Impact of a Health Coach–Led, Text-Based, Digital Behavior Change Intervention on Weight Loss and Psychological Well-Being in Patients Receiving a Procedureless Intragastric Balloon Program: A Prospective, Single-Arm Study

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Abstract

Background: Digital health interventions show promise for weight management. However, few text-based behavior change interventions have been designed to support patients receiving intragastric balloons, and none have simultaneously evaluated weight loss, psychological well-being, and behavior change despite the crucial interplay of these factors in weight management.

Objective: To assess whether a health coach-led, asynchronous text-based, Digital Behavior Change Coaching Intervention (DBCCI) delivered to participants receiving an intragastric balloon and its after-care program: (1) was feasible and acceptable to participants, and (2) supported improved outcomes including weight loss, psychological well-being, and lifestyle behavior change conducive to weight loss maintenance.

Methods: This 12-month, single-arm, prospective study enrolled adults 21-65 years with body mass index (BMI)?27 kg/m2 receiving a procedureless intragastric balloon (PIGB) at 5 bariatric clinics in the United Kingdom and the Netherlands. Participants received both the DBCCI and the clinic-led PIGB after-care program (remotely delivered) for 6 months after PIGB placement, then no interventions for an additional 6 months. The DBCCI was an evidence-based, personalized, digital behavior change coaching intervention wherein health coaches supported participants via exchanged asynchronous, in-app text messages. Over the 12-month study, we assessed percentage of total body weight loss (TBWL) and psychological well-being via self-administered validated questionnaires (Warwick-Edinburgh Mental Wellbeing Scale [WEMWBS], Generalized Anxiety Disorder [GAD-7], Impact of Weight on Quality of Life-Lite Clinical Trials Version scale [IWQOL-Lite-CT], Loss of Control Over Eating Scale-Brief [LOCES], Weight Efficacy Lifestyle questionnaire-Short Form [WEL-SF], and Barriers to Being Active Quiz [BBAQ]). Participant engagement and acceptability of the intervention were assessed via self-reported surveys.

Results: 107 participants (89.7% female, mean baseline BMI=35.4 kg/m2) were included in the analysis. Mean TBWL was 13.50% at the end of the DBCCI and 11.22% at the 12-month follow-up (P<.001). Significant improvements were observed for all psychological well-being measures throughout the 12 months, except for GAD-7 (improvement at Month 1) and BBAQ (improvements at Months 3 and 6). Surveys showed overall high levels of engagement with, and acceptability of the health coaching provided via the DBCCI, especially during the active intervention period.

Conclusions: This study provides evidence that a health coach–led, asynchronous text-based, digital behavior change intervention was engaging and acceptable to participants with overweight and obesity. This behavior change intervention, delivered alongside the PIGB and its after-care program, supported improved weight loss outcomes and psychological well-being versus baseline, and was associated with lifestyle behavior changes known to help achieve and maintain long-term weight loss

and improved health outcomes. Findings at follow-up suggest a potential need for longer-term, more intense coaching to focus on weight loss maintenance and support ongoing self-coaching. This could be achieved by leveraging artificial intelligence to provide ongoing automated behavior change coaching support to augment human-led care. Clinical Trial: ClinicalTrials.gov NCT05884606

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(Structured abstract; word count: 446/450)

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Trial Registration: ClinicalTrials.gov NCT05884606

Keywords: Intragastric Balloon; Obesity; Behavior Change; Health Coaching; Digital Health; Weight Management; Well-Being

Introduction

The effective management of obesity requires a multimodal approach based on evidence-based behavior change strategies to achieve lifestyle modification, which are delivered alongside interventions including cognitive behavioral therapy (CBT) for obesity, medical nutritional therapy, bariatric interventions, and antiobesity medications, all on a personalized basis [1-5].

The psychological well-being of patients with obesity is crucial to the management of this disease. However, the role it plays is complex due to the bidirectional relationship between psychological correlates and weight outcomes [6]. How these psychological factors impact weight loss and subsequent weight maintenance remains unclear [7]. Compared with populations who are not living with obesity, many patients who perceive themselves as living with obesity show poorer psychological well-being [8]. In turn, these patients experience greater difficulties making and sustaining lasting behavior changes and tend to lose less weight than those with better psychological well-being [6, 9]. Understanding the mechanisms by which psychological factors influence the achievement of long-lasting lifestyle habits is imperative for the management of obesity [10].

Intragastric balloons are a nonsurgical treatment option for suitable patients with overweight and obesity. Similar to bariatric surgery and other medical options, it is recommended that treatment with intragastric balloons be delivered alongside lifestyle modification and behavioral support to achieve and maintain lifestyle changes conducive to sustained weight loss and improved health outcomes [11, 12]. Among interventions to deliver lifestyle support and promote healthy lifestyle habits, digital health interventions have become increasingly attractive due to their advantages over face-to-face approaches. These include anytime access, anonymity, fewer interpersonal barriers relating to social anxiety or weight-related stigma, affordability, and a reduction in healthcare costs by virtue of the potential for widespread scalability [13-15].

A growing number of studies demonstrate the effectiveness of digital health coaching or digital behavior change intervention, compared to in-person support, in improving weight loss, behavior change, or psychological well-being outcomes in patients with overweight or obesity [16-19]. However, to the authors' knowledge, no studies on digital behavior change interventions have assessed all three outcomes at the same time in this population. Given the complex interrelation between weight loss, behavior change, and psychological well-being, it would be relevant to consider and evaluate all three simultaneously. In addition, research about digital health interventions in patients eligible for metabolic or bariatric surgery—including those who receive intragastric balloons—is also lacking (eg, [15]). Furthermore, little is known about whether digital coaching interventions that are layered on top of a standard after-care program, and delivered entirely via text-based in-app messaging are acceptable to patients.

In order to provide evidence to address these gaps, this study aimed to assess a novel digital health coaching intervention in patients with overweight and obesity being treated with an intragastric balloon in combination with the balloon after-care program (a clinic-led weight management program). In particular, the study aimed to assess: (1) whether an asynchronous, text-based behavior change health coaching intervention delivered entirely remotely was feasible to implement, and acceptable to this patient population; and (2) whether it was associated with improvements in weight loss, psychological well-being, and patient satisfaction, including factors related to behavior change.

Materials and Methods

Study Design

This was a single-arm, prospective study conducted in 3 bariatric clinics in the United Kingdom and

2 in the Netherlands between July 2021 and November 2022.

Ethical Approval

The ethics committee at the Central Committee on Research Involving Human Subjects (CCMO) in the Netherlands approved the study protocol (reference number NL78284.096.21). UK Health Research Authority confirmed that ethics committee approval was not required for UK sites, since eligible participants were not NHS patients, and no NHS sites or services were to be used.

Participants

Adults aged 21 to 65 years were eligible to participate in the study if they met all inclusion criteria: (1) providing informed consent; (2) having a BMI≥27 kg/m^2; (3) weighing <180 kg; (4) having no contraindications for the use of the procedureless intragastric balloon (PIGB; Allurion Technologies) (Multimedia Appendix 1); (5) having received a PIGB in accordance with the approved indications for use on the day of potential enrollment; (6) owning an Android or iPhone smartphone; (7) being proficient in reading the English language; and (8) being willing to download the Allurion patient app, use the Allurion connected scale, and wear the Allurion smartwatch for the duration of the study. Study participants covered the cost for their treatment with the PIGB weight management program.

