019 #113}Can the artificial intelligence technique of reinforcement learning use continuously-monitored digital data to optimize treatment for weight loss?	Wrong intervention
{Hermsen, 2019 #741}Now You Know: Using Feedback from Digital Technology to Disrupt and Change Habitual Behaviour	Wrong study design
{Ho, 2022 #10}Predictive capacity of COVID-19-related risk beliefs on weight management behaviors on a commercial weight loss program and speed of COVID-19 vaccination uptake: prospective cohort study	Wrong intervention
{Jerome, 2020 #79}Weight management program for first responders: Feasibility study and lessons learned	Wrong intervention
{Kim, 2020 #226}Smartphone-based health program for improving physical activity and tackling obesity for young adults: A systematic review and meta-analysis	Wrong study design
{Kim, 2020 #76}Effect of mHealth With Offline Antiobesity Treatment in a Community-Based Weight Management Program: Cross-Sectional Study	Wrong intervention
{Koutoukidis, 2021 #509}The effect of the magnitude of weight loss on non-alcoholic fatty liver disease: a systematic review and meta-analysis	Wrong study design
{Lau, 2020 #75}Personalised eHealth interventions in adults with overweight and obesity: A systematic review and meta-analysis of randomised controlled trials	Wrong study design
{Lim, 2021 #195}Effect of a Smartphone App on Weight Change and Metabolic Outcomes in Asian Adults with Type 2 Diabetes: A Randomized Clinical Trial	Wrong intervention
{Lugones-Sanchez, 2020 #62}Effectiveness of an mHealth Intervention Combining a Smartphone App and Smart Band on Body Composition in an Overweight and Obese Population: Randomized Controlled Trial (EVIDENT 3 Study)	Wrong intervention
{Manchester University NHS Foundation Trust, 2022 #445}Manchester Intermittent and Daily Diet Type 1 Diabetes App Study (MIDDAS-Type 1)	Ongoing study
{Morrison, 2021 #403}Digital Solutions Supporting Healthy Weight Management and the Type 2 Diabetes Prevention Framework	Wrong study design
{Nature, 2021 #608}REmote SUpport for Low-Carbohydrate Treatment of Type 2 Diabetes	Ongoing study
{Nct, 2022 #655}Digital Diabetes Remission Trial	Ongoing study
{Nezami, 2022 #180}A pilot randomized trial of simplified versus standard calorie dietary self-monitoring in a mobile weight loss intervention	Wrong intervention
{O'Boyle, 2022 #178}The Effects of mHealth Versus eHealth on Weight Loss in Adults A Systematic Review	Wrong study design

{Oviva AG, 2022 #448}Weight management with a digital lifestyle intervention in persons with obesity	Ongoing study
{Parker, 2022 #157}Preventing chronic disease in overweight and obese patients with low health literacy using eHealth and teamwork in primary healthcare (HeLP-GP): A cluster randomised controlled trial	Wrong intervention
{Pellegrini, 2018 #132}Daily and Seasonal Influences on Dietary Self-monitoring Using a Smartphone Application	Wrong intervention
{Pintozzi, 2022 #423}Lâ€™avenir des applications nutritionnelles	Wrong study design
{Popp, 2022 #166}Soluble Receptor for Advanced Glycation End Products (sRAGE) Isoforms Predict Changes in Resting Energy Expenditure in Adults with Obesity during Weight Loss	Wrong intervention
{Putra, 2023 #408}EFEKTIVITAS PENGGUNAAN MOBILE HEALTH DALAM MENURUNKAN FAKTOR RISIKO YANG DAPAT DIMODIFIKASI PADA OBESITAS	Wrong study design
{Rumbo-Rodriguez, 2020 #59}Use of Technology-Based Interventions in the Treatment of Patients with Overweight and Obesity: A Systematic Review	Wrong study design
{Shikapwashya, 2022 #595}The Benefits of Mobile Health Applications for Individuals with Type 2 Diabetes	Wrong study design
{Shoneye, 2022 #151}Dietary assessment methods used in adult digital weight loss interventions: A systematic literature review	Wrong study design
{Stubbs, 2021 #46}Evidence-Based Digital Tools for Weight Loss Maintenance: The NoHoW Project	Wrong intervention
{Van Rhoon, 2022 #396}BUILDING THE EVIDENCE BASE FOR THE DEVELOPMENT AND IMPLEMENTATION OF AN IRISH NATIONAL DIGITAL TYPE 2 DIABETES PREVENTION PROGRAMME	Wrong study design
{Veazie, 2020 #596}Evidence brief: virtual diet programs for diabetes	Wrong study design
{Villinger, 2019 #92}The effectiveness of app-based mobile interventions on nutrition behaviours and nutrition-related health outcomes: A systematic review and meta-analysis	Wrong study design
{Wang, 2020 #70}Effectiveness of Mobile Health Interventions on Diabetes and Obesity Treatment and Management: Systematic Review of Systematic Reviews	Wrong study design
{Willmott, 2019 #94}Reported theory use in electronic health weight management interventions targeting young adults: a systematic review	Wrong study design

Table 5.1. Prioritised outcomes from publications in searches

Study	Weight change	Adherence/ completion
Gro Health (precursor)		
Abdelhameed et al. 2022 https://preprints.jmir.org/preprint/47224 **AMBER**		896/1767 (50.7%) completed the educational component of the app
Hanson et al. 2021 **AMBER**	Unknown number of patients invited; data on 105 patients who were interested in using the app at baseline; paired data were available from 48 (45.7%) Low Carb Program app users for body weight at a mean of 5 months: mean difference (95% CI): –2.7 (–4.3 to –1.1) kg; p=0.001. Mean (SD) change in control group: –1.1 (6.5) kg, n=92; p=0.12 between groups.	90 of the 105 patients who were interested in using the app (86%) completed the Low Carb Program app registration process and engaged with the Low Carb Program app program. A total of 88 participants (84%) actively engaged with the Low Carb Program app within the previous 30 days. Only a minority of participants (19/105, 18%) completed the entire Low Carb Program app program (defined as completing ≥9 of the 12 education modules available).
Liva		

Study	Weight change	Adherence/ completion
Christensen et al. 2022a AMBER	136 participants (40%), n=81 from the intervention group and n=55 from the control group, who completed 24-month follow-up: Mean body weight reduced significantly for completers in both groups, not significant between groups −4.4 (CI −6.1; −2.8) kg versus −2.5 (CI −3.9; −1.1) kg, P = 0.101.	78 out of 200 randomised (39.0%) used the app at 24 months (defined as login within the last 6 weeks)
Komkova et al. 2019 AMBER	Mean reduction 4.78 kg (4.3% of initial body weight) over mean of 7 months; P<.05	
Pedersen et al. 2019 AMBER		Dropout = patients not using the platform for 4 consecutive weeks; dropouts in the first 14 days were excluded from this study. 53.99% (1449/2684) had dropped out, 39.43% (1060/2684) were active, 3.7% (100/2684) had completed the intervention (finished intervention after >12 months), and 3% (75/2684) were in the retention phase (>12 months in program). More than 1 in 4 dropouts had occurred in the first month of the program (between day 14 and 31, n=388, 26.8% of dropouts
Tsai et al. 2023 AMBER		94% of the intervention participants were retained after 3 months.
Oviva		
Finnie et al. 2022 [abstract] AMBER	Weight data were available for 490 (19%) of participants. Average weight loss was 4.9% (n=230) in App and 2.9% in phone (n=260) participants at 12 weeks (end of intervention)	1,459/2,578 (56.6%) of participants completed the 12 weeks of diabetes structured education: 57.8% of App and 55.2% of phone participants
Haas et al. 2019 AMBER	Median change at 12 months was −4.9 kg (range: −21.9 to 7.5; P<.001)	36/43 (83.7%) completed study

Study	Weight change	Adherence/ completion
Huntriss et al. 2020 [abstract] AMBER	Completers (6 out of 9 participants) achieved average weight loss of 15.4kg (p<0.001) at three months and 16.6kg (p<0.0001) at six months	Of the 9 people, 6 (67%) completed six months
Huntriss et al. 2021a [abstract] AMBER	469/907 (51.7%) achieved a relative weight loss of ≥ 3% at 12 weeks	
Huntriss et al. 2021b GREEN	Mean (SD) change in weight kg; % at 12 week follow up: Face to face n=21: −5.3 (5.5); -4.1%; P< .001 vs. baseline App n=46: −6.1 (4.9); -4.5%; P< .001 vs. baseline; not significantly different from face to face Phone n=3: −4 (5.3); -3.4%	Completed 50% of dietetic sessions: Face to face n=48 95.8% App n=109: 96.3% Phone n=12: 83.3%. Attended all the dietetic sessions: 85.4%, 66.1% and 33.3% of patients, respectively. 70 participants (41.4%) attended the optional 12-weekfollow-up appointment: 21 Face-to-face group, 46 App group, and three for the Phone group
Jones et al. 2018 [abstract] AMBER	Weight loss outcomes only presented for 22/42 (52.4%) participants: at six months following completion of the 12-week programme, mean 4.7% body weight reduction	
Kanehl et al. 2022 [abstract] AMBER	Mean (SD) relative weight change at week 12+/- 2 weeks was -3.51 (4.19) %	
McDiarmid et al. 2022 AMBER	At 1 year, percentage weight loss was mean (95% CI) -5.4% (-7.6, -3.1%) for ILED and -6.0% (-7.9, -4.0%) for CLED groups	Of the initial app users (n=70; 88.6% of the 79 enrolled) who completed the trial (n=51; 72.9% of initial users; 64.6% of enrolled), 44/51 (86% of completers; 62.9% of initial users; 55.7% of enrolled) still used the app at 52 weeks
Miller et al. 2021a [abstract] AMBER	Average weight loss at 12 weeks was 3.62 kg (3.68%) (available for n=188/598 [31.4%] participants)	73% of those who started completed the programme
Miller et al. 2022a [abstract] AMBER	Average weight loss at 12 weeks was 2.94kg (3.22%; available for n=199/1384 [14.4%] participants).	64% of those who started the programme completed it

Study	Weight change	Adherence/ completion
Miller et al. 2022b [abstract] **AMBER**	Average weight loss at week 12 was 10.9kg (n=30; 81%) and at six months was 11kg (n=27; 72%).	30/37 (81%) patients completed the 12-week total diet replacement phase and 27/37 (72%) completed six months
Miller et al. 2022c [abstract] **AMBER**	Average weight loss at week 12 was 13.7 kg (n=26; 92.9%); at 6 months was 14.2 kg (n=25; 89.3%) and at 12 months was 14.7 kg (n=19; 67.9%)	19/28 (68%) completed 12 months
Schirmann et al. 2022a **AMBER**	Of 25,706 participants, only 58.3% of people had weight data at 1 month; 37.1% at 3 months; 16.4% at 6 months and 3.8% at 12 months: At 1 month, weight loss −1.89 ± 7.82 kg (−1.63 ± 5.94%); n= 15,012. At 3 months: −4.02 ± 7.82 kg (−3.61 ± 5.82%); n= 9526 At 6 months: −5.82 ± 9.10 kg (−5.28 ± 6.94%); n= 4204 At 12 months: −7.22 ± 9.67 kg (−6.55 ± 8.22%); n= 979	
Schirmann et al. 2022b [abstract] **AMBER**	20 patients lost on average 1.65% at week 4, 2.86% at week 8, and 3.06% at week 12	
Sutter et al. 2021 [abstract] **AMBER**	App/hybrid patient group (n=72) achieved a mean (SD) weight loss of 6.8kg (5.6), after 6 months vs. face to face group (n=14) 6.4 kg (6), both P<0.001 vs. baseline.	
Watt et al. 2021 **AMBER**	Mean (SD) weights at baseline and 6 months were 99.4 (25) and 95.5 (24.2) kg, difference 3.9 kg; p=0.00003	
Roczen		
Brown et al. 2022 [abstract] **AMBER**	At 12 weeks: -7.7 (4.4) kg; at 24 weeks: -9.5 (5.9) kg; p<0.001 vs. baseline	244/653 enrolled (37.4%) completed 6 months
Falvey et al. 2023 [abstract] **AMBER**	At 12 months (n=121/732; 16.5%): mean (SD) -8.9 (7.0) kg	Engaging with the clinical team by messaging on the app or attending follow up consultations: at 6 months: 69.0%; at 12 months: 43.0% of 732
Phung et al. 2023 [abstract] **AMBER**	Mean (SD) weight loss was 7.3 (7.2) kg; mean (SD) time on the programme was 49 (24) weeks	

Study	Weight change	Adherence/ completion
Second Nature/OurPath		
Davies et al. 2022; Davies et al. 2023 [abstracts] **AMBER**	At 3 years: mean (SD) weight loss for 1072 participants who registered readings at 36 months was 5.68 (9.41) kg (5.83%; P < 0.001 vs. baseline). The mean (SD) weight loss for the 344 participants who registered readings at 5 years was 5.71 (11.26) kg (5.65%; p< 0.001 vs. baseline).	
Hampton et al. 2017 **AMBER**	Mean (SE) % weight loss: At 6 weeks: 5.3% (0.4%); p<0.01 vs. baseline; n=77 (85% of original number of participants) At 3 months: 6.7% (0.6%); p<0.01 vs. baseline; n=42/69 with potential for 3-month data (61%) At 6 months: 8.2% (1.2%); p<0.01 vs. baseline; n=15/29 with potential for 6-month data (51%)	98 participants signed up to the OurPath programme, completed the initial assessment and online setup process, and began the intervention, of whom 77 (85%) completed the full 6 weeks of the core programme
Hampton et al. 2019a [abstract] **AMBER**	112/150 (74.7%) with 3-month outcome data: mean % weight loss 6.6%; p<0.01 vs. baseline. 51 (34.0%) with 6-month outcome data: mean 8.3% weight loss, p=0.02	
Hampton et al. 2019b; Hampton et al. 2020 [abstracts] **AMBER**	Results presented by whether participants were self-referred (commercial) or referred by a GP (NHS) to the digital behaviour change programme. Clinically significant weight loss at three months was achieved for both the commercial (-7.1%; p<0.01) and NHS (-7.5%; p<0.01) populations. Users with available six month data showed a further increased weight loss from baseline (commercial -8.6%; n=186; NHS -9.2%, n=155). Mean (SD) weight loss for 304 participants who registered readings at 24 months was 5.7 (8.3) kg (6.0%; p<0.001).	

Study	Weight change	Adherence/ completion
Idris et al. 2020 **AMBER**	Of the 3649 people who signed up for OurPath, data only presented for 896 people (less than 25%) with weight readings at 6 and 12 months: Statistically significant change in weight at 6 months (mean −7.1 kg, SD 6.4; −7.5%; P<.001) and at 12 months (mean −6.1 kg, SD 7.0; −6.5%; P<.001).	
Kar et al. 2020 **AMBER**	Data from 94 participants who provided readings at 12 months showed a statistically significant change in weight vs. baseline: mean (SD) -7.8 (8.6) kg; -7.5%; p<0.001.	
Comparative study		
Ross et al. 2022; Murray et al. 2019 UK **AMBER**	At 12 months: Liva: Mean (95% CI) −2.4 (−3.1 −1.6) kg OurPath: Mean (95% CI) −6.2 (−7.1 −5.4) kg Oviva: Mean (95% CI) −2.5 (−2.9 −2.1) kg	

Table 5.2. Results for prioritised outcomes from the unpublished In Confidence studies from the companies

Author, year	Study name	Weight	Adherence
CheqUp			
[redacted]	[redacted]	[redacted]	

Author, year	Study name	Weight	Adherence
Gro Health			
[redacted]	[redacted]	[redacted]	
Liva			
[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Author, year	Study name	Weight	Adherence
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
Oviva			
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Author, year	Study name	Weight	Adherence
[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	
Roczen			
[redacted]	[redacted]	[redacted]	

Author, year	Study name	Weight	Adherence
[redacted]	[redacted]	[redacted]	
Second Nature			
Second Nature did not provide information In Confidence; all the publications they provided were already included.			
Wellbeing Way			
None supplied			
Gloji			
None supplied			
Habitual			
[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	

Author, year	Study name	Weight	Adherence
[redacted]	[redacted]	[redacted]	
Juniper			
[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	

Table 5.3. Important outcomes from searches

Study	Change in BMI	Engagement	HRQoL	Psychological outcomes
Gro Health				
Abdelhameed et al. 2022; Abdelhameed et al 2022 https://preprints.jmir.org/preprint/47224 Single arm **AMBER**			There was a significant and clinically meaningful increase in EQ-5D mean Health index scores among app users between baseline (0.746 [SD 0.234]) and 6-month follow-up (0.792 [SD 0.224], p<0.001). VAS scores were also analysed for participants, and these also demonstrated a significantly positive change over time (mean at baseline: 61.7 (SD 18.1), follow-up: 73.0 (SD 18.8), p<.001).	
Hanson et al. 2023 Full text Only single arm reported **AMBER**		62/199 (31.2%) of people on a waiting list for tier 3 weight management services who were offered the app engaged with it (defined as having opened the app or imputed data within the last month); mean duration of engagement 184.5 (SD 24.55) days.		

Study	Change in BMI	Engagement	HRQoL	Psychological outcomes
Summers et al. 2021 Full text Single arm **AMBER**		Mean number of engaged minutes with the well-being function of the Gro Health app was 36.74 (SD 25.9) minutes		At 12 weeks: statistically significant reductions in: • PHQ-9 scores from baseline mean 7.07 (SD 4.62) to follow-up 4.74 (3.82); P<.001; • GAD-7 scores from baseline 6.85 (3.25) to 4.67 (3.08); P<.001; • perceived stress scores from baseline 17.24 (3.43) to 13.11 (2.87); P<.001
LIVA				
Christensen et al. 2022a; Hesseldal et al. 2022a **AMBER**	BMI: reduction at 12 months: Intervention group: –1.5 kg/m^2, 95% CI –1.9 to –1.2 vs. usual care: –0.5 kg/m^2, 95% CI –0.9 to –0.1; P<.001		Quality of life was unchanged in both groups	Mental health was unchanged in both groups
Komkova et al. 2019 **AMBER**	1.58-point change in BMI from baseline mean (SD) 36.0 (5.2) kg/m^2			
Oviva				
Haas et al. 2019 **AMBER**	At 12 months, median -1.8 (range -6.9 to 2.5) kg/m^2		Quality of life was unchanged	
Huntriss et al. 2021b **GREEN**	Mean (SD) change in BMI (kg/m^2) at 12 weeks: Face to face n=48: −1.9 (1.9) App n=109: −2.2 (1.7) Phone n=12: −1.5 (1.9)			

Study	Change in BMI	Engagement	HRQoL	Psychological outcomes
Jones et al. 2018 **AMBER**		Programme uptake: 74% of all eligible referrals (n=142)		
Lawson et al. 2022 **AMBER**				The average PHQ-9 score at baseline (N=54) was 9.33, at three months 7.33 (p=0.0026), and at six months 6.89 (p=0.0022)
McDiarmid et al. 2022 **AMBER**		Uptake to the Oviva app: 70/79 (89%) willing to use the app from baseline.		
Miller et al. 2021a **AMBER**		73% of referrals (n=598) started the programme		
Miller et al. 2022a **AMBER**		72% started the programme		
Roczen				
Brown et al. 2022 **AMBER**				Significant reductions vs. baseline in depression (2.2±3.4, p<0.001) and anxiety (1.9±4.0; p<0.001) scores for the 244 completers out of 653 eligible adults enrolled (37.4%)

Study	Change in BMI	Engagement	HRQoL	Psychological outcomes
Second Nature (OurPath)				
Kar et al. 2020 AMBER		190 people entered the service, 150 (78.9%) completed the registration and 144 (75.8% of those entering the service) started the programme. From the participants with data available, 134/144 (93% of starters; 70.5% of people entering the service) had at least one interaction during the programme.		

Table 5.4. Results for the important outcomes from the unpublished In Confidence studies reported from the companies

Author, year	Study name	BMI	Engagement	Psychological outcomes
CheqUp				
[redacted]			[redacted]	

Author, year	Study name	BMI	Engagement	Psychological outcomes
Gro Health				
[redacted]	[redacted]		[redacted]	
Liva				
[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]			
[redacted]	[redacted]			

Author, year	Study name	BMI	Engagement	Psychological outcomes
[redacted]	[redacted]			
[redacted]	[redacted]			
[redacted]	[redacted]			
Oviva				
[redacted]	[redacted]		[redacted]	
[redacted]	[redacted]		[redacted]	

Author, year	Study name	BMI	Engagement	Psychological outcomes
Roczen				
[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]			
Second Nature				
Second Nature did not provide information In Confidence; all the publications they provided were already included.				
Wellbeing Way				
None supplied				
Gloji				
None supplied				

Author, year	Study name	BMI	Engagement	Psychological outcomes
Habitual				
None supplied for these outcomes				
Juniper				
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	

Appendix C: supplementary search methods

Searches were originally run by Newcastle Early Assessment Group in May 2023 and June 2023 to identify evidence on apps to support weight loss for a previous version of this report ("Assessment report: GID-HTE10007 Diet and activity apps"). Two further named digital technologies have since been identified as within scope: Gloji (Tribal Thrive) and Habitual (Habitual). A MEDLINE (OvidSP) search strategy targeted to only identify studies of these two digital technologies for managing weight loss was therefore developed and is presented below. The searches follow the structure, term selection and resource selection of the searches presented in the previous report where possible.

The main structure of the strategy comprised four concepts:

- Gloji app (search line 1)
- Habitual app (search line 2)
- weight loss (search line 3)
- digital technologies (search lines 5 to 19).

The concepts were combined as follows: (Gloji app OR Habitual app) AND weight loss AND digital technologies.

The search terms for weight loss replicated the supplementary searches undertaken for "Assessment report: GID-HTE10007 Diet and activity apps".

The NICE search filter for identifying evidence on health apps [CITE] (search lines 5 to 19) was used for the digital technologies concept.

Reflecting the search date from the previous version of the report, the search was limited to 2018 onwards (line 21). The strategy was not limited by language.

The final Ovid MEDLINE strategy was peer-reviewed before execution by a second Information Specialist. Peer review considered the appropriateness of the strategy for the review scope and eligibility criteria, inclusion of key search terms, errors in spelling, syntax and line combinations, and application of exclusions.

Search limitations

The search is limited to two named digital apps: Gloji (Tribal Thrive) and Habitual (Habitual). The search will only retrieve records where the name of the app or the app developer appears in the title, abstract, keywords or institution fields of the record.

The weight loss terms are limited to those used in the searches for a previous version of this report. These target relevant terms that may appear in multiple fields of a database record but do not include specific subject headings. The search strategies for some of the resources searched used a limited number of these terms to ensure that a balance of sensitivity and precision was achieved. This replicated the approach taken in the searches for “Assessment report: GID-HTE10007 Diet and activity apps”.

Searching for one of the named digital apps (Habitual) proved to be problematic due to the relatively common usage of the word “habitual” in the weight loss literature. A pragmatic approach was taken and the MEDLINE and Embase searches were limited by adding the NICE filters to identify evidence on health apps. The search strategies for some of the other resources used a limited number of terms for digital apps, these terms were sourced from the Google Scholar search strategy in "Assessment report: GID-HTE10007 Diet and activity apps”.

The approach taken in the search strategy was designed to strike an appropriate balance of sensitivity and precision.

Resources searched

We conducted the literature search in the databases and information resources shown in “Assessment report: GID-HTE10007 Diet and activity apps”.

Table 13.1. The selection of resources replicated the approach used in “Assessment report: GID-HTE10007 Diet and activity apps”.

Table 13.1: Databases and information sources searched

Resource	Interface / URL
Databases	
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
CINAHL Ultimate	EBSCOHost
Cochrane Central Register of Controlled Trials (CENTRAL)	Cochrane Library/Wiley
Google Scholar	https://scholar.google.com/
MedRxiv	https://www.medrxiv.org/search
International HTA database	https://database.inahta.org/
NIHR Journals Library	https://www.journalslibrary.nihr.ac.uk/#/
Trials Registers	
WHO International Clinical Trials Registry Platform (ICTRP)	https://trialsearch.who.int/
Scan Medicine	https://scanmedicine.com/
ClinicalTrials.gov	https://clinicaltrials.gov/
Other	
Reference list checking	n/a
Company submissions	n/a

The trials register sources listed above (ICTRP, Scan Medicine and ClinicalTrials.gov) were searched to identify information on studies in progress.

