Document cover sheet

Assessment report: GID-HTE10023 Digitally enabled weight management programmes

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Economic evidence reviewer: N/A

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<br>J Patterson<br>R McCool<br>S Woods<br>A Varghese | 04/09/23 | 04/09/23 |
| 2.0 | Amendments in light of NICE comments | J Patterson<br>S Woods<br>A Varghese<br>R McCool | 18/09/23 | 18/09/23 |
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# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Early Value Assessment

## GID-HTE10023 Digitally enabled weight management programmes

## External Assessment Group report

Produced by: York Health Economics Consortium

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Date completed: 18/09/2023

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.


## Acknowledgements

Dr Karen Coulman, HEE/NIHR Clinical Lecturer (Research Fellow), University of Bristol and North Bristol NHS Trust




## 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:<br>• CheqUp (CheqUp)<br>• Gro Health W8Buddy (DDM Health Ltd)<br>• Liva UK (Liva UK)<br>• Oviva (Oviva)<br>• Second Nature (Second Nature)<br>• Roczen (Reset Health)<br>• Xyla Health and Wellbeing (Xyla Health and Wellbeing)<br>Additional technologies identified August 2023:<br>• Gloji (Thrive Tribe)<br>• Habitual (Habitual Health Ltd)<br>• 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:<br>• specialist weight management services (including tier 3 and 4; face-to-face, remote or hybrid)<br>• no treatment or waiting list | Single arm studies without comparators included but coded **AMBER** |
| **Outcomes** | Outcome measured to be prioritised are:<br>• Change in weight<br>• Intervention adherence, rates of attrition (dropouts) and completion<br>• Intervention-related adverse events (including how they are monitored and reported within each programme)<br>• 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)<br>Other important outcomes include:<br>• Change in body mass index (BMI)<br>• Programme engagement<br>• Health-related quality of life<br>• Patient experience and acceptability<br>• Psychological outcomes<br>• | |
| **Cost analysis** | Costs will be considered from an NHS and Person Social Services perspective. Costs for consideration may include:<br>• Cost of the technologies<br>• Cost of other resource use (e.g., associated with managing obesity, adverse events, or complications):<br>o GP or secondary care appointments<br>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.<br>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** | 3 single arm studies plus one non-randomised comparative study | [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]

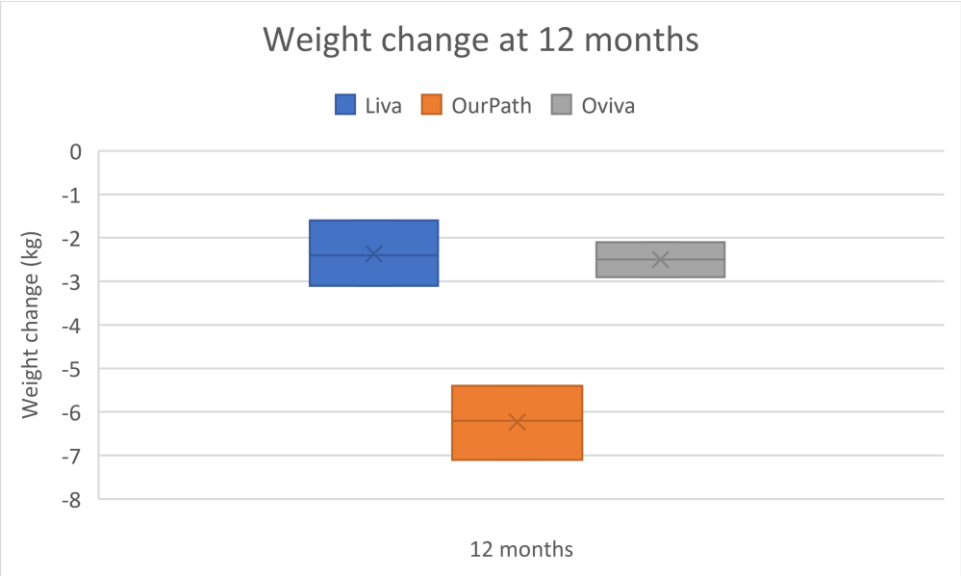
**Table 5.5. Outcomes by technology**

| | **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 | x |
| 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 three single arm studies reporting mental health outcomes, one reported improvements in depression and anxiety (Roczen), and one reported improvements in depression (Oviva); the other 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<br>• No treatment |

| | |
|---|---|
| | • Delayed treatment |
| Outcomes | • Incremental costs<br>• 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.

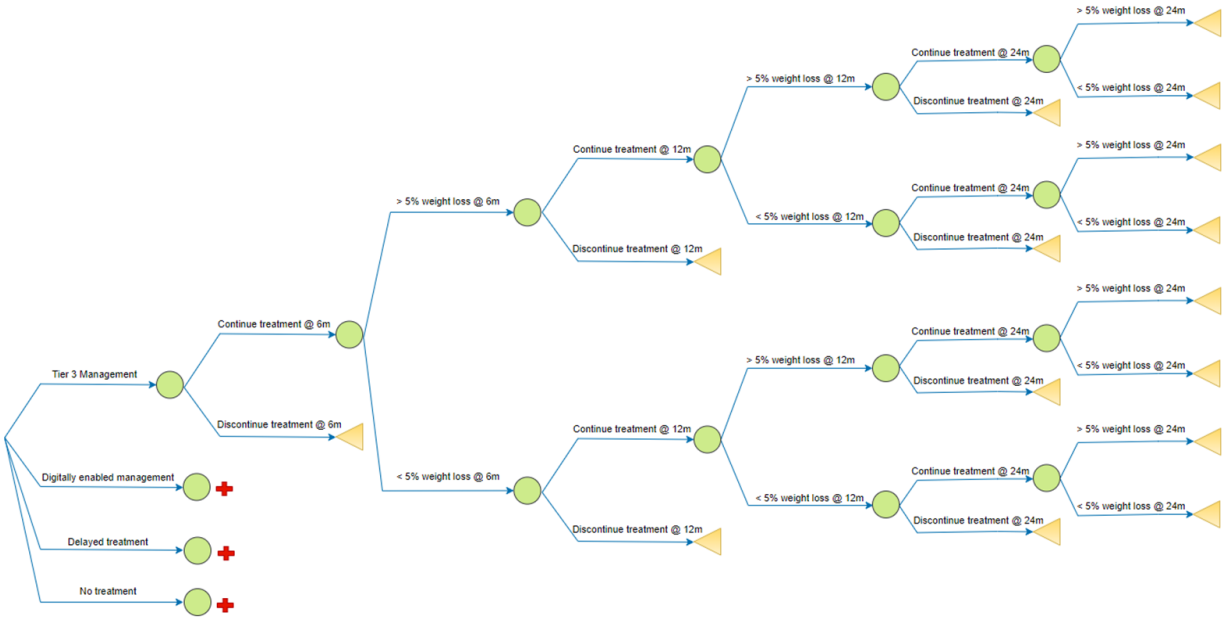
The model structure consisted of a decision tree to capture short-term treatment outcomes at 6, 12, and 24 months. The key clinical outcome was weight loss greater than or less than 5% of the body weight. At each time point the patient could either continue or discontinue treatment, and those who continue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