Study Sites and Recruitment Process

A convenience sample of 5 bariatric clinics in the United Kingdom and the Netherlands were chosen. These included varied geographic location and degree of urbanization, clinic size, and number of balloon placements. The aim was to provide a representative sample of European participants to better generalize to the target population of patients receiving a PIGB. Eligible participants were given the participant information sheet in their local language and were invited to participate by clinic staff. After reviewing the participant information sheet, all study participants provided written informed consent, in person or via email, before study enrollment on the day of PIGB placement. Enrollment included downloading and registering on the patient app.

Intervention

The Digital Behavior Change Coaching Intervention (DBCCI) is a health coach–led behavior change intervention delivered via remote, asynchronous, in-app, text-based messaging over 6 months. The DBCCI was delivered in combination with standard care—a clinic-led weight management program.

Clinic-Led Weight Management Program

Prior to study start, participants underwent an initial medical and dietary history, and lifestyle assessment, to determine eligibility for the intragastric balloon. At the baseline visit, participants received the PIGB, which is swallowed and requires no anesthesia or endoscopy for placement, making it possible to place in the outpatient setting [20-26]. Before and after filling it with 550 ml distilled water, the correct positioning of the PIGB in the stomach is confirmed by X-Ray visualization of its radiopaque components. In addition to the PIGB, which takes up space in the stomach and delays gastric emptying (to help participants feel fuller quicker on smaller portions and fuller for longer), the clinic-led weight management program also consists of remote patient monitoring and communication tools (smartphone app, wireless connected body composition scale, and smartwatch) to support patients during treatment, and to provide the clinic team an opportunity to closely monitor their patients' progress and intervene if needed. After approximately 4 months, the

PIGB self-empties via a release valve that opens automatically, allowing the contents to empty into the stomach, and the collapsed balloon passes naturally through the gastrointestinal tract.

For 6-months after PIGB placement, participants received the PIGB after-care program offered by the study clinics at time of study conduction. This program consisted of personalized symptom, nutritional, dietary, physical activity, and lifestyle management advice delivered by the clinic team, including a physician or a nurse (or both) and a registered dietitian or lifestyle coach. Between baseline visit and month 6 after PIGB placement, participants had 4-6 telehealth consultations with their clinic team. Due to the COVID-19 pandemic, all provider-to-participant after-care treatment and support were delivered remotely (via video or phone calls, email, and messaging apps such as WhatsApp).

Digital Behavior Change Coaching Intervention (DBCCI)

The DBCCI consisted of multicomponent, theoretically driven, evidence-based, and personalized behavior change coaching, delivered remotely by health coaches via asynchronous one-to-one text messaging (it did not include telehealth interactions). The overall goal of the DBCCI was to facilitate behavior change to support weight management, including implementing behavioral actions relating to diet, physical activity, sleep, self-regulation, and psychological well-being. As a personalized intervention, the aim of the DBCCI was to identify suitable behavioral actions that were realistic and achievable for each participant, and to apply behavior change techniques (BCTs) to support the participant in the process of successful habit formation. In particular, the DBCCI aimed to promote participant autonomy, enhance self-efficacy, and support the development of self-regulation skills to manage challenges and potential relapses to unhelpful patterns of behavior.

Development of the Intervention

The DBCCI was designed by the Behavioral Science team at Allurion Technologies using the behavior change wheel, an internationally recognized framework for behavior change intervention development [27]. As a first step, a literature review was conducted to identify appropriate and effective BCTs for weight management and common barriers and facilitators to weight-related behavior change (the latter comprising psychological, social, environmental, physical, and cognitive aspects). This information was combined with previous quantitative and qualitative survey data collected from patients who had received the PIGB. All these data were then mapped on to the capability-opportunity-motivation-behavior model (COM-B; that is, a theoretical framework involving the 3 essential conditions that influence behavior change) and to the Theoretical Domains Framework (TDF; that is, the 14 domains within the COM-B providing further details about the drivers of behavior) [27]. From this, relevant BCTs to help address the barriers to change and enable sustained behavior change were identified using the BCT Taxonomy v1 [28]. These BCTs constituted the main components of the intervention, as described below.

Components of the Intervention

Core BCTs were delivered to all participants and included: goal setting, action planning, problem solving, and self-monitoring (self-tracking) of behavior. Additional BCTs were offered on a personalized, ad hoc basis as required. Examples include restructuring the physical or social environment and providing prompts, cues, and rewards to action. To help identify suitable new behaviors (habits) to focus on, participants also received evidence-based “weight loss actions”, which were developed based on an adaptation of the weight loss actions described in the PREVAIL (People Regulating Themselves to Achieve Weight Loss) study [29].

The DBCCI provided participants with written guidance on the rationale for the weight loss actions and the core BCTs designed to help implement them. Whenever required, other techniques based on CBT and acceptance and commitment therapy (ACT) [1, 30] were also utilized by the health coaches, including support with cognitive restructuring, behavioral and emotional self-regulation,

stress management, sleep hygiene, and relapse prevention. Motivational interviewing techniques [31] were applied where necessary to support participants expressing ambivalence about lifestyle change. In addition, whenever any specific balloon-related dietary or symptom management concerns arose, or a request for personalized nutrition advice was made during the health coaching, the coaches referred participants back to their clinic teams.

Delivery of the Intervention and Access by Participants

The DBCCI started between baseline and day 10 after PIGB placement and it finished at the end of Month 6 to coincide with the end of the clinic-led program (after which no further communication occurred). As part of the DBCCI, participants were requested to download the patient app, weigh themselves with the connected scale at least weekly, wear the smartwatch as often as possible, and engage with their health coach as needed up to Month 6.

The DBCCI was delivered by experienced health coaches trained in evidence-based BCTs who had an undergraduate or higher degree in health psychology, nutrition, physical activity, or a behavior change-related subject. Coaches had access to professional supervision from two psychologists trained in CBT and a senior registered dietitian throughout the DBCCI period. Of note, coaches did not use any of the psychological well-being outcome data collected during this study to personalize their coaching.

The DBCCI was delivered to participants via the patient app, while coaches and clinics utilized a separate web-based app designed for remote patient management, monitoring, and communication (Allurion Insights).

Health coaches provided asynchronous personalized, text-based coaching support via messaging, 7 days per week, and responded to participant messages within 24 hours. Participants were closely monitored, and records kept of the participants action plans and revisions, their goals, and any information relevant to their progress. These records were accessible to all health coaches. The frequency of support was participant-led, with health coaches contacting participants at least once weekly to check in and provide support and feedback on their progress in relation to their weight change, physical activity, and sleep data collected as part of the PIGB after-care support program. All participants were able to access the coaches daily for asynchronous support as needed, during the 6-month period.

Participants received in-app notifications when a message was received. Health coaches were notified via the web-based app when messages were opened by a participant. Participants had access to the health coach messages and to the electronic materials shared with them 7 days per week during the 6-month intervention period.

Assessments and Outcomes

Weight

Weight data (in kg) were obtained via the connected scale at baseline (defined as time of first weight recording within 7 days from study start) and each month (defined as each 30-day period [±7 days] after study start), except for Month 12 in which weight data were obtained via connected scale or via self-reporting through the participant-reported satisfaction survey.