Running the search strategies and downloading results

We conducted searches using each database or resource listed above, translating the agreed Ovid MEDLINE strategy appropriately. Translation included consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The final translated database strategies were peer-reviewed by a second Information Specialist. Peer review considered the appropriateness of the translation for the database being searched, errors in syntax and line combinations, and application of exclusions.

Where possible, we downloaded the results of searches in a tagged format and loaded them into bibliographic software (EndNote). The results were deduplicated using

several algorithms and the duplicate references held in a separate EndNote database for checking if required. Results from resources that did not allow export in a format compatible with EndNote were saved in Word or Excel documents as appropriate and manually deduplicated.

Literature search results

The searches were conducted between 15 August and 16 August 2023 (**Table 13.2**).

Table 13.2: Literature search results

Resource	Number of records identified
Databases	
MEDLINE(R) ALL	15
Embase	26
CINAHL Ultimate	15
Cochrane Central Register of Controlled Trials (CENTRAL)	32
Google Scholar	64
MedRxiv	1
International HTA database	0
NIHR Journals Library	0
Total records identified through database searching	**153**
Trials Registers	
WHO International Clinical Trials Registry Portal (ICTRP)	5
Scan Medicine	20
ClinicalTrials.gov.	44
Total records identified through trials register searching	**69**
Other sources	
Reference list checking	0
Company evidence	0
Total additional records identified through other sources	**0**
Total number of records retrieved	**222**
Total number of records after deduplication	**178**

Search strategies

A.1: Source: MEDLINE ALL

Interface / URL: OvidSP

Database coverage dates: 1946 to 14 August 2023

Search date: 15/08/23

Retrieved records: 15

Search strategy:

1 (Gloji* or Thrive Tribe*).ti,ab,kf,in. (0)

2 (habitual or habitualr or habitualtm).ti,ab,kf,in. (21243)

3 (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. (614901)

4 (1 or 2) and 3 (2107)

5 Mobile Applications/ (11597)

6 exp Internet/ (97827)

7 exp Cell Phone/ (22483)

8 exp Computers, Handheld/ (13107)

9 Medical Informatics Applications/ (2551)

10 Therapy, Computer-Assisted/ (6973)

11 (app or apps).ti,ab. (43372)

12 (online or web or internet or digital*).ti. (138947)

13 ((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap*)).ab. (79508)

14 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti. (27166)

15 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3 (based or application* or intervention* or program* or therap*)).ab. (16992)

16 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti. (8526)

17 ((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (based or application* or intervention* or program* or therap*)).ab. (5904)

18 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab. (21890)

19 or/5-18 (344536)

20 4 and 19 (23)

21 limit 20 to yr="2018 -Current" (15)

A.2: Source: Embase

Interface / URL: OvidSP

Database coverage dates: 1974 to 14 August 2023

Search date: 15/08/23

Retrieved records: 26

Search strategy:

1 (Gloji* or Thrive Tribe*).ti,ab,kf,dm,dv,in. (0)

2 (habitual or habitualr or habitualtm).ti,ab,kf,dm,dv,in. (26607)

3 (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. (1089672)

4 (1 or 2) and 3 (3509)

5 exp mobile application/ (25372)

6 internet/ (123158)

7 exp mobile phone/ (47256)

8 text messaging/ (7635)

9 personal digital assistant/ (1827)

10 computer assisted therapy/ (4858)

11 (app or apps).ti,ab. (58830)

12 (online or web or internet or digital*).ti. (158699)

13 ((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap*)).ab. (106450)

14 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti. (32158)

15 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3 (based or application* or intervention* or program* or therap*)).ab. (22632)

16 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti. (9371)

17 ((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (based or application* or intervention* or program* or therap*)).ab. (6439)

18 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab. (26856)

19 or/5-18 (439969)

20 4 and 19 (46)

21 limit 20 to yr="2018 -Current" (26)

A.3: Source: CINAHL Ultimate

Interface / URL: EBSCOHost

Database coverage dates: 1937 to 16 August 2023. Information found at: https://www.ebsco.com/news-center/press-releases/ebsco-creates-collections-nursing-allied-health-lit-biomed-journals

Search date: 16/08/2023

Retrieved records: 15

Note: This search uses a translation of the NICE filter for identifying health apps in MEDLINE. However, there was no direct translation of the MeSH “Medical informatics applications” and so this term was omitted.

Search strategy:

S18 S3 and S17 15
S17 S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 276,964
S16 TI ((mobile* N3 (based or application* or intervention* or device* or technolog*))) OR AB ((mobile* N3 (based or application* or intervention* or device* or technolog*))) 10,659
S15 AB (("mobile health" or mhealth or m-health or ehealth or e-health or emental or e-mental) N3 (based or application* or intervention* or program* or therap*)) 2,704
S14 TI ("mobile health" or mhealth or m-health or ehealth or e-health or emental or e-mental) 5,616
S13 AB ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) N3 (based or application* or intervention* or program* or therap*)) 8,693
S12 TI (phone* or telephone* or smartphone* or cellphone* or smartwatch*) 14,700
S11 AB ((online or web or internet or digital*) N3 (based or application* or intervention* or program* or therap*)) 34,130
S10 TI (online or web or internet or digital*) 81,869
S9 TI ((app or apps)) OR AB ((app or apps)) 13,817
S8 (MH "Therapy, Computer Assisted") 5,538
S7 (MH "Computers, Hand-Held+") 8,696
S6 (MH "Cellular Phone+") 10,503
S5 (MH "Internet+") 164,910

S4 (MH "Mobile Applications") 12,458

S3 S1 and S2 1,401

S2 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*))) 457,718

S1 TI (habitual or habitualtm or habitualr or gloji* or "thrive tribe*") OR AB (habitual or habitualtm or habitualr or gloji* or "thrive tribe*") 6,831

A.4: Source: Cochrane Central Register of Controlled Trials (CENTRAL)

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 8 of 12, August 2023

Search date: 15/08/2023

Retrieved records: 32

Search strategy:

#1 (Gloji* or Thrive NEXT Tribe*) 0

#2 (habitual or habitualr or habitualtm) 7184

#3 (obes* or preobes* or overweight or "over weight") 61372

#4 ((bmi or (body NEXT mass NEXT index*)) and "kg m") 7309

#5 (weight* NEAR/5 (loss or lose or losing or loses or lost or manag* or reduc* or control*)) 49661

#6 #1 or #2 7184

#7 #3 or #4 or #5 91932

#8 #6 and #7 1538

#9 [mh ^"mobile applications"] 1580

#10 [mh "internet"] 6200

#11 [mh "cell phone"] 3146

#12 [mh "computers, handheld"] 1375

#13 [mh ^"medical informatics applications"] 38

#14 [mh ^"therapy, computer-assisted"] 1478

#15 (app or apps):ti,ab 9550

#16 (online or web or internet or digital*):ti 16962

#17 ((online or web or internet or digital*) near/3 (based or application* or intervention* or program* or therap*)):ab 19650

#18 (phone* or telephone* or smartphone* or cellphone* or smartwatch*):ti 6914

#19 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) near/3 (based or application* or intervention* or program* or therap*)):ti,ab 10040

#20 ("mobile health" or mhealth or "m health" or ehealth or "e health" or emental or "e mental"):ti 2426

#21 (("mobile health" or mhealth or "m health" or ehealth or "e health" or emental or "e mental") near/3 (based or application* or intervention* or program* or therap*)):ab 2448

#22 (mobile* near/3 (based or application* or intervention* or device* or technolog*)):ti,ab 6460

#23 #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 51784

#24 #8 and #23 with Publication Year from 2018 to 2023, in Trials 32

A.5: Source: Google Scholar

Interface / URL: https://scholar.google.com/

Database coverage dates: Information not found.

Search date: 16/08/2023

Retrieved records: 65, exported 64 (one was a duplicate and not exported)

Search strategy:

Advanced search:

Search 1:

Must include: habitual (title only)

Must include *at least one of the words*: blended hybrid digital remote app smartphone telehealth telemedicine telecare (title only)

= 25 results (limit 2018-2023)

Search 2:

Must include: habitual (title only)

Must include *at least one of the words*: obesity obese overweight (title only)

= 32 results (limit 2018-2023)

Search 3:

Habitualtm (title only)

Must include *at least one of the words*: obesity obese overweight (title only)

= 0 results (limit 2018-2023)

Search 4:

Habitualtm (title only)

Must include *at least one of the words*: blended hybrid digital remote app smartphone telehealth telemedicine telecare (title only)

= 0 results (limit 2018-2023)

Search 5:

Must include: habitualr (title only)

Must include *at least one of the words*: obesity obese overweight (title only)

= 0 results (limit 2018-2023)

Search 6:

Must include: habitualr (title only)

Must include *at least one of the words*: blended hybrid digital remote app smartphone telehealth telemedicine telecare (title only)

= 0 results (limit 2018-2023)

Search 7:

Must include: gloji (anywhere in article)

Must include *at least one of the words*: blended hybrid digital remote app smartphone telehealth telemedicine telecare (anywhere in article)

= 7 results (limit 2018-2023)

Search 8:

Must include: gloji (anywhere in article)

Must include *at least one of the words*: obesity obese overweight (anywhere in article)

= 1 result (limit 2018-2023)

Search 9:

glojitm

= 0 results (limit 2018-2023)

Search 10:

glojir

= 0 results (limit 2018-2023)

Search 11:

“tribal thrive”

= 0 results (limit 2018-2023)

Search 12:

“tribal thrivetm”

= 0 results (limit 2018-2023)

Search 13:

“tribal thriver”

= 0 results (limit 2018-2023)

A.6: Source: MedRxiv

Interface / URL: https://www.medrxiv.org/search

Database coverage dates: Information not found.

Search date: 16/08/2023

Retrieved records: 1

Search strategy:

Advanced search, title and abstract search:

All searches limited to 01/01/2018 to 16/08/2023

Title/abstract must contain: habitual obese = 1 result

Title/abstract must contain: habitual obesity = 0 results

Title/abstract must contain: habitual overweight = 0 results

Title/abstract can contain any of the following: habitualtm habitualr gloji glojitm glojir = 0 results

Title/abstract must contain phrase: tribal thrive = 0 results

Title/abstract must contain phrase: tribal thriver = 0 results

Title/abstract must contain phrase: tribal thrivetm = 0 results

A.7: Source: WHO International Clinical Trials Registry Portal (ICTRP)

Interface / URL: https://trialsearch.who.int/

Database coverage dates: Information not found. On the date of search, files had been imported from data providers between November 2022 and August 2023.

Search date: 16/08/2023

Retrieved records: 5
Search strategy:

Search 1:

5 records for 5 trials found for: (habitual AND (obes* OR overweight)) AND (blended OR hybrid OR digital* OR remote* OR app OR apps OR telehealth OR "tele health" OR smartphone* OR "smart phone*" OR telemedicine OR "tele medicine" OR telecare OR "tele care")

Search 2:

No results were found for: (habitualtm OR habitualr)

Search 3:

No results were found for: (gloji* OR "tribal thrive*")

A.8: Source: Scan Medicine

Interface / URL: https://scanmedicine.com/

Database coverage dates: Information not found. Scan Medicine searches 11 registries.

Search date: 16/08/2023

Retrieved records: 20

Search strategy:

20 results found in 11 registries for ((habitual | habitualtm | habitualr | gloji | glojir | glojitm | "tribal thrive" | "tribal thrivetm" | "tribal thriver") + (obesity | "over weight" | overweight) + (blended | hybrid | digital | remote | app | telehealth | smartphone | telemedicine | telecare))

A.9: Source: ClinicalTrials.gov

Interface / URL: https://clinicaltrials.gov/ct2/home

Database coverage dates: Information not found. ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The site was made available to the public in February 2000.

Search date: 16/08/2023

Retrieved records: 44

Search strategy:

Search 1:

44 Studies found for: (habitual AND (obese OR obesity OR overweight)) AND (blended OR hybrid OR digital OR digitally OR remote OR remotely OR app OR apps OR telehealth OR tele-health OR "tele health" OR smartphone OR smartphones OR smart-phone OR smart-phones OR "smart phone" OR EXPAND[Concept] "smart phones" OR telemedicine OR tele-medicine OR "tele medicine" OR telecare OR tele-care OR "tele care")

Search 2:

(habitualr OR habitualtm OR gloji OR glojitm OR glojir OR "tribal thrive" OR "tribal thrivetm" OR "tribal thriver") = 0 results

A.10: Source: HTA database

Interface / URL: https://database.inahta.org/

Database coverage dates: Information not found. The former database was produced by the CRD until March 2018, at which time the addition of records was stopped as INAHTA was in the process of rebuilding the new database platform. In July 2019, the database records were exported from the CRD platform and imported into the new platform that was developed by INAHTA. The rebuild of the new platform was launched in June 2020.

Search date: 16/08/2023

Retrieved records: 0

Search strategy:

4 #3 AND #2 AND #1 0

3 (habitual OR habitualtm OR habitualr OR gloji OR glojitm OR glojir OR "tribal thrive" OR "tribal thrivetm" or "tribal thriver") 15

2 (obesity OR overweight OR "over weight") 278

1 (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) 426

A.11: Source: NIHR Journals Library

Interface / URL: https://www.journalslibrary.nihr.ac.uk/#/

Database coverage dates: Information not found. The NIHR Journals Library website provides access to information about research funded by the National Institute for Health and Care Research (NIHR) (https://www.journalslibrary.nihr.ac.uk/about-us/).

Search date: 16/08/2023

Retrieved records: 0

Search strategy:

Searched individual terms:

habitual (4 results, 2 in progress, 2 not relevant)
0 results for habitualtm, habitualr, gloji, glojitm, glojir, “tribal thrive”, “tribal thrivetm”, “tribal thriver”.

Addendum to GID-HTE10023 Digitally enabled weight management programmes

On September 4th, 2023, we received information from the Companies on two additional technologies that the Companies suggested were eligible for inclusion in the EVA GID-HTE10023 Digitally enabled weight management programmes: Weight Loss Clinic (Virtual Health Partners Inc.) and Counterweight (Counterweight).

The following information is to be viewed alongside the main report and the impact of this additional material on the main report will be highlighted. The numbering of Sections and Tables will follow the numbering in the main report for comparison.

Executive summary

Quality and relevance of the clinical evidence

The additional material comprised 16 publications (9 full texts, 4 abstracts and 3 protocols only with no outcomes) relating to 14 studies. None matched the scope in all areas, and only three studies stated that the intervention was used in a tier 3 or 4 service.

Quality and relevance of the economic evidence

NA

Evidence gap analysis

The additional material does add three relevant RCTs that partially matched the scope, plus two non-randomised comparative studies published as abstracts, that add to the data in the main report and suggest a greater completion and weight loss for the app vs. F2F intervention. In addition, at least one of the ongoing RCTs or service evaluations aims to add data for each of the prioritized and important outcomes apart from the psychological outcomes, which are potentially important missing indicators. Also, resource use is not addressed. The new material here does not address the issue flagged in the main report that there is no information on the comparative impact of the intervention against waiting lists or no treatment.

1 Decision problem

Two additional technologies added as Interventions in **Table 1.1.1: Summary of decision problem**, so the box for Intervention Scope becomes:

Digitally enabled weight management programmes providing specialist weight management services (such as tier 3 or tier 4) for adults with obesity. This includes: • CheqUp (CheqUp) • Gro Health W8Buddy (DDM Health Ltd) • Liva UK (Liva UK) • Oviva (Oviva) • Second Nature (Second Nature) • Roczen (Reset Health) • Xyla Health and Wellbeing (Xyla Health and Wellbeing) Additional technologies identified August 2023: • Gloji (Thrive Tribe) • Habitual (Habitual Health Ltd) • Juniper (Juniper Technologies UK Ltd) • Weight Loss Clinic (Virtual Health Partners Inc.) • Counterweight (Counterweight).

The Table is otherwise unchanged.

2 Overview of the technology

2.1 Included technologies

The additional two technologies Weight Loss Clinic (Virtual Health Partners Inc.) and Counterweight (Counterweight) bring the total up to 12 technologies assessed (10 in the main report and 2 here). Their regulatory status is shown below.

Table 2.1.1: Included technologies

Technology (Company)	Regulatory Status
Weight Loss Clinic (Virtual Health Partners Inc.)	This platform does not require CE/UKCA mark. This platform complies with all applicable portions of DTAC. Currently the company has not completed a DTAC audit by a third party, but has worked internally to ensure compliance where appropriate. The company holds SOC2 certification.
Counterweight (Counterweight).	The technology does not require CE/UKCA approval. It is not classified as a medical device under MHRA guidance as it does not make any automated diagnosis or care prescriptions. If this were to change, the company would get the necessary regulatory approval.

	The company has passed annual Cyber Essentials Plus and Data Security and Protection Toolkit assessments and follows NHS best practice guidance for clinical safety and risk management. DTAC status: Currently under assessment by NHS England.

2.2 Key features of Weight Loss Clinic

The platform can only be accessed via a direct referral from a healthcare professional. The program can be accessed from a computer, smartphone or tablet. There is both a web browser and a mobile app version.

This platform includes:

- 1:1 coaching with dietitians
- 24/7 instant messaging with dietitians
- Food diary
- Fitness trackers
- Personalized goal setting and tracking
- Exercise classes
- Supportive educational content including recipes, meal plans, cooking demos, and resources for stress management, healthy habit change, sleep hygiene, and more.

There is also a companion platform for healthcare professionals that enables them to view patient's activity on the platform, overall progress, collect a variety of data and to interact with patients.

Should patients require additional support, registered dietitians who interact with patients coordinate with the healthcare team to immediately connect patients to resources as the need arises.

The intended population for this technology is patients who are actively enrolled in a weight loss programme, which may include weight loss medications. The technology

enables patients to access much of their care virtually versus having to travel for visits. The use of the 24/7 messenger also lends to additional availability of support. The platform also has a suite of supportive materials to help patients achieve their goals. This technology is suitable for a wide variety of users; however, it is not intended to be used by children.

Patients who are overweight or obese, and who are engaged in a treatment or action portion of the NHS obesity pathway, are identified by their health professional team as eligible. The patient is referred to the programme as part of the treatment pathway for overweight or obesity with The Weight Loss Clinic. This technology is considered an adjunct for the standard of care. The treatment does not displace elements of standard care. There are no changes or infrastructure needed to adopt this technology. Additional resources include a small amount of time (1-2 hours per month) on the part of healthcare professionals and office staff. The platform is designed to streamline delivery of care for both the patient and the healthcare professional.

This technology streamlines care delivery for health professionals, as well as access to care for patients. Patients can access many aspects of their care in one place, and health professionals can monitor all aspects of the patient's progress, in the same platform. For example, a patient in our weight loss programme logs their food intake, weighs themselves on a Bluetooth-enabled scale, tracks activity on a Bluetooth-enabled wearable, and sets a behaviour goal for themselves within the platform. The health professional can view all these activities in the health professional companion platform, as well as view other activities completed by the patient, including content they've interacted with. This gives the health professional a holistic view of the patient's progress. The ability to deliver efficient, secure virtual services also streamlines care for all parties and 6 of 13 may increase patient compliance. With virtual services, the staffing pool is also expanded and we're able to hire the best registered dietitians available to have robust, consistent staffing and appointment availability. All of these components lead to better patient care, satisfaction, and clinical outcomes, with demonstrated sustained weight loss.

Data including activity and weights are used to show the user their trends over time.

There are no risks, known adverse events, or safety issues for people using this technology. We are not aware of any safety alerts for this technology.

More information is included in the Appendix.

2.3 Key features of Counterweight

Counterweight provides a tier 3 specialist weight management programme for adults living with obesity and obesity mediated medical conditions.

The services are delivered either 1:1 or in groups by a multidisciplinary (MDT) team and educational content (diet, physical activity and behaviour change) is provided using the Counterweight App or hardcopy workbook.

The main features of the App are:

- Self Monitoring and Goal Setting
    - ➔ Ability to log measurements and review progress (weight, BP, BG, mood etc)
    - ➔ Recording daily journals/diaries (food, fluids, bowels) and behaviour change
    - ➔ Setting and monitoring goals
- In App Support
    - ➔ 24/7 access to MDT team text chat- replies within 1-working day
    - ➔ 24/7 access to Coach facilitated peer support text chat
- Dietary Approaches
- Total Diet Replacement
    - ➔ Meal Replacement
    - ➔ Low Carb
    - ➔ Low Fat
    - ➔ Intermittent Fasting

- Educational Content

    ➔ Delivered in written, audio, video, Easy Read

    ➔ Topics covered include: nutrition, physical activity, wellbeing, hints and tip, programme specific content

    ➔ Recipes (simple, budget friendly recipes tailored to dietary/cultural needs)

    ➔ Exercise videos (yoga, pilates, cardio, strength, stretch, dance)

    ➔ Access to a habit/behavioural toolkit containing 35 strategies

    ➔ Cultural toolkit (tailored nutrition and activity information for different cultures and eating practices e.g. Ramadan, Halal, Vegan, Vegetarian etc)

The main features of the Dashboard for clinicians managing patients is:

- Ability to view patient progress , e.g. reviewing measurements, journal, goals, educational content read, engagement etc
- Patient support (text chat and facilitated peer support)
- Unlocking educational content
- Electronic health record
- Information on service personalisation

The Counterweight App is accessible through a smartphone (mobile phone), tablet or desktop (computer). To offer an equitable service we offer a hardcopy workbook to those who are digitally excluded or those who prefer to access educational content as a workbook.

More information is included in the Appendix.

3 Clinical context

This section is not changed by the additional information.

4 Clinical evidence selection

4.1 Evidence search strategy and study selection

4.1.1 Weight loss clinic

The Company (VHP) submitted three completed studies (shown in Appendix Table 4.1a.i) and no ongoing studies for Weight Loss Clinic. Additional searches of PubMed, clinicaltrials.org, DRKS and the Chinese Clinical Trials Registry found no further completed or ongoing studies for the VHP app.

4.1.2 Counterweight

The Company (Counterweight) submitted details of 11 publications relating to nine studies (shown in Appendix Table 4.1a.ii), plus titles of a further 16 relevant publications relating to some of these studies (listed), plus six ongoing studies (shown in Table 9.4). PubMed, clinicaltrials.org, DRKS and the Chinese Clinical Trials Registry were searched for additional completed or ongoing studies for the Counterweight app. Searches of PubMed found 8 additional papers relating to these same studies (listed). Searches of DRKS and the Chinese Clinical Trials Registry each found no additional studies; clinicaltrials.org found 2 completed (Table 4.1a.iii) and 0 ongoing studies.

4.2 Included and excluded studies

An additional 16 publications (9 full texts, 4 abstracts and 3 protocols only with no outcomes) relating to 14 studies.

No studies completely matched the scope (scoring **GREEN**). Ten studies only partially matched the scope (**AMBER**) in at least one of these areas and the three protocols plus one of the abstracts did not match the scope at all (**RED**) in at least one area (no outcome data reported).

Ten were stated to be exclusively in participants with obesity; the remainder had a mixed population (not exclusively those with obesity), participants other than those with obesity, or obesity was not stated. Three studies stated that it was a tier 3 or 4 service; the remainder did not. Eight stated that the app included an MDT; the remainder did not. Five had a comparator group; the remainder did not. Ten reported at least one of the listed outcomes; the remainder did not. The three Weight Loss Clinic studies were conducted in the USA and the 11 Counterweight studies were conducted in the UK.

Details of the new included studies found in the searches or published material from the Companies are shown in Appendix B Tables 4.1a.i, 4.1a.ii and 4.1a.iii and there were no unpublished studies provided by the Companies so Appendix B Table 4.3 is unchanged.