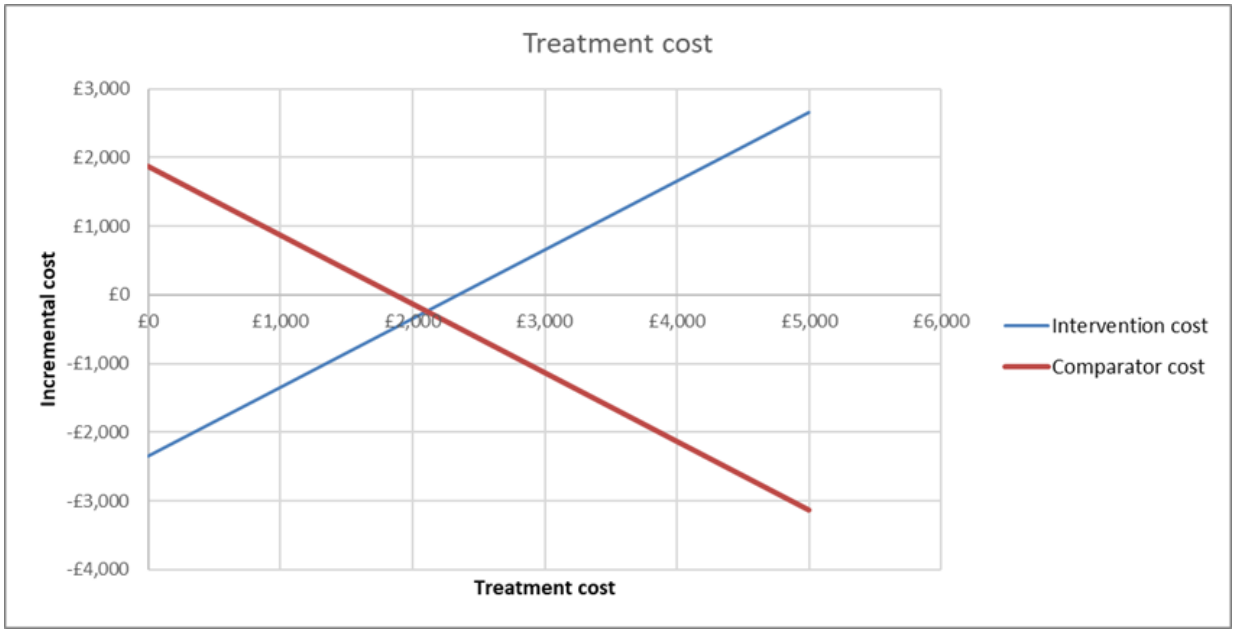


**Table 8.7: Base case results (24 months)**

| | 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)<br>RCT: NCT04880005<br>Last Update Posted: May 10, 2021<br>Sponsor: University of Southern Denmark<br>Denmark | **Participants**: T2DM **AMBER (not stated to have overweight/obesity)**<br>**Intervention**: Liva for participants plus decision support tool for doctors and integrating patient registered outcomes to GP record **AMBER (not stated to have MDT)**<br>**Comparator:** Usual care **GREEN**<br>**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**<br>**Setting**: General practice **AMBER (not tier 3/4)** | None | December 30, 2024 |
| Oviva (Oviva) | | | |
| The DR-EAM Type 2 Diabetes Study<br>Single arm study: NCT05626842<br>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**<br>**Intervention**: Total Diet Replacement (800kcal/day). The intervention will be led by Diabetes Specialist Dietitians | None | September 30, 2023 |