Psychological Well-Being

The following self-administered validated questionnaires were used to assess the psychological well-being of participants:

- The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) is a 14-item internationally used measure of well-being in the general population [32, 33]. Total scores range from 14 to 70, with higher scores indicating better well-being [33].
- The Generalized Anxiety Disorder (GAD-7) is a 7-item scale widely used to measure anxiety

in non-psychiatric populations [34]. Total scores range from 0 to 21, with higher scores indicating more severe levels of anxiety, associated with functional impairment [34].

- The Impact of Weight on Quality of Life-Lite Clinical Trials Version scale (IWQOL-Lite-CT) is a 20-item measure of weight-related impact on physical and cognitive and emotional functioning [35]. The IWQOL-Lite-CT includes two domains, for which scores are reported here along with total score: the physical domain (7 items) and the psychosocial domain (13 items). IWQOL-Lite-CT total scores and scores for each domain range from 0 to 100, with higher values indicating higher levels of functioning. Score changes of ≥13.5 (physical domain), ≥16.2 (psychosocial domain), or ≥16.6 points (total score) indicate meaningful responses to treatment [36].
- The Loss of Control Over Eating Scale-Brief version (LOCES-Brief) is a 7-item measure of perceived degree of control versus impulsivity for eating and overeating [37]. Total scores range from 0 to 28, with higher scores indicating less control over eating.
- The Weight Efficacy Lifestyle questionnaire-Short Form (WEL-SF) is an 8-item measure of weight-related self-efficacy [38]. Total scores range from 0 to 80, with higher scores indicating greater confidence or self-efficacy.
- The Barriers to Being Active Quiz (BBAQ) is a 21-item measure of the cognitive, environmental, social, and health-related barriers to physical activity [39]. Total scores range from 0 to 63, with higher scores indicating a greater degree of difficulty to being active.

Questionnaires were completed via Qualtrics software survey tool (Qualtrics) at baseline and at Months 1, 3, 6, and 12. Invitations to complete the questionnaires were sent via patient app messaging and email.

Participant Engagement, Acceptability of the Intervention, and Impact on Behavior Change

To assess participant engagement and acceptability of the intervention, participant-reported satisfaction surveys were conducted to measure perceived usefulness of the intervention and its components and level of satisfaction with the intervention and their weight management journey overall. The surveys also included items to assess self-reported mediators of lifestyle behavior change, which are factors known to have a direct impact on successful behavior change (for example, having made a plan to change eating or physical activity habits). The surveys consisted of non-validated questions, with items rated on a 5-point Likert scale (“0: strongly disagree”, “1: slightly disagree”, “2: unsure”, “3: slightly agree”, “4: strongly agree”) or an 11-point scale (0 to 10, with 0 as “not at all” and 10 as “completely”) The questions were developed with input from a multidisciplinary panel of experts in the field of obesity research and behavioral science. Participants completed the evaluation surveys through the Qualtrics survey tool at Months 1, 3, 6, and 12; some items were not included at all timepoints, depending on the intended measurement and its relevance and timing relative to the intervention. Invitations to complete the questionnaires were sent via patient app messaging and email.

Statistical Analyses

Statistical analyses were performed using R software (version 4.1.1; R Foundation for Statistical Computing). All R packages used were included in the Comprehensive R Archive Network (CRAN) dated 19 December 2022 (latest version at the time of analysis). Imputation analyses were performed using SAS software (version 9.4).

Since this was a study for exploratory purposes, no formal study size or power calculations were performed a priori. Based on the average number of patients receiving the PIGB in the clinics that participated in the study, it was estimated that we would be able to recruit up to 150 participants

during the recruitment period of the study.

Demographic characteristics (age, sex, ethnicity, body weight, BMI, BMI category, weight loss goal, and highest education level) were summarized descriptively, using frequency and proportion for categorical variables and mean and standard deviation (SD) for continuous variables. BMI categories were defined as follows: overweight, 25 kg/m^2 to <30 kg/m^2; obesity class I, 30 kg/m^2 to <35 kg/m^2; obesity class II, 35 kg/m^2 to <40 kg/m^2; and obesity class III, ≥40 kg/m^2 [40].

The multiple imputation method was selected and applied to handle missing weight data. After data imputation, the least-square means for change in weight compared with baseline were obtained for each timepoint using a generalized estimation equation (GEE) model that included weight as the dependent variable, and visit, age, country and visit-by-country interaction as covariates. Subject and intercept were treated as random effects. Least-square means for change in weight were then converted to an estimated mean percent change (referred to as total body weight loss [TBWL] and expressed as %). Standard error of the mean TBWL was obtained using Taylor-based expansion, while two-sided *P* values were derived from the GEE model (with a .05 significance level). Weight loss maintenance was calculated as the percentage of mean TBWL at the end of the follow-up in relation to the mean TBWL at a given timepoint during the study.

Mean scores and SDs were calculated for each of the validated questionnaires to assess participants' psychological well-being at each timepoint. Change in score over time was expressed as a difference score, calculated as score at timepoint of interest minus score at baseline. Difference scores versus baseline were tested using two-sided paired t-tests, with a .05 significance level. Mean difference scores, SD, 95% CIs, and *P* values of the comparison versus baseline were obtained for all questionnaires and timepoints.

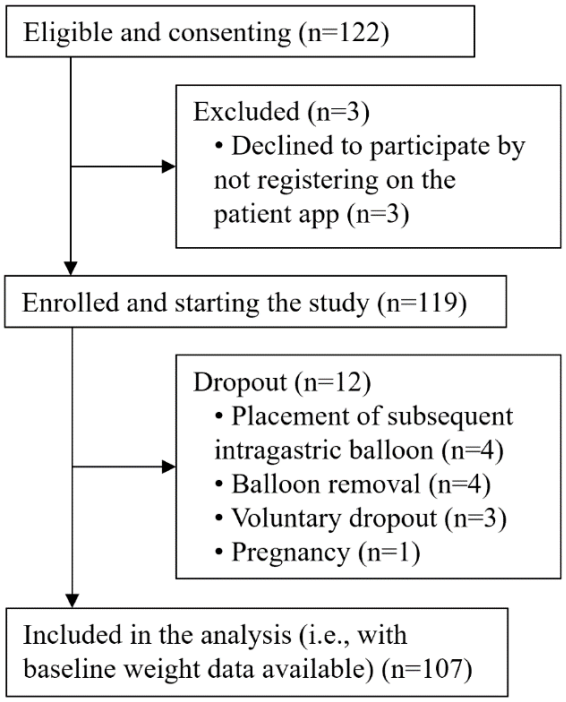
For the analysis of the participant-reported satisfaction surveys measuring feasibility, acceptability, and impact on behavior change, the number and percentage of respondents who scored positively to items at Months 1, 3, 6, and 12 were summarized. A positive score was defined as a score ≥3 for question items rated on a 5-point (0-4) Likert scale, and a score ≥5 for items rated on an 11-point (0-10) Likert scale. An average of the percentage of positive responders during the DBCCI intervention (Months 1, 3, and 6) was also calculated.

Results

Study Population

Out of the 122 eligible participants who provided consent to participate in the study, 119 were enrolled and 107 were included in the analysis; reasons for dropout are detailed in Figure 1. The number of participants for whom data were available and included in the analyses of the outcomes at each timepoint is shown in Multimedia Appendix 2.

Figure 1. Participant flow diagram.



n, number of participants.

