Addendum to GID-HTE10023 Digitally enabled weight management programmes

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

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

Executive summary

Quality and relevance of the clinical evidence

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

Quality and relevance of the economic evidence

NA

Evidence gap analysis

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

1 Decision problem

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

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

The Table is otherwise unchanged.

2 Overview of the technology

2.1 Included technologies

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

Table 2.1.1: Included technologies

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

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

2.2 Key features of Weight Loss Clinic

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

This platform includes:

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

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

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

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

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

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

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

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

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

More information is included in the Appendix.

2.3 Key features of Counterweight

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

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

The main features of the App are:

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

- Educational Content

    ➔ Delivered in written, audio, video, Easy Read

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

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

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

    ➔ Access to a habit/behavioural toolkit containing 35 strategies

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

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

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

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

More information is included in the Appendix.

3 Clinical context

This section is not changed by the additional information.

4 Clinical evidence selection

4.1 Evidence search strategy and study selection

4.1.1 Weight loss clinic

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

4.1.2 Counterweight

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

4.2 Included and excluded studies

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

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

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

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

Table 4.4 Summary of literature

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

5 Clinical evidence review

5.1 Overview of methodologies of all included studies

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

5.2 Critical appraisal of studies

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

5.3 Results from the evidence base

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

Table 5.5 below summarises the outcome data available by technology

Table 5.5. Outcomes by technology

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

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

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

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

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

6 Adverse events and clinical risk

6.1 Adverse events

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

6.2 Discontinuation and reasons

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

7 Evidence synthesis

No change from the main report.

8 Economic evidence

NA

9 Interpretation of the evidence

9.1 Interpretation of the clinical and economic evidence

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

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

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

9.2 Integration into the NHS

No change from the main report.

9.3 Ongoing studies

9.3.1 Ongoing studies identified through searches of registries

No additional ongoing studies were identified in the searches.

9.3.2 Ongoing studies identified through company website

No additional ongoing studies were identified.

9.3.3 Studies identified through company submissions

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

Table 9.4 Counterweight ongoing studies

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

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

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

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

10 Evidence gap analysis

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

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

Table 10.1: Evidence gap analysis

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

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

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

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

10.1 Summary and conclusions of evidence gap analysis

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

10.2 Key areas for evidence generation

As for the main report.

11 Conclusions

11.1 Conclusions from the clinical evidence

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

11.2 Conclusions from the economic evidence

As for the main report.

11.3 Conclusions on the gap analysis

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

12 References

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Appendix B: Information received 4 September for additional technologies

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

1 Weight Loss Clinic (Virtual Health Partners Inc.)

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

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

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

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

This platform includes:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Completed evidence:

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

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

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

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

No ongoing studies were supplied by the Company.

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

2 Counterweight

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

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

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

DTAC status: Currently under assessment by NHS England.

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

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

[redacted].

The main features of the App are:

Self Monitoring and Goal Setting

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

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

➔ Setting and monitoring goals

In App Support

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

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

Dietary Approaches

➔ Total Diet Replacement

➔ Meal Replacement

➔ Low Carb

➔ Low Fat

➔ Intermittent Fasting

Educational Content

➔ Delivered in written, audio, video, Easy Read

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

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

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

➔ Access to a habit/behavioural toolkit containing 35 strategies

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

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

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

➔ Patient support (text chat and facilitated peer support)

➔ Unlocking educational content

➔ Electronic health record

➔ Information on service personalisation

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

The technology can be used in two ways:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

