NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health technology evaluation

Assessment report overview

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

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

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

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

This overview also contains:

- Appendix A: Sources of evidence

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1 The technology

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

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

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

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

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

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

2 Proposed use of the technology

2.1 Disease or condition

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

Obesity is typically measured by calculating a person's body mass index (BMI). It is defined as 30.0 kg/m^2 and above and severe obesity is defined as

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

2.2 Patient group

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

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

2.3 Unmet need and current management

There is an unequal distribution of specialist weight management services across the NHS. This could create a postcode lottery for accessing weight management medication. In some areas there is no access to specialist weight management services. In areas with established services, there is an increasing number of people on waiting lists because of limited resources and funding. Services offered can vary widely across the country. Providing specialist weight management services using digitally enabled technologies could improve access to these services. These technologies could also

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reduce the number of in-person appointments and increase the capacity of service delivery in areas that have established services.

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

2.3 Proposed management with new technology

Digitally enabled technologies would be offered as an option to adults with obesity that are eligible for treatment in specialist weight management services. People would be clinically assessed and referred within the NHS. Weight management medication prescription and monitoring would be done within the NHS. Patient preference and engagement should be considered when helping people make decisions about the care that they want to receive.

3 The decision problem

Details of the decision problem are described in the scope. The EAG has provided further clarification to how evidence has been included in relation to the decision problem (see Table 1.1.1 of the external assessment report [EAR]).

4 The evidence

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

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

4.1 Summary of evidence of clinical benefit

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

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

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Table 1: Summary of included studies for each technology

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

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Summary of the clinical outcomes

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

Gro Health W8Buddy

3 single arm studies (Abdelhameed et al. 2022; Hanson et al. 2023; Summers et al. 2021) and 1 non-randomised comparative study (Hanson et al. 2021) was considered relevant to the decision problem by the EAG. The single-arm prospective cohort study (Hanson et al. 2023) reported that 51.3% of people offered free access to the technology were interested in using the technology (102 of 199). Of those who were interested, 34.2% engaged with the technology (68 of 102). The study reported that 4% of people (n=4) were unable to engage with the digitally enabled weight management programme because of the lack of a smart phone or internet connection. Abdelhameed et al. (2022) reported significant and clinically meaningful increase in EQ-5D mean Health index scores among app users between baseline (0.746 [SD 0.234]) and 6-month follow-up (0.792 [SD 0.224], $p<0.001$). It also reported that 896 of 1767 participants (50.7%) completed the educational component of the app.

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

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

[redacted]

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[redacted]

Liva

Ten publications including 1 RCT (compared with face-to-face care), 4 single arm studies and 6 unpublished studies were considered relevant to the decision problem. The RCT reported a statistically significant difference in absolute weight reduction (Christensen et al., 2022a) and BMI (Hesseldal et al., 2022) for people using Liva compared with face-to-face weight management services at 6 and 12 months ($p<0.001$). There was also a reported difference in weight loss between the groups at 24 months, but this was not statistically significant. This RCT, however, was limited by large drop-out rates (around 41% dropped out by 12 months). Christensen et al. (2022a) states that low completion rates were due to the COVID-19 pandemic. Non-comparative evidence generally showed a reduction in weight compared to baseline.

In the RCT (Christensen et al., 2022a), greater levels of adherence (based on data presented in GID-HTE10007 EAR) were reported for people using Liva compared with face-to-face weight management services at 6 months (74.0% compared to 60.0%), 12 months (63.5% compared to 52.1%) and 24 months (40.5% compared to 36.4%).

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

Oviva

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

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A retrospective comparative study (Huntriss et al., 2021) reported no statistically significant difference in absolute weight reduction or change in BMI between people using Oviva compared with face-to-face weight management services at 12 to 16 weeks and 24 to 28 weeks. All of the remaining studies reporting weight loss outcomes for Oviva reported a mean or median reduction in weight and a reduction in BMI (where reported) when compared to baseline.

A before-and-after study (Haas et al., 2019) reported no change in mental or physical component summary scores (from SF-12) at 3 months when compared with baseline. However, another before-and-after study (Lawson et al., 2023) reported a statistically significant change in PHQ-9 at 3 months ($p=0.0026$) and 6 months ($p=0.0022$) when compared with baseline.

A retrospective non-randomised comparative study (Huntriss et a., 2021) reported a higher uptake of Oviva (64.5%) compared with face to face (28.4%) and telephone based (7.1%) weight management services.