Seventy-four (69.2%) of the 107 participants received the intervention in the United Kingdom, and 33 (30.8%) in the Netherlands. Table 1 shows the demographic characteristics of the study population. Most participants (96/107, 89.7%) were female, with an average age of 41.8 years. The mean BMI was 35.4 kg/m^2 and participants had an average TBWL goal of 20.8% at baseline (Table 1).

Table 1. Demographic characteristics of the study population.

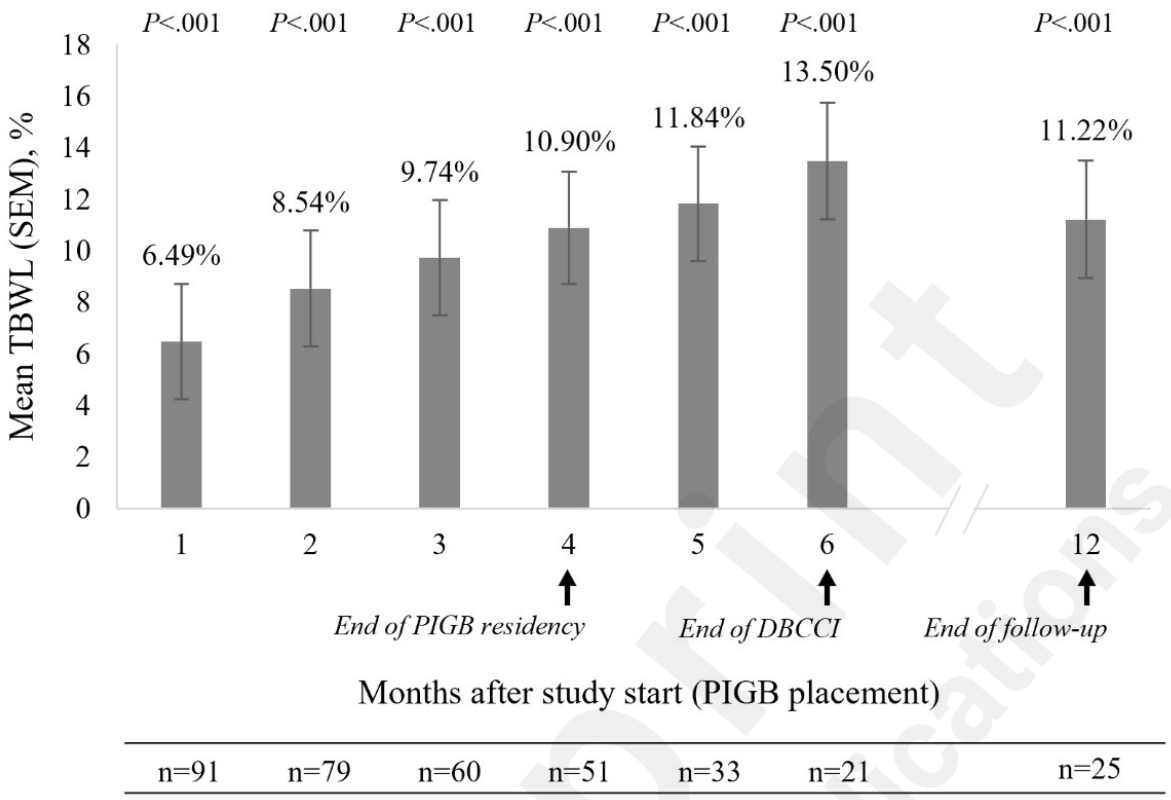
	Study population (N=107)
Age, mean (SD), years	41.8 (10.6)
Female sex, n (%)	96 (89.7)
Race and ethnicity, n (%)[a]	
Arab	1 (0.9)
Asian	11 (10.3)
Black	2 (1.9)
Multiethnic	5 (4.6)
White	64 (59.9)
Other	24 (22.4)
Body weight, mean (SD), kg	99.4 (18.6)
BMI, mean (SD), kg/m^2	35.4 (5.4)
BMI category, n (%)[b]	
Overweight	12 (11.2)
Obesity class I	46 (43.0)
Obesity class II	32 (29.9)
Obesity class III	17 (15.9)
Weight loss goal set by participant, mean (SD), % of baseline body weight	20.8 (5.6)
Highest education level, n (%)[c]	
Secondary school	7 (6.5)
Vocational education	10 (9.3)
University degree	72 (67.2)
Other	18 (16.8)

[a]"Arab" category includes "Moroccan"; "multiethnic" includes "Antillean", "mixed Netherlands", "mixed United Kingdom", and "Suriname"; "White" includes "Nederland" and "White"; "other" includes "not available", "not specified", and "other".
[b]BMI categories were defined as: overweight, 25 kg/m^2 to <30 kg/m^2; obesity class I, 30 kg/m^2 to <35 kg/m^2; obesity class II, 35 kg/m^2 to <40 kg/m^2; and obesity class III, ≥40 kg/m^2 [40].
[c]"University degree" includes "college", "bachelor's degree", "master's degree", and "PhD"; "other" includes "not available" and "other".
BMI, body mass index; n, number of participants in the category indicated; N, total number of participants; PhD, Doctor of Philosophy; SD, standard deviation.

Weight Loss

One month after study start, participants achieved a mean TBWL of 6.49% (Figure 2). The TBWL further increased to 10.90% at Month 4 (when PIGB residency ended) and peaked at 13.50% at Month 6 (when both the clinic standard after-care program and DBCCI ended). The TBWL remained at 11.22% at the 12-month follow-up—that is, 8 months after end of PIGB residency and 6 months after end of the DBCCI (Figure 2). The TBWL was statistically significant versus baseline at all timepoints evaluated (P<.001). In terms of body weight loss maintenance, the mean TBWL at 12-month follow-up represented 103% of the TBWL at Month 4 (end of PIGB residency) and 83.1% of the TBWL at Month 6 (end of DBCCI).

Figure 2. TBWL over the study period.



Note: at Month 12, weight data were obtained via connected scale (n=11 participants) and via self-reporting through the participant-reported satisfaction survey (n=14 participants). A multiple imputation method was used to handle missing weight data. TBWL was estimated using GEE models adjusting for age, visit, and country. Error bars represent SEM. *P* values for the comparison versus baseline.
DBCCI, Digital Behavior Change Coaching Intervention; GEE, generalized estimation equation; n, number of participants with available data at that timepoint; PIGB, procedureless intragastric balloon; SEM, standard error of the mean; TBWL, total body weight loss.

Psychological Well-Being

WEMWBS results

A mean WEMWBS score of 45.9 was observed at baseline (N=91; Table 2). During the intervention period, statistically significant increases in this score were observed at all timepoints, reaching a high of 51.2 at Month 6, when the DBCCI ended (mean difference score versus baseline=4.7, 95% CI 1.8-7.6; *P*=.002). At the 12-month follow-up, scores slightly decreased to 48.0 but remained significantly higher than at baseline (*P*=.02).

Table 2. Psychological well-being outcomes over the study period.