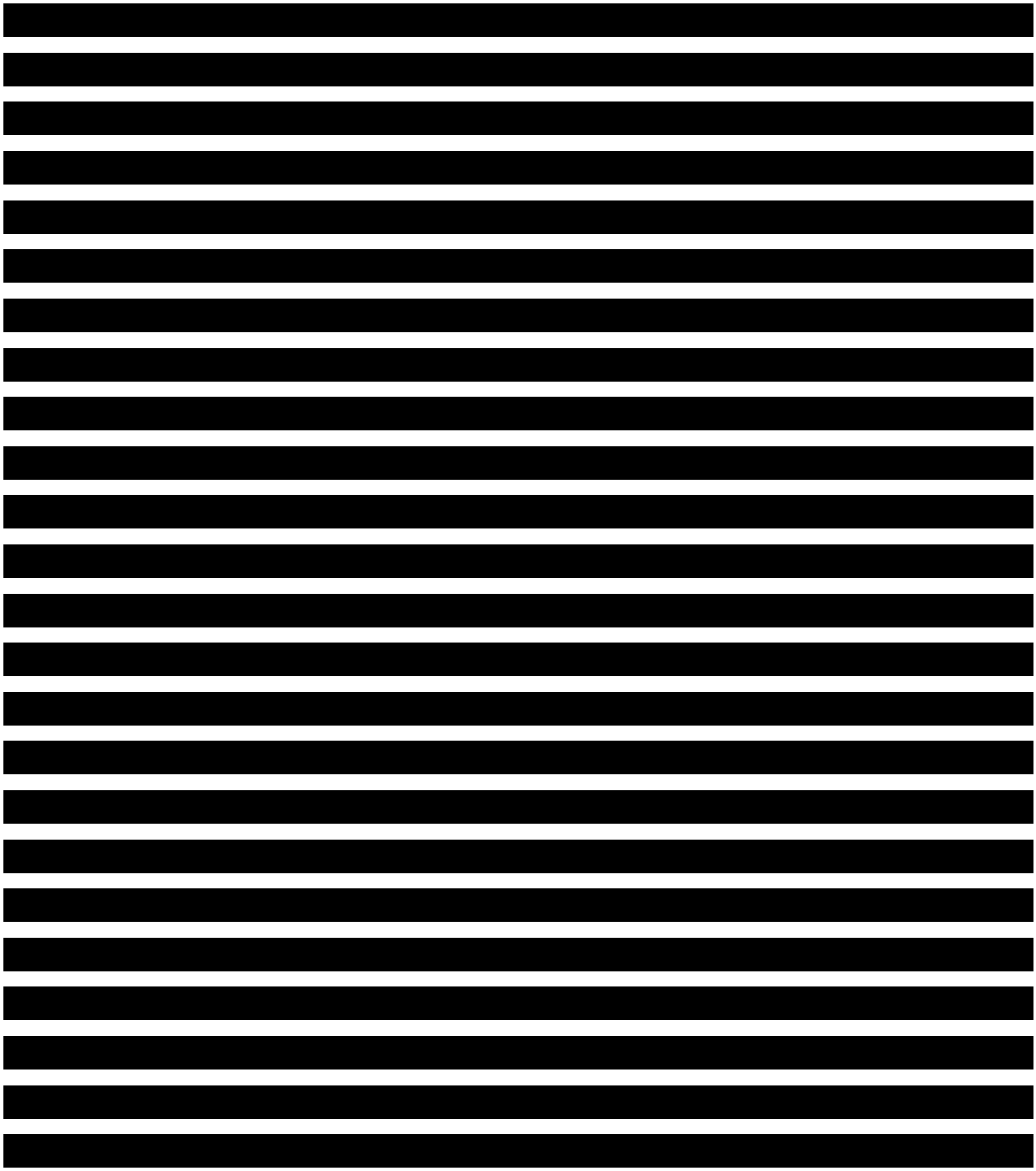
➔ **Enhanced Text Chat Engine:** In response to the evolving demands of user engagement, the text chat engine has received a significant update. This update introduces features such as emojis and support for attachments, contributing to more dynamic and interactive user interactions.

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

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

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

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



[redacted].

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

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

Patients:

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

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

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

Clinicians:

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

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

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

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

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

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

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

- Cardiovascular disease
- Type 2 diabetes
- Atherosclerosis
- Hypertension

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Licence Model:

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

Refer Out Model:

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

The most relevant comparator is standard care which could include:

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

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

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

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

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

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

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

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

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

Benefits to Patients:

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

Benefits to Healthcare Professionals:

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

Benefits to Health Systems:

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

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

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

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

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

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

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

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

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

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

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

[redacted]

Information collected by this technology:

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

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

Potential Risks and Safety Concerns:

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

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

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

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

Mitigation and Addressing Challenges:

Addressing these challenges requires a comprehensive approach that involves:

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

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

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

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

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

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

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

Counterweight Service Cost per patient (excl. VAT)

6 Months £920

12 Months £1,200

24 Months £1,560

Per patient prices are fully inclusive of all technology costs.

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

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

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

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

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

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

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

* Other publications for the DIRECT trial:

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

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

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

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

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

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

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

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

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

Type 2 diabetes remission: 2 year within-trial and lifetime-horizon cost-effectiveness of the Diabetes Remission Clinical Trial (DiRECT)/Counterweight-Plus weight management programme. Diabetologia. https://doi.org/10.1007/s00125-020-05224-2.

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

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

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

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

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

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

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

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

Ongoing studies for Counterweight:

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

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

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

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

- Xin Y, Davies A, Briggs A, McCombie L, Messow CM, Grieve E, Leslie WS, Taylor R, Lean MEJ. Type 2 diabetes remission: 2 year within-trial and lifetime-horizon cost-effectiveness of the Diabetes Remission Clinical Trial (DiRECT)/Counterweight-Plus weight management programme. Diabetologia. 2020 Oct;63(10):2112-2122. doi: 10.1007/s00125-020-05224-2. Epub 2020 Aug 10. PMID: 32776237; PMCID: PMC7476973.

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

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

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

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

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

and 1 additional paper for the OPPORTUNITY study:

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

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

Table 4.1a.iii Completed studies:

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

Table 5.1. Prioritised outcomes from publications in searches

Study	Weight change	Adherence/ completion
Weight Loss Clinic		

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

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

Table 5.3. Important outcomes from searches

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