| | | | |
|---|---|---|---|
| Sponsor: Oviva UK Ltd<br>UK | (DSD) via the Oviva app, telephone, or video calls. **AMBER (not stated to have MDT)**<br>**Comparator:** None **AMBER (no comparator)**<br>**Outcomes:** HbA1c, weight, lipids, BP, physical activity, QoL, participant experience **GREEN**<br>**Setting**: GP Practices **AMBER (not tier 3/4)** | | |
| The Transform Type 2 Diabetes Study (Transform)<br>Non-randomised controlled trial: NCT05648903<br>Last Update Posted: December 13, 2022<br>Sponsor: Oviva UK Ltd<br>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)**<br>**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)**<br>**Comparator:** As above but group not one to one; support through video group sessions not Oviva app **GREEN**<br>**Outcomes:** HbA1c, weight, lipids, BP, NHS resource use including medication cost; QoL; diabetes remission; acceptability, motivations and preferences; engagement with the programme **GREEN**<br>**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)<br>RCT: NCT04674384<br>Last Update Posted: May 10, 2023<br>Sponsor: Manchester University NHS Foundation Trust | **Participants**: 12 patients with type 1 diabetes and obesity **GREEN**<br>**Intervention**: Both groups had Oviva **GREEN**<br>**Comparator:** Intermittent Low Energy Diet (ILED) versus Continuous Low Energy Diet (CLED) **AMBER (no non-Oviva comparator)**<br>**Outcomes:** Glucose monitoring; adverse events; adherence; diet; engagement; satisfaction; MDT and dietitian resource use **GREEN**<br>**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<br>RCT: DRKS00025291<br>Last update in DRKS:<br>18 August 2022<br>Sponsor: Oviva<br>Germany | **Participants**: 168 people with BMI 30–40 kg/m$^2$ **GREEN**<br>**Intervention**: Oviva (app-based lifestyle intervention for 12 weeks, followed by 12 weeks of follow-up) **GREEN**<br>**Comparator:** delayed start of Oviva (current lifestyle for 12 weeks, followed by 12 weeks of app-based lifestyle intervention) **GREEN**<br>**Outcomes:** Weight, QoL **GREEN**<br>**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)<br>RCT: NCT04916314<br>Last Update Posted: May 11, 2023<br>Sponsors and Collaborators:<br>University of Oxford<br>Second Nature<br>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**<br>**Intervention**: Second Nature **GREEN**<br>**Comparator:** Standard NHS type 2 diabetes care **GREEN**<br>**Outcomes:** HbA1c, diabetes remission, weight, BP, lipids, ALT, QoL, diet, engagement, satisfaction **GREEN**<br>**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)<br>RCT: NCT05647226<br>Last update posted: December 12, 2022<br>Sponsors and Collaborators: Habitual Health Ltd; Lindus Health<br>UK | **Participants:** 100 adults with type 2 diabetes and BMI ≥28 kg/m$^2$ **AMBER (not exclusively overweight/obesity)**<br>**Intervention:** Habitual Remission Programme (digital therapeutics + 12-week 800kcal/day low-energy diet, delivered remotely) **GREEN**<br>**Comparator:** standard care as delivered by the NHS **GREEN**<br>**Outcomes:** HbA1c, weight, waist circumference, blood pressure, side-effects and any changes in medication **GREEN**<br>**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:**<br>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.<br>**Evaluation of the Effectiveness of Gro Health App in London Hospitals:**<br>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.<br>**Evaluation of the Feasibility of Gro Health to Provide Personalized Nutrition:**<br>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<br>**Type 2 diabetes remission and SAFE-LCD**<br>Oviva has been awarded a grant from Innovate UK to conduct a research project, SAFE-LCD.<br>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.<br>Research on SAFE-LCD will begin this year, in partnership with Hull University Teaching Hospital, University College London and Insight Health Improvement.<br>The RCT to show that patients on insulin therapy can safely achieve Type 2 diabetes remission via a digitally delivered low calorie diet intervention.<br>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**

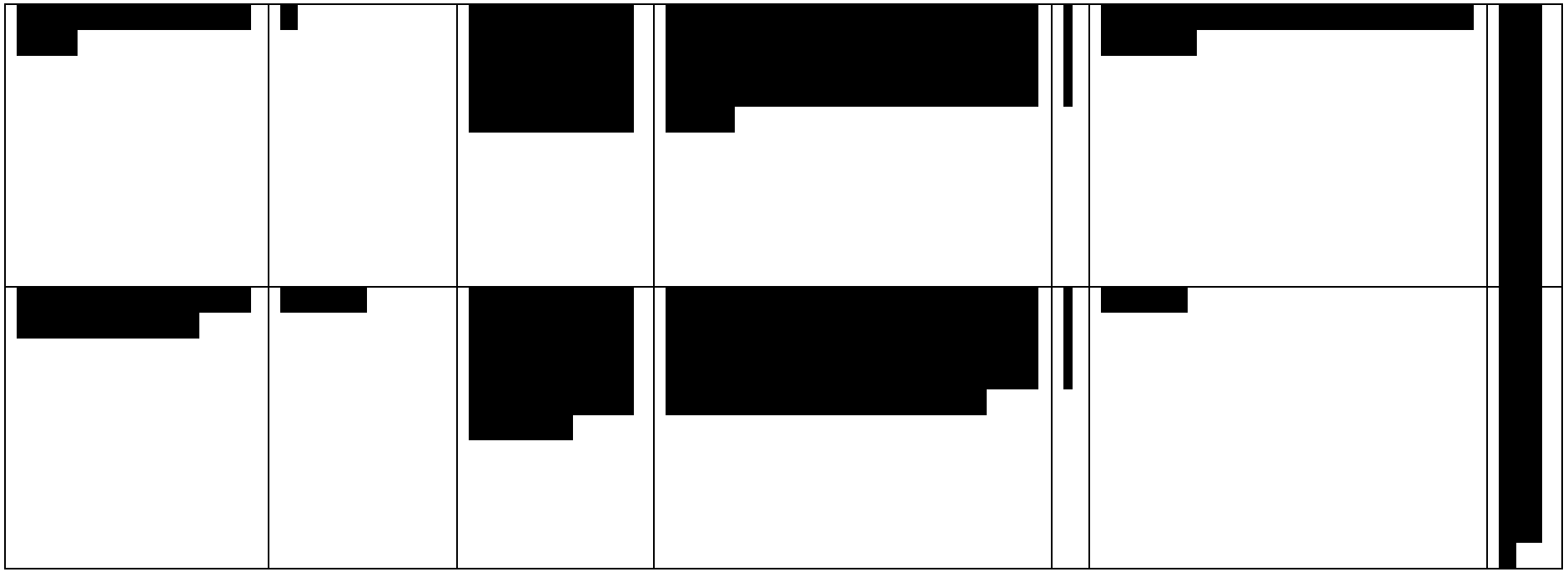
| Study name | Country | Study type | Intervention | Comparator | Outcomes | Expected quarter and year for data availability |
|---|---|---|---|---|---|---|
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

[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 | Glooji | Habitual | Juniper |
|---|---|---|---|---|---|---|---|---|---|---|
| Prioritised outcomes | | | | | | | | | | |
| Weight | No studies<br>**RED** | 1 comparative study and 1 single arm study<br>**AMBER**<br>[redacted]<br>**AMBER** | 1 RCT; 1 comparative study and 1 single arm study **AMBER**<br>[redacted]<br>**AMBER** | 1 comparative study<br>**GREEN**<br>1 RCT but all had Oviva; 3 comparative studies and 12 single arm studies | 3 single arm studies<br>**AMBER**<br>[redacted]<br>**AMBER** | 1 comparative study and 6 single arm studies | No studies<br>**RED** | No studies<br>**RED** | [redacted]<br>**AMBER** | No studies<br>**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 and 1 single arm 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 | 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 |