		Timepoint after study start			
	Baseline	**Month 1**	**Month 3**	**Month 6 (end of DBCCI)**	**Month 12 (end of follow-up)**
WEMWBS					
N at timepoint	91	69	58	42	43
Absolute score, mean (SD)	45.9 (8.7)	49.5 (7.8)	50.6 (9.7)	51.2 (7.9)	48.0 (10.7)

Difference score versus baseline[a]					
N of difference score	NA	68	57	41	39
Mean (SD)	NA	3.8 (7.0)	4.0 (8.0)	4.7 (9.3)	3.7 (9.2)
95% CI	NA	2.1-5.5	1.9-6.1	1.8-7.6	0.7-6.7
P value	NA	**<.001**	**<.001**	**.002**	**.02**
GAD-7					
N	90	69	58	42	43
Absolute score, mean (SD)	6.0 (4.3)	4.8 (4.1)	5.3 (4.5)	5.1 (3.9)	5.4 (4.8)
Difference score versus baseline[a]					
N of difference score	NA	67	56	40	38
Mean (SD)	NA	–1.3 (3.9)	–0.8 (4.2)	–0.3 (4.6)	–1.2 (4.9)
95% CI	NA	–2.2 to –0.3	–1.9 to 0.3	–1.7 to 1.2	–2.8 to 0.4
P value	NA	**.009**	.16	.73	.14
IWQOL-Lite–CT					
N	91	69	58	41	42
Absolute score, mean (SD)	45.2 (15.6)	56.5 (14.1)	62.8 (16.3)	63.4 (15.6)	57.5 (19.1)
Difference score versus baseline[a]					
N of difference score	NA	68	57	40	38
Mean (SD)	NA	11.8 (13.1)	17.3 (14.9)	19.2 (18.6)	13.6 (17.0)
95% CI	NA	8.6-14.9	13.3-21.2	13.3-25.2	8.0-19.2
P value	NA	**<.001**	**<.001**	**<.001**	**<.001**
IWQOL-Lite–CT – physical domain					
N	91	69	58	41	42
Absolute score, mean (SD)	55.9 (17.9)	65.7 (16.3)	73.5 (16.8)	72.5 (20.6)	67.8 (20.3)
Difference score versus baseline[a]					
N of difference score	NA	68	57	40	38
Mean (SD)	NA	10.8 (14.7)	17.9 (14.8)	16.9 (19.2)	13.3 (17.7)
95% CI	NA	7.3-14.4	13.9-21.8	10.7-23.0	7.4-19.1
P value	NA	**<.001**	**<.001**	**<.001**	**<.001**
IWQOL-Lite–CT – psychosocial domain					
N	91	69	58	41	42
Absolute score, mean (SD)	39.5 (17.7)	51.6 (16.3)	57.1 (19.0)	58.5 (16.0)	52.0 (21.0)
Difference score versus baseline[a]					

N of difference score	NA	68	57	40	38
Mean (SD)	NA	12.3 (15.1)	16.9 (17.6)	20.5 (20.3)	13.8 (17.8)
95% CI	NA	8.6-16.0	12.3-21.6	14.0-27.0	7.9-19.6
P value	NA	**<.001**	**<.001**	**<.001**	**<.001**
LOCES-Brief					
N	91	69	58	41	41
Absolute score, mean (SD)	25.0 (7.0)	13.9 (4.8)	16.6 (6.6)	16.5 (6.0)	18.1 (7.7)
Difference score versus baseline[a]					
N of difference score	NA	68	57	40	38
Mean (SD)	NA	−10.8 (8.0)	−8.3 (8.6)	−8.2 (7.4)	−6.3 (6.7)
95% CI	NA	−12.8 to −8.9	−10.5 to −6.0	−10.6 to −5.8	−8.5 to −4.1
P value	NA	**<.001**	**<.001**	**<.001**	**<.001**
WEL-SF					
N	83	68	57	41	40
Absolute score, mean (SD)	40.8 (15.6)	51.1 (16.4)	50.7 (17.0)	53.4 (13.4)	47.0 (19.5)
Difference score versus baseline[a]					
N of difference score	NA	62	52	37	33
Mean (SD)	NA	11.3 (15.4)	11.3 (18.1)	9.2 (17.6)	6.9 (16.3)
95% CI	NA	7.4-15.2	6.3-16.3	3.4-15.1	1.1-12.6
P value	NA	**<.001**	**<.001**	**.003**	**.02**
BBAQ					
N	90	66	57	40	40
Absolute score, mean (SD)	22.9 (10.9)	20.6 (10.5)	17.4 (11.8)	14.3 (9.8)	21.8 (14.2)
Difference score versus baseline[a]					
N of difference score	NA	65	56	39	36
Mean (SD)	NA	−1.7 (8.0)	−4.1 (11.0)	−5.6 (7.7)	−1.2 (9.2)
95% CI	NA	−3.7 to 0.3	−7.0 to −1.2	−8.1 to −3.1	−4.3 to 2.0
P value	NA	.09	**.007**	**<.001**	.45

[a]Difference scores were calculated as score at the timepoint of interest minus score at baseline. Bolded *P* values denote statistically significant difference versus baseline ($P<.05$).
BBAQ, Barriers to Being Active Quiz; CI, confidence interval; DCCBI, Digital Behavior Change Coaching Intervention; GAD-7, Generalized Anxiety Disorder 7-item scale; IWQOL-Lite-CT, Impact of Weight on Quality of Life-Lite Clinical Trials Version scale; LOCES-Brief, Loss of Control Over Eating Scale-Brief version; N, number of participants with available data; NA, not applicable; SD, standard deviation; WEL-SF, Weight Efficacy Lifestyle questionnaire-Short Form; WEMWBS, Warwick-Edinburgh Mental Wellbeing Scale.

GAD-7 results

The mean GAD-7 score at baseline was 6.0 (N=90; Table 2), which significantly decreased to 4.8 at Month 1 (mean difference=–1.3, 95% CI –2.2 to –0.3; *P*=.009). From Month 3, scores ranged between 5.1 and 5.4, with no significant differences compared with baseline (Table 2).

IWQOL-Lite-CT results

The total IWQOL-Lite-CT mean score at baseline was 45.2 (N=91; Table 2). Scores gradually and significantly increased up to 63.4 at Month 6, when the DBCCI ended (mean difference=19.2, 95% CI 13.3-25.2; *P*<.001). At the 12-month follow-up, the mean score decreased to 57.5, but remained statistically higher than at baseline (*P*<.001).

Scores for the physical and psychological domains of the IWQOL-Lite-CT scale also increased during the study. At baseline, IWQOL-Lite-CT–Physical domain score was 55.9 (N=91; Table 2), which significantly increased during the DBCCI intervention (mean difference at Month 6=16.9, 95 CI 10.7-23.0; *P*<.001). At Month 12, scores modestly decreased to 67.8 but remained significantly higher than at baseline (*P*<.001). A similar change over time was seen for the IWQOL-Lite-CT–psychological domain, with a baseline score of 39.5 (N=91; Table 2) that increased progressively until Month 6 (mean difference=20.5, 95% CI 14.0-27.0; *P*<.001). Scores slightly decreased to 52.0 at the 12-month follow-up; however, scores at all timepoints were significantly higher than at baseline *(P*<.001).

LOCES-Brief results

The mean LOCES-Brief score at baseline was 25.0 (N=91; Table 2). This decreased significantly to 13.9 at Month 1 (mean difference=–10.8, 95% CI –12.8 to –8.9; *P*<.001), then remained stable at 16.5-16.6 up to Month 6, with statistically significant reductions at all timepoints compared with baseline (*P*<.001). At Month 12, the absolute score increased to 18.1 but remained significantly lower than at baseline (*P*<.001).