Roczen

Three single-arm cohort studies (reported as abstracts) and 2 unpublished abstracts for Roczen were considered relevant to the decision problem. Studies reported a consistent reduction in absolute weight loss was when compared to baseline. One published abstract (Brown et al., 2022) reported this change as statistically significant ($p<0.001$) at both 12 and 24 weeks. Another abstract (Falvey et al. 2023) reported 71% of participants achieved a clinically significant weight loss (>5%) at 12 months. [redacted]

There is limited data on engagement and adherence for Roczen. Adherence was reported as 69% at 6 months and 43% at 12 months in 1 abstract (Falvey et al., 2023). Another abstract (Brown et al., 2022) reported programme

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completion of 37.4% (244 out of 653) at 6 months.

[redacted]

Second Nature

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

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

The same study reported that 24.6% of users had data available at baseline, 6 months and 12 months. The study reported higher rates of adherence (47.5%) for users referred directly from the NHS. A prospective cohort study (Hampton et al. 2017) reported that retention rates ranged from 78.6% at 6 weeks to 29.6% at 6 months.

CheqUp

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

Habitual

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

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[redacted]

Juniper

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

[redacted]

Weight Loss Clinic

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

Counterweight

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

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

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

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

Additional evidence

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

EAG comments on the quality of the clinical evidence

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

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

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

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

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

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

4.2 Summary of economic evidence

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

Early economic modelling

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

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

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

The model structure (figure 1) consisted of a decision tree to capture short-term treatment outcomes at 6, 12, and 24 months. The model allows people eligible and referred for tier 3 specialist weight management services to receive current standard care (face-to-face specialist weight management services), a digitally enabled weight management programme, delayed treatment (for 6 or 12 months), or no treatment. A time horizon of 24 months was chosen to reflect the length of a typical specialist weight management programme. At each time point (6 months, 12 months and 24 months) people can continue using the service or drop out of the service. People continuing to use the service can lose less than 5% of their body weight or more than 5% of their body weight.

Due to lack of data on costs and outcomes, the EAG's model assumed a class effect using the data provided by Liva. For further information about the model structure, see section 8.2 of the EAR.

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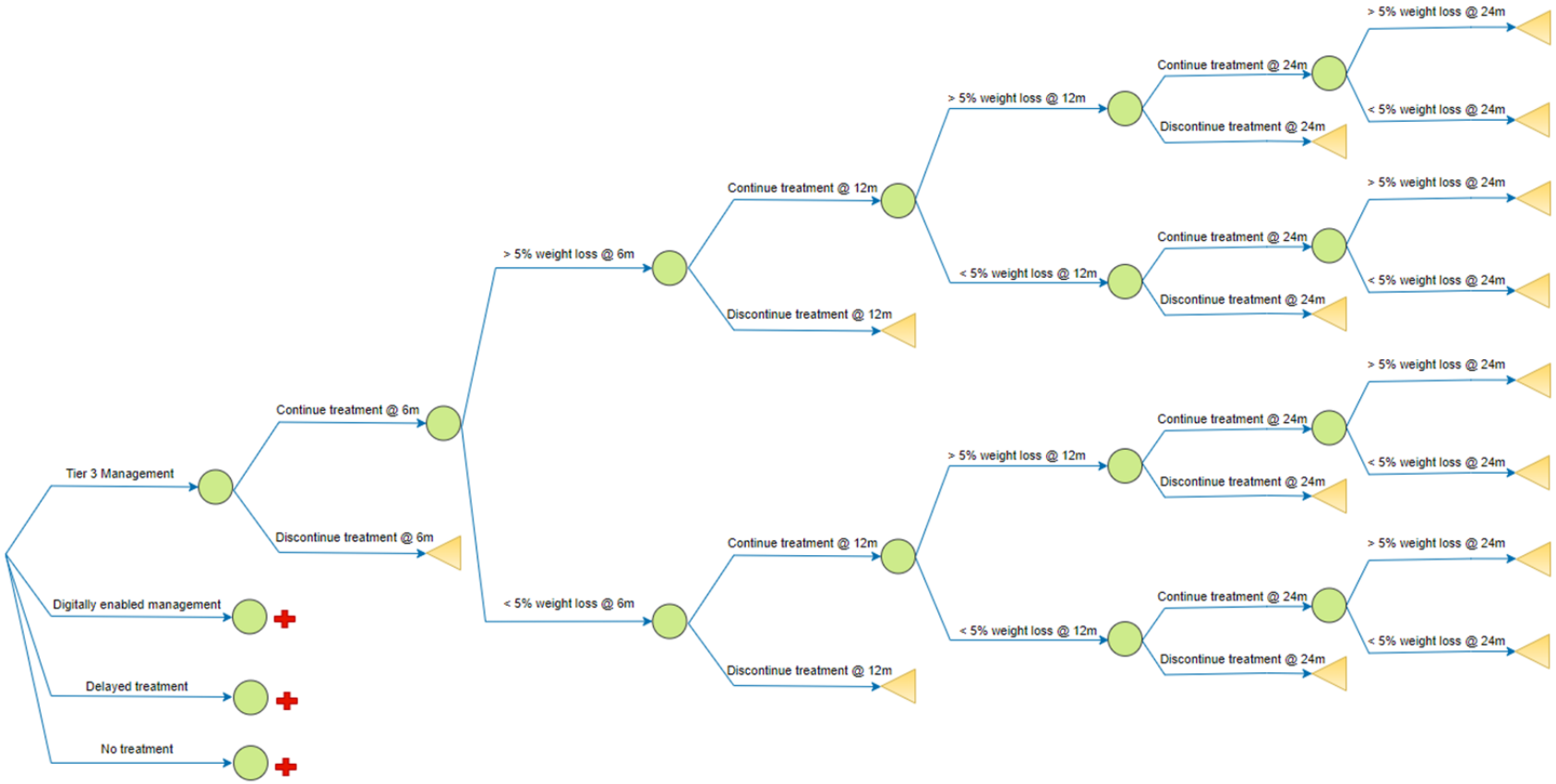
Figure 1: Structure of the EAG's conceptual model