**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<br>**RED** | No studies<br>**RED** | No studies<br>**RED** | No studies<br>**RED** | No studies<br>**RED** | [redacted]<br>[redacted]<br>**AMBER** | No studies<br>**RED** | No studies<br>**RED** | No studies<br>**RED** | No studies<br>**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?<br>a) If the technology does not currently have regulatory approval, has this process started and when do you expect to receive it?<br>[redacted]<br>**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.<br>*DTAC ready as of 14/08/2023.* |
| What is the main purpose of this technology? Please describe:<br>a) the main features of the technology<br>b) how it is delivered (e.g., computer, smart phone, tablet)<br>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<br>d) how is the technology accessed (e.g., referral from a healthcare professional required or can it be access widely by the public)<br>e) how weight management services are incorporated into the use of the technology<br>f) if there is a system in place if people need additional support<br>*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<br><br>ClinicalTrials.gov Identifier: NCT05647226 | UK | RCT | Habitual Digital Diabetes Remission Programme (Low calorie + digital behaviour change) | Standard Care | 1ry Outcome<br><br>1)Weight Loss > 15kg<br>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<br>UK<br>[abstract]<br>Abdelhameed et al. 2022 full paper<br>https://preprints.jmir.org/preprint/47224<br>Study: 1<br>Publications: 2<br>Full: 1<br>Abstracts: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Gro Health<br>MDT: Not stated<br>Comparator: None (single arm study)<br>Funding: Not stated but 3 authors employed by DDM Health Ltd<br>**AMBER (no comparator)** | N=1767; people with diabetes/prediabetes<br>Age: mean (SD) 49.2 (12.7) years<br>Female: 1129 (63.8%).<br>BMI: Not stated<br>Tier: Not stated<br>**AMBER (no information on BMI; no requirement for overweight/obesity; tier not stated)** | EuroQol-5D (EQ-5D)<br>**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<br>UK<br>Study: 2<br>Publications: 1<br>Full: 1<br>Abstracts: 0 | Non-randomised comparative study (but data for intervention group only)<br>Intervention: Gro Health<br>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<br>Comparator: Usual care<br>Funding: Health Education England<br>**AMBER (no MDT)** | N=199 people on a waiting list for tier 3 weight management services<br>Age range 18-81; median (IQR) 40 (32-51) years<br>Gender: 154 (77.4%) female<br>BMI: median (IQR) 45.5 (41.9-51) kg/m$^2$<br>Tier: tier 3<br>**GREEN** | Engagement (intervention group only)<br>**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<br>UK<br>Study: 3<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study)<br>Intervention: Gro Health<br>MDT: No<br>Comparator: None (single arm study)<br>Funding: Not stated but 1 author employed by DDM Health<br>**AMBER (no comparator; no MDT)** | N= 45 participants with type 2 diabetes or prediabetes<br>Age: mean (SD) 54.85 (13.22) years (<br>Gender: 19 (42%) female<br>BMI: Not stated but mean weight was 89.4 kg (SD 13.8; range 70-135)<br>Tier: Not stated<br>**AMBER (not stated to be tier 3/4; not all participants with overweight/obesity)** | Engagement; completion; HbA1c; weight; adverse events<br>**GREEN** | Limitations: No comparator; no MDT; not stated to be tier 3/4; not all participants with overweight/obesity |
| **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)<br>Denmark<br>Study: 4<br>Publications: 7<br>Full: 5<br>Abstract: 2 | RCT<br>Intervention: LIVA<br>MDT: not mentioned; telehealth lifestyle-coaching by a dietitian<br>Comparator: standard face to face care (standard municipal secondary or tertiary preventive care service)<br>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.<br>**AMBER (no MDT)** | N=340 people with obesity<br>Age: 18-70 years; mean around 52 years<br>Gender: 213 (62.6%) female<br>BMI: 30–45 kg/m$^2$<br>Tier: 3/4 (secondary or tertiary care service)<br>**GREEN** | Adherence, BMI, weight loss, HbA1c, waist circumference, hip circumference, waist-hip ratio, quality of life<br>**GREEN** | Limitations included high drop-out rate:<br>At 12 months: 138 of 338 (40.8%)<br>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;<br>Study: 5<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study)<br>Intervention: LIVA<br>MDT: No: local healthcare professional coaching<br>Comparator: None (single arm study)<br>Company funded<br>**AMBER (no comparator; no MDT)** | N=103 people with obesity and diabetes<br>Age: Mean (SD) 55.6 (10.8) years<br>Gender: 57 (55.3%) female<br>BMI: mean (SD) 36.0 (5.2) kg/$m^2$<br>Tier: Tier 2 local healthcare setting<br>**AMBER (not Tier 3/4)** | BMI, weight loss<br>**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<br>Denmark<br>Study: 6<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study): predictive models of risk of dropout<br>Intervention: Liva<br>MDT: Not stated<br>Comparator: None (single arm study)<br>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.<br>**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%)<br>Age: mean (SD) 48.6 (13.2) years<br>Gender: 1943 (72.39%) female<br>BMI: mean (SD) 33.6 (6.0) kg/$m^2$<br>Tier: Not stated<br>**AMBER (not all had overweight/obesity; not stated to be Tier 3/4)** | Adherence/ completion<br>**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<br>Germany<br>[Abstract]<br>Study: 7<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-randomised comparative study; outcome data for intervention group only<br>Intervention: LIVA<br>MDT: Not stated<br>Comparator: Not stated<br>Funding: Not stated<br>**AMBER (comparator unclear; MDT not stated)** | N=63 people with overweight/obesity and type 2 diabetes<br>Age: >18 years<br>Gender: 51% female<br>BMI: 25-40 $kg/m^2$; mean 33.4 $kg/m^2$<br>Tier: Not tier 3/4: recruited from social media campaigns<br>**AMBER (not all participants with obesity; not tier 3/4)** | Adherence, HbA1c reduction<br>**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** | | | | |