WEL-SF results

The mean score for WEL-SF at baseline was 40.8 (N=83; Table 2). Scores increased to 53.4 at Month 6 (mean difference=9.2, 95% CI 3.4-15.1; *P*=.003), then decreased to 47.0 at Month 12. WEL-SF scores remained significantly higher at all timepoints compared with baseline (Table 2).

BBAQ results

The mean BBAQ score at baseline was 22.9 (N=90; Table 2). After a modest, non-statistically significant decrease at Month 1, mean scores significantly and steadily decreased until Month 6, when they reached a minimum of 14.3 (mean difference=–5.6, 95% CI –8.1 to –3.1; *P*<.001). At Month 12, mean scores increased to 21.8, with no statistical difference compared to baseline (Table 2).

Participant Engagement, Acceptability of the Intervention, and Impact on Behavior Change

The detailed results on participant engagement, acceptability, and impact on behavior change are presented in tabular format in Multimedia Appendix 3. In general, participants reported high levels of satisfaction with the DBCCI. On average, 81.9% scored positively (ie, agreed, be it slightly or strongly) to the item “I have found the health coaching useful/helpful”. Such percentage of agreement remained high up until Month 6, when the DBCCI ended.

An average 81.6% of participants agreed with the items “I feel supported by my health coach towards meeting my weight goals” and “My study health coaches helped me to meet my weight

goals". Percentages were higher at Month 1 (54/63, 85.7%) than at Month 6 (30/39, 76.9%). Throughout Months 1 to 6, an average 73.0% of participants agreed with the item "My health coach has helped me develop strategies to lose weight", with percentages increasing from 69.4% (43/62) at Month 1 to 80.0% (32/40) at Month 6.

A total of 67.7% (44/65) of participants at Month 1 and 66.1% (37/56) at Month 3 agreed with the item "I feel confident that I can reach my goal weight and maintain it". In relation to that, 90.9% (60/66) of participants at Month 1 and 91.2% (52/57) at Month 3 agreed with the item "I feel confident about making changes to help me lose weight". When asked at Months 6 and 12, the percentages of participants agreeing with the item "I feel confident about maintaining my weight loss" dropped to 57.5% (23/40) and 45.0% (18/40), respectively.

An average 65.4% of participants agreed with the item "I have been able to put the information and actions from the articles (weight loss actions) into practice", with higher rates at earlier than later timepoints (49/64, 76.6%; 34/54, 63.0%; and 21/37, 56.8%; at Months 1, 3, and 6, respectively). In terms of mediators of behavior change, 85.0% (34/40) of participants or more agreed with the item "I have made a plan to change my eating habits", and 81.8% (45/55) or more agreed with the item "I have made a plan to change my physical activity habits", when asked during the DBCCI. Rates dropped to 77.5% (31/40) and 65.0% (26/40), respectively, at Month 12.

When asked about barriers to reaching a goal weight, 84.4% of participants on average (Months 1-6) agreed with the item "I am aware of some of the barriers to me reaching my weight goals". This percentage was high at Months 1 (59/66, 89.4%) and 3 (51/57, 89.5%), then decreased to 55.0% (22/40) at Month 12. On average during the 6-month DBCCI, 66.2% of participants agreed with the item "My health coaching was personalized to my needs", with the percentage being highest at Months 1 (45/63, 71.4%) and 3 (41/56, 73.2%) then declining to 53.9% (21/39) at Month 6.

When asked "How satisfied have you been tracking your weight, using the connected scales, on a scale from 0 (not at all satisfied) to 10 (completely satisfied)?", an average 85.4% of participants over the 6-month DBCCI answered positively, whereas 95.8% (23/24) did so at Month 12.

Discussion

This study provides evidence that a health coach-led, digital behavior change intervention delivered entirely remotely via text-based messaging (the DBCCI) was feasible to implement and was acceptable to participants with overweight or obesity who participated in a clinic-led weight management program. The DBCCI, along with the PIGB after-care program, was associated with improved weight loss and sustained psychological well-being outcomes over the 12-month study follow-up as compared with baseline. In addition, participants reported high levels of engagement with, and acceptability of, the health coaching provided. Many reported having made behavior change plans, feeling more confident about lifestyle change, and having put what they had learned into practice.

Weight Loss

The mean 10.90% TBWL at the end of PIGB residency (Month 4) in this study falls in the range of 10%-15% mean TBWL at balloon passage reported in other PIGB studies [20, 21, 23, 41-43]). The mean values of TBWL being higher in other PIGB studies could be explained by more intense support programs in those studies compared to this one. For instance, in the registry-based study by Ienca et al [20], which reported a 14.2% TBWL at Month 4, all participants were reportedly recruited from clinics that provided their standard after-care program with more intense and frequent support to patients compared to this study. A similar situation applies to a prospective, BMI-matched

controlled study by Raftopoulos et al [43], which combined the PIGB with a high-intensity, 12-month after-care program and reported a 14.9% TBWL at Month 4. Hence, more intense support to participants appears to lead to higher values of TBWL at balloon passage.

After end of PIGB residency, participants in this study continued losing weight steadily for 2 months until end of the DBCCI (mean TBWL at Month 6: 13.50%). One could argue that this continuous weight loss between Month 4 and Month 6 may have been attributed (to some degree) to the DBCCI, although no direct causality can be assumed since this study did not include a control group. Among the previous PIGB studies that assessed TBWL from end of PIGB residency to Month 6, Jamal et al reported a change from 10.7% to 10.9% in a non-controlled, single-center study [21], whereas the abovementioned Raftopoulos et al study reported a change from 14.9% to 15.3% [43].

Regarding long-term weight loss outcomes, previous PIGB studies have reported TBWL from Month 4 (end of PIGB residency) to Month 16 (ie, 12 months after end of PIGB residency), with varied results: from 10.7% to 7.9% in a single-center study [21]; from 13.8% to 10.1% in a non-controlled multicenter study [44]; and from 13.9% to 13.4% in a non-controlled, international multicenter study [45]. In this study, the TBWL at Month 12 (longest follow-up timepoint) was 11.22%, which represents a sustained weight loss compared with the 10.90% TBWL observed at end of PIGB residency (weight loss maintained at Month 12 versus Month 4: 103%). The abovementioned PIGB study by Raftopoulos et al reported a TBWL improvement from 14.9% at Month 4 to 16.9% at Month 12 [43], which represents a 113% weight loss maintenance at Month 12 versus Month 4. These results by Raftopoulos et al at Month 12 could possibly be due to the combination of the PIGB with a high-intensity, after-care program delivered until Month 12 [43], which is in line with the idea that a more intense and continued support to patients beyond PIGB residency seems to provide more sustained impact in the long term (see “Implications for Practice” further down).

Psychological Well-Being

A statistically significant impact of the DBCCI combined with the PIGB after-care program was observed on several measures of psychological well-being. In particular, we found improved well-being, mood, weight-related quality of life, and increased self-efficacy and control over eating throughout the study. A small reversion in scores across the majority of these measures was detected between Months 6 and 12, however this is to be expected given the coaching support ended at Month 6. Despite this, the majority of scores at Month 12 remained significantly improved compared to baseline, indicating a lasting impact of the intervention. Previous studies suggest that impaired psychological well-being is associated with weight regain and may hinder healthy behavior promotion among patients with obesity [9]. It could be argued, therefore, that the positive outcomes observed in this study are likely to help contribute to lasting weight loss, by facilitating a greater actioning of behavior change strategies long term, improved self-regulation, and reduced emotional eating.