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

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Key parameters

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

The key assumptions used were:

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

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

Costs and resource use

Technology costs

Eleven out of 12 companies provided who provided costs which are summarised in the following table (Table 2). Due to the heterogeneity of the

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costs, the EAG used cost estimates for Liva in the base case. The EAG also included additional costs in the model for a tablet computer and for the monthly cost of a mobile internet connection to address potential barriers of digital exclusion for every person in the digitally enabled technology arm.

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

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Table 2: Summary of technology costs provided by companies

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

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	Cheq Up	W8Buddy (Gro Health)	W8Buddy+ (Gro Health)	Liva	Oviva	Roczen	Second Nature	Wellbeing Way	Juniper	Habitual	Gloji	Weight Loss Clinic	Counter-weight
6 months				£1,000								£70 (3 months = £207)	£920
12 months				£1,200								£920	£1,200
18 months				£1,400									
24 months				£1,600	£900								£1,506
Additional resources from company information	Price with fitbit scales adds £15 per patient per month to cost	Price with weight scale adds £75 per patient to cost	Price with weight scale adds £75 per patient to cost										

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Health state utilities

The EAG calculated a baseline utility using a weighted average (0.777) of the mean EQ-5D-3L score in the 30 to 35 BMI group (0.813, n=577) and the greater than 35 BMI group (0.731, n=448) from Breeze et al. (2022). These BMI categories are eligible for Tier 3 weight management services and, therefore, were included for baseline utility calculations. In line with the modelling assumptions applied in GID-HTE10007 EVA, the EAG estimated improvements in utility based on an improvement in weight loss. The utility values used in the model are summarised in Table 8.6 of the EAR.

Results

EAG base case results are summarised in the following table (Table 3). The base case results suggest that digitally enabled weight management programmes are cost saving and cost effective compared with standard care (face-to-face specialist weight management services) and a 6-month delay to standard care. With a longer delay in treatment (12 months), digital technologies become cost incurring but still lead to increased QALYs (ICER of £17,000). When compared to no treatment, digitally enabled technologies are cost incurring but results in increased QALYs with an ICER of £125,000. The EAG noted that the QALYs for no treatment is likely to be overestimated and QALYs for treatment are likely to be underestimated. The EAG noted that there is uncertainty in both the cost and QALY outcomes as long-term outcomes such as associated comorbidities are not included in the analysis.

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Table 3: EAG base case results (24 months)

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

Additional analyses

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

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5 Ongoing research

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

6 Evidence gap analysis

The EAG presented a summary of the evidence gaps for prioritised and important outcomes. The EAG considered the relevance of the evidence to the decision problem, the generalisability of findings and evidence quality. Table 5 contains the evidence gaps for the outcomes based on the current evidence and table 6 listed the evidence gaps that could be addressed by the ongoing research. For more detail on the EAG's evidence gap analysis see section 10, Table 10.1 and Table 10.2 of the EAR and EAR addendum.

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

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

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

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

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

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

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

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Summary and conclusions of evidence gap analysis

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

Study design and duration

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

Population

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

Intervention

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

Comparator

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- Unknown number of specialist weight management service providers in the NHS as well as the number of people accessing these services. The NHS Obesity Audit will enable monitoring of accessibility to these services over time.