| Study name and location | Design and intervention(s); MDT mentioned? | Participants and setting; Tier 3 or 4 mentioned? | Outcomes (green highlight = prioritised) | EAG comments |
|---|---|---|---|---|
| Finnie et al. 2022<br>UK<br>[Abstract]<br>Study: 8<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-randomised comparative study<br>Intervention: behaviour change support from a specialist coach via Oviva<br>MDT: No: specialist coach<br>Comparator: behaviour change support from a specialist coach via phone coaching<br>Funding: This work was carried out within Oviva UK<br>**AMBER (not MDT)** | N= 2,578 participants of diabetes structured education<br>Age: Not stated<br>Gender: Not stated<br>BMI: Not stated<br>Tier: Not stated<br>**AMBER (not stated to be tier 3/4; not stated to have overweight/obesity)** | Completion, weight loss, HbA1c<br>**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<br>Switzerland<br>Study: 9<br>Publications: 3<br>Full: 2<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: No (dietitian)<br>Comparator: None (single arm study)<br>Funding: Innosuisse-Suisse Innovation Agency and Oviva<br>**AMBER (no comparator, no MDT)** | N=43 people with BMI between 26 and 33 kg/m$^2$<br>Age: range 20–67 years<br>Gender: 36 (84%) female<br>BMI: range 26.4–33 kg/m$^2$; median 30.2 kg/m$^2$<br>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.<br>**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<br>**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<br>UK<br>[Abstract]<br>Study: 10<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: No: dietitian only<br>Comparator: None (single arm study)<br>Funding: Not stated but one author employed by Oviva<br>**AMBER (no comparator, no MDT)** | N=9 people with type 2 diabetes<br>Age: mean (SD) 47.6 (11.8) years<br>Gender: Not stated<br>BMI: mean (SD) 39.1 (6.7) kg/m$^2$<br>Tier: tier 2 (recruited from GP practice)<br>**AMBER (not all participants with obesity; not Tier 3/4)** | Weight loss,<br>HbA1c,<br>completion<br>**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<br>UK/Germany<br>[Abstract]<br>Study: 11<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: Coach only mentioned<br>Comparator: None (single arm study)<br>Funding: Oviva<br>**AMBER (no comparator, no MDT)** | N=907 people with obesity<br>Age: Mean (SD) among those who achieved a relative weight loss of ≥3%: 45 (12) years and those who did not: 45 (13) years<br>Gender: 72% and 74% female, respectively<br>BMI: not stated<br>Tier: Not stated<br>**AMBER (tier not stated)** | Weight loss ≥3%<br>**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<br>UK<br>Study: 12<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-randomised comparative study<br>Intervention: Oviva<br>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.<br>Comparator: Face to face or phone support<br>Funding: Not stated but two authors employed by Oviva<br>**GREEN** | N=169 people with BMI ≥ 45 kg/m$^2$ or ≥40 kg/m$^2$ with a complex comorbidity<br>Age: mean (SD) 46.6 (13.8) years<br>Gender: 79.3% female<br>BMI: range 37.1–66.2 kg/m$^2$; mean (SD) 48.3 (6.2) kg/m$^2$<br>Tier: Tier 3<br>**GREEN** | Adherence, weight, BMI<br>**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<br>UK<br>[Abstract]<br>Study: 13<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: No: coaching by registered dietitians only<br>Comparator: None (single arm study)<br>Funding: Authors affiliated to Oviva<br>**AMBER (no comparator; no MDT)** | N=42 adults with Type 2 diabetes<br>Age: mean 59 years<br>Gender: 21 (50%) female<br>BMI: 36.8 kg/m$^2$<br>Tier: Not stated<br>**AMBER (not stated to be tier 3/4; not exclusively people with overweight/obesity)** | Engagement (programme uptake), HbA1c, weight loss<br>**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<br>Germany<br>[Abstract]<br>Study: 14<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: Not stated: "blended-care weight loss interventions at a specialized nutritional care provider"<br>Comparator: None (single arm study)<br>Funding: Authors affiliated to Oviva<br>**AMBER (no comparator; no MDT)** | N=11758 obese patients<br>Age: Not stated<br>Gender: 8194 (69.7%) female<br>BMI: mean (SD) 37.3 (6.1) kg/m$^2$<br>Tier: Not stated<br>**AMBER (not stated to be tier 3/4)** | Weight loss<br>**GREEN** | Limitations: Abstract only; little information; no comparator, no MDT; not stated to be tier 3/4 |
| Lawson et al. 2022<br>UK<br>Study: 15<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: Yes<br>Comparator: None (single arm study)<br>Funding: Not stated but 7 of 8 authors employed by Oviva<br>**AMBER (no comparator)** | N=54 people with BMI of >35kg/m² with comorbidities<br>Age: Not stated<br>Gender: 78% female<br>BMI: Not stated<br>Tier: Tier 3<br>**GREEN** | Psychological outcome: depression score on PHQ-9<br>**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]<br>Issa et al. 2020 [abstract]<br>UK<br>Study: 16<br>Publications: 3<br>Full: 1<br>Abstract: 2 | RCT in which all had Oviva<br>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<br>MDT: Yes for both groups<br>Comparator: see above; all participants had Oviva so no non-Oviva comparator<br>Funding: Néstle Health Science and Oviva UK Limited<br>**AMBER (no non-Oviva comparator)** | N=79 people with overweight/obesity and type 2 diabetes<br>Age: mean (SD): 55.5 (11.3) years<br>Gender: 37 (47% female)<br>BMI: mean (SD): 36.4 (5.8) kg/m$^2$<br>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<br>**AMBER (not tier 3/4)** | Engagement, adherence, weight loss, diet quality, physical activity, adverse events, HbA1c, body fat, waist and hip circumference<br>**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)<br>UK<br>[Abstract]<br>Study: 17<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: No: programme coach<br>Comparator: None (single arm study)<br>Funding: Not stated but author affiliated to Oviva<br>**AMBER (no comparator; not stated to use MDT)** | N=598 adults with type 2 