Table 4.4 Summary of literature

Technology	Published studies	Unpublished In Confidence material
Weight Loss Clinic	3 studies from Company (Table 4.1a.i; one survey and two non-randomised comparative studies vs. F2F or hybrid) plus 0 from searches	0
Counterweight	9 from Company (Table 4.1a.ii; three RCTs; five non-comparative studies and one protocol) plus 2 from searches (Table 4.1a.iii; non-comparative single arm study and its extension study)	0

5 Clinical evidence review

5.1 Overview of methodologies of all included studies

Three studies were RCTs (DIRECT, STANDBY and Sharma 2023) which randomised participants to remote vs. F2F delivery of Counterweight Plus; one additional RCT (BEYOND maintenance study; protocol only) randomised participants to Counterweight Plus and Experimental: Intermittent energy restriction (4 x formula food [202-209kcal] total diet replacement per day, on 2 days per week) vs. Counterweight Plus and Active Comparator: Continuous energy restriction (1 x formula food [202-209kcal] meal replacement per day). Two non-randomised comparative studies compared Weight Loss Clinic app vs. F2F. All the other studies were non-comparative.

5.2 Critical appraisal of studies

As for the main report, formal critical appraisal checklists were not performed for each publication, but limitations of each publication are included in Appendix B Tables 4.1a.i, 4.1a.ii and 4.1a.iii; these were similar to those listed in the main report.

5.3 Results from the evidence base

Prioritised outcomes (except Adverse events; see Section 6) are shown in Appendix B: in Table 5.1 and important outcomes (except Discontinuation and reasons; see Section 6) in Appendix B in Tables 5.3.

Table 5.5 below summarises the outcome data available by technology

Table 5.5. Outcomes by technology

	Prioritised outcomes		Important outcomes			
Technology	**Weight loss**	**Adherence**	**BMI**	**Engagement**	**HRQoL**	**Psychological outcomes**
Weight loss clinic	P	P	x	x	x	x
Counterweight	P	P	P	P	P	x

For the prioritized outcomes in the Counterweight app versus non-app RCTs studies, completion was reported as 94.3% at 16 weeks in one study (Sharma). Weight change was greater in the intervention than the non-app (F2F) control groups: 12.1 kg more at 16 weeks (Sharma); 8.8 kg more at 12 months and 5.4 kg more at 24 months (DIRECT) and 6.5% more (STANDBY).

For the non-randomised comparative studies of Weight Loss Clinic vs. F2F; compliance was 49.8% for the app group vs. 16% in the F2F group in one study (Swei) and a 31% relatively greater compliance in the other study (Wisotsky), which also reported a 32% relatively greater weight loss in the app group.

In other studies, completion ranged from 30.0 to 78.4%. Weight changes ranged from -7.1 kg at 16 weeks to -12.4 kg at 12 months.

For the important outcomes, BMI was reported in one study as 39.4 at baseline and 34.1 at 6 months. Engagement ranged from 17.1% to 96.2%. HRQoL improved in the DIRECT study by 7.2 (21.3) points in the intervention group vs. worsening by 2.9 (15.5) points in the control group. None of the studies reported psychological outcomes.

6 Adverse events and clinical risk

6.1 Adverse events

Lean 2017 (DiRECT) reported that at 12 months, nine serious adverse events were reported by seven (4%) of 157 participants in the intervention group and two were reported by two (1%) participants in the control group. Two serious adverse events (biliary colic and abdominal pain), occurring in the same participant, were deemed potentially related to the intervention (Counterweight). No serious adverse events led to withdrawal from the study. At 24 months, serious adverse events were similar to those reported at 12 months, but were fewer in the intervention group than in the control group in the second year of the study (nine vs 22). No other studies reported adverse events.

6.2 Discontinuation and reasons

Brosnahan 2023 reported that the main reasons for failure to complete Counterweight were life events. No other studies reported discontinuation reasons.

7 Evidence synthesis

No change from the main report.

8 Economic evidence

NA

9 Interpretation of the evidence

9.1 Interpretation of the clinical and economic evidence

No additional studies matched the scope in all areas. The additional RCTs did show higher compliance and weight loss among the app participants than the F2F

participants, although completion and weight loss reduced over time (e.g. DIRECT: weight loss 8.8 kg more in the control group at 12 months but only 5.4 kg more at 24 months and by 5 years, only 57% of participants remained in the intervention group).

Based on the evidence identified, it is plausible that the use of apps may be a safe and effective alternative to face to face management that would enable access to weight management services for users who may not have services in their local area, or who may have difficulty in accessing in-person services due to transport, mobility or comorbidity issues.

9.2 Integration into the NHS

No change from the main report.

9.3 Ongoing studies

9.3.1 Ongoing studies identified through searches of registries

No additional ongoing studies were identified in the searches.

9.3.2 Ongoing studies identified through company website

No additional ongoing studies were identified.

9.3.3 Studies identified through company submissions

Counterweight supplied information on six ongoing studies, shown in Table 9.4.

Table 9.4 Counterweight ongoing studies

Study name / reference	Country	Study type (e.g. RCT)	Intervention	Comparator(s)	Outcomes	Expected month / year for data availability
Weight loss to support breast cancer survival: WeSureCan Beekin & Smith https://doi.org/10.1186/ISRCTN12000313	UK	RCT BMI between 27 and 45 kg/m² **AMBER (not all participants with obesity)**	Remote delivery of Counterweight Plus (using App and hardcopy workbook): TDR (12 weeks), Food Reintroduction (12 weeks), and Weight Loss Maintenance (up to 1 year) with the option of a Rescue Plan (4 weeks); delivered by MDT team (dietitian or nurse, with GP medical monitoring). **GREEN**	Enhanced Usual Care **GREEN**	**Primary:** Patients screened; eligible; consented; randomised; lost-to-follow-up; withdrew; questionnaire completion; missing data; with weight measurements; with physical activity monitor data; Intracluster Correlation Coefficient (ICC). **Secondary:** adherence; acceptability of products and consultations; completion; barriers, facilitators reasons for non-attendance / non-compliance; SAEs and RUSAEs Participant-reported outcomes; weight; frequency of wearing physical activity monitor; reasons of not wearing it; impact on physical activity and sleep. **GREEN**	April 2024

A Multi-Ethnic, multi-centre raNdomised, controlled trial of a low-energy Diet for improving functional status in Heart failure with PRESERVED ejection fraction (AMEND-PRESERVED) McCann *et al* https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/amend-preserved/ NCT05887271	UK	RCT Obese adults with heart failure and preserved ejection fraction **GREEN**	Remote delivery of Counterweight Plus (using App and hardcopy Workbooks) in three phases Total Diet Replacement (12 weeks), Food Reintroduction (12 weeks), and Weight Loss Maintenance (up to 1 year) with the option of a Rescue Plan (4 weeks) and was delivered by MDT team (dietitian or nurse, with GP medical monitoring). **GREEN**	Health advice on how to lose weight **GREEN**	**Primary**: Whether weight loss improves physical function (6MWT). **Secondary**: Effect of weight loss on cardiovascular remodelling; exercise capacity; muscle power; HF symptoms; quality of life; skeletal and cardiac muscle energetics; metabolic profile; physical activity. **Exploratory**: biomarkers; proteomic and metabolomics; . potential barriers and enablers to sustained lifestyle changes **GREEN**	September 2025
MetaboliC, multi-orgAn and microvascular effects of a Low-calorIe diet in younger oBese with pRediabetEs and/or metabolic syndrome (CALIBRATE). Cuthbertson et al. https://classic.clinicaltrials.gov/ct2/show/NCT04786418	UK	RCT BMI 30-40 kg/m^2, BMI>27 kg/m^2 for Chinese/ South Asians **AMBER (not stated to be tier 3/4)**	Counterweight Plus 12 weeks total diet replacement, 12 weeks food reintroduction, and up to 12 months weight loss maintenance. Delivered by specialist practitioners (dieticians, research nurses or research associates), either one to one or in groups, and using a	Usual care **GREEN**	Changes in liver fat >5 percent; BMI; weight; waist circumference; BP; alanine transaminase; HbA1c; lipid profile; metabolic measures of fatty liver; markers of fibrosis in liver; NAFLD scoring screening tool; peripheral insulin sensitivity; hepatic insulin sensitivity; insulin secretion; fatty acid metabolism; neuropathy; functional MRI; appetite; fat volumes; cardiac	Aim for December 2023

			mixture of F2F and remote support **AMBER (not stated to have an MDT)**.		structure; early diastolic strain rate; changes in load and contractility of the cardiac function; organ fat content; multi-organ MRI measure for pancreas, spleen and kidney; multi organs pancreas, spleen and kidney volume; multi organs pancreas, spleen and kidney fat content **GREEN**	
Using a Teachable Moment to effect Positive Health Behaviour Prior to Surgery. A Randomised Controlled Feasibility study: Osteoarthritis Preoperative Package for care of Orthotics, Rehabilitation, Topical and oral agent Usage and Nutrition to Improve ouTcomes at a Year (OPPORTUNITY) Simpson et al. https://www.isrctn.com/ISRCTN96684272	UK	Randomised controlled feasibility trial Participants undergoing a knee arthroplasty for OA.; meet at least one of the following threshold criteria: (a) BMI ≥ 30 kg/m^2 (b): Inability to perform straight-leg raise (no extensor lag) or patient-reported 'giving way' (c): Not taking an appropriate level of analgesia (d): Not using shock-absorbing footwear	Participants were randomised (2:1) to the intervention, consisting of (1) weight-loss (Counterweight Plus delivered by nurses in primary care with support of MDT), (2) exercises, (3) analgesia advice and/or (4) insoles, or usual care. **AMBER (not stated to be tier 3/4 or to have an MDT)**	1) weight-loss, (2) exercises, (3) analgesia advice and/or (4) insoles, or usual care. **GREEN**	Primary: acceptability and feasibility of delivering intervention; recruitment; retention; adherence; weight change; EQ-5D; joint specific scores and qualitative interviews. **GREEN**	Protocol published: Osteoarthritis Preoperative Package for care of Orthotics, Rehabilitation, Topical and oral agent Usage and Nutrition to Improve ouTcomes at a Year (OPPORTUNITY); a feasibility study protocol for a randomised controlled trial. Trials. https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3709-5. Accepted for publication The Lancet Rheumatology. Publication due September 2023.

		AMBER (not all patients with obesity)				
Counterweight Plus remission service Dr Rinki Murphy et al.	NZ	Service evaluation of Counterweight Plus delivered in an ethnically diverse population in New Zealand (Maori and Pacific Island)	Counterweight Plus delivered in F2F groups by an MDT (Physician, Endocrinologist, Dietitians, Health Coach, Psychologist); using App and hardcopy workbooks. Patients on the bariatric waiting list at Te Whatu Ora are invited to join Counterweight Plus (aim to recruit 120 patients). **GREEN**	N/A **AMBER (no comparator)**	Uptake; retention; weight change; remission; user experience **GREEN**	August 2024
Partial meal replacement for weight loss in people awaiting arthroplasty: Findings from a feasibility study. Dr Milan Piya et al.	Australia	Prospective pilot feasibility cohort study	Remote group and 1:1 MDT support (dietitian, physician, doctor). Virtual Group sessions; remote (telephone) 1:1 sessions; Meal Replacement Plan delivered using the Counterweight App. Ongoing access to Counterweight App. **GREEN**	N/A **AMBER (no comparator)**	Primary: weight loss at 12 weeks following the PMR plan **GREEN**.	Paper has been submitted for publication in Obesity Research and Clinical Practice (decision pending).

10 Evidence gap analysis

The three new RCTs identified for Counterweight partially met the scope, and two studies for the Weight Loss Clinic were non-randomised comparative studies; however, the other studies did not have comparators.

The gap analysis for the new studies is shown in Table 10.1 and evidence gaps that could be filled by ongoing studies are shown in Table 10.2.

Table 10.1: Evidence gap analysis

Outcomes	Weight loss clinic	Counterweight
Prioritised outcomes		
Weight	1 non-randomised comparative study **AMBER**	3 RCTs **AMBER** 5 non-comparative studies **AMBER**
Adherence	2 non-randomised comparative studies **AMBER**	2 RCTs **AMBER** 5 non-comparative studies **AMBER**
Important outcomes		
BMI	No studies **RED**	1 non-comparative study **AMBER**
Engagement	No studies **RED**	2 non-comparative studies **AMBER**
HRQoL	No studies **RED**	1 RCT **AMBER** 1 non-comparative study **AMBER**
Psychological outcomes	No studies **RED**	No studies **RED**

Table 10.2: Evidence gaps that could be addressed by the ongoing research

Outcomes	Weight loss clinic	Counterweight
Prioritised outcomes		
Weight	No studies **RED**	4 RCTs **AMBER** 1 service evaluation **AMBER**

Outcomes	Weight loss clinic	Counterweight
		1 non-comparative study **AMBER**
Adherence	No studies **RED**	2 RCT **AMBER** 1 service evaluation **AMBER**
Important outcomes		
BMI	No studies **RED**	1 RCT **AMBER**
Engagement	No studies **RED**	1 service evaluation **AMBER**
HRQoL	No studies **RED**	1 RCT **AMBER**
Psychological outcomes	No studies **RED**	No studies **RED**

10.1 Summary and conclusions of evidence gap analysis

The additional material does add three relevant RCTs that partially matched the scope, plus two non-randomised comparative studies published as abstracts, that add to the data in the main report and suggest a greater completion and weight loss for the app vs. F2F intervention. In addition, at least one of the ongoing RCTs or service evaluations aims to add data for each of the prioritized and important outcomes apart from the psychological outcomes, which are potentially important missing indicators. Also, resource use is not addressed. The new material here does not address the issue flagged in the main report that there is no information on the comparative impact of the intervention against waiting lists or no treatment.

10.2 Key areas for evidence generation

As for the main report.

11 Conclusions

11.1 Conclusions from the clinical evidence

As for the main report, except that the new material suggests a greater completion and weight loss for the app vs. F2F intervention.

11.2 Conclusions from the economic evidence

As for the main report.

11.3 Conclusions on the gap analysis

The newly identified ongoing studies may help to address data gaps for each of the prioritized and important outcomes apart from the psychological outcomes, which are potentially important missing indicators. Also, resource use is not addressed.

12 References

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Appendix B: Information received 4 September for additional technologies

On September 4th, 2023, we received information from the Companies on two additional technologies that the Companies suggested were eligible for inclusion:

1 Weight Loss Clinic (Virtual Health Partners Inc.)

The following information was collected in the “Request for Information” process:

This platform does not require CE/UKCA mark. This platform complies with all applicable portions of DTAC. Currently the company has not completed a DTAC audit by a third party, but has worked internally to ensure compliance where appropriate. The company holds SOC2 certification.

The platform can only be accessed via a direct referral from a healthcare professional.

The program can be accessed from a computer, smartphone or tablet. There is both a web browser and a mobile app version.

This platform includes:

- 1:1 coaching with dietitians
- 24/7 instant messaging with dietitians
- Food diary
- Fitness trackers
- Personalized goal setting and tracking
- Exercise classes
- Supportive educational content including recipes, meal plans, cooking demos, and resources for stress management, healthy habit change, sleep hygiene, and more.

There is also a companion platform for healthcare professionals that enables them to view patient's activity on the platform, overall progress, collect a variety of data and to interact with patients.

Should patients require additional support, registered dietitians who interact with patients coordinate with the healthcare team to immediately connect patients to resources as the need arises.

For any clinicians and health professionals who will be using the app, we will coordinate a brief training session (around 1 hour). This training will cover:

- Features of the patient platform, and how to explain the program to patients
- Features of the health professional platform, including patient visibility, data, and reporting
- How to conduct virtual sessions on the platform (if applicable)

This technology is currently used by both private and public healthcare professionals in the UK for supporting patients in reaching their weight loss goals, and for those with Crohn's disease. The technology has been available in the UK since 2018.

The intended population for this technology is patients who are actively enrolled in a weight loss programme, which may include weight loss medications. The technology enables patients to access much of their care virtually versus having to travel for visits. The use of the 24/7 messenger also lends to additional availability of support. The platform also has a suite of supportive materials to help patients achieve their goals. This technology is suitable for a wide variety of users; however, it is not intended to be used by children.

Patients who are overweight or obese, and who are engaged in a treatment or action portion of the NHS obesity pathway, are identified by their health professional team as eligible. The patient is referred to the programme as part of the treatment pathway for overweight or obesity with The Weight Loss Clinic. This technology is considered an adjunct for the standard of care. The treatment does not displace elements of standard care. There are no changes or infrastructure needed to adopt this technology. Additional resources include a small amount of time (1-2 hours per

month) on the part of healthcare professionals and office staff. The platform is designed to streamline delivery of care for both the patient and the healthcare professional.

This technology streamlines care delivery for health professionals, as well as access to care for patients. Patients can access many aspects of their care in one place, and health professionals can monitor all aspects of the patient's progress, in the same platform. For example, a patient in our weight loss programme logs their food intake, weighs themselves on a Bluetooth-enabled scale, tracks activity on a Bluetooth-enabled wearable, and sets a behaviour goal for themselves within the platform. The health professional can view all these activities in the health professional companion platform, as well as view other activities completed by the patient, including content they've interacted with. This gives the health professional a holistic view of the patient's progress. The ability to deliver efficient, secure virtual services also streamlines care for all parties and 6 of 13 may increase patient compliance. With virtual services, the staffing pool is also expanded and we're able to hire the best registered dietitians available to have robust, consistent staffing and appointment availability. All of these components lead to better patient care, satisfaction, and clinical outcomes, with demonstrated sustained weight loss.

The platform collects name, email, phone number, height, weight, and birthday as required fields. There are many optional data fields end-users can provide including: additional weight measurements, food diary entries, activity tracking, and steps. An end user does not have to use the mobile app, but if they do, the apps will collect additional fields during every active session the user engages in. These fields include: location (to provide correct time zone for classes), device ID, usage data, iHealth data, and content the user creates within the platform. None of these data fields are used for marketing or targeting. These data fields are used to improve user experience, recommend content, and run diagnostics (for example, on app slowdowns). Data including activity and weights are used to show the user their trends over time.

There are no risks, known adverse events, or safety issues for people using this technology. We are not aware of any safety alerts for this technology.

The cost is based on the Package that a user has assigned to them or chosen. Package cost varies, depending on the length of the packages and the number/types of live services available. For example, a 6-month package of on-demand access, with one 15-minute nutrition appointment costs £70. A 3-month package of on-demand access, with 3 15-minute nutrition appointments, 1 30-minute health coach appointment, 10 lifestyle classes, and 10 nutrition classes, costs £207. This is exclusive of VAT.

There are no hardware, software, or maintenance costs. Instead, the cost is based on the length of time and number of services each end-user is given access to (the “Package” cost). There are no costs beyond the Package cost, unless the company is asked to build custom features or branding.

Completed evidence:

Completed studies submitted by company **Table 4.1a.i**

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Weight Loss Clinic (Virtual Health Partners Inc.) delivered via VHPGO platform				
Rachel Moore, MD FACS 2021 [abstract] Patient perception of access to care increases with virtual platform USA	Survey VHPGO is a comprehensive HIPAA and privacy compliant platform for nutrition, lifestyle, and fitness support. VHPGO offers live individualized care, group events, an on-demand library, monitoring tools, and messaging with health experts. Assume MDT No comparator **AMBER**	904 VHPGO patients that are active on the platform were sent a survey. 10.3% of patients who were sent the survey responded. All participants who filled out the survey within the given time frame were given a gift card. Gift cards were given to everyone who qualified and were in no way tied to a participant's survey answers. Referred by health professional but not stated to be tier 3/4 **AMBER**	Patient perceptions of support/cost-effectiveness: The use of a live virtual solution made patients feel that they had an increase in support and access to care. Of those who replied, 79% reported access to experts using the VHPGO messenger feature made them feel more supported than prior to using the platform. 95% of users felt that VHPGO was more cost effective than other options they have looked at for follow-up care. 95% of users reported that having access to on-demand materials was a helpful part of their journey. 84% of users reported that they found it helpful to have access to 1:1 nutrition appointments virtually, rather than having to go into an office. **RED**	No comparator; not stated to be tier 3/4; no prioritised or important outcomes

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Eric Swei, Miles Rothstein, Abigail Lowe, Shelby A. Sullivan 2020 Use Of A Novel Virtual Health Program Improves Compliance With Lifestyle Intervention After Endoscopic Bariatric Therapy USA	Non-randomised comparative study vs. face-to-face or hybrid Intervention: Starting August 2018, all new and existing patients were enrolled into a virtual health platform that replaced regular in-office or telephone-based lifestyle coaching visits (traditional visits) with virtual face-to-face visits via a mobile app (Virtual Health Partners®, VHP). n=36 app only and 16 patients were in the first year of therapy when VHP was started and therefore had both traditional and VHP visits (hybrid). Comparator: 27 patients who underwent Endoscopic Bariatric Therapy (EBT) at the University of Colorado underwent monthly follow up visits with a registered dietician (F2F). Only dietitian mentioned, not MDT. **AMBER**	From 2016-2019, 79 patients who underwent EBT. Assume tier 4. **GREEN**	Primary outcome: visit compliance (adherence), defined as (number of visits that actually occurred/number of visits that could have occurred) x 100%. Secondary: percentage of patients who achieved moderate or high-intensity lifestyle therapy and the relationship between visit compliance and patient factors such as previous weight loss attempts and history of depression. **GREEN**	Non-randomised comparative study; small number in each group; MDT not mentioned

Study name and location	Design and intervention(s); MDT mentioned?	Participants and setting; Tier 3 or 4 mentioned?	Outcomes (green highlight = prioritised)	EAG comments
Willo Wisotsky, PhD, William Wisotsky, MA, Cynthia Cervoni, MA 2016 Virtual Health Partners (Vhp) Demonstrates Increased Weight loss & Patient Compliance With Access To The 24/7 Vhp Portal: A Pilot Study of Patient Compliance USA	Non-randomised comparative before and after study VHP vs. F2F Yes MDT **GREEN**	Post-procedure population Assume Tier 4 **GREEN**	Compliance pre and post introduction of app; weight loss **AMBER**	Number of participants not stated; unclear if population overlaps with above study; relative increase in % compliance and weight loss but no baseline. Unable to trace publication.

No ongoing studies were supplied by the Company.

Searches of PubMed, clinicaltrials.org, DRKS and the Chinese Clinical Trials Registry found no further completed or ongoing studies for the VHP app.

2 Counterweight

The following information was collected in the “Request for Information” process:

The technology does not require CE/UKCA approval. It is not classified as a medical device under MHRA guidance as it does not make any automated diagnosis or care prescriptions. If this were to change, the company would get the necessary regulatory approval.

The company has passed annual Cyber Essentials Plus and Data Security and Protection Toolkit assessments and follows NHS best practice guidance for clinical safety and risk management.

DTAC status: Currently under assessment by NHS England.

Counterweight provides a tier 3 specialist weight management programme for adults living with obesity and obesity mediated medical conditions.

The services are delivered either 1:1 or in groups by a multidisciplinary (MDT) team and educational content (diet, physical activity and behaviour change) is provided using the Counterweight App or hardcopy workbook.

[redacted].

The main features of the App are:

Self Monitoring and Goal Setting

➔ Ability to log measurements and review progress (weight, BP, BG, mood etc)

➔ Recording daily journals/diaries (food, fluids, bowels) and behaviour change

➔ Setting and monitoring goals

In App Support

➔ 24/7 access to MDT team text chat- replies within 1-working day

➔ 24/7 access to Coach facilitated peer support text chat

Dietary Approaches

➔ Total Diet Replacement

➔ Meal Replacement

➔ Low Carb

➔ Low Fat

➔ Intermittent Fasting

Educational Content

➔ Delivered in written, audio, video, Easy Read

➔ Topics covered include: nutrition, physical activity, wellbeing, hints and tip, programme specific content

➔ Recipes (simple, budget friendly recipes tailored to dietary/cultural needs)

➔ Exercise videos (yoga, pilates, cardio, strength, stretch, dance)

➔ Access to a habit/behavioural toolkit containing 35 strategies

➔ Cultural toolkit (tailored nutrition and activity information for different cultures and eating practices e.g. Ramadan, Halal, Vegan, Vegetarian etc)

The main features of the Dashboard for clinicians managing patients is:

➔ Ability to view patient progress , e.g. reviewing measurements, journal, goals, educational content read, engagement etc

➔ Patient support (text chat and facilitated peer support)

➔ Unlocking educational content

➔ Electronic health record

➔ Information on service personalisation

The Counterweight App is accessible through a smartphone (mobile phone), tablet or desktop (computer). To offer an equitable service we offer a hardcopy workbook to those who are digitally excluded or those who prefer to access educational content as a workbook.