Well-being scores at baseline (based on WEMBWS) were slightly below values reported in the general population (45.9 versus 51.0; [33]), as might be expected in people with overweight or obesity seeking treatment. To the authors’ knowledge, there is a paucity of studies measuring psychological well-being using WEMWBS in people living with obesity specifically, therefore direct comparisons with a similar cohort are not possible. In this study, WEMWBS scores improved during the DBCCI, reaching values comparable to those in general population at Months 3 and 6.

Baseline GAD-7 scores in this study were slightly higher than those reported pre surgery in a similar population of patients undergoing bariatric surgery published elsewhere (6.0 compared to 5.6; [46]). Nonetheless, both studies report only mild anxiety levels according to established cut-off points for GAD-7 [34]. Anxiety levels in this study significantly decreased at Month 1 versus baseline. This could reflect a positive effect of the DBCCI combined with the PIGB after-care program, or else a

relief at the successful balloon placement and cessation of initial symptoms that could follow. Further research is needed to fully interpret this observation. As of Month 3, no further significant changes versus baseline were noted in GAD-7 scores.

In terms of weight-related quality of life, IWQoL-Lite-CT scores at baseline were lower (worse) than in a comparative study of a similar population (45.2 versus 63.49) [36]. It is unclear why we see this difference, and further research is needed to explore this. Nevertheless, changes in IWQoL-Lite-CT scores (difference score) at Months 3 and 6 were above the defined threshold for meaningful response to treatment for all 3 scores—total, physical, and psychosocial—and higher than seen in other studies [36]. This suggests that the DBCCI and PIGB after-care program produced a meaningful improvement in quality of life. However, 6 months after end of the DBCCI, although significantly improved compared to baseline, the changes in score were no longer clinically meaningful based on published clinical thresholds [36], emphasizing again that more research is needed to determine how improvements to quality of life are better maintained.

Weight-related self-efficacy—which includes participants' self-reported belief in their ability to put behavioral actions into practice—significantly improved at all timepoints over the course of the study. The highest improvement in WEL-SF scores was seen towards the end of the DBCCI (Month 6). At Month 12, scores reduced but remained significantly higher than at baseline, indicating a lasting effect of the intervention well after it finished. Given that self-efficacy is thought to play a crucial role in effective behavior change [47-49], it could be argued that the DBCCI combined with the PIGB after-care program may contribute to successful behavior change. When comparing with WEL-SF scores obtained in a sample of patients living with obesity being considered for bariatric surgery [38], participants in this study presented with lower (worse) self-efficacy at baseline (average WEL-SF score of 40.8 versus 54.3; [38]).

The decrease in LOCES-Brief scores at all timepoints during this study indicates that the DBCCI combined with the PIGB after-care program may have increased the level of control that participants felt they had over their eating. Unfortunately, no LOCES-Brief data have been published in patients from comparable populations, which precludes comparison of our results.

BBAQ scores (barriers to physical activity) at Months 3 and 6 were lower than at baseline, indicating fewer difficulties relating to being active, and a potential positive effect of the DBCCI and PIGB after-care program. At Month 12, scores returned to near-baseline levels, which suggests the need to better target barriers to sustained physical activity behavior change specifically. No BBAQ data have been published in a comparable population, so these results cannot be compared with other studies.

Impact on Behavior Change

The participant satisfaction surveys included items that allowed us to assess mediators of lifestyle behavior change. For example, most participants reported making an action plan to adopt new eating and physical activity habits within the first months of the intervention. This is a positive outcome, given this BCT is proven to significantly increase the likelihood of sustained behavior change [50]. Additionally, at least 89.4% (59/66) of participants reported a good understanding of their personal barriers to reaching their weight goals early in the study; however, this understanding worsened over time. Participants may have discovered that the presumed barriers were not impeding behavior change as initially thought in practice. This emphasizes the importance of coaching models that utilize behavioral science strategies, supporting patients to uncover the often-subconscious drivers and barriers to health behavior change [51].

Most of the participants in this study reported feeling supported or helped by their health coach and confident about making changes to their lifestyle behaviors, although slight drops were observed at Month 6, which could be expected with the end of the intervention approaching. Participants might have feared a return to old habits or a weight plateau or regain. Guidance on how to identify other sources of social support post intervention and how to continue their own "self-coaching" practice

utilizing the techniques learned, could be given greater emphasis in a future iteration of the DBCCI.

Implications for Practice

Even though the TBWL observed in this study is in line with results from other PIGB studies [20, 23, 41-43], the desired weight loss goal of participants at baseline (20.8% of body weight on average) suggests that participants' goals may not have been in line with what studies suggest are realistic and what medical associations recommend in their official guidelines [52, 53]. Therefore, participants may have set unrealistic and unattainable goals in this study, which could have led to disappointment. Patients' unrealistic expectations and unhelpful beliefs about what they "should" achieve may benefit from cognitive therapeutic approaches, which support participants to develop a mindset that is self-compassionate, balanced, and more realistic about the need for a trial-and-error, small steps approach to behavior change in order to achieve lifelong change and weight management success [1, 54].

Following up with participants at 12 months allowed us to assess the extent to which outcomes changed after end of the DBCCI. In terms of weight outcomes, the TBWL at end of follow-up was statistically significant compared with baseline, and similar to the TBWL at the end of PIGB residency (weight loss maintained versus Month 4: 103%); yet TBWL at end of follow-up was lower than at end of the DBCCI (weight loss maintained versus Month 6: 83.1%). This observation, together with the results obtained in terms of participant engagement and behavior change and its impact, reflect the common trajectory for habit change: success in the early stages when participant motivation is high, followed by challenges to sustaining this long term [55]. These data suggest a need for longer coaching support, greater focus on weight maintenance, and "self-coaching" promotion and practice. CBT techniques, incorporated specifically at the latter stages of support, can be introduced to help maintain self-regulatory behaviors associated with weight loss maintenance [1]. Our findings highlight the need for and importance of this intensive support at balloon passing and DBCCI end, when weight maintenance becomes paramount.

Remote Aspect of the Intervention and Future Directions

Aside from the balloon placement, both the DBCCI and clinic-led PIGB after-care program were delivered entirely remotely. The TBWL outcomes in this study were comparable to those obtained in other PIGB studies with in-person PIGB after-care program support (eg, [23, 41, 42]), and the remote intervention was associated with positive outcomes and high levels of acceptability and participant satisfaction. This suggests that remote delivery can be as effective as in-person patient support, which is in line with literature in the field comparing these approaches. A study reported similar effectiveness of online versus traditional, face-to-face after-care support programs following placement of an intragastric balloon [56]. Bus and colleagues found no significant weight differences of in-person versus online health coaching [16]. Furthermore, a systematic review found no differences in weight or BMI changes between web-based and offline interventions for weight loss and lifestyle habit changes in adults living with overweight and obesity [57].

Although a number of evidence-based BCTs were included in the DBCCI, their effectiveness was dependent on participant engagement with coaching messages delivered asynchronously, which may have affected their accessibility and impact. Furthermore, the DBCCI (and all patient communication) ended at month 6 after PIGB placement. Had there been continued support to 12 months, engagement until the end of the study is likely to have been higher. Providing this support in an instant, synchronous manner would likely improve accessibility and patient engagement even further.