diabetes following a digitally-enabled diabetes structured education programme<br>Age: Not stated<br>Gender: Not stated<br>BMI: Not stated<br>Tier: Not stated<br>**AMBER (not stated to be tier 3/4; not stated to have overweight/obesity)** | Weight loss, engagement, completion<br>**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)…)<br>UK<br>[Abstracts]<br>Study: 18<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: No: programme coach<br>Comparator: None (single arm study)<br>Funding: Not stated but author affiliated to Oviva<br>**AMBER (no comparator; not stated to use MDT)** | N=1384 adults with type 2 diabetes following a digitally-enabled diabetes structured education programme<br>Age: Not stated<br>Gender: Not stated<br>BMI: Not stated<br>Tier: Not stated<br>**AMBER (not stated to be tier 3/4; not stated to have overweight/obesity)** | Weight loss, engagement, completion<br>**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)<br>UK<br>[Abstracts]<br>Study: 19<br>Publications: 4<br>Full: 0<br>Abstract: 4 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: No: coach support<br>Comparator: None (single arm study)<br>Funding: Not stated but author affiliated to Oviva<br>**AMBER (no comparator; not stated to use MDT)** | N=37 adults with T2DM<br>Age: Not stated<br>Gender: Not stated<br>BMI: Not stated<br>Tier: Not stated<br>**AMBER (not stated to be tier 3/4; not stated to have overweight/obesity)** | Completion, weight loss, HbA1c<br>**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<br>[Abstract]<br>UK, Germany<br>Study: 20<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: Not stated<br>Comparator: None (single arm study)<br>Funding: Not stated; all authors employed by Oviva<br>**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<br>Age: Not stated<br>Gender: 2681 (84.7%) female<br>BMI: Not stated<br>Tier: Not stated<br>**AMBER (not stated to be tier 3/4)** | Meal log data<br>**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<br>Switzerland<br>Study: 21<br>Publications: 3<br>Full: 2<br>Abstract: 1 | Non-comparative feasibility study (case series/before and after study)<br>Intervention: Oviva<br>MDT: No: dietitians only<br>Comparator: None (single arm study)<br>Funding: funded in part by Innosuisse under the framework of the project medipiatto (Project Nr. 33780.1 IP-LS). Two authors employed by Oviva<br>**AMBER (no comparator; no MDT)** | N= 24 weight loss patients with BMI > 27 kg/m$^2$<br>Age: mean (SD) 46.9 (13.1) years<br>Gender: 21 (87.5%) female<br>BMI: mean (SD) 31.8 (4.4) kg/m$^2$<br>Tier: Unclear; recruited by dietitians who were treating participants<br>**AMBER (tier not stated; not all people with obesity)** | Food frequency; satisfaction<br>**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<br>UK, Germany, and Switzerland<br>Study: 22<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: Only coaching by a healthcare professional (certified health coaches and/or dietitians) stated<br>Comparator: None (single arm study)<br>Funding: No external funding; all authors employed by Oviva<br>**AMBER (no comparator; not stated to use MDT)** | N=25,706 patients who used Oviva for prevention or therapy of various nutrition-related conditions<br>Age: mean (SD) 47.3 (10.96) years<br>Gender: 17,749 (69.0%) female<br>BMI: not stated but baseline mean (SD) weight 106.7 (21.4) kg for the 15,012 people with weight data at 1 month<br>Tier: not stated (not exclusively tier 3/4<br>**AMBER (not exclusively people with overweight/obesity; not only tier 3/4)** | Weight<br>**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<br>Germany<br>[Abstract]<br>Study: 23<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: No: starting call with a dietitian and chat interactions, if needed<br>Comparator: None (single arm study)<br>Funding: Not stated but authors affiliated to Oviva<br>**AMBER (no comparator; not MDT)** | N=20 people with obesity that completed the 12-weeklong Oviva Direkt digital therapy<br>Age: mean 48.25 years<br>Gender: 17 (85%) female<br>BMI: mean 35.31 kg/m$^2$<br>Tier: not stated to be tier 3/4<br>**AMBER (tier not stated)** | Weight loss<br>**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<br>Switzerland<br>[Abstract]<br>Study: 24<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-randomised comparative study<br>Intervention: Oviva plus face to face counselling<br>MDT: No: individual nutritional counseling by registered dietitians<br>Comparator: Face to face counseling<br>Funding: Not stated but authors affiliated to Oviva<br>**AMBER (no MDT)** | N=166 people with type 2 diabetes under individual nutritional counselling by registered dietitians integrated in Swiss GP practices<br>Age: mean (SD) 60 (11) years<br>Gender: 72 (43.4%) female<br>BMI: mean (SD) 33 (6) kg/m² in Oviva group and 32.6 (5.3) kg/m² in comparator group<br>Tier: Tier 2 GP practices<br>**AMBER (not all participants with obesity; community tier 2 not tier 3 service)** | HbA1c<br>**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<br>[Abstract]<br>Study: 25<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-randomised comparative study<br>Intervention: Oviva<br>MDT: No: nutritionist<br>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<br>Funding: Not stated<br>**AMBER (no MDT)** | N=86 with obesity<br>Age: Mean (SD) 43.9 (13.3) years<br>Gender: 59 (68.6%) female<br>BMI: Mean (SD) 36.6 (6.3) kg/m$^2$<br>Tier: Not stated<br>**AMBER (not stated to be a tier 3/4 service)** | Weight loss<br>**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<br>UK<br>Study: 26<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study)<br>Intervention: Oviva<br>MDT: Not stated; telephone and text-based education<br>Comparator: None (single arm study)<br>Funding: Sustainability and Transformation Programme<br>**AMBER (no comparator; not MDT)** | N=47 people recently diagnosed with type 2 diabetes; not stated to have overweight/obesity<br>Age: mean (SD) 61.3 (13.7) years<br>Gender: 18 (38.3%) female<br>BMI: Not stated; baseline mean (SD) weight 99.4 (25) kg<br>Tier: Tier 2 (GP/community)<br>**AMBER (not all participants with obesity; community tier 2 not tier 3/4 service)** | Weight, HbA1c<br>**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<br>UK<br>[Abstract]<br>Study: 27<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Roczen<br>MDT: Yes<br>Comparator: None (single arm study)<br>Funding: Not stated, all authors affiliated with Reset Health.