The technology can be used in two ways:

1. **Counterweight Licence Model:** In this model, Counterweight provides training to the NHS MDT (Multi-Disciplinary Team) to enable them to deliver the Counterweight Service. This includes the use of the Counterweight App and Dashboard.

2. **Counterweight Refer Out Model:** This model involves the entire Counterweight Service being managed and delivered by the Counterweight MDT team. The team uses the Counterweight App and Dashboard for various aspects of the service. This model can be combined with the Licence Model to help reduce waiting times and integrate the service with various NHS components like primary care, secondary care, community services, and voluntary organisations. This integration might involve referring or guiding patients from Counterweight to other local NHS services when needed. For the Refer Out Model, the technology includes both on-platform support and external support sessions for remote assistance. The MDT team uses the platform for text-based chats, peer support, educational content, and tracking patients' progress. Additionally, remote support sessions are conducted via telephone or video calls.

MDT Team Roles and Responsibilities: The MDT team consists of various healthcare professionals with specific roles:

➔ Programme Support Team: They assist patients with administrative tasks related to the Counterweight programme.

➔ Dietitians, Nutritionists, Health Coaches: They provide support to patients throughout the Counterweight programme, offering guidance on nutrition and healthy habits.

- ➔ Psychologists (Clinical and Health): These professionals offer support to patients and coaches by incorporating psychological aspects into the services provided.

- ➔ Medical Doctor (special interest in weight management and type 2 diabetes): They oversee the medical management and protocols of the service, particularly in relation to weight management and type 2 diabetes.

- ➔ Specialist Exercise Therapist: They assist patients by creating tailored approaches to physical activity and exercise.

- ➔ Future Roles (Nurses, GP with special interest, psychiatrist, pharmacist, physiotherapist): These roles are currently being scoped and will be integrated into the MDT team soon. Their specific responsibilities will contribute to the holistic care provided by the team.

The technology can be accessed in two ways: either self-referral with GP approval to undertake the programme, or referral from a healthcare professional. Referral pathways can be integrated with primary and secondary care IT systems.

We have established systems and processes for both our licence and refer out service delivery models to ensure additional support is provided to patients where needed.

Our screening protocol includes a variety of screening tool to assess if additional support is required, e.g. ask patients about support needs they have, ask about disabilities, or any needs for programme personalisation.

In addition we undertake screening for disordered eating (including emotional eating) and obesity stigma. This is done to assess if patients need additional support from specialist dietitians, psychologists or medical doctors to optimise programme outcomes.

The table below outlines how Counterweight assesses the need for additional support.

Identified need	**How we provide additional support**
Disordered eating or emotional eating	➔ Disordered Eating Screening as part of Assessment. Additional screening and assessment from a clinical psychologist. ➔ Continued screening for disordered eating throughout the programme. ➔ Signposting to other disordered eating support charities

People with disabilities (e.g. visual, hearing, cognitive impairment, learning, problems with manual dexterity)	➔ Document disabilities or specific needs for personalised Coaches/PST support ➔ Provide service information and educational content in preferred formats (written, audio, video, Easy Read) ➔ Educational content adhering to the NHS Digital Service Manual and NHS Accessible Information Standard e.g. considerations for low literacy etc ➔ Extend session durations, e.g. 40-60 minutes ➔ Allow for the presence of carers, family, or service animals ➔ Train Coaches/PST in safeguarding policies
Culturally diverse population with different languages, cultures, religions, and ethnicities	➔ Translated educational content in key languages required. Content is already available in English, Polish, Urdu, Punjabi and Arabic. ➔ Use multilingual coaches where available ➔ Provide translation services or allow patients to involve family/friends for translation ➔ Address cultural and ethnic diversity with personalised Coach support (e.g. discussing food option at local Polish shops or supermarkets etc.) and localised Coach training ➔ Provide "cultural toolkits" with tailored nutrition and activity information for different cultures and eating practices e.g. for cultural reasons some Polish people do not eat meat on Fridays (fish instead) etc. ➔ Listen to patients to understand cultural barriers and collaborate to overcome them
People living in areas of deprivation, temporary accommodation	➔ Consider personal health budgets for mobile data top-up and food affordability ➔ Tailor food recommendations based on budget, living circumstances, and cooking facilities/skills ➔ Collaborate with community organisations ➔ Recommend affordable activity options, e.g. parkrun and walking groups etc ➔ Listen to patients to understand misconceptions and barriers to engagement and collaborate to achieve goals

Digital poverty, including those unfamiliar with digital technology or who do not have access to digital devices (mobile phone, tablet, computer) or the internet	➔ Discuss local services with free Wi-Fi or accessible equipment e.g. libraries ➔ Provide hardcopy Workbooks and resources or Counterweight App available on smartphone, tablet and desktop ➔ Collaborate with the Digital Inclusion teams
People with work, caregiving, or other commitments	➔ Offer flexible session times, including mornings - evenings, and weekends
People with dietary preferences, allergies, or intolerances	➔ Provide clear information on TDR products (allergens and dietary suitability) ➔ Document and accommodate allergies/intolerances/ preferences, e.g. Coeliac, low carbohydrate etc.

there was a previous version (V1). The evolution from V1 to the present V2 has the following enhancements and refinements for a more impactful and effective user experience:

➔ **Rearchitected Backend:** The underlying architecture of Counterweight App/Dashboard has undergone a substantial overhaul, resulting in a more efficient, scalable, and auditable system. This revamp lays the foundation for improved performance and future expansions.

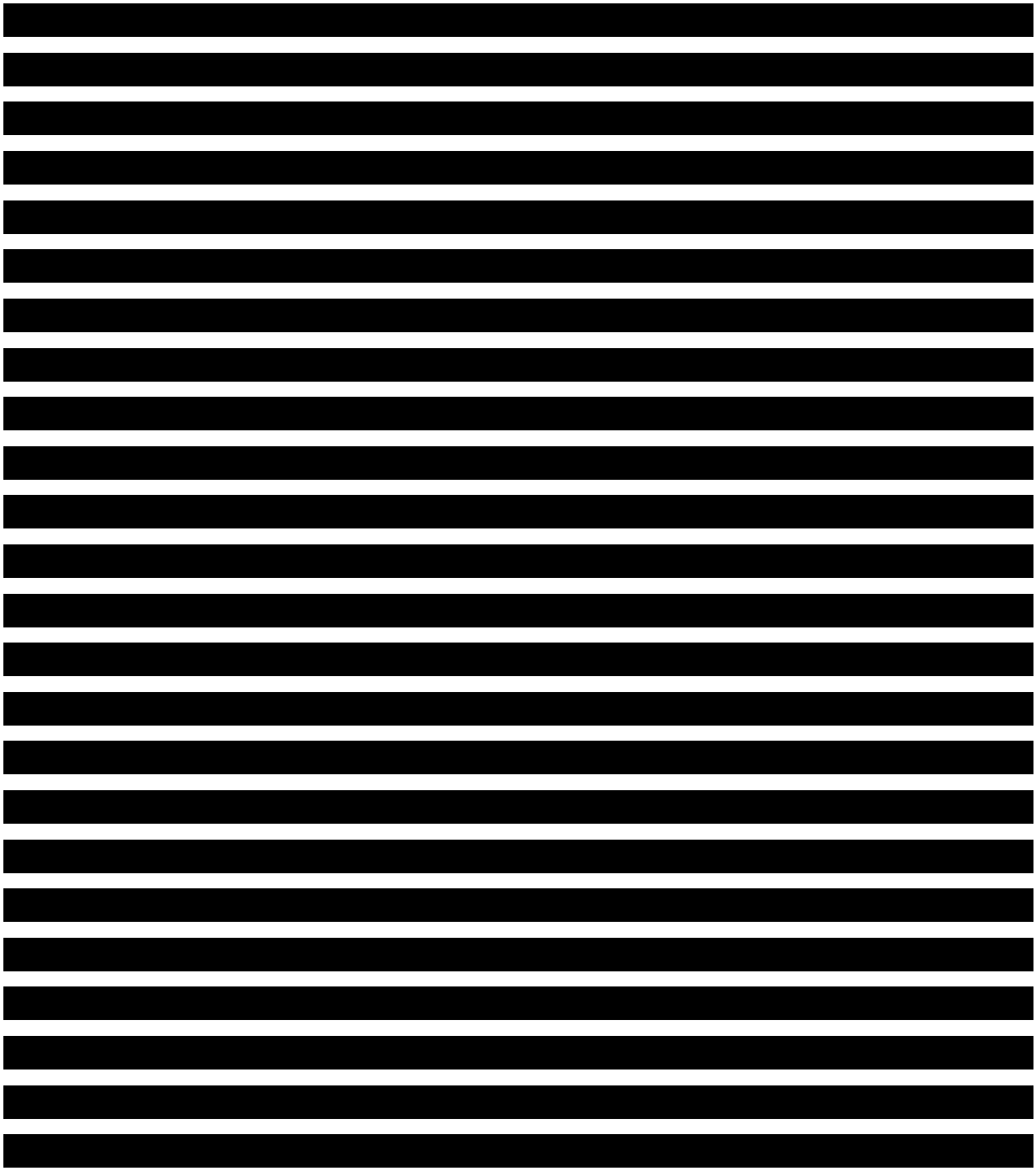
➔ **Enhanced Text Chat Engine:** In response to the evolving demands of user engagement, the text chat engine has received a significant update. This update introduces features such as emojis and support for attachments, contributing to more dynamic and interactive user interactions.

➔ **Improved Clinician User Interface:** Counterweight App/Dashboard V2 places an emphasis on the user interface for clinicians. The interface has been redesigned to provide an optimised and intuitive experience for healthcare professionals.

➔ **Expanded Reporting Capabilities:** Users now benefit from enhanced reporting functionalities. Counterweight App/Dashboard V2 empowers both clinicians and

users with more comprehensive and insightful reporting features, enabling them to track progress and outcomes more effectively.

Web Access Addition: Acknowledging the diverse preferences and accessibility needs of users, Counterweight App/Dashboard V2 introduces web access alongside the existing mobile interface. This addition ensures that users can engage with the technology using their preferred platform which enhances accessibility and varying user preferences.



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We have undertaken significant user testing and refinement of the Counterweight App, to optimise the patient and clinician use of our technology. The App and Dashboard have an easy-to-follow user interface, therefore training is minimal. However, for those who do need guidance and assistance we provide training resources irrespective of their level of comfort in the event they need further assistance. The resources are:

- App User Guide (Video/Hardcopy/Digital)
- Dashboard User Guide
- Remote Support Guides (joining Telephone and Video calls)

Patients:

The App training is provided by our Programme Support Team in various formats, namely:

- a video tutorial on how to use the App;
- a written App User Guide detailing all the App features;
- FAQ page; and
- Access to our Programme Support Team who are able to handle App queries and can escalate to our Tech team for assistance where needed.

Prior to App onboarding the patient's comfort with digital technology is assessed and a training session is offered by the Programme Support Team should they require more extensive training.

Clinicians:

App and Dashboard training will be provided to Clinicians via self-paced modules on the Counterweight Learn Platform as well as live Q&A sessions run by Counterweight

dietitians. As part of this training they will be taken through all of the App and Dashboard features, including:

- a video tutorial on how to use the App and Dashboard;
- a written App User Guide detailing all the App and Dashboard features;
- FAQ page; and
- Access to our Programme Support Team who are able to handle App and Dashboard queries and can escalate to our Tech team for assistance where needed.

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[redacted]Counterweight programmes are intended for the adult population, 18yrs and older. From published evidence, the average age for accessing Counterweight programmes is around 45-50yrs old.

The technology is intended to be used with Individuals living with overweight or obesity, typically defined by a BMI (Body Mass Index) of 25.0-25.9 kg/m2 or 30.0 kg/m² or higher respectively.

For individuals with specific ethnic backgrounds, lower thresholds for obesity are used. These thresholds are usually reduced by 2.5 kg/m² and are relevant for individuals with a South Asian, Chinese, other Asian, Middle Eastern, Black African, or African-Caribbean family background.

The technology is particularly targeted at individuals who are at an increased risk of developing various health conditions. These conditions include, but are not limited to:

- Cardiovascular disease
- Type 2 diabetes
- Atherosclerosis
- Hypertension

- Dyslipidaemia
- Stroke
- Fertility-related issues
- Cancer and secondary cancer prevention

The technology also aims to assist individuals living with other medical conditions that are closely associated with obesity. These conditions include:

- Non-alcoholic fatty liver disease
- Non-diabetic hyperglycaemia
- Subfertility
- Osteoarthritis
- Chronic Kidney Disease
- Dyslipidaemia
- Obstructive sleep apnoea
- Idiopathic intracranial hypertension
- Long Covid

Our technology is tailored for a diverse range of individuals facing unique circumstances and challenges including:

- **Rural Residents and Limited Transport Access:** Individuals residing in rural areas or those with limited transportation options to access in-person tier 3 or 4 services. The technology ensures vital healthcare support is accessible irrespective of location.
- **Busy Individuals and Caregivers:** People who are managing work commitments or have significant caregiving responsibilities. The technology offers flexibility,

enabling them to manage their health journeys without disrupting their demanding schedules.

- **Mental Health Challenges:** Individuals living with mental health conditions like agoraphobia, anxiety, depression, and others that may impact on their ability to attend face-to-face services..

- **Limited Mobility or Disabilities:** Those with poor mobility or various disabilities that may pose barriers to attending in-person services. The technology ensures inclusivity by offering accessible and accommodating platforms for their healthcare needs.

- **Diverse Demographics:** Specific demographic groups, including younger individuals, males, and various ethnic backgrounds, have shown high uptake rates compared to face-to-face alternatives. Notably, Counterweight are observing an average uptake rate of 93% within these demographics.

We have taken proactive steps to ensure our App accommodates individuals with protected characteristics, encompassing disabilities, languages, cultures, such as Easy Read for learning disabilities, educational content in Arabic, Urdu, Punjabi, Polish and cultural sensitivity staff training and cultural toolkits for recipes, adapted Eatwell Guide and eating practices.

We also recognise that some patients fall within the category of being digitally excluded. This includes individuals who are unfamiliar with digital technology, feel uncomfortable using it, prefer hardcopy resources, or lack access to digital devices such as mobile phones, tablets, computers, and the necessary internet/data connectivity.

To address the needs of these digitally excluded patients, we have developed a comprehensive workbook. This hardcopy resource contains all the educational content, measurement monitoring logs, trackers, journals, and diaries necessary for their health journey. We have successfully implemented interventions using this workbook in combination with longer telephone consultations. This approach has had comparable patient outcomes to those achieved through the use of digital technology.

The Counterweight App and Dashboard have been seamlessly integrated into the NHS weight management services, spanning both Tier 2 and Tier 3 levels of care. The delivery of treatment is facilitated through the Counterweight App, supported by the Counterweight Multidisciplinary Team (MDT) or where a contract is using our licence model, support is provided by the Local MDT. The local MDT team has access to ongoing support and mentoring from the Counterweight MDT.

The process of patient identification and inclusion involves a structured screening pathway. This pathway includes specific criteria to determine the suitability of different dietary approaches based on the individual's medical and health goals. To ensure a personalised experience, patient preferences, physical conditions, psychological factors, and cultural considerations are all assessed.

This evaluation guides the tailoring of dietary, behavioural, and physical activity strategies, aligning them with the patient's unique requirements, to optimise dietary intake.

The Counterweight App offers the flexibility for patients to adjust their dietary approach (such as Total Diet Replacement, Meal Replacement, Low Carb, Low Fat and Intermittent Fasting) or change their level of support as needed. In cases where engagement isn’t as high as we’d prefer, there are processes in place to identify individuals who may require additional support.

The treatment can be delivered as part of a face to face intervention, remote (Video, Telephone, text chat) or a hybrid approach. The service is delivered in groups or 1:1.

The support element of the treatment is delivered by the CWT MDT as one to one or group or a combination of these, or in cases where the licence model is utilised, support is delivered by the NHS MDT.

Peer support is embedded into the intervention for those who want this. This is predominantly delivered in closed groups with an optional nationwide Facebook Group or as facilitated groups in our App.

The treatment ends upon the completion of the agreed number of sessions or if an individual decides to withdraw from the service. The duration of treatment is designed to cater to the needs of the individual, but typically spans 12 weeks of intensive weight

loss followed by a tailored duration of weight loss maintenance intervention (ranging from 6 months to 24 months). The length of the weight loss maintenance treatment is tailored to align with the requirements of the relevant health commissioners.

The Counterweight App and Dashboard can be used to either replace or serve as an adjunct to standard care Tier 3 services.

Counterweight App and Dashboard can be used as an adjunct to improve access to standard care in Tier 4 services.

Counterweight has experience working with the NHS to replace services where capacity has been unavailable; to provide digital services as an adjunct to their standard care where capacity has been unable to meet demand leading to waiting lists or no service; to provide a service where no service has been available.

Both models can be used simultaneously or stand alone. This provides local NHS teams to upskill their specialist healthcare staff in up to date evidence based non-surgical, intensive weight management and at the same time scale up their service to meet demand when local capacity cannot meet this. This model protects local health care skills whilst meeting the demands of the service.

Licence Model:

Local healthcare teams purchase an annual licence to access Counterweight programmes. Local staff complete competency based training on the Counterweight Learn platform and receive ongoing support from the Counterweight specialist team which includes annual competency assessment. The local teams who have completed the Competency based training and support can then support patients to go through the Counterweight programme using digital App +/- hard copy workbook. All resources are provided to local staff to deliver all elements of the programme from Screening to Intervention to data collection and reporting. These include: programme pathways, inclusion/exclusion criteria; medical management protocols; screening for disordered eating protocols; patient education; data collection and reporting tools; IG templates; access to Counterweight Meal Replacements including delivery.

Refer Out Model:

Counterweight programmes are delivered to SU's by Counterweight MDT using the Digital App +/- hardcopy workbook. Reporting of KPI's are shared with NHS services.

The most relevant comparator is standard care which could include:

a) specialist weight management services (including tier 3 and 4; face-to-face, remote or hybrid) no treatment or waiting list

It could displace the need for education content sharing sessions as all education is in the App or Hard copy workbook.

The service may reduce the duration of appointments (as educational content is provided in the App). In our service delivery model, we have seen a reduction in appointment times by 50% with our App.

Local IG/DPIA documentation/process will need to be completed. Counterweight has experience working with the NHS to complete this process and has a number of templates to share.

If NHS services want to integrate Counterweight Technology into their internal systems then this will require time and expertise.

Additional training will be required for local healthcare staff if they choose to use the licence model as part of their implementation plans. However if they choose to commission the Refer out service then the training will be minimal awareness training.

Regarding expertise, Counterweight works closely with NHS teams to ensure KPI's are being met which would involve some regular meetings. These can be kept to a minimum with only key personnel attending. Agenda and minutes will be made available to ensure the efficiency of such meetings. These meetings are invaluable as a means of changing strategies if a KPI is not being met.

In our Bexley service, we implemented personalised recruitment strategies for populations at risk of health inequalities, specifically Black/Asian younger men. Through GP practice searches and SMS/letter invitations, we achieved an outstanding 45% uptake surpassing the 7% seen in other local services. Our continuous monitoring identified an initial low uptake. In response, we collaborated with stakeholders and

implemented additional recruitment methods such as promotion at health events, local press advertising, and GP referral webinars resulting in referrals exceeding targets by 200%.

Benefits to Patients:

- ➔ **Savings in Time and Costs:** Patients experience reduced travel time, leading to potential cost savings on transportation for them.
- ➔ **Seamless Integration:** The technology effortlessly integrates into daily routines, making health management convenient and non-disruptive.
- ➔ **Flexible Support:** Patients receive 24/7 support through various channels, enabling them to access assistance when needed, this ensures continued engagement.
- ➔ **Continuous Multidisciplinary Support:** Beyond scheduled appointments, patients can access the Multidisciplinary Team (MDT) for continuous guidance.
- ➔ **Empowerment through Peer Support:** Patients engage in peer support networks, offering shared experiences and motivation.
- ➔ **Prompt Programme Initiation:** Rapid processing of referrals and screenings ensures minimal waiting times to start the programme.

Benefits to Healthcare Professionals:

- ➔ **Streamlined Consultations:** Professionals can efficiently focus on interpreting patient measurements, enhancing consultation quality.
- ➔ **Centralised Health Records:** The technology consolidates patient data, simplifying record-keeping for informed decision-making.
- ➔ **Enhanced Communication:** Improved communication among healthcare services, providers, and patients ensures coordinated care.

Benefits to Health Systems:

➔ **Reduced Patient Waiting Times:** Swift programme initiation leads to quicker interventions and improved health outcomes.

➔ **Enhanced Patient Satisfaction:** Patients experience a user-focused approach, promoting engagement and satisfaction.

➔ **Operational Efficiency:** The technology minimises administrative burdens and reduces costs, improving overall system efficiency.

This technology has the potential to effectively address several unmet clinical and system needs within the NHS, contributing to improved healthcare delivery and patient outcomes. Some of these key unmet needs include:

- **Enhanced Accessibility:** The technology addresses the challenge of access to healthcare services. It caters to individuals who face geographical barriers, limited mobility, or lack of access to transportation. By enabling remote consultations and interventions, the technology ensures that healthcare reaches patients who might otherwise face difficulties in accessing services due to their location or mobility.

- **Personalised and Tailored Interventions:** One of the unmet clinical needs is the requirement for more personalised and tailored interventions. The technology offers a comprehensive assessment of patients' physical, psychological, and cultural requirements. This enables the delivery of interventions that align with individual needs, promoting better engagement, adherence, and ultimately more effective outcomes.

- **Reduced Waiting Times and Timely Interventions:** Long waiting times for appointments and interventions are a considerable challenge within the NHS. The technology significantly reduces waiting times by streamlining referral and screening processes. This facilitates prompt programme initiation, leading to timely interventions and improved patient outcomes.

- **Holistic Patient-Centred Care:** The technology addresses the need for holistic and patient-centred care. It not only focuses on medical factors but also considers psychological, cultural, and social aspects. This approach embeds patient

empowerment, engagement, and overall well-being, aligning with the NHS's emphasis on patient-centred care models.

- **Effective Use of Healthcare Professionals' Time:** The technology optimises healthcare professionals' time by automating certain tasks and centralising patient data. This enables professionals to focus on other aspects of care, leading to more efficient consultations, enhanced patient-provider relationships, and improved quality of care.

- **Data-Driven Decision-Making:** The technology enables data-driven decision-making through its centralised electronic health record and streamlined communication channels. This addresses the need for evidence-based care planning, enabling healthcare professionals to make informed decisions that lead to better patient outcomes.

[redacted]

Information collected by this technology:

Information collected	**How often/time points**
Demographic information (name, surname, ethnicity, gender, address, age, date of birth). Contact details (email, phone number). Medical conditions and medications	Collected at initial assessment and on an as needed basis should information change

Phone system (Android/iOS) and App version	Collected on App onboarding. Version is updated as completed by the patient.
Measurements (weight, blood pressure, blood glucose, waist circumference, HbA1C)	Collected at every session and/or agreed time points between patient and clinician.
Steps (integrated with Apple Health/Google Fit)	Collected continuously
Journal/diary entries	As entered by patient
Goals (past and active)	As entered by patient or agreed upon with clinician
Text chat messages	Upon message exchange in text chat space
Educational content reading progress	Collected continuously
Number of sessions attended, session duration, date, time, method of delivery (phone call, video call, text chat etc)	Collected at every session, entered on the Dashboard by the Clinician. Anonymously fed into the Report Dashboard.
Clinical electronic health record	Collected at every session, entered on the Dashboard by the Clinician (only visible to the Clinician)

Potential Risks and Safety Concerns:

Data Security and Privacy: A significant concern involves the potential for data breaches and unauthorised access to sensitive patient information. Such breaches could lead to privacy violations, identity theft, and compromise patients' confidential health data.