Outcomes

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

Decision modelling

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

Key areas for evidence generation

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

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

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7 Comments from patient and carer organisations

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

- Diabetes UK

Advice was summarised in 4 key points:

- Digitisation will provide greater access to weight management services
- Digital methods should not completely replace face-to-face due to this being potentially detrimental to those in certain groups
- Providing a choice of delivery method will likely increase adherence and allow flexibility around other commitments due to a lack of need to travel to appointments
- Weight management services should be consistently accessible across the country. They should be person centred and aim to reduce the stigma of body weight and weight management services

8 Comments from healthcare professional organisations

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

- British Dietetic Association

Advice was summarised in the following key points:

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

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

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

9 Comments from patients

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

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

10 Equality considerations

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

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protected characteristics and others. Several potential equality issues have been identified. Key aspects include:

- Obesity rates increase with age and people aged 45 and over have an increased risk of obesity.
- Obesity rates differ between socio-economic groups. People living in the most deprived areas are more likely to be living with obesity than those in the least deprived areas.
- People with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background are prone to central adiposity and have an increased risk of chronic health conditions at a lower BMI.
- Digitally enabled weight management programmes are accessed via a mobile phone, tablet, or computer. People will need regular access to a device with internet access to use the technologies. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies or people who do not have access to smart devices or the internet.
- People with visual, hearing, or cognitive impairment; problems with manual dexterity; a learning disability; or who are unable to read or understand health-related information (including people who cannot read English) or neurodivergent people may need additional support to use digitally enabled programmes.
- Some people would benefit from digitally enabled weight management programmes in languages other than English. People's ethnic, religious, and cultural background may affect their views of digitally enabled weight management interventions. Healthcare professionals should discuss the language and cultural content of digitally enabled programmes with patients before use.
- Age, disability, race, and religion or belief are protected characteristics under the Equality Act 2010.

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11 Implementation

Variations and uncertainties in the care pathway

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

Costs

The costs of implementing different technologies varies. Implementation of digitally enabled weight management programmes could initially increase staff workload and costs to set up new pathways and change service delivery. Smaller service areas may have higher costs per user due to not needing as many licenses for the technology. Digitally enabled programmes may be chosen based on the balance between costs and expected outcomes. Clinical experts stated that costs for healthcare professional time for prescribing and monitoring weight management medication would need to be considered when using technologies that do not include prescription and medication management as part of the service.

12 Issues for consideration by the committee

12.1 Unmet need

- The committee may wish to consider that digitally enabled weight management programmes can be used to improve access to specialist weight management services and weight management medication. In some areas there is no access to weight management services and in areas where there are services, there is an increasing number of people on waiting lists because of limited resources and funding, creating a postcode lottery. Clinical experts estimated that 30 to 70% of

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people do not have access to local specialist weight management services. They also estimated that 10 to 30% of people are unable to attend face–to-face appointments because of time commitments or mental health reasons.

12.2 Clinical evidence

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

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12.3 Cost evidence

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

10.4 Evidence gap analysis

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

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

13 Authors

Amy Barr and Charlotte Pelekanou, technical leads

Lizzy Latimer, technical adviser

NICE Medical Technologies Evaluation Programme

October 2023

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

Details of assessment report:

- Holmes H. et al., Digitally enabled weight management programmes to support weight management medication (alternative service model) [GID-HTE10023] External Assessment Group report, September 2023

  For a list of the organisations that accepted the invitation to participate in this assessment as stakeholders and the Expert Adviser Specialist Committee members, see the published project documents. They were invited to attend the scoping workshop and to comment on the external assessment report.

Manufacturers and developers of technologies included in the final scope:

- CheqUp (CheqUp)
- Gro Health W8Buddy (DDM Health Ltd)
- Liva (Liva)
- Oviva (Oviva)
- Wellbeing Way (Xyla Health and Wellbeing)
- Roczen (Reset Health)
- Second Nature (Second Nature)
- Juniper (Juniper Technologies UK Ltd)
- Habitual (Habitual Health Ltd)
- Gloji (Thrive Tribe)
- Counterweight (Counterweight)
- Weight Loss Clinic (Virtual Health Partners)

Related NICE guidance:

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- Semaglutide for managing overweight and obesity. NICE technology appraisal guidance 875 (2023). Available from www.nice.org.uk/guidance/TA875
- Obesity: identification, assessment and management. NICE clinical guideline 189 (2022). Available from www.nice.org.uk/guidance/CG189
- Liraglutide for managing overweight and obesity. NICE technology appraisal guidance 664 (2020). Available from http://www.nice.org.uk/guidance/TA664
- Digitally enabled technologies to support treatment with weight-management medication in specialist weight-management services: early value assessment (2023). Available from https://www.nice.org.uk/guidance/indevelopment/gid-hte10007/

References

Please see external assessment report for full list of references.

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