<br>**AMBER (no comparator)** | N=653 adults<br>Age: Not stated<br>Gender: Not stated<br>BMI: Mean (SD) 35.2 (6.4) kg/m$^2$<br>Tier: Not stated<br>**AMBER (not all participants with obesity; not stated to be tier 3/4 service)** | Weight loss, completion<br>**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<br>UK<br>[Abstract]<br>Study: 28<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Roczen<br>MDT: Clinicians and mentors<br>Comparator: None (single arm study)<br>Funding: All authors affiliated with Reset Health<br>**AMBER (no comparator)** | N=732 adults completing programme<br>Age: Not stated<br>Gender: Not stated<br>BMI: Mean (SD) 349 (6.3) kg/m$^2$<br>Tier: Not stated<br>**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<br>**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<br>UK<br>[Abstract]<br>Study: 29<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Roczen<br>MDT: Yes<br>Comparator: None (single arm)<br>Funding: Not stated but 4 authors affiliated to Reset Health<br>**AMBER (no comparator)** | N=82 people with type 2 diabetes<br>Age: mean (SD) 53 (8.6) years<br>Gender: 45 (54.9%) female<br>BMI: mean (SD) 35 (6.7) kg/m$^2$<br>Tier: Not stated<br>**AMBER (not all participants with obesity; tier not stated)** | Weight loss, HbA1c<br>**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)<br>Davies et al. 2023a<br>(p116; referred subgroup at 3, 6 and 12 months)<br>UK<br>[Abstract]<br>Study: 30<br>Publications: 3<br>Full: 0<br>Abstract: 3 | Non-comparative study (case series/before and after study)<br>Intervention: Second Nature<br>MDT: Not stated<br>Comparator: None (single arm)<br>Funding: Not stated but all authors employed by Second Nature<br>**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<br>Subgroup of N=344 participants who registered readings at 5 years<br>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<br>Age: Not stated<br>Gender: Not stated<br>BMI: Not stated<br>Tier: Tier 2; private self-funded and referred by NHS GP.<br>**AMBER (not Tier 3/4; not stated to have overweight/obesity)** | Weight change<br>**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<br>[Abstract]<br>UK<br>Study: 31<br>Publications: 2<br>Full: 1<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Our Path<br>MDT: No; health coaching by dietitian<br>Comparator: None (single arm)<br>Funding: Not stated but one author co-founder and CEO of OurPath<br>**AMBER (no comparator, not MDT)** | N=77 people with BMI ≥23 kg/m$^2$<br>Age: mean 46 years<br>Gender: 74% female<br>BMI: mean 31 kg/m$^2$<br>Tier: recruited online through digital advertising on Facebook and Google, using diet and weight loss-related keywords; not referred to Tier 3/4 service<br>**AMBER (not Tier 3/4; not all participants with obesity)** | Adherence, weight loss<br>**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<br>UK<br>[Abstract]<br>Study: 32<br>Publications: 1<br>Full: 0<br>Abstract: 1 | Non-comparative study (case series/before and after study)<br>Intervention: Second Nature<br>MDT: No: health-coaching from a registered dietitian<br>Comparator: None (single arm)<br>Funding: Solent Diabetes Association<br>**AMBER (no comparator, not MDT)** | N=190 referred; 150 enrolled; people with type 2 diabetes<br>Age: Not stated<br>Gender: Not stated<br>BMI: Mean (SD) 35.1 (6.7) kg/m$^2$<br>Tier: recruited by practice and specialist nurses working in the NHS; likely Tier 2 but not stated<br>**AMBER (not stated to have overweight/obesity; not Tier 3/4)** | Weight loss, HbA1c<br>**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)<br>Hampton et al. 2020 (24 months)<br>UK<br>[Abstracts]<br>Study: 33<br>Publications: 2<br>Full: 0<br>Abstract: 2 | Non-comparative study (case series/before and after study)<br>Intervention: OurPath<br>MDT: Not stated<br>Comparator: None (single arm)<br>Funding: Not stated but 3 of the 4 authors employed by OurPath<br>**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.<br>Age: Not stated<br>Gender: Not stated<br>BMI: Not stated<br>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.<br>**AMBER (not stated to have overweight/obesity; not Tier 3/4)** | Weight loss<br>**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<br>UK<br>Study: 34<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study)<br>Intervention: OurPath<br>MDT: No; one-to-one health coaching from a registered dietitian<br>Comparator: None (single arm)<br>Funding: Not stated but 2 authors employed by OurPath<br>**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<br>Age: mean (SD) 49.4 (12.6) years<br>Gender: 627 (70.0%) female<br>BMI: mean (SD) 33.7 (6.1) kg/m$^2$<br>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)<br>**AMBER (not patients referred into tier 3/4)** | Weight change<br>**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<br>UK<br>Study: 35<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study)<br>Intervention: Second Nature<br>MDT: No; mentoring from a registered dietitian or nutritionist (health coach)<br>Comparator: None (single arm)<br>Funding: Solent Diabetes Association<br>**AMBER (no comparator, not MDT)** | N=144 people with Type 2 diabetes (overweight or obesity not specified)<br>Age: mean (SD) 51.6 (11.0) years<br>Gender: 80 (55.5%) female<br>BMI: mean (SD) 35.9 (6.7) kg/m$^2$<br>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.<br>**AMBER (not patients referred into tier 3/4; not all participants with obesity)** | Weight, HbA1c, engagement<br>**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 |