Interoperability Challenges: The lack of seamless communication and interoperability among various digital tools and systems can result in fragmented patient data. This can lead to miscommunications, errors in care coordination, and ultimately impact patient safety.

Cybersecurity Threats: Healthcare systems and connected devices are vulnerable to cyberattacks, including ransomware and malware. These threats can disrupt critical operations, compromise patient data, and even jeopardise patient care.

Health Disparities and Trust Concerns: There is a risk that unequal access to technology may exacerbate existing healthcare disparities, leaving certain groups with limited or no access to essential healthcare services. Moreover, excessive data collection and surveillance can erode patient trust, infringing upon patient autonomy and raising concerns about the security of their personal health information.

Mitigation and Addressing Challenges:

Addressing these challenges requires a comprehensive approach that involves:

Robust Security Measures: Implementing stringent security protocols and encryption methods to protect patient data and prevent unauthorised access.

Training and Education: Offering thorough training to healthcare professionals and patients on using the technology securely and responsibly.

Regulatory Compliance: Adhering to relevant data protection regulations and healthcare standards to ensure patient privacy and safety.

Equitable Access: Ensuring that the technology is accessible to all patient groups, regardless of socioeconomic or demographic factors.

Patient-Centric Approach: Prioritising patient well-being and autonomy by providing transparent information about data collection and usage.

Counterweight has established a comprehensive Adverse Event policy aligned with appropriate NHS regulations. This policy is developed and reviewed by the Clinical Safety Officer, Medical Director, and Dietetic Supervisor. It aims to ensure the safety of service users, linking with the overall risk management strategy to address any potential adverse events and ensure patient well-being.

Refer Out (Counterweight delivers all components of the service (as described above)

Counterweight Service Cost per patient (excl. VAT)

6 Months £920

12 Months £1,200

24 Months £1,560

Per patient prices are fully inclusive of all technology costs.

Current published evidence as reported by the Company is shown below in **Table 4.1a.ii.**

Author, year Study name	Country Study type (e.g. RCT) Intervention	Comparator(s)	Outcomes	EAG comments
Haag et al, 2023 The remote diet intervention to reduce Long COVID symptoms trial (ReDIRECT): protocol for a randomised controlled trial to determine the effectiveness and cost-effectiveness of a remotely delivered supported weight management programme for people with Long COVID and excess weight, with personalised improvement goals https://openresearch.nihr.ac.uk/articles/2-57/v2	UK RCT Remotely delivered Counterweight-Plus weight management programme, which includes a Counterweight dietitian supported delivery of 12 weeks total diet replacement, food reintroduction, and long-term weight loss maintenance. The intervention includes access to the Counterweight App and is delivered remotely using telephone or video technology. **AMBER (not stated to be participants with obesity or tier 3/4)**	A total of 120 individuals will receive the personalised, professionally supported weight management programme (treatment group), and 120 participants are allocated to usual care (control group). **GREEN**	Of 240 participants recruited (Dec 2021 to Jul 2022), 235 were randomised. Participants were mainly women (84%) of white ethnicity (90%), with at least graduate education (61%). Participants lived in England (63%), Scotland (31%), Wales (5%) and Northern Ireland (1%). A minority (13%) were from the 20% most deprived areas of the UK. Mean (SD) age was 46 (10) years, median BMI was 35 kg/m² (IQR 31 - 40). Prior to starting the study, 31% had had more than one COVID infection. In total, 82% of infections were confirmed with one or more positive tests (PCR 65%, LFT 47%, antibody test 16%). LC was mainly diagnosed by a GP (71%), other healthcare professionals, such as hospital consultants or LC specialists (8%) or was self-diagnosed (21%). The number of reported LC symptoms ranged from 4 to 30, with self-selected	No listed outcomes

			dominant LC symptoms including fatigue (55%), breathlessness (16%), pain (13%), anxiety/depression (2%) and "other" self-selected dominant symptoms (15%), such as cognitive issues, tinnitus, and loss of taste and smell. Further data to be published December 2023. **RED**	
Sharma et al, 2023 https://classic.clinicaltrials.gov/ct2/show/NCT03858608 A Total Diet Replacement Weight Management Program for Difficult-to-Treat Asthma Associated With Obesity: A Randomized Controlled Feasibility Trial https://journal.chestnet.org/article/S0012-3692%2823%2900117-4/fulltext	UK RCT Remote and face to face delivery of Counterweight Plus in three phases Total Diet Replacement (0-12 weeks), food reintroduction (13-18 weeks), and weight loss maintenance (19-52 weeks) and was delivered by MDT team (dietitian, physician). **AMBER (not stated to be tier 3/4)**	Usual Care GREEN	Weight loss **GREEN**	Not stated to be tier 3/4
Sattar, Welsh et al, 2022 † Dietary weight-management for type 2 diabetes remissions in South Asians: the SouTh AsiaN Diabetes remission feasiBilitY and randomised trial (STANDby) http://dx.doi.org/10.2139/ssrn.4162716	UK RCT Remote and face to face delivery of Counterweight Plus in three phases Total Diet Replacement (TDR) (0-12 weeks), food reintroduction (6-8 weeks).	Usual care **GREEN**	Weight change **GREEN**	Not stated to be participants with obesity or tier 3/4

	Delivered by MDT team (dietitian, physician). **AMBER (not stated to be participants with obesity or tier 3/4)**			
Marples et al, 2022 Real-World Data of a Group-Based Formula Low Energy Diet Programme in Achieving Type 2 Diabetes Remission and Weight Loss in an Ethnically Diverse Population in the UK: A Service Evaluation http://dx.doi.org/10.3390/nu14153146	UK Service Evaluation Remote and face to face delivery of Counterweight Plus in three phases Total Diet Replacement (0-12 weeks), food reintroduction (13-18 weeks), and weight loss maintenance (19-52 weeks) and was delivered by MDT team (two diabetes specialist dietitians (DSD), two diabetes specialist nurses (DSN) and one diabetes specialist psychological therapist). **AMBER (not stated to be tier 3/4)**	N/A **AMBER (no comparator)**	Weight loss, quality of life measures **GREEN**	Not stated to be tier 3/4; no comparator
Brosnahan et al, 2023 Service evaluation of the remote delivery of a digital tier 2 weight management programme. Obes Facts 2023;16(suppl 1):1–351 DOI: 10.1159/000530456	UK Service Evaluation The 16-week programme was delivered using video/telephone support by trained dietitians/coaches, using the Counterweight app and home-delivered meal replacements. Tier 2	N/A **AMBER (no comparator)**	Number who completed the intervention, reasons for failure to complete, weight change **GREEN**	Not tier 3/4; no comparator

	AMBER (not stated to be participants with obesity; not tier 3/4)			
Lean et al, 2017 Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open- label, cluster-randomised trial. https://doi.org/10.1016/S0140-6736(17)33102-1	UK RCT Face to face delivery of Counterweight Plus in three phases Total Diet Replacement (3 months, extendable to 5 months), food reintroduction (2-8 weeks), and weight loss maintenance (up to 2 years) and was delivered by MDT team (dietitian or nurse, with GP medical monitoring). **AMBER (not stated to be participants with obesity or tier 3/4)**	Best-practice care guidelines **GREEN**	Weight loss of 15 kg or more, mean bodyweight, quality of life, as measured by the EuroQol 5 Dimensions visual analogue scale, serious adverse events **GREEN**	Not stated to be participants with obesity or tier 3/4; multiple other publications may include resource use
Lean et al, 2019. 24 month follow up of DIRECT study* Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. https://www.thelancet.com/journals/landia/article/PIIS2213-8587(19)30068-3/fulltext	As above	As above	Weight loss of at least 15 kg, change in bodyweight, serious adverse events **GREEN**	As above
Lean et al. 2023. 5 year follow up of DIRECT study (Accepted for publication Lancet Diabetes September 2023) Five-year follow-up of the randomised Diabetes Remission Clinical Trial (DiRECT): Extension study of continued support for weight loss maintenance	As above	As above	Weight loss **GREEN**	As above
McCombie et al, 2018 Filling the intervention gap: service evaluation of an intensive nonsurgical weight management programme for severe and complex obesity. https://doi.org/10.1111/jhn.12611	UK Service Evaluation Face to face delivery (with option for remote delivery) of Counterweight Plus in	N/A **AMBER (no comparator)**	Weight loss of ≥15 kg at 12 months, mean weight loss **GREEN**	No comparator

	three phases: Total Diet Replacement (12 weeks), Food Reintroduction (12 weeks), and Weight Loss Maintenance (6-18 months) with the option of a Rescue Plan (4 weeks) and was delivered by MDT team (dietitian or nurse, with GP medical monitoring). **GREEN (severe and complex obesity so assume tier 3/4)**			
Lean et al, 2013. Feasibility and indicative results from a 12-month low-energy liquid diet treatment and maintenance programme for severe obesity. https://doi.org/10.3399/bjgp13X663073	UK Feasibility study Face to face delivery of Counterweight Plus (with option for remote delivery) in three phases: Total Diet Replacement (12 weeks), Food Reintroduction (6-8 weeks), and Weight Loss Maintenance (up to 12 months) and was delivered by MDT team (dietitian or nurse, with GP medical monitoring). **GREEN (severe obesity so assume tier 3/4)**	N/A **AMBER (no comparator)**	Completion, weight loss The indicative cost of providing this entire programme for wider implementation would be £861 per patient entered, or £2611 per documented 15 kg loss achieved. **GREEN**	No comparator
Thom et al., 2020‡ The role of appetite-related hormones, adaptive thermogenesis, perceived hunger and stress in long-term weight-loss maintenance: a mixed-methods study. European Journal of Clinical Nutrition. https://doi.org/10.1038/s41430-020-0568-9	UK Non-comparative single arm study Weight-stable (≤5 kg weight loss in previous 6 months) females aged 18–	None **AMBER (no comparator)**	Drop outs; weight measurements, BMI. **GREEN**	Not stated to be MDT or tier 3/4; no comparator

	65 years with body mass index (BMI) 30–45 kg/m^2 having Counterweight Plus in three phases: Total Diet Replacement (3-5 months), Food Reintroduction (1-2 months), and Weight Loss Maintenance (around 18 months); delivered by registered dietitian. **AMBER (not stated to be MDT or tier 3/4)**			

* Other publications for the DIRECT trial:

Physical activity, inactivity and sleep during the Diabetes Remission Clinical Trial (DiRECT)
Diabetic Medicine https://pubmed.ncbi.nlm.nih.gov/36398460/

Delivering the Diabetes Remission Clinical Trial (DiRECT) in primary care: Experiences of healthcare professionals. Diabetic Medicine https://doi.org/10.1111/dme.14752.

Participant experiences in the Diabetes Remission Clinical Trial (DiRECT). Diabetic Medicine https://doi.org/10.1111/dme.14689.

Antihypertensive medication needs and blood pressure control with weight loss in the Diabetes Remission Clinical Trial (DiRECT). Diabetologia https://doi.org/10.1007/s00125-021-05471-x

Brief formula low-energy-diet for relapse management during weight loss maintenance in the Diabetes Remission Clinical Trial (DiRECT). Journal of Human Nutrition and Dietetics https://doi.org/10.1111/jhn.12839.

Weight loss-induced increase in fasting ghrelin concentration is a predictor of weight regain: Evidence from the Diabetes Remission Clinical Trial (DiRECT). Diabetes, Obesity and Metabolism. https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14274

2-year remission of type 2 diabetes and pancreas morphology: a post-hoc analysis of the DiRECT open-label, cluster-randomised trial. The Lancet Diabetes & Endocrinology. https://doi.org/10.1016/S2213-8587(20)30303-X

Predictors of type 2 diabetes remission in the Diabetes Remission Clinical Trial (DiRECT). Diabetic Medicine. https://doi.org/10.1111/dme.14395

Time course of normalization of functional β-cell capacity in the Diabetes Remission Clinical Trial after weight loss in type 2 diabetes. Diabetes Care. https://doi.org/10.2337/dc19-0371

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. Diabetologia. https://doi.org/10.1007/s00125-020-05224-2.

The DiRECT principles: giving Type 2 diabetes remission programmes the best chance of success. Diabetic Medicine. https://doi.org/10.1111/dme.14126

Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. The Lancet Diabetes and Endocrinology. https://doi.org/10.1016/S2213-8587(19)30068-3

Within-trial cost and 1-year cost-effectiveness of the DiRECT/Counterweight-Plus weight-management programme to achieve remission of type 2 diabetes. Lancet Diabetes and Endocrinology. https://doi.org/10.1016/S2213-8587(18)30346-2.

Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial. The Lancet. https://doi.org/10.1016/S0140-6736(17)33102-1
Clinical and metabolic features of the randomised controlled Diabetes Remission Clinical Trial (DiRECT) cohort. Diabetologia. https://doi.org/10.1007/s00125-017-4503-0
The Diabetes Remission Clinical Trial (DiRECT): protocol for a cluster randomised trial. BMC Family Practice. https://doi.org/10.1186/s12875-016-0406-2.
Hepatic lipoprotein export and remission of human type 2 diabetes after weight loss. Cell Metabolism. https://doi.org/10.1016/j.cmet.2019.11.018
Remission of Human Type 2 Diabetes Requires Decrease in Liver and Pancreas Fat Content but Is Dependent upon Capacity for b Cell Recovery. Cell Metabolism. https://doi.org/10.1016/j.cmet.2018.07.003

† Other publications for STANDby:
Dietary weight-management for type 2 diabetes remissions in South Asians: the SouTh AsiaN Diabetes remission feasiBilitY and randomised trial (STANDby). Lancet Regional Health Southeast Asia. http://dx.doi.org/10.2139/ssrn.4162716

‡ Other publications for Thom et al, 2020:
'I have been all in, I have been all out and I have been everything in-between': A 2-year longitudinal qualitative study of weight loss maintenance. Journal of Human Nutrition and Dietetics. https://doi.org/10.1111/jhn.12826

Other publications (comment/editorial type):
Low-calorie diets in the management of type 2 diabetes mellitus. Nature Reviews/Endocrinology. https://doi.org/10.1038/s41574-019-0186-6.
Beating type 2 diabetes into remission. BMJ. https://doi.org/10.1136/bmj.j4030

Publications on the Counterweight programme (delivered in person; not an app):
A community pharmacy weight management programme: an evaluation of effectiveness. BMC Public Health. https://doi.org10.1186/1471-2458-13-282 (pharmacy staff delivered patient education)
The implementation of the Counterweight Programme in Scotland, UK. Family Practice. https://doi.org/10.1093/fampra/cmr074 (Counterweight Specialists (dietitians specializing in weight management) led and facilitated programme implementation in the 13 Health Boards)
A patient-centred approach to estimate total annual healthcare cost by body mass index in the UK Counterweight programme. International Journal of Obesity. https://doi.org/10.1038/ijo.2012.186 (not apps).
The Counterweight programme: Prevalence of CVD risk factors by body mass index and the impact of 10% weight change. Obesity Research & Clinical Practice. https://doi.org/10.1016/j.orcp.2008.01.002 (not apps).
Engaging patients, clinicians and health funders in weight management: the Counterweight Programme. Family Practice. https://doi.org/10.1093/fampra/cmn081 (general practice not app)
Tricks and tools for the primary care provider: the counterweight programme: a continuous improvement methodology model of weight management in UK primary care. International Journal of Obesity. https://www.semanticscholar.org/paper/Tricks-and-tools-for-the-primary-care-provider-The-McQuigg-Broom/c84aed0f3729e579d70e4cfa7167be56b11d3f1e (general practice not app).
Influence of body mass index on prescribing costs and potential cost savings of a weight management programme in primary care. Journal of health services research & policy. http://www.jstor.org/stable/26751614 (general practice not app)
Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement. British Journal of General Practice. https://bjgp.org/content/bjgp/58/553/548.full.pdf (general practice not app)
Empowering primary care to tackle the obesity epidemic: the Counterweight Programme. European Journal of Clinical Nutrition. https://doi.org/10.1038/sj.ejcn.1602180 (general practice not app)
Current approaches to obesity management in UK Primary Care: the Counterweight Programme. Journal of Human Nutrition and Dietetics. https://doi.org/10.1111/j.1365-277X.2004.00528.x (general practice not app)
A new evidence based model for weight management in primary care: the Counterweight Programme. Journal of Human Nutrition and Dietetics. https://doi.org/10.1111/j.1365-277X.2004.00517. (general practice not app)

Ongoing studies for Counterweight:

PubMed, clinicaltrials.org, DRKS and the Chinese Clinical Trials Registry were searched for additional completed or ongoing studies for the Counterweight app.

Searches of PubMed found 7 additional papers for the DIRECT study (ISRCTN 03267836):

- Cassidy S, Trenell M, Stefanetti RJ, Charman SJ, Barnes AC, Brosnahan N, McCombie L, Thom G, Peters C, Zhyzhneuskaya S, Leslie WS, Catt C, Catt M, McConnachie A, Sattar N, Sniehotta FF, Lean MEJ, Taylor R. Physical activity, inactivity and sleep during the Diabetes Remission Clinical Trial (DiRECT). Diabet Med. 2023 Mar;40(3):e15010. doi: 10.1111/dme.15010. Epub 2022 Nov 29. PMID: 36398460; PMCID: PMC10099825.),

- Leslie WS, Ali E, Harris L, Messow CM, Brosnahan NT, Thom G, McCombie EL, Barnes AC, Sattar N, Taylor R, Lean MEJ. Antihypertensive medication needs and blood pressure control with weight loss in the Diabetes Remission Clinical Trial (DiRECT). Diabetologia. 2021 Sep;64(9):1927-1938. doi: 10.1007/s00125-021-05471-x. Epub 2021 May 31. PMID: 34056684; PMCID: PMC8382659.

- Xin Y, Davies A, Briggs A, McCombie L, Messow CM, Grieve E, Leslie WS, Taylor R, Lean MEJ. 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. Diabetologia. 2020 Oct;63(10):2112-2122. doi: 10.1007/s00125-020-05224-2. Epub 2020 Aug 10. PMID: 32776237; PMCID: PMC7476973.

- Xin Y, Davies A, McCombie L, Briggs A, Messow CM, Grieve E, Leslie WS, Taylor R, Lean MEJ. Type 2 diabetes remission: economic evaluation of the DiRECT/Counterweight-Plus weight management programme within a primary care randomized controlled trial. Diabet Med. 2019 Aug;36(8):1003-1012. doi: 10.1111/dme.13981. PMID: 31026353.

- Xin Y, Davies A, McCombie L, Briggs A, Messow CM, Grieve E, Leslie WS, Taylor R, Lean MEJ. Within-trial cost and 1-year cost-effectiveness of the DiRECT/Counterweight-Plus weight-management programme to achieve remission of type 2

diabetes. Lancet Diabetes Endocrinol. 2019 Mar;7(3):169-172. doi: 10.1016/S2213-8587(18)30346-2. Epub 2018 Dec 20. PMID: 30581081; PMCID: PMC6383752.

- Taylor R, Leslie WS, Barnes AC, Brosnahan N, Thom G, McCombie L, Sattar N, Welsh P, Peters C, Zhyzhneuskaya S, Hollingsworth KG, Al-Mrabeh A, Rodrigues AM, Rehackova L, Adamson AJ, Sniehotta FF, Mathers JC, Ross HM, McIlvenna Y, Kean S, Ford I, McConnachie A, Lean MEJ. Clinical and metabolic features of the randomised controlled Diabetes Remission Clinical Trial (DiRECT) cohort. Diabetologia. 2018 Mar;61(3):589-598. doi: 10.1007/s00125-017-4503-0. Epub 2017 Nov 30. PMID: 29188339; PMCID: PMC6448967

- Leslie WS, Ford I, Sattar N, Hollingsworth KG, Adamson A, Sniehotta FF, McCombie L, Brosnahan N, Ross H, Mathers JC, Peters C, Thom G, Barnes A, Kean S, McIlvenna Y, Rodrigues A, Rehackova L, Zhyzhneuskaya S, Taylor R, Lean ME. The Diabetes Remission Clinical Trial (DiRECT): protocol for a cluster randomised trial. BMC Fam Pract. 2016 Feb 16;17:20. doi: 10.1186/s12875-016-0406-2. PMID: 26879684; PMCID: PMC4754868..

and 1 additional paper for the OPPORTUNITY study:

- Simpson AHRW, Howie CR, Kinsella E, Hamilton DF, Conaghan PG, Hankey C, Simpson SA, Bell-Higgs A, Craig P, Clement ND, Keerie C, Kingsbury SR, Leeds AR, Ross HM, Pandit HG, Tuck C, Norrie J. Osteoarthritis Preoperative Package for care of Orthotics, Rehabilitation, Topical and oral agent Usage and Nutrition to Improve ouTcomes at a Year (OPPORTUNITY); a feasibility study protocol for a randomised controlled trial. Trials. 2020 Feb 19;21(1):209. doi: 10.1186/s13063-019-3709-5. Erratum in: Trials. 2020 Apr 20;21(1):345. PMID: 32075663; PMCID: PMC7031939.

Searches of DRKS and the Chinese Clinical Trials Registry each found no additional studies; clinicaltrials.org found 2 completed (and 0 ongoing) studies, shown below:

Table 4.1a.iii Completed studies:

Study name / reference	Country	Study type (e.g. RCT)	Intervention	Comparator(s)	Outcomes	EAG comments
BEYOND Weight Loss Study (BEYOND) NCT02340793	UK	Non-comparative single arm study; 23 participants (BMI ≥30 kg/m^2 and < 45kg/m^2) **GREEN**	The BEYOND study will administer Counterweight Plus; a nutritionally replete Total Diet Replacement Plan (TDR) of 800+ Calories followed by structured Food Reintroduction, and Weight Loss Maintenance programmes. **AMBER (not stated to be tier 3/4 or to have an MDT)**	None **AMBER (no comparator)**	Weight loss; metabolic adaptation; muscle/fat mass of specific muscle groups; adherence and acceptability of rescue packages to patients **RED: relevant outcomes but protocol only no data reported**	Not stated to be tier 3/4 or to have an MDT; no comparator
BEYOND Weight Loss Maintenance Study NCT02683798	UK	RCT; 63 participants who Completed Counterweight Plus Total Diet Replacement and Food Reintroduction stages and achieved >10kg weight loss **GREEN**	Counterweight Plus and Experimental: Intermittent energy restriction: 4 x formula food (202-209kcal) total diet replacement per day, on 2 days per week **AMBER (not stated to be tier 3/4 or to have an MDT)**	Counterweight Plus and Active Comparator: Continuous energy restriction: 1 x formula food (202-209kcal) meal replacement per day **AMBER (no non-app comparator)**	Weight change, acceptability, behaviour change strategies used, eating behaviours, EuroQoL-5D, cost of interventions **RED: relevant outcomes but protocol only no data reported**	Not stated to be tier 3/4 or to have an MDT; no non-app comparator

Table 5.1. Prioritised outcomes from publications in searches

Study	Weight change	Adherence/ completion
Weight Loss Clinic		

Study	Weight change	Adherence/ completion
Swei 2020 AMBER		Total compliance during period 2016-2019: 28.7% (n=79). F2F compliance: 16% (n=27). App only compliance: 49.8% (n=36, p=0.0002 vs. F2F). Hybrid: compliance after switching to VHP was higher, but this was not statistically significant (22.4% vs 11.2%, p=0.17; n=16). Patients who used VHP had significantly better success achieving moderate intensity lifestyle intervention than those who did not (42% vs 0%). In multivariate analysis, only activation of VHP was shown to significantly affect patient compliance (β=22.4, p=0.0001)
Wisotsky 2016 AMBER	VHP demonstrated 32% increase in weight loss with increased VHP nutrition visits. VHP demonstrated 48% increase in weight loss with increased activity on the VHP portal. This is a relative increase in % weight loss but no baseline.	Nutrition visit compliance increased 31% once VHP was introduced to a post procedure population that initially did not have access to VHP. This is a relative increase in % compliance but no baseline.
Counterweight		
Sharma 2023 AMBER	Weight loss was greater in the Counterweight Plus than Usual Care group (mean difference, –12.1 kg; 95% CI, –16.9 to –7.4; P < .001).	33/35 (94.3%) at 16 weeks
Sattar 2022 AMBER	At 105 days, mean (SD) weight change after TDR was -7.7 (7.2) % in the intervention group (n=13), and -1.2 (1.4) % in the usual-care control group (n=12) (p=0.005)	
Marples 2022 AMBER	At 12 months, mean bodyweight loss of 11.6 (8.9) kg. Completers lost 15.8 (5.3) kg, with 31.4% of participants achieving ≥15 kg weight loss.	29/37 (78.4%)
Brosnahan 2023 AMBER	Of 230 contacted at 26-weeks, 190 (82%) provided a follow up weight. Weight change at 16 weeks (n=162) was -7.1kg and 26 weeks (n=190) -7.8kg.	162/230 (70%) completed the intervention (attended 4/6 appointments and provided a 16-week weight measure).