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|---|---|---|---|---|
| Thomson et al. 2022<br>UK<br>Study: 36<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-comparative study (case series/before and after study)<br>Intervention: Second Nature<br>MDT: No: dietitian acted as health coach<br>Comparator: None (single arm)<br>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<br>**AMBER (no comparator; no MDT)** | N=48 people with BMI ≥25<br>Age: mean (range) 49.09 (26–74) years<br>Gender: 40 (83%) female<br>BMI: mean (range) 31.6 (24.2–44.4) kg/m$^2$<br>Tier: Not Tier 3/4: Participants were recruited via the Second Nature online behavioural weight management programme<br>**AMBER (not Tier 3/4; not all with obesity)** | Qualitative study of how COVID-19 and perception of risk interacted with weight loss attempts<br>**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<br>UK<br>Study: 37<br>Publications: 2<br>Full: 2<br>Abstract: 0 | Non-randomised comparative study<br>MDT: Not stated<br>Comparators: Liva, Oviva and OurPath<br>Funding: NHS England, as part of the Digital Diabetes Prevention Programme.<br>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.<br>AL is funded by the HEE Deanery (North Thames)<br>**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.<br>Age, gender and BMI not stated by intervention type<br>Tier: from GP practices<br>**AMBER (not Tier 3/4; not all with overweight/obesity)** | Weight<br>**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<br>UK<br>Study: 38<br>Publications: 1<br>Full: 1<br>Abstract: 0 | Non-randomised comparative observational study<br>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.<br>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<br>Funding: Not stated; two authors employed by DDM Health<br>**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<br>Age: mean (SD): intervention: 48.8 (12.7) years; control: 44.4 (13.3) years; p=0.01<br>Gender: 59 (56.2%) and 74 (58.7%), respectively, p=0.02<br>BMI: Not stated; weight 130.2 (29.2) kg and 137.1 (27.0) kg, respectively; p=0.07<br>Tier: Tier 3<br>**GREEN** | Weight<br>**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<br>https://preprints.jmir.org/preprint/47224<br>**AMBER** | | 896/1767 (50.7%) completed the educational component of the app |
| Summers et al. 2021<br>**AMBER** | Mean reduction 2.77 kg (SD 2.62 kg; p<0.001) | All 45 (100%) completed at least 40% of the lessons, 32 (71%) individuals completed more than nine lessons, and 29 (64%) completed all 12 core lessons of the program; 37 (82%) reported outcomes at 12 months |
| Hanson et al. 2021<br>**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.<br>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<br>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<br>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<br>AMBER | Mean reduction 4.78 kg (4.3% of initial body weight) over mean of 7 months; P<.05 | |
| Pedersen et al. 2019<br>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<br>AMBER | | 94% of the intervention participants were retained after 3 months. |
| **Oviva** | | |
| Finnie et al. 2022 [abstract]<br>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<br>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]<br>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]<br>AMBER | 469/907 (51.7%) achieved a relative weight loss of ≥ 3% at 12 weeks | |
| Huntriss et al. 2021b<br>GREEN | Mean (SD) change in weight kg; % at 12 week follow up:<br>Face to face n=21: −5.3 (5.5); -4.1%; P< .001 vs. baseline<br>App n=46: −6.1 (4.9); -4.5%; P< .001 vs. baseline; not significantly different from face to face<br>Phone n=3: −4 (5.3); -3.4% | Completed 50% of dietetic sessions: Face to face n=48 95.8%<br>App n=109: 96.3%<br>Phone n=12: 83.3%.<br>Attended all the dietetic sessions: 85.4%, 66.1% and 33.3% of patients, respectively.<br>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]<br>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]<br>AMBER | Mean (SD) relative weight change at week 12+/- 2 weeks was -3.51 (4.19) % | |
| McDiarmid et al. 2022<br>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]<br>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]<br>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]<br>**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]<br>**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<br>**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:<br>At 1 month, weight loss −1.89 ± 7.82 kg (−1.63 ± 5.94%); n= 15,012.<br>At 3 months: −4.02 ± 7.82 kg (−3.61 ± 5.82%); n= 9526<br>At 6 months: −5.82 ± 9.10 kg (−5.28 ± 6.94%); n= 4204<br>At 12 months: −7.22 ± 9.67 kg (−6.55 ± 8.22%); n= 979 | |
| Schirmann et al. 2022b [abstract]<br>**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]<br>**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<br>**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]<br>**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]<br>**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]<br>**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]<br>**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).<br>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<br>**AMBER** | Mean (SE) % weight loss:<br>At 6 weeks: 5.3% (0.4%); p<0.01 vs. baseline; n=77 (85% of original number of participants)<br>At 3 months: 6.7% (0.6%); p<0.01 vs. baseline; n=42/69 with potential for 3-month data (61%)<br>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]<br>**AMBER** | 112/150 (74.7%) with 3-month outcome data: mean % weight loss 6.6%; p<0.01 vs. baseline.<br>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]<br>**AMBER** | Results presented by whether participants were self-referred (commercial) or referred by a GP (NHS) to the digital behaviour change programme.<br>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.<br>Users with available six month data showed a further increased weight loss from baseline (commercial -8.6%; n=186; NHS -9.2%, n=155).<br>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<br>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:<br>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<br>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;<br>-7.5%; p<0.001. | |
| **Comparative study** | | |
| Ross et al. 2022; Murray et al. 2019<br>UK<br>AMBER | At 12 months: Liva: Mean (95% CI) −2.4 (−3.1 −1.6) kg<br>OurPath: Mean (95% CI) −6.2 (−7.1 −5.4) kg<br>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<br>Full text<br>Single arm<br>**AMBER** | | 100 recruited; 45 engaged (45%) | | |
| **LIVA** | | | | |
| Christensen et al. 2022a; Hesseldal et al. 2022a<br>**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<br>**AMBER** | 1.58-point change in BMI from baseline mean (SD) 36.0 (5.2) kg/m$^2$ | | | |
| **Oviva** | | | | |
| Haas et al. 2019<br>**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<br>**GREEN** | Mean (SD) change in BMI (kg/m$^2$) at 12 weeks:<br>Face to face n=48: −1.9 (1.9)<br>App n=109: −2.2 (1.7)<br>Phone n=12: −1.5 (1.9) | | | |
| Jones et al. 2018<br>**AMBER** | | Programme uptake: 74% of all eligible referrals (n=142) | | |
| Lawson et al. 2022<br>**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) |

| Study | Change in BMI | Engagement | HRQoL | Psychological outcomes |
|---|---|---|---|---|
| McDiarmid et al. 2022<br>**AMBER** | | Uptake to the Oviva app: 70/79 (89%) willing to use the app from baseline. | | |
| Miller et al. 2021a<br>**AMBER** | | 73% of referrals (n=598) started the programme | | |
| Miller et al. 2022a<br>**AMBER** | | 72% started the programme | | |
| **Roczen** | | | | |
| Brown et al. 2022<br>**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%) |
| **Second Nature (OurPath)** | | | | |
| Kar et al. 2020<br>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] | |
| Gro Health | | | | |
| [redacted] | [redacted] | | [redacted] | |
| Liva | | | | |
| [redacted] | [redacted] | [redacted] | | |

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

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

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

| Author, year | Study name | BMI | Engagement | Psychological outcomes |
|---|---|---|---|---|
| | | [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”.