Study	Weight change	Adherence/ completion
Lean 2017; Lean 2019; Lean 2023 (DiRECT) AMBER	At 12 months, weight loss of 15 kg or more in 36/149 (24%) participants in the intervention group and no participants out of 149 in the control group (p<0.0001). Mean bodyweight fell by 10.0 kg (SD 8.0) in the intervention group and 1.0 kg (3.7) in the control group (adjusted difference –8·8 kg, 95% CI –10.3 to –7.3; p<0.0001). At 24 months, 17 (11%) intervention participants and three (2%) control participants had weight loss of at least 15 kg (adjusted odds ratio [aOR] 7.49, 95% CI 2.05 to 27.32; p=0·0023). The adjusted mean difference between the control and intervention groups in change in bodyweight was −5·4 kg (95% CI −6.9 to −4.0; p<0·0001). At 5 years: data from 85 of the original DiRECT intervention group (57.0%) showed a mean 5-year weight loss of 6.1kg.	57.0% at 5 years
McCombie 2018 AMBER	A weight loss of ≥15 kg at 12 months was achieved by 48 patients, representing 22.1% of all who started and 40% of those who maintained engagement. For complete cases, mean (95% confidence interval) weight loss was 13.3 (12.1–14.4) kg at 3 months, 16.0 (14.4–17.6) kg at 6 months and 14.2 (12.1–16.3) kg at 12 months (all P < 0.001). Mean loss at 12 months by ITT analyses was: single imputation –10.5 (9.5) kg, last observation carried forward –10.9 (11.6) kg and baseline observation carried forward –7.9 (11.1) kg.	120/288 (41.7%) maintained engagement
Lean 2013 AMBER	At 14.4 (SD 6.0) weeks: mean weight loss of 16.9 kg (SD = 6.0 kg). At 12 months, weight was recorded for 68/91 (75%) patients, with a mean loss of 12.4 kg (SD = 11.4 kg). Of these, 30 (33% of all 91 patients starting the programme) had a documented maintained weight loss of ≥15 kg at 12 months, six (7%) had a 10–15 kg loss, and 11 (12%) had a 5–10 kg loss.	58/91(64%) completed the LELD stage, with a mean duration of 14.4 weeks (SD = 6.0 weeks)
Thom 2020 AMBER	Weight: mean (SD) baseline 103.0 (15.5) kg and 6 months: 89.2 (15.2) kg; p<0.001; weight loss 13.8 (6.3) kg (13.5 [5.5] %). Between 6 and 24 months, weight increased by 6.1 (6.3) kg (p = 0.002) but remained 7.7 (9.7) kg below baseline (P = 0.009).	50 expressed interest; 28 not eligible and 22 enrolled; 7 drop outs; 15 (30.0%) had weight measurements at 6 and 24 months.

Table 5.3. Important outcomes from searches

Study	Change in BMI	Engagement	HRQoL	Psychological outcomes
Weight Loss Clinic				
No studies reported these outcomes				
Counterweight				
Marples 2022 **AMBER**		37/216 (17.1%)	Quality of life measures showed significant improvements	
Brosnahan 2023 **AMBER**		230/239 (96.2%)		
Lean 2017 (DiRECT) **AMBER**			Quality of life, as measured by the EuroQol 5 Dimensions visual analogue scale, improved by 7.2 points (SD 21.3) in the intervention group, and decreased by 2.9 points (15.5) in the control group (adjusted difference 6.4 points, 95% CI 2.5–10.3; p=.0012).	
Thom 2020 **AMBER**	BMI at baseline: 39.4 (4.3) and at 6 months: 34.1 (4.8); p <0.001.			

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health technology evaluation

Assessment report overview

Digitally enabled weight management programmes to support treatment in specialist weight management services: early value assessment

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 EAG 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

Digitally enabled technologies can be used to deliver specialist weight management programmes, following clinical assessment and referral by a relevant NHS healthcare professional. The technologies can also be used to support treatment with weight management medication. They can be accessed online or via an app and provide users with support from a multidisciplinary team (MDT) of healthcare professionals. Digitally enabled technologies 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. Twelve digitally enabled technologies designed to support specialist weight management services are included in the evaluation. Detailed descriptions of the technologies are provided in the scope. Technologies or versions of technologies considered in this evaluation do not include a weight management medication prescribing or monitoring function. Technologies with these functions are considered in NICE's early value assessment on digitally enabled technologies for delivering specialist weight-management services to manage treatment with weight-management medication.

The following technologies are included in the scope of this evaluation:

- CheqUp (CheqUp Health)
- Counterweight (Counterweight)
- Gloji (Thrive Tribe)
- Gro Health W8Buddy (DDM Health Ltd)
- Habitual (Habitual Health Ltd)
- Juniper (Juniper Technologies UK Ltd)
- Liva (Liva)

- Oviva (Oviva)
- Roczen (Reset Health)
- Second Nature (Second Nature)
- Weight Loss Clinic (Virtual Health Partners)
- Wellbeing Way (Xyla Health and Wellbeing)

Information on Weight Loss Clinic (Virtual Health Partners) and Counterweight (Counterweight) was received late and so are described here and in the addendum of the EAG assessment report (EAR).

Gloji (Thrive Tribe) and Wellbeing Way (Xyla Health and Wellbeing) did not provide information to NICE on their technology for this assessment, and so any information used is based on publicly available sources and information from NICE's early value assessment on digitally enabled technologies for delivering specialist weight-management services to manage treatment with weight-management medication.

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 with obesity who are eligible for treatment in specialist weight management services, including adults who are eligible for treatment with weight management medication. Specialist weight management services include but are not limited to tier 3 and tier 4 services. Tier 3 and 4 specialist weight-management services for people with overweight and obesity are defined in NHS England's guidance for Clinical Commissioning Groups (CCGs): Service Specification Guidance for Obesity Surgery (2016) and NICE's clinical guideline on obesity: identification, assessment and management.

Adults who are eligible for treatment with weight management medication for the management of overweight and obesity, include but are not limited to the population in NICE's technology appraisal guidance for semaglutide for managing overweight and obesity.

2.3 Unmet need and current management

There is an unequal distribution of specialist weight management services across the NHS. This could create a postcode lottery for accessing weight management medication. In some areas there is no access to specialist weight management services. In areas with established 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. Providing specialist weight management services using digitally enabled technologies 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.

The intensity, frequency and variety of support from an MDT of healthcare professionals varies between specialist weight management programmes. A typical MDT should include an obesity physician, specialist nurse, specialist dietician, psychologist, and physiotherapist. It should also have access to healthcare professionals with expertise in surgical assessments. Support may be offered in person, remotely via telephone or video call, or a combination of in person and remote support. Most programmes last between 12 and 24 months, but some may only be 6 months. The criteria for accessing these services may vary depending on the area and local funding.

2.3 Proposed management with new technology

Digitally enabled technologies would be offered as an option to adults with obesity that are eligible for treatment in specialist weight management services. People would be clinically assessed and referred within the NHS. Weight management medication prescription and monitoring would be done within the NHS. 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 how evidence has been included in relation to the decision problem (see Table 1.1.1 of the external assessment report [EAR]).

4 The evidence

For this assessment, the EAG rescreened the records identified by the digitally enabled technologies to support treatment with weight-management medication in specialist weight-management services: early value assessment (GID-HTE10007) EAR. Additional searches were conducted for the 2 newly

identified technologies (Gloji and Habitual) and an addendum was added to summarise evidence from 2 additional technologies (Weight Loss Clinic and Counterweight).

4.1 Summary of evidence of clinical benefit

Published evidence for 7 out of the 12 technologies was identified (Oviva [n=19], Counterweight [n=11], Second Nature [n=7], Liva [n=4], Gro Health [n=5], Roczen [n=3] and Weight Loss Clinic [n=3]). One additional study compared Liva, Oviva and Our Path (now called Second Nature). A total of 53 published studies reported across 76 publications were considered relevant to the decision problem by the EAG. The EAG noted that there is an unknown likelihood of overlap between some of the publications. In addition to published studies, 21 unpublished studies for 7 out of 12 technologies were provided by companies (Liva [n=6], Oviva [n=6], Habitual [n=3], Juniper [n=2], Roczen [n=2], CheqUp [n=1] and GroHealth [n=1]). For further details about study inclusion and exclusion see sections 4.1 and 4.2 of the EAR and section 4.2 of the EAG report addendum.

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

Table 1: Summary of included studies for each technology

Technology	Published studies (participants not on weight loss medication)	Unpublished studies
CheqUp	0	[redacted]
Counterweight	3 RCTs, 6 non-comparative studies with an extension study from 1 of these and 1 protocol	0
Gro Health	4 single arm studies and 1 non-randomised comparative study	[redacted]
Gloji	0	0
Habitual	0	[redacted]
Juniper	0	[redacted]
Liva	5 studies including 1 RCT (compared with face to face), 1 study comparing Liva, Oviva and Our Path, and 3 single arm studies	[redacted]
Oviva	20 studies including 1 RCT (comparing diet not the technology), 4 non-randomised comparative studies (compared with phone or face to face), 1 study comparing Liva, Oviva and Our Path, and 14 single arm studies	[redacted]
Roczen	3 single arm studies	[redacted]
Second Nature (previously Our Path)	1 study comparing Liva, Oviva and Our Path and 7 single arm studies	0
Weight Loss Clinic	2 non-randomised comparative studies (compared to face to face or hybrid care) and 1 survey	0
Wellbeing Way	0	0
Total	53	21

Summary of the clinical outcomes

Evidence for outcomes including weight loss, adherence, BMI, engagement, health-related quality of life and psychological outcomes across 10 of the 12 included technologies (CheqUp, Counterweight, Gro Health, Habitual, Juniper, Liva, Oviva, Roczen, Second Nature and Weight Loss Clinic) was identified and considered relevant (or partially relevant) to the decision problem. Comparative studies reported little difference between digitally enabled programmes and non-digitally enabled programmes. Non-comparative studies reported weight loss compared with baseline. The EAG stated that digitally enabled technologies may be a safe alternative to face-to-face management and could improve access for people who may not have services in their local area, or who may have difficulty in accessing in-person services due to transport, mobility or comorbidity issues. For more detail on the outcomes reported in the evidence base see section 5.3 and tables 5.1 to 5.3 of the EAR and EAR addendum.

Gro Health W8Buddy

3 single arm studies (Abdelhameed et al. 2022; Hanson et al. 2023; Summers et al. 2021) and 1 non-randomised comparative study (Hanson et al. 2021) was considered relevant to the decision problem by the EAG. 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. Abdelhameed et al. (2022) reported significant and clinically meaningful increase in EQ-5D mean Health index scores among app users between baseline (0.746 [SD 0.234]) and 6-month follow-up (0.792 [SD 0.224], $p<0.001$). It also reported that 896 of 1767 participants (50.7%) completed the educational component of the app.

The company stated that Hanson et al. (2021) is eligible for inclusion as it is on their technology under a previous name 'Low Carb Programme' which delivered a tier 3 weight management service. Hanson et al. (2021) is a non-randomised comparative observational study compared to a retrospective control group who had access to face-to-face weight management services. The study reports a mean body weight difference at 5 months of -2.7kg (p=0.001). Of the people interested in using the app (n=105), 90 completed the Low Carb Program app registration process and engaged with the Low Carb Program app program. However, only 19 people (18%) completed the entire Low Carb Program app program (defined as completing more than or equal to 9 of the 12 education modules available). The EAG also included a single arm evaluation of the Low Carb Programme (Summers et al. 2021), that reported a mean reduction of 2.77kg (p<0.001) in adults with prediabetes or type 2 diabetes. Participants had a mean weight of 89.4kg. All participants (n=45) completed at least 40% of the lessons, and 64% (n=29) completed all 12 core lessons.

The company also provided 2 additional studies (a poster presentation and an unpublished manuscript) during and after the consultation for NICE's early value assessment on digitally enabled technologies for delivering specialist weight-management services to manage treatment with weight-management medication. The poster reports that 19.2% (121 out of 631) of people offered W8Buddy activated it in Coventry and 53% (160 out of 302) of people offered W8Buddy activated it in London. At a mean follow up of 3.5 months for 68 people, a mean weight loss of 3.3 kg (SD 6.6, 95% CI 1.7 to 4.9) was reported from baseline and was considered statistically significant.

[redacted]

[redacted]

Liva

Ten publications including 1 RCT (compared with face-to-face care), 4 single arm studies and 6 unpublished studies 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. This RCT, however, was limited by large drop-out rates (around 41% dropped out by 12 months). Christensen et al. (2022a) states that low completion rates were due to the COVID-19 pandemic. Non-comparative evidence generally showed a reduction in weight compared to baseline.

In the RCT (Christensen et al., 2022a), greater levels of adherence (based on data presented in GID-HTE10007 EAR) 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%).

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

25 publications including 1 pilot RCT (comparing Oviva plus an intermittent low-energy diet to Oviva with a continuous low-energy diet), 4 non-randomised comparative studies, 14 single arm studies and 6 unpublished studies were considered relevant to the decision problem.

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 and a reduction in BMI (where reported) when compared to baseline.

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.

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.

Roczen

Three single-arm cohort studies (reported as abstracts) and 2 unpublished abstracts 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]

There is limited data on engagement and adherence for Roczen. Adherence 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]

Second Nature

Seven single arm studies and well as 1 study comparing Liva, Oviva and Our Path (now called Second Nature) and were considered relevant to 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.

CheqUp

The EAG considered 1 unpublished single arm study (participants on weight loss medication) as relevant to the decision problem. Results of patient-declared weight indicate weight loss greater than that reported as the average for the clinical trials for the specific weight management medication. Engagement in the programme is reported to be at 94% (measured by engagement in diarised appointments with clinicians). High engagement could be due to patients paying for the technology.

Habitual

The EAG considered 3 unpublished [redacted] as relevant to the decision problem. The studies reported a

[redacted]

Juniper

The EAG considered [redacted] as relevant to the decision problem.

[redacted]

Weight Loss Clinic

Two non-randomised comparative studies compared the technology with a face-to-face service (Swei et al. 2020; Wisotsky et al. 2016). Wisotsky et al. (2016) was a pilot study published as a white paper and so has not been peer reviewed. Compliance was 49.8% for the technology only group compared to 16% in the face-to-face group in one study (Swei et al. 2020) and a 31% relatively greater compliance in the other study (Wisotsky et al. 2016). Wisotsky et al. (2016) also reported a 32% relatively greater weight loss in those with increased nutritional compliance in the app group. The company provided an additional abstract on a survey about the usability of the technology (Moore et al. 2021).

Counterweight

Three studies were RCTs (DiRECT, STANDby and Sharma et al. 2023) which randomised participants to Counterweight Plus or usual care. The populations in these studies varied with the focus on people with asthma and obesity (Sharma et al. 2023) and Type 2 diabetes (STANDby and DiRECT). Completion rate was reported as 94.3% at 16 weeks in one study (Sharma et al. 2023). Weight change was greater in the intervention than the usual care control groups: 12.1 kg more at 16 weeks (Sharma et al. 2023); 8.8 kg more at 12 months and 5.4 kg more at 24 months (DiRECT); and 6.5% more

(STANDBY). HRQoL improved in the DiRECT study by 7.2 (21.3) points in the intervention group but worsened by 2.9 (15.5) points in the control group. One additional RCT submitted as a protocol only (BEYOND maintenance study) which is a trial following on from a single arm study (BEYOND). Here two different weight loss maintenance strategies are being compared with both using the app.

Lean et al. (2017; DiRECT) reported that at 12 months, 9 serious adverse events were reported by 7 (4%) of 157 participants in the intervention group and 2 were reported by 2 (1%) participants in the control group. Two serious adverse events (biliary colic and abdominal pain), occurring in the same participant, were deemed potentially related to the intervention (Counterweight).

The company additionally provided results from 6 non-comparative studies. Details of which can be found in the EAG assessment report addendum.

Additional evidence

In addition to the publications presented on individual technologies, there was 1 non-randomised comparative study (Ross et al. 2022) published comparing Liva, Oviva and Our Path (now called Second Nature). At 12 months, mean weight loss was 2.4 kg (95% CI: 3.1 to 1.6) for Liva, 6.2 kg (7.1 to 5.4) for Our Path and 2.5 kg (2.9 to 2.1) for Oviva.

EAG comments on the quality of the clinical evidence

- **Publication type** – more than half of the publications assessed were published as abstracts and lack methodological detail. Due to the lack of detail, there is an unknown likelihood of crossover between the populations included in the studies.

- **Comparator** – There is a limited number of comparative studies, with a total of 4 RCTs on 3 technologies and 2 non-randomised comparative studies for 1 technology.

- **Dropout rates** – There is a large dropout rate reported across the evidence base. Christensen et al. 2022a reported a high dropout rate at 12 months (40.8%) and 24 months (59% for the intervention group and 61% for the control group). McDiarmid et al. (2022) reported that 55.7% of people who enrolled in the programme still used the app at 52 weeks.

- **Follow up** – The EAG stated that there was an inadequate length of follow up across the evidence base (ranging from 1 month to 5 years, but most studies were less than 12 months) given the chronic nature of the condition.

- **Outcome reporting** – The EAG noted that some outcomes were self-reported which may lead to reduced accuracy and reporting bias. It also noted that reporting data only for a small number of participants (such as people who complete the programme) also introduces bias.

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

The EAG did not search for existing economic models, as it considered this was appropriately reflected in the digitally enabled technologies to support treatment with weight-management medication in specialist weight-management services: early value assessment (GID-HTE10007) external assessment report (EAR). Here, no relevant economic evaluations were identified in line with the decision problem. For further information, see sections 7.1 and 8.2 of the GID-HTE10007 EAR.

Early economic modelling

The EAG adapted the model developed for GID-HTE10007 by the Newcastle upon Tyne Hospitals NHS Trust NICE external assessment group. The model

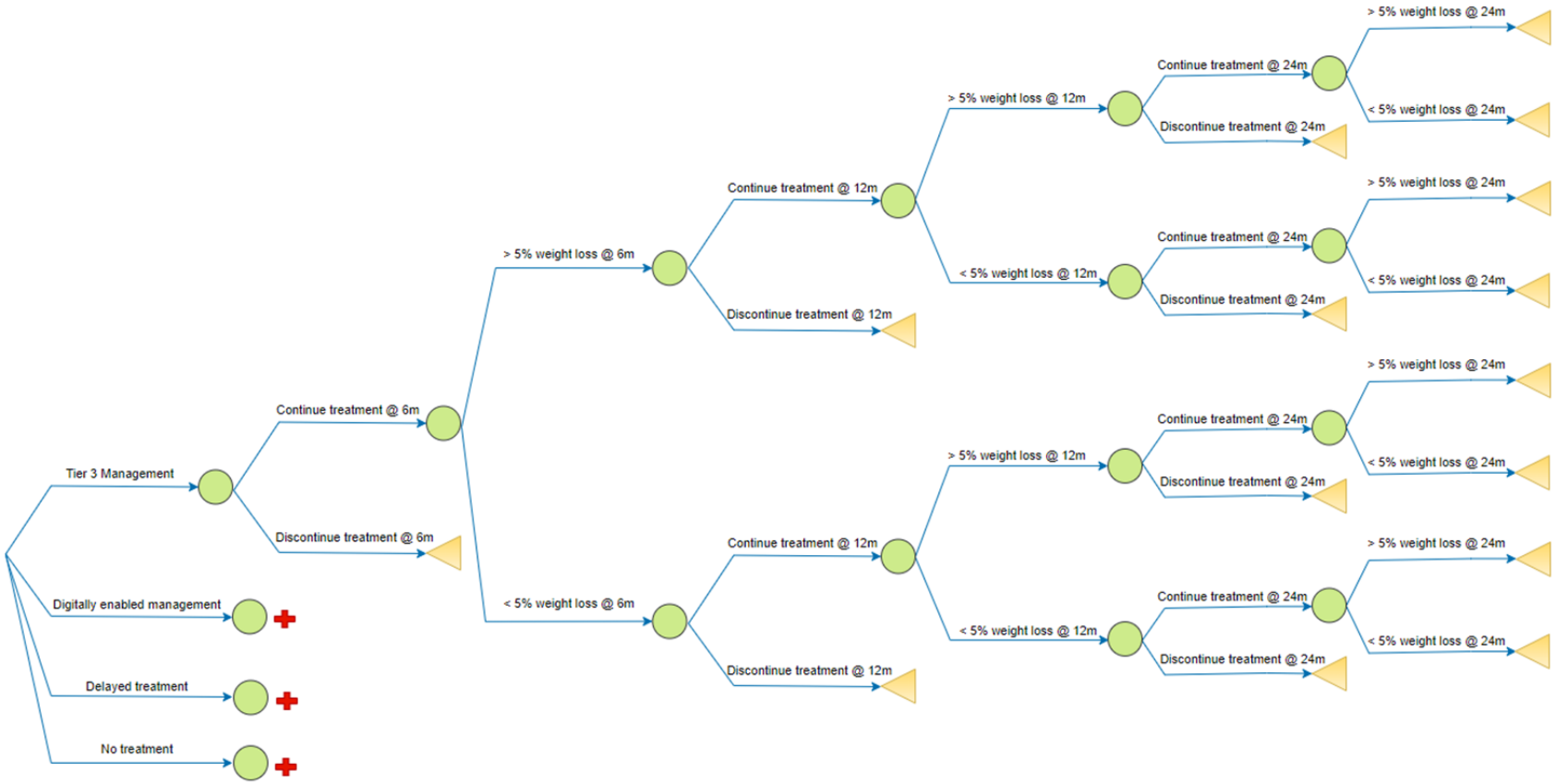
was adapted to include additional comparators relevant to the decision problem.

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).

The model structure (figure 1) consisted of a decision tree to capture short-term treatment outcomes at 6, 12, and 24 months. The model allows people eligible and referred for tier 3 specialist weight management services to receive current standard care (face-to-face specialist weight management services), a digitally enabled weight management programme, delayed treatment (for 6 or 12 months), or no treatment. A time horizon of 24 months was chosen to reflect the length of a typical specialist weight management programme. 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.

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 8.2 of the EAR.

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.

Key parameters

Key parameters in the model were rates of weight loss and discontinuation of treatment. A 5% weight loss was used as the clinically significant level of weight loss. Due to the lack of data for included technologies, the rate of weight loss and treatment discontinuation for Liva and standard care, reported across 2 publications (Hesseldal et al. 2022 and Christensen et al. 2022a) were used in the model. The EAG note that the limitations of these studies are that they were done in Denmark and so may not be fully generalisable to a UK NHS setting.

The key assumptions used were:

- Less than 5% reduction in body weight may include people who had both less than 5% body weight loss and no change in weight
- For the standard treatment and digital technology arms, everyone was assumed to lose weight (i.e., no one remained the same or gained weight) due to limited evidence
- For the no treatment and delayed treatment, up to the point of commencing treatment, everyone was assumed to remain at the same weight (i.e., no one lost weight) due to limited evidence
- An increase in body weight was not modelled due to lack of data available
- Those who discontinue treatment an assumption that the drop out was due to unsuccessful treatment was applied
- For the groups who had delayed treatment, the same proportions as standard care was applied from the point of commencing treatment.

For further information about key model parameters, see section 8.2.3.1 and Tables 8.2 and 8.3 in the EAR.

Costs and resource use

Technology costs

Eleven out of 12 companies provided who provided costs 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 and for the monthly cost of a mobile internet connection to address potential barriers of digital exclusion for every person in the digitally enabled technology arm.

The EAG calculated the cost of standard care (face-to-face specialist weight management services) using advice from clinical experts alongside unit costs from the 2022 Personal Social Services Research Unit (Jones et al., 2022). The cost applied in the model was directly sourced from GID-HTE10007 EVA. For further details on the costs in the model see Table 8.5 of the EAR. The EAG notes that the cost of current Tier 3 weight management services is very uncertain given the heterogeneity of how the services are provided across the NHS.

Table 2: Summary of technology costs provided by companies

	Cheq up	W8Buddy (Gro Health)	W8Buddy+ (Gro Health)	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Juniper	Habitual	Gloji	Weight Loss Clinic	Counter weight
Licence cost per participant per year based on number of participants						£540	£504	£2,456*	£540**	£250-£500			
500													
1,000													
1,500													
<1,000	£1,200	£390	£840										
>1,000	£1,140	£300	£705										
Licence cost based on programme duration													

	Cheq Up	W8Buddy (Gro Health)	W8Buddy+ (Gro Health)	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Juniper	Habitual	Gloji	Weight Loss Clinic	Counter-weight
6 months				£1,000								£70 (3 months = £207)	£920
12 months				£1,200								£920	£1,200
18 months				£1,400									
24 months				£1,600	£900								£1,506
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										

Health state utilities

The EAG calculated a baseline utility using 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). These BMI categories are eligible for Tier 3 weight management services and, therefore, were included for baseline utility calculations. In line with the modelling assumptions applied in GID-HTE10007 EVA, the EAG estimated improvements in utility based on an improvement in weight loss. The utility values used in the model are summarised in Table 8.6 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) and a 6-month delay to standard care. With a longer delay in treatment (12 months), digital technologies become cost incurring but still lead to increased QALYs (ICER of £17,000). When compared to no treatment, digitally enabled technologies are cost incurring but results in increased QALYs with an ICER of £125,000. The EAG noted that the QALYs for no treatment is likely to be overestimated and QALYs for treatment are likely to be underestimated. The EAG noted that there is uncertainty in both the cost and QALY outcomes as long-term outcomes such as associated comorbidities are not included in the analysis.

Table 3: EAG base case results (24 months)

	Total (per person)		Incremental (per person)		NHB	ICER
	Costs	QALYs	Costs	QALYs		
Digital intervention	£1,874	1.543	-	-	-	-
Standard care	£2,342	1.537	-£468	0.006	0.029	Dominant
Delayed standard care (6 months)	£2,298	1.535	-£425	0.008	0.029	Dominant
Delayed standard care (12 months)	£1,735	1.534	£139	0.008	0.001	£16,862
No treatment	£0	1.528	£1,874	0.015	-0.079	£125,259

Additional analyses

The EAG did a number of sensitivity analyses detailed in section 8.3 of the EAR. A 12-month scenario analysis found digital weight management technologies to be cost incurring but with increased QALYs.

5 Ongoing research

The EAG identified 24 ongoing studies (through searches or company submissions) related to 8 out of the 12 included technologies. No ongoing trials were identified for CheqUp, Wellbeing Way, Gloji or Weight Loss Clinic. For more detail about ongoing studies see section 9.3 in the EAR.

6 Evidence gap analysis

The EAG presented a summary of the evidence gaps for prioritised and important 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 based on the current evidence and table 6 listed the evidence gaps that could be addressed by the ongoing research. For more detail on the EAG's evidence gap analysis see section 10, Table 10.1 and Table 10.2 of the EAR and EAR addendum.

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

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper	Weight loss clinic	Counterweight
Prioritised outcomes												
Weight	1 single arm unpublished study AMBER	1 comparative study and 1 single arm study AMBER [redacted] AMBER	1 RCT; 1 comparative study and 1 single arm study AMBER [redacted] AMBER	1 comparative study GREEN 1 RCT but all had Oviva; 3 comparative studies and 12 single arm studies AMBER [redacted] AMBER	3 single arm studies AMBER [redacted] AMBER	1 comparative study and 6 single arm studies AMBER	No studies RED	No studies RED	[redacted] AMBER	2 single-arm unpublished studies AMBER	1 non-randomised comparative study AMBER	3 RCTs AMBER 5 non-comparative studies AMBER
Adherence	1 unpublished study AMBER	1 comparative study and 1 single	1 RCT and 1 single arm study AMBER	1 comparative study GREEN	2 single arm studies	1 single arm study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	2 non-randomised comparative studies	2 RCTs AMBER

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper	Weight loss clinic	Counterweight
		arm study **AMBER**	[redacted] **AMBER**	1 RCT but all had Oviva; 1 comparative study and 6 single arm studies **AMBER** [redacted] **AMBER**	**AMBER**						**AMBER**	5 non-comparative studies **AMBER**
Important outcomes												
BMI	No studies **RED**	No studies **RED**	1 RCT and 1 single arm study **AMBER** [redacted] **AMBER**	1 comparative study **GREEN** 1 single arm study **AMBER**	[redacted] **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	1 non-comparative study **AMBER**

Engagement	[redacted] AMBER	2 single arm studies AMBER [redacted] AMBER	No studies RED	1 RCT but all had Oviva and 3 single arm studies AMBER [redacted] AMBER	No studies RED	1 single arm study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	2 non-comparative studies AMBER
HRQoL	No studies RED	1 single arm study AMBER	1 RCT AMBER	1 single arm study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	1 RCT AMBER 1 non-comparative study AMBER
Psychological outcomes	No studies RED	No studies RED	1 RCT AMBER	1 single arm study AMBER	1 single arm study AMBER [redacted] AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED

Table 6: Evidence gaps that could be addressed by the ongoing research

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper	Weight loss clinic	Counter weight
Prioritised outcomes												
Weight	No studies **RED**	No studies **RED**	1 RCT **AMBER**	1 RCT GREEN 1 comparative study; 1 single arm AMBER	No studies **RED**	1 RCT **AMBER** [redacted] **AMBER**	No studies **RED**	No studies **RED**	1 RCT **AMBER**	3 single arm studies **AMBER**	No studies **RED**	4 RCTs **AMBER** 1 service evaluation **AMBER** 1 non-comparative study **AMBER**
Adherence	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	2 RCT **AMBER** 1 service evaluation **AMBER**
Resource use	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT; 1 comparative study **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**		
Important outcomes												
BMI	No studies	No studies	No studies	No studies	No studies	No studies	No studies	No studies	No studies	3 single arm	No studies	1 RCT

Outcomes	CheqUp	Gro Health	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Gloji	Habitual	Juniper	Weight loss clinic	Counter weight
	RED	**RED**	**RED**	**RED**	**RED**	**RED**	**RED**	**RED**	**RED**	studies **AMBER**	**RED**	**AMBER**
Engagement	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT; 1 comparative study **AMBER**	No studies **RED**	1 RCT **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	2 single arm studies **AMBER**	No studies **RED**	1 service evaluation **AMBER**
HRQoL	No studies **RED**	No studies **RED**	1 RCT **AMBER**	1 RCT **GREEN** 1 comparative study; 1 single arm **AMBER**	No studies **RED**	1 RCT **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT **AMBER**
Psychological outcomes	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	[redacted] **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**

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

- Limited number of randomised or non-randomised comparative evidence with any of the scoped comparators for all included technologies. There was 1 RCT for Liva (versus face to face care), 1 for Oviva (but both arms had Oviva), 3 RCTs identified for Counterweight (face to face versus remote delivery of the technology), and 2 studies for Weight Loss Clinic were non-randomised comparative studies (with face to face care as the comparator).
- The EAG state that there was an inadequate length of follow up across the evidence base (ranging from 1 month to 5 years, but most studies were less than 12 months) given the chronic nature of the condition

Population

- Very few studies focused exclusively on people living with obesity in tier 3 or 4 services
- Only 9 unpublished studies reported outcomes in patients receiving liraglutide or semaglutide [redacted]
- Lack of evidence for how different populations engage with digitally enabled weight management programmes

Intervention

- No evidence was available for Gloji and Wellbeing Way. There was limited evidence for CheqUp, Habitual and Juniper with all evidence for these technologies being unpublished.

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

- There is a lack of evidence reporting a number of prioritised or important outcomes including HRQoL, psychological outcomes, engagement and adherence.

Decision modelling

- Lack of direct economic evaluations related to all of the included technologies. An assessment of the costs associated with standard care are and how it varies between centres would be important to appropriately cost the comparator arm in a future economic model.

Key areas for evidence generation

The key evidence gap is the lack of high quality RCT evidence (or non-randomised comparative data) that matches the scope. The outcomes collected should include those listed as prioritised or important.

The EAG states that a further economic evaluation, with a more comprehensive modelling approach over a lifetime time horizon, is required to fully evaluate the potential of digitally enabled weight management services to be cost-effective. This model should consider the differential rates of developing or worsening comorbidities that changes in weight can have. This could take the form of a cohort-based or patient-level simulation approach depending on available data to inform the relationship between patient history, changes in weight and occurrence of events.

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 and allow flexibility around other commitments due to a lack of need to travel to appointments
- Weight management services should be consistently accessible across the country. They should be person centred and aim to reduce the stigma of body weight and weight management services

8 Comments from healthcare professional organisations

Expert advice was sought from healthcare professional organisations. The following healthcare professional organisation responded:

- British Dietetic Association

Advice was summarised in the following key points:

- There is an unmet need in this population, the number of referrals to current specialist weight management services exceeds capacity. There are parts of the country have no access to specialist weight

management services. People need access to specialist weight management services, with a choice of face-to-face, digital or hybrid.

- People living with severe obesity and severe mental illness or learning difficulties are more likely to struggle with digital technology and are less likely to have access. People from lower socioeconomic background may also struggle to access digital technologies. Some people may not have the privacy to engage with the technologies.
- User fatigue with technologies could happen over time.
- Consideration is needed around how the technologies monitor and report unmet need locally such as disordered eating, social need, community connection and food insecurity
- Consideration is needed around how the technologies will be informed by user feedback and how transparent the reporting process will be as well as how the technologies will share health data within local system
- Consideration is needed around how the technologies will integrate with local care pathways across primary, community and secondary care and mental health

9 Comments from patients

Patient feedback about specialist weight management services (including digitally enabled technologies) was sought via an online survey. A total of 3 responses were received from 2 people who have received specialist weight management services through the NHS, and 1 person who was offered the service, but was unable, or chose not to attend.

For the full responses to the survey please see the Patient survey summary report document.

10 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.

11 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. Clinical experts stated that costs for healthcare professional time for prescribing and monitoring weight management medication would need to be considered when using technologies that do not include prescription and medication management as part of the service.

12 Issues for consideration by the committee

12.1 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.

12.2 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). A total of 53 published studies reported across 76 publications were considered relevant to the decision problem by the EAG. Published evidence for 7 out of the 12 technologies was identified (Oviva [n=19], Second Nature [n=7], Liva [n=4], Gro Health [n=5] and Roczen [n=3], Weight Loss Clinic [n=3] and Counterweight [n=11]). One additional study compared Liva, Oviva and Our Path (now called Second Nature). Twenty-one unpublished studies for 7 out of 12 technologies were provided by companies (Liva [n=6], Oviva [n=6], Habitual [n=3], Juniper [n=2], Roczen [n=2], CheqUp [n=1] and GroHealth [n=1]).
    - There are 4 RCTs for 3 technologies (Liva, Oviva and Counterweight) and 2 non-randomised comparative studies for 1 technology (Weight Loss Clinic).
    - Roczen and Second Nature all have published single arm studies on their technologies
    - There is 1 non-randomised comparative study comparing Liva, Our Path (now called Second Nature) and Oviva
    - The evidence for CheqUp, Habitual and Juniper is unpublished and limited in quality
    - At present there are no peer-reviewed or unpublished studies for Gloji and Wellbeing Way

12.3 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) and a 6-month delay to standard care. With a longer delay in treatment (12 months), digital technologies become cost incurring but still lead to increased QALYs (£17,000 per QALY gained). When compared to no treatment, digitally enabled technologies are cost incurring but results in increased QALYs with an ICER of £125,000. The EAG noted that the QALYs for no treatment is likely to be overestimated and QALYs for treatment are likely to be underestimated. As the evidence base for digitally enabled weight management programmes is limited and uncertain, the results from the early economic analysis should be treated with caution.

10.4 Evidence gap analysis

- Outcomes that potentially need to be prioritised for future evidence generation include engagement, intervention adherence, intervention related adverse events, BMI, weight loss, health-related quality of life (including psychological outcomes), resource use

- The EAG identified several ongoing studies for most interventions. However, only a small number of these studies may partly address the research gaps

13 Authors

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NICE Medical Technologies Evaluation Programme

October 2023

Appendix A: Sources of evidence considered in the preparation of the overview

Details of assessment report:

- Holmes H. et al., Digitally enabled weight management programmes to support weight management medication (alternative service model) [GID-HTE10023] External Assessment Group report, September 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 (CheqUp)
- Gro Health W8Buddy (DDM Health Ltd)
- Liva (Liva)
- Oviva (Oviva)
- Wellbeing Way (Xyla Health and Wellbeing)
- Roczen (Reset Health)
- Second Nature (Second Nature)
- Juniper (Juniper Technologies UK Ltd)
- Habitual (Habitual Health Ltd)
- Gloji (Thrive Tribe)
- Counterweight (Counterweight)
- Weight Loss Clinic (Virtual Health Partners)

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
- Digitally enabled technologies to support treatment with weight-management medication in specialist weight-management services: early value assessment (2023). Available from https://www.nice.org.uk/guidance/indevelopment/gid-hte10007/

References

Please see external assessment report for full list of references.

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence

Early value Assessment

Early Value Assessment: Digitally enabled weight management programmes to support treatment with weight management medication (alternative service model): (Provisional Title)

Professional organisation submission

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 13 pages.

NICE National Institute for Health and Care Excellence

About you

1. Your name	Deepti Loomba
2. Name of organisation	British Dietetic Association (BDA)
3. Job title or position	Obesity Specialist Dietitian in Primary Care and BDA Obesity Specialist Group Consultation Officer
4. Are you (please select Yes or No):	An employee or representative of a healthcare professional organisation that represents clinicians? Yes A specialist in the treatment of people with this condition? Yes A specialist in the clinical evidence base for this condition or technology? No Other (please specify): representative of BDA representing dietitians with expertise in obesity.
5a. Brief description of the organisation (including who funds it).	The British Dietetic Association (BDA) is the only body in the UK representing the whole of the dietetic workforce. We are a trade union and professional body representing the professional, educational, public and workplace interests of our members.
5b. Has the organisation received any funding from any company with a technology included in the evaluation in the last 12 months? [Please refer to the final scope for a full list of technologies included.] **If so, please state the name of company, amount, and purpose of funding.**	No
5c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

Unmet need

6. In your view, is there an unmet need for people with obesity who are eligible for treatment in specialist weight management services (tier 3 or tier 4)	Yes, the number of referrals to current specialist weight management services exceeds capacity. This results in very long waiting lists, or in some circumstances, specialist weight management services have closed to new referrals. In addition, parts of the country have no access to specialist weight management services.
7. Do you consider digitally enabled weight management technologies to be innovative and how might the technology improve the way that current need is met? This can relate to the technology or specific technologies included in the scope.	Yes, digitally enabled weight management services are innovative. They may help improve access to services, reducing face to face appointments and the need to travel. The technologies must be supported by specialist healthcare professionals skilled in obesity management. Patients must be able to access and use the technology and also have a safe, confidential space in which to use it.

What is the expected place of the technology in current practice?

8a. Are any relevant clinical guidelines we should be aware of, and if so, which?	NICE Clinical Guidelines 189 Obesity
8b. What impact would the technology have on current care in the NHS? Consider differences in	It could reduce the need for patients to travel for face-to-face appointments, although many current services are now carrying out a mixture of face to face and virtual consultations, for both individual and group settings. There will still be the need to have measurements weight, blood pressure, blood tests such as thyroid function, HbA1c, lipids, haematinics and vitamin D. Specialist weight management requires a holistic approach, and

the care pathway, how it is used, who can access it and resource use.	patients with severe obesity have many complex issues. Therefore, patients will need to be assessed by a specialist dietitian and an obesity physician and receive ongoing care as a minimum in tier 3, and a specialist dietitian and bariatric surgeon is tier 4. Many people living with obesity are living in low socioeconomic areas. Not all have access to smartphones, tablets, laptops or the internet. They may not have the privacy in their home to have confidential access to technology. The technology could improve access; however, it could have a negative impact on care if support is from non-healthcare professionals, or non-specialist healthcare professionals. The specialist weight management services (tier 3) and bariatric surgery services (tier 4) in most parts of the country are separate services. The tier 3 will have an obesity physician and specialist dietitian and it is in this service that medications such as GPL-1 would be considered, initiated and monitored. The tier 4 service is a bariatric surgery service with a bariatric surgeon and specialist dietitian, with the focus is on preparation for surgery, surgery and two-year follow-up. It would be unusual for GPL-1 to be considered or needed in the service, unless there is a long waiting list for surgery. These two services seemed to be grouped together for this guidance, however, the draft guidance applies to tier 3 services.
9. What investment is needed to introduce the technology into the NHS? (For example, for facilities, equipment, or training.)	Investment in healthcare professionals for specialist weight management services is needed – specialist dietitian, obesity physician, psychologist. For those healthcare professionals new to specialist weight management, training will be required. Patients may require access to smartphones, tablets and the internet and training to use the technology. Patients also need access to a confidential area in which to have a consultation or use the technology.
10. Do you expect the technology to provide clinically meaningful benefits compared with current care?	Based on the information given, it is difficult to determine this. Although it is noted by the clinical experts that the multidisciplinary teams can vary significantly between weight management programmes in current care, all specialist weight management teams must have a specialist dietitian as a core member of the team. The specialist dietitian has a pivotal role in the full clinical assessment and in the multidisciplinary team decisions regarding appropriate treatment options including medication and whether onward referral to a psychologist is required. The specialist dietitian undertakes a nutrition and dietetic

	assessment, including the patient's current nutritional status, which is key before commencing an energy restricted diet. Deficiencies of iron, folate, vitamin B12 and vitamin D are frequently found in people living with obesity. Dietitians are the only healthcare professionals, regulated by law, with specialist skills in identifying and managing malnutrition, which is important to consider when people are on restricted diets. This is particularly important as people on GLP-1 receptor agonists (GLP-1 RA) can have gastrointestinal side effects resulting in nausea and sickness. Obesity is a complex condition which requires specialist dietetic support, and the key role of a specialist dietitian in specialist weight management services appears to have been overlooked. There is no mention of dietitian involvement when discussing digital interventions involving GLP-1 RAs. As these drugs for obesity at higher doses are new, trials so far have not examined malnutrition risk or nutritional factors. They have very much focused on efficacy in terms of weight change, glycaemic improvement, quality of life and CVD risk to prove cost-effectiveness. Figure S3 (p. 30) of the supplement to: Wilding JPH, Batterham RL, Calanna S, et al. Once-weekly semaglutide in adults with overweight or obesity. N Engl J Med 2021;384:989-1002. DOI: 10.1056/NEJMoa2032183 clearly shows there is significant variation in weight loss response, with patients on the left of the curve who have an 'over-response' to treatment and lose a vast amount of weight; and very likely to be at high risk of malnutrition. Consequently, patients will require direct access to dietitians and ongoing support, to aid improvement in eating behaviours, and ensure that the patient is able to consume a nutritionally balanced diet without risk of developing malnutrition or nutritional deficiencies. Visual assessment and nutritional blood tests may form an important part of follow-up with the medications. In addition to those that do not response, there is a need to help these individuals manage their dietary and lifestyle changes. In standard care, dietitians are core members of specialist weight management teams, with patients having direct access to dietitians and receiving ongoing assessment, monitoring and support. It is not clear whether these four providers will provide patients with direct access to a dietitian and ongoing dietetic support. There is no mention of dietitian in the recommendations, and this is of concern, given the important role of dietitians in this specialist area. No other team member or health trainer can undertake this role. Are the four providers planning to provide direct access to dietitians? Currently, the technology is being linked to the roll out of the medications but without any consideration that some people will not want to take the medications or may not be able to because of contraindications and thus alternative services are still going to be required to help support these individuals.

	There is little detail about the dietary guidance that the four providers promote. Currently none of the evidence has looked at how accessible the different dietary approaches are to people from a diversity of socioeconomic background and for people living with food insecurity. The evidence summarised of the diet quality is very limited of those participating in the four providers' programmes. How will nutritional deficiencies be detected, monitored and corrected? There is no information provided on the commissioning costs of the four providers. We assume that the patients will not pay for support alongside the medication. There is no information regarding: • The length of time someone will be prescribed the medication. • The length of time patients will be receiving support alongside the medication. • How many patients will have access to the support in total? Will it be everyone who requires access to specialist services or is it just going to increase the postcode lottery? • What support will be offered after the medication has been stopped, given that the evidence to date shows significant weight regain as soon as the medication is stopped? • What are the plans to ensure ongoing support is provided to prevent weight regain? Much of the evidence has focussed on comparison with standard care however, it is acknowledged that standard care varies nationally with some areas having no access and thus the cost will also vary considerably. For cost-effectiveness, the focus is on efficacy in terms of weight change and cardiovascular disease risk etc; however, the risk of malnutrition and nutritional deficiencies also needs to be considered. Will this be factored into the evidence collection?
11. Will the technology be easier or more difficult to use for patients or healthcare professionals than current care? Are	There is recognition that not everyone will have the ability (or desire) to use digital technology. We are pleased to see that some provision for those with digital poverty has been considered, with the suggestion that the NHS provide tablets and monthly internet access. However, there is a lack of clarity about how would this work in practice. If this is being considered for this project, would patients in standard care also be provided with these resources if needed, in recognition of equality?

there any practical implications for its use (for example, additional clinical requirements, factors affecting patient acceptability or ease of use or additional tests or monitoring needed.)	Currently, the technology is being linked to the roll out of the medications but without any consideration that some people will not want to take the medications or may not be able to because of contraindications and thus alternative services are still going to be required. There will still be a need for ongoing monitoring various parameters including patients' weights, blood pressure, lipids, and nutritional blood tests. In primary care, the Advanced Dietetic Practitioner would be particularly well placed to act as the gate-keeper and monitor in primary care. Referrals to non-NHS providers have traditionally been viewed as partnerships with the healthcare professional having the pivotal role in ensuring the patient is receiving the appropriate complementary support, and indeed the 12-week programme model was initially designed to ensure that the patient then touched based with a suitably qualified healthcare professional. This will be important in this pathway given that if the person does lose a significant amount of weight, other medications may need to be reduced. It is not clear currently how this is going to be manage. Consideration needs to be given to the following: • How the technologies monitor and report unmet need locally e.g. disordered eating, social need, community connection, food insecurity • How the technologies will share health data within local system • How the technologies will be informed by user feedback and how transparent the reporting process will be • How companies will share internal performance in terms of workforce competencies, turnover, satisfaction and reported safety of caseloads etc. • How the technologies will integrate with local care pathways across primary, community and secondary care and mental health

12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population?	People living with severe obesity and severe mental illness or learning difficulties are more likely to struggle with digital technology and are less likely to have access.

13. Are there any risks, side effects or adverse effects associated with the technology and how do they affect the patient's quality of life?	People, especially those in lower socioeconomic areas, may be more likely to struggle with technology or be able to access it. There may be user fatigue with technology over time. Some people have difficult personal circumstances making it difficult to access technology or have a conversation in a private and confidential area. Non-verbal cues may be more difficult to pick up.

Sources of evidence

14. Are you aware of any relevant evidence that might not be found by a systematic review of the evidence?	We note the scope of the assessment in Table 1 of the final scope document; however, the research questions are difficult to find and appear to be in Table 33 of the assessment report. It, therefore, is difficult to determine if all relevant evidence has been considered. There is no mention of nutritional assessment or nutritional status of patients in the outcomes. Eating habits are mentioned in outcomes but appear to be related to fruit and vegetable intake (page 65 in the assessment document), rather than habits such as meal patterns, snacking, and emotional eating. The interventions considered are "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". It appears that only one of the four providers has any evidence of

	working with patients who have been referred for weight management medication. Hence it is unclear as to why the other three providers are being considered. Given that it appears evidence of working with weight management medication does not appear to be essential, we would like to enquire the reason other commercial weight management companies, such as Slimming World and Counterweight, who have published evidence of supporting people with severe and complex obesity through their online programmes, have not been considered. The evidence considered (from the four providers) does not include any data beyond 12 month follow up and therefore does not adequately demonstrate effectiveness of weight loss maintenance. There is little detail about the dietary guidance that the four providers promote. Currently none of the evidence has looked at how accessible the different dietary approaches are to people from a diversity of socioeconomic backgrounds.

Equality

15a. Are there any potential equality issues that should be taken into account when considering this treatment?	Yes, people from lower socioeconomic classes, or with severe mental illness or learning difficulties may be disadvantaged. Investing in preventative services to reduce the risk of people developing severe obesity is also important, to prevent people moving up the BMI weight categories as well as looking after those people who are a healthy weight.
15b. Consider whether these issues are different from issues with current care and why.	In current care, some of these patients in these groups may benefit from face-to-face consultations, and attending with family members or support workers. Longer consultation times are often required, with liaison with their wider healthcare teams or support networks.

In up to 5 bullet points, please summarise the key messages of your submission.	• Specialist weight management services have specialist dietitians as core members of their multidisciplinary teams, and this appears to have been overlooked in the draft guidance • People with obesity who have the newer medications require access to a specialist dietitian to assess and monitor nutritional status, eating behaviours, diet quality and appropriate rates of weight loss, and prevent and address nutritional deficiencies. Dietitians are the only regulated healthcare professionals with specialist skills in identifying and managing malnutrition, which is important to consider when people are on restricted diets or these medications. • People with obesity require access to specialist weight management services, with a choice of face-to-face, digital or hybrid. • Investment in current specialist weight management services is needed. • There must be consideration to collecting data on nutritional parameters and both total weight loss and rate of weight loss so that the impact of new medications on nutritional status can be assessed.

Thank you for your time.

Please log in to your NICE Docs account to upload your completed submission.

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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	Eoin.mcginley@live.co.uk
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. 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
4. 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.
5. ONS (2019) Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/releases/exploringtheuksdigitaldivide (Accessed: 28th June 2023).
6. 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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Impact of the symptoms, condition or disease	
1.	**How do symptoms and/or the condition or disease affect people's lives or experiences?** 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.
2.	**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.
3.	**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 without 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

6. 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

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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

7. 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
-

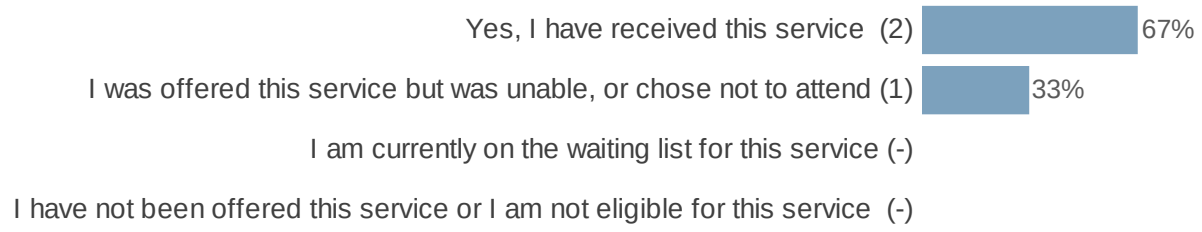
Thank you for your time. Please return your completed submission to helen.crosbie@nice.org.uk and medtech@nice.org.uk

Digitally enabled weight management programmes for specialist weight management

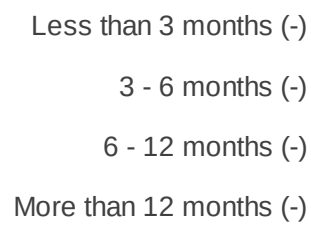
This report was generated on 14/09/23. Overall 3 respondents completed this questionnaire. The report has been filtered to show the responses for 'All Respondents'. A total of 3 cases fall into this category.

The following charts are restricted to the top 12 codes. Lists are restricted to the most recent 100 rows.

Have you received, or previously been offered, specialist weight management services as a treatment option by the NHS?



How long have you been on the waiting list for this service?



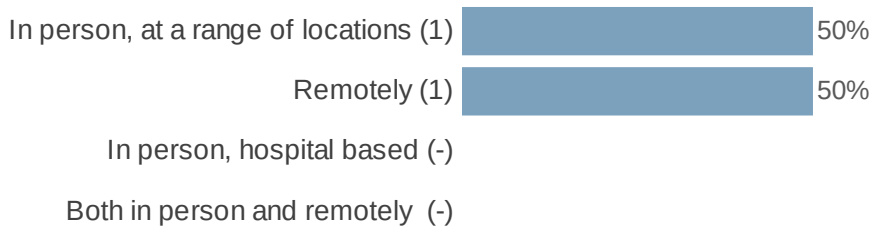
Please explain why you were unable, or chose not to attend this service?

Because it was an inappropriate referral from a consultant who failed to listen to me and treated me based on his prejudices about my size. Plus the evidence shows that most weight loss attempts fail over the long term and can cause a lot of damage so I was stunned the NHS is still recommending it instead of taking a Healthy at Every Size approach.

Please describe the impact of obesity on your life and your experience of treatment for weight management in the NHS

The impact of obesity on my life was that in the end, I was diagnosed with Type 2 Diabetes, which profoundly affected all areas of my life - My experience of my treatment initially on being diagnosed was to take Metformin and hope I could control my HbA1C - Which to a certain extend I did, but this was all in vain as I needed to lose weight to truly have an impact here - On receiving info about the Oviva Remission Program, I took part, lost 21Kg of weight, learnt lots of new things, felt happier and more energetic than I'd been for years, needed an entire new wardrobe, started walking, then running, and have since joined a running club and entered into running races incl. Parkrun! - Couldn't be happier!
The main impact is weight stigma, prejudice and being treated poorly by health professionals who make assumptions about me based on my size. Also dieting has harmed my relationship with food which has taken a long time to unpick. If we could eliminate weight stigma, my size would have no negative impact on my life at all.
Prevented much needed surgery and affected my life since 8 years old

Which of the following best describes how you are, or have, accessed specialist weight management services?



Access to the service

Access was via the Oviva App - Very straightforward and easy to understand
Too easy - I had to go private to receive the actual treatment I needed after the NHS consultant tried to blame the treatable condition that was making me gain weight on the fact that I'd gained weight. I explained that I'd started to feel unwell before I gained weight but he just scoffed at me like I didn't know what I was talking about - it was a mortifying experience.
Was via a self referral online system on recommendation of HCP. In person access was in a local community centre room which wasn't fit for purpose at all, no windows, no air, dirty and dark.

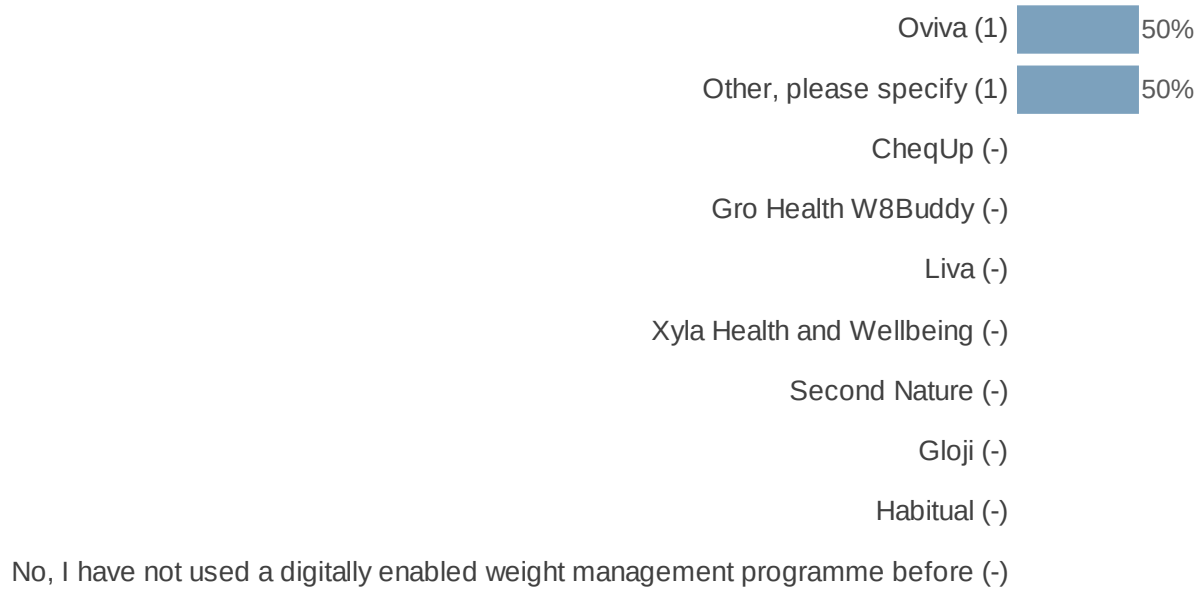
Length of treatment

12 Months
N/A
12 week programme

Quality of the service provided

Great
How can it be a quality service when the long-term outcomes are so poor and the unintended harms so dangerous?
Shocking - no tailored personalised care, group weigh in and everyone at different stages so no group in it together feeling.

You told us that you have accessed some weight management services remotely. Have you used any digitally enabled weight management technologies listed below as part of your specialist weight management programme? Please tick all that apply.



Please specify:

My fitness pal

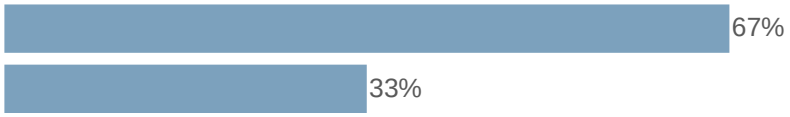
Please describe your experience of accessing digitally enabled weight management technologies

There's too much to write here, but... I had to read between the lines as to how I was going to move forward for the rest of my life without the support after the 12 months was complete... I had to find my own ways of learning how to eat - all from scratch - there was lots of help, but I had to pick the parts which suited me - I found these new ways, however...it's important for people to understand it's their life not Oviva - it's what fits in with you as opposed to what someone is telling you to do - I found the service great, but for a lot of people, I can see that they will only follow the process and not really think about what's good for them - so once the 12 months is complete, i can see if you're not mindful, it could be back to square on in a few months... I'm over 2 years in Remission and I haven't gained weight - I intend this to be the case for many years to come - it's a lifestyle change not a quick fix...

I lost weight then maintained my weight over the first 3 years but then started gaining weight, becoming obsessed with high calorie foods that I previously wasn't interested in and found the constant monitoring of food completely exhausting. I ended up heavier than ever. Now I'm deeply suspicious of any weight loss intervention that stops monitoring before 5 years because it wasn't until year 4 and 5 that the harm became clear. I'm positive I'd be a lower weight now if I'd never tried dieting. I followed all the NHS and high-quality advice I could find, losing weight slowly and it utterly failed me.

Access easy but needs a personalised approach. Nothing around that is tailored to me and my obesity issue.

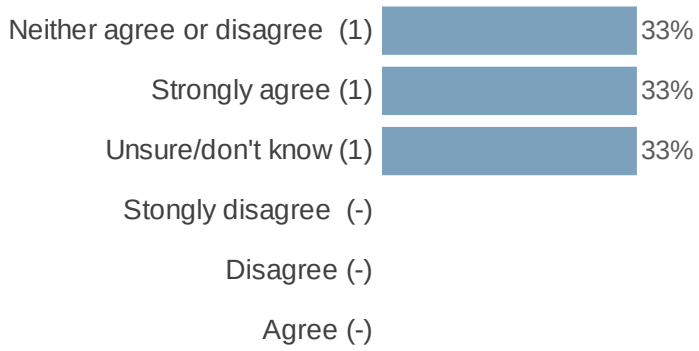
Which of the following best describes your preferred way to access specialist weight management programmes?



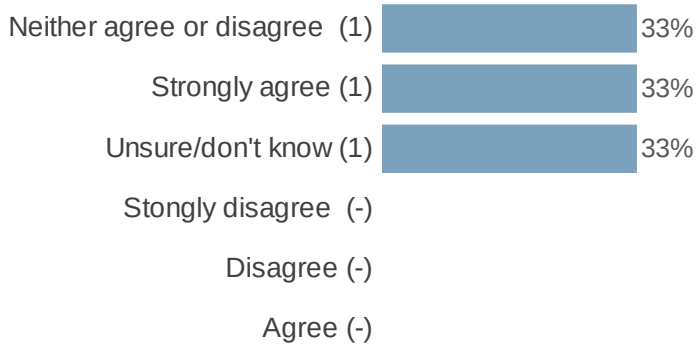
Why do you say that?

I embrace the remote digital technologies wholeheartedly, however it's important to have people check-ins too - I still visit my Diabetic Nurse every 6 months for a check-up, I find these on-going checks useful, so although remote is great and it worked for me, it still needs the human element so to speak...
They’re all dangerously bad, please do a proper review about the harms of weight stigma, weight cycling and eating disorders caused by weight management services.
Either way the issue isn’t digital or f2f it is personalised care that is needed.

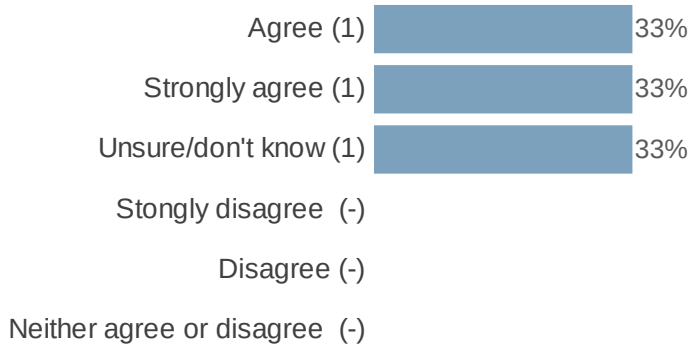
To what extent do you agree or disagree the following statements (You may use the back button to review the information provided about digital weight management services if needed)
(If standard care delivery weight management services were not available in my area, I would consider a digitally enabled programme)



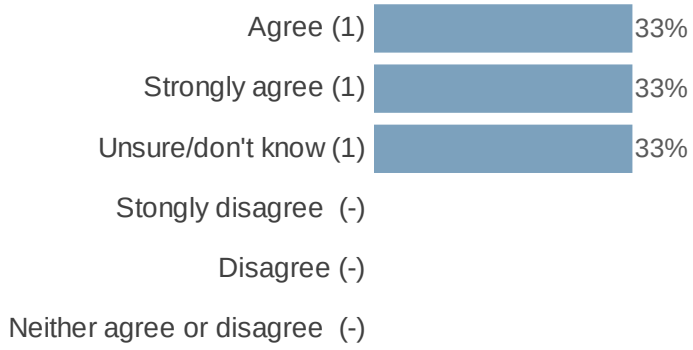
To what extent do you agree or disagree the following statements (You may use the back button to review the information provided about digital weight management services if needed)
(If there was a wait list to attend standard care delivery weight management services, I would consider a digitally enabled programme)



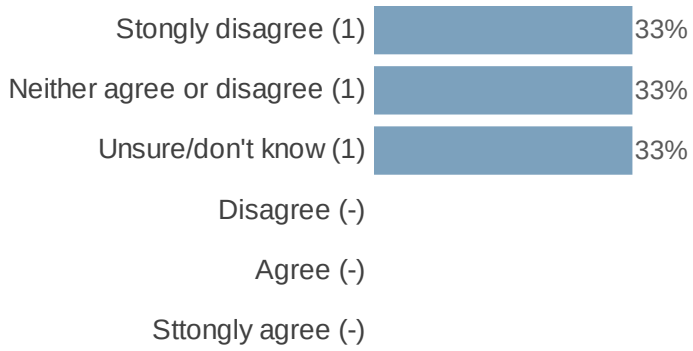
To what extent do you agree or disagree the following statements (You may use the back button to review the information provided about digital weight management services if needed)
(If it supported faster access to weight management medication than standard care, I would consider a digitally enabled programme)



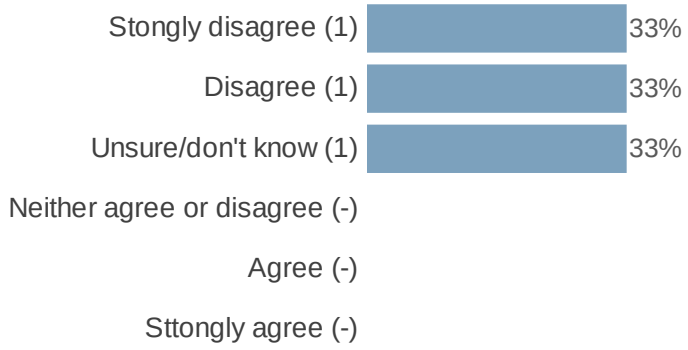
To what extent do you agree or disagree the following statements (You may use the back button to review the information provided about digital weight management services if needed)
(The flexibility of being able to access weight management services remotely (not at in person appointments) appeals to me)



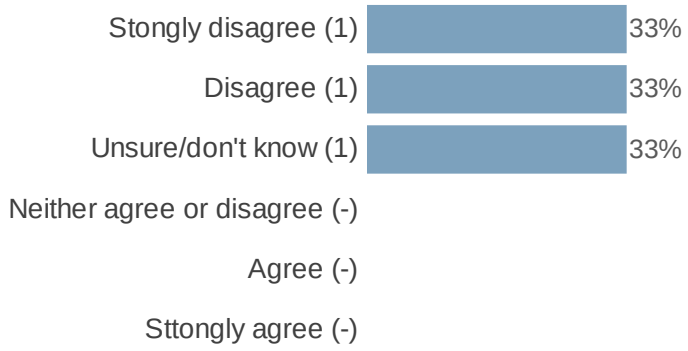
To what extent do you agree or disagree the following statements (You may use the back button to review the information provided about digital weight management services if needed) (I would be concerned about the quality of clinical support provided by a digitally enabled programme)



To what extent do you agree or disagree the following statements (You may use the back button to review the information provided about digital weight management services if needed) (I would be concerned with data security when sharing personal information within a digitally weight management enabled programme)



To what extent do you agree or disagree the following statements (You may use the back button to review the information provided about digital weight management services if needed) (I would be concerned about how medication management (e.g. monitoring and reporting side-effects) would be facilitated within a digitally enabled weight management programme)



If there is anything else you would like to share about your views and experience of weight management programmes, please use the box below

The program I completed, was a total turnaround to what was offered previously (Namely Metformin!) - I know have some understanding of what food is, and what I should eat at any given time, it's been a great help- saved my life really, but there are potential issues if care isn't taken to make sure people understand it's a 'lifelong change of lifestyle' as opposed to a quick fix - there's no quick fix here...
There’s a desperate need for an in depth review into the harms caused by these programmes and a move to a Heath at Every Size approach. I’ve recently got much fitter as a result of physio to address an injury where I really appreciated a weight-neutral approach. I’m much more motivated by feeling stronger than I am by trying to manage my weight which is influenced by 100s of factors, and the evidence shows I’m not the only one. Some examples of the evidence I mentioned: https://escholarship.org/uc/item/2811g3r3 https://www.cell.com/iscience/fulltext/S2589-0042(21)00963-9 https://doi.org/10.1186/1475-2891-9-30
So much money is being spent on weight management and it is clearly not working, it is a multi facetted issue and different for all without treatment pathways led by those who access services co producing personalised care ways to help we will just keep going round and round. Obesity is a sugar addiction result and until it is seen as such it won't be properly addressed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

124th MTAC meeting – Friday 06 October 2023

DECLARATIONS OF INTEREST – MTAC 06 October 2023

Declaration of interests register

Medical Technologies Advisory Committee **Publication Date: 04 January 2024**

Topic: GID-HTE10023 Digitally enabled weight management programmes to support treatment with weight management medication: alternative service model

Name	Role with NICE	Type of interest	Description of interest	Relevant dates			Comments
				Interest arose	Interest declared	Interest ceased	
Dr Andrew Currie	Specialist Committee member	*Non-financial professional*	*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*	*July 2023*	*April 2020*	No action other than open declaration
Mrs Irena Cruickshank	Specialist Committee member	*Nil*	*n/a*	*n/a*	*n/a*	*n/a*	No action
Dr Jennifer James	Specialist Committee Member	*Nil*	*n/a*	*n/a*	*n/a*	*n/a*	No action
Dr Karen Coulman	Specialist Committee Member	*Indirect - financial*	*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*	*March 2021*	*July 2023*	*December 2021*	No action other than open declaration

			academic role at the University of Bristol. The fee for this work (approx. £500 was charged and paid to me through the University of Bristol)				
		Indirect - professional	*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*	*July 2023*	*Ongoing*	No action other than open declaration
			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. (https://www.endocrinology.org/clinical-practice/research-projects/national-obesity-database/)	*March 2021*	*July 2023*	*Ongoing*	No action other than open declaration
			I undertake research funded through a Health Education England/National Institute for Health Research (HEE/NIHR) Clinical Lectureship Award:	*April 2019*	*July 2023*	*Ongoing*	No action other than open declaration

			"Understanding barriers to referral for specialist weight management services and bariatric surgery and identifying ways to improve access".				
			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*	*July 2023*	*Ongoing*	No action other than open declaration
Dr Helen Parretti	Professional expert	*Direct-financial*	*Member of current NICE committee for weight management guidelines (update)*	*2021*	*July 2023*	*Ongoing*	No action other than open declaration
		Direct-financial	*Member of working group funded by Novo Nordisk educational grant developing an algorithm for the management of obesity in primary care published in Guidelines*	*2020*	*July 2023*	*2021*	No action other than open declaration
		Direct-financial	*Organised and delivered an educational webinar on MDT Exploration of Medically Unexplained Bariatric Complications for the British Obesity and Metabolic Surgery Society, supported by Johnson & Johnson – honorarium received*	*2021*	*July 2023*	*2021*	No action other than open declaration
		Direct-financial	*Worked at Fakenham Weight Management Service, which has now been recommissioned and is now working for OneNorwich*	*2022*	*July 2023*	*Ongoing*	No action other than open declaration

			Practices in Weight Intervention Norwich				
		Direct-financial	*Expenses paid to attend an event on setmelanotide by Rhythm Pharmaceuticals*	*2022*	*July 2023*	*2022*	No action other than open declaration
Dr Laura Power	Specialist Committee Member	*Nil*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*
Dr Jessica Munafi	Specialist Committee Member	*Direct-financial*	*Private practice (individual therapy/group work), some of which involves working with people on their weight management goals*	*2011*	*October 2023*	*Ongoing*	No action other than open declaration
Mrs Rebecca Fahey	Specialist Committee Member	*Direct-financial*	*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*	*July 2023*	*Ongoing*	No action other than open declaration
Ms Sarah Le Brocq	Lay Specialist Committee member	*Indirect-financial*	*Honorarium for presentations – Novo Nordisk*	*2018*	*July 2023*	*2023*	No action other than open declaration
		Indirect-financial	*Hosting of podcast series – J&J*	*2020*	*July 2023*	*2020*	No action other than open declaration
		Non-financial professional	*Director of All About Obesity*	*2020*	*July 2023*	*Ongoing*	No action other than open declaration
		Non-financial professional	*Trustee of ASO*	*2021*	*July 2023*	*Ongoing*	No action other than open declaration
		Non-financial professional	*Member of National Obesity Audit*	*2022*	*July 2023*	*Ongoing*	No action other than open declaration
		Non-financial professional	*Strategic Council Member – APPG Obesity*	*2020*	*July 2023*	*Ongoing*	No action other than open declaration
Richard Cordes	Lay/Patient expert	*Nil*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*