There is early evidence that generative artificial intelligence (AI) conversational agents can deliver

automated, immediate, text-based behavior change interventions and positively impact lifestyle behaviors, including in populations living with overweight and obesity [58, 59]. If proven safe and effective in this application, AI-driven automated coaching support could be developed and implemented in a remote behavior change coaching intervention for weight management. AI also provides opportunities for scaling weight management interventions across cultures and different languages [58, 59], and it opens the possibility of augmenting human-led care to reduce the demand on humans—for example, implementing automated health coaching check-ins between in-person consultations. Future research on the use of AI-driven technologies to automate patient care, including delivery of behavior change interventions for weight management, is needed within well-designed clinical trials. Importantly, as with any new technologies, ensuring safety and efficacy is crucial.

Limitations and Strengths of this Study

This study has some limitations. Its exploratory nature and single-arm design mean that no causality between intervention and outcomes can be determined. In addition, the combined intervention (DBCCI plus PIGB after-care program) adds an extra layer of difficulty in attributing causality to one component or another, or their combination (for instance, as part of their standard PIGB after-care program, clinic teams were likely to use certain BCTs while providing lifestyle advice; yet these BCT components were not itemized and their potential impact on outcomes, if any, is difficult to assess). However, using a combined, multimodal intervention such as the one in this study is the approach that best aligns with real-world practice and weight management recommendations [2-5]. As mentioned earlier in the discussion, there seem to be greater weight loss mean values in other PIGB studies where a more intense and frequent PIGB after-care program was delivered (eg, [20, 43]), as compared with the after-care program provided by the participating clinics at the time of study (during the COVID-19 pandemic). Based on this and other scientific evidence collected, current best practices for the PIGB after-care program involve high-quality and higher-intensity programs. This is to be considered when interpreting this study with other PIGB studies or with results obtained with this after-care program in the clinical practice setting.

The number of participants who provided weight data at later timepoints of this study reduced over time (eg, n=25 at Month 12 versus n=107 at baseline).This is in line with what has been reported in other studies of remotely delivered interventions [60-63], in follow-up appointments after bariatric surgery [64], or in trials of treatments for managing obesity, where up to 85% attrition after 12 months has been reported [65]. To account for missing weight data in this study, we used an imputation method at all timepoints. Nonetheless, we acknowledge that the smaller number of participants with available weight data at Month 12 may not represent the whole cohort. Since this study was conducted, to help improve patient adherence to the weight management program, an AI model has been implemented to highlight to clinic teams which of their patients are not predicted to achieve minimally sufficient weight loss, so the clinic team can intervene early in the program with those patients [66]. Additionally, weighing reminder notifications have been introduced in the patient app of the weight management program to encourage higher rates of self-monitoring of weight. In any case, despite the lower amount of weight data available at Month 12 in this study, a greater proportion of participants were still engaged with the study at the end of follow-up, as shown by the higher number of participants (compared with weight data) who did complete the psychological well-being questionnaires and non-validated surveys at Month 12 (n=43 and n=40, respectively).

Another limitation of this study is the fact that, at the time of study conduction, it was not possible to collect accurate data on behavior change self-monitoring (eg, tracking). Future research would benefit from assessing this outcome. In terms of methodology, some items used to measure feasibility, participant engagement, and impact on behavior change, which were rated via Likert

scale, may be difficult to interpret given the repeated measures testing used. For instance, making a plan for eating and physical activity is a dichotomous variable: one either makes or does not make a plan. Participants may have made a plan at timepoints earlier than Month 12, thus scoring low at Month 12 (when no new plans were needed). In addition, this study may have suffered from a selection bias: the fact that participants recruited in this study paid for their PIGB treatment might have made them potentially more committed to the treatment than those undergoing reimbursable bariatric procedures. In any case, this circumstance is representative of the typical patient population receiving a PIGB in the United Kingdom and the Netherlands at the time. Related to this, however, one should apply caution when generalizing the study findings to other populations globally, given the demographic characteristics of the study population (eg, most participants were of White ethnicity). Such limited external validity derives from the exploratory nature of this study; future research in larger, more diverse populations would help address this limitation.

The main strength of this study is the obtention of data under real-world circumstances, in clinical practice and in a representative sample of PIGB patients in the study countries. In addition, this study reports exhaustive data on psychological well-being outcomes using instruments for which little published data exist in this specific population, which contributes new evidence to the field and a pool of data for future comparison in similar populations. Lastly, as discussed above, the use of a text-based approach in this study lays down the potential for automation and application of AI-driven technologies to this type of intervention.

Conclusion

This study provides evidence that a health coach-led, digital behavioral intervention delivered via asynchronous text-based messaging was feasible, acceptable, and satisfactory to participants and appears to support improved weight loss, psychological well-being, and mediators of lifestyle behavior change that could be conducive to weight loss and maintenance. Insights obtained during this study, along with the text-based nature of the remote intervention described here, open the door to the possibility of developing behavior change coaching approaches that take advantage of AI-driven automated support. Future research is needed to evaluate the benefits, risks, and impact of such approaches in supporting patients living with overweight and obesity.

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MG was affiliated with the Behavioral Science Team at Allurion Technologies, Inc. at the time of the study and currently has no academic affiliation. JED was affiliated with the Behavioral Science Team at Allurion Technologies, Inc. at the time of the study and is currently affiliated with Norsas Consultancy Ltd. and Chilli Consultancy Ltd. EA is currently also affiliated with WeightWorks Clinics. JWG was affiliated with the Nederlandse Obesitas Kliniek (Dutch Obesity Clinic) at the time of the study and is currently affiliated with Weight Doctors Netherlands, Quole Medical Center, and

NUTRIM at Maastricht University.

Authors' Contributions

PMS oversaw all aspects of the study, including study conception, design, and delivery; data analysis; interpretation of the findings; and writing and revision of the manuscript. EF contributed to the design of the study; data analysis; interpretation of the findings; and writing and revision of the manuscript. VR contributed to the design of the study and the intervention content; delivery of the intervention; interpretation of the findings; and writing and revision of the manuscript. JW contributed to the delivery of the intervention; data collection and analysis; interpretation of the findings; and writing and revision of the manuscript. MG contributed to the data processing, cleaning, and analysis; interpretation of the results; and revision of the manuscript. JED contributed to the data processing, cleaning, and analysis; interpretation of the results; and revision of the manuscript. EA, DE, JWG, and IP-M contributed to the conduction of the study and to the revision of the manuscript. RC contributed to the conception and design of the study and to the revision of the manuscript. All authors approved the final version of the manuscript before publication.

Conflicts of Interest

PMS was a full-time employee (Vice President Behavioral Science) at Allurion Technologies and a former consultant for Allurion Technologies, which includes receipt of financial support for attending conferences and meetings, and for presenting company research at educational events; he has stock options in Allurion Technologies; and he is a Director and shareholder of Healthy Weight Partnership Inc., a company dedicated to supporting families living with obesity. EF was an employee at Allurion Technologies; she is the owner of BOUNCE Behavioural Science Ltd.; and she has stock options in Allurion Technologies. VR was an employee at Allurion Technologies; she has stock options in Allurion Technologies; and she is a student of the Professional Doctorate in Health Psychology at the University of the West of England. JW was an employee at Allurion Technologies. MG and JED are former consultants for Allurion Technologies. EA is medical director at WeightWorks Clinics and Allurion Kliniek; he participates in the medical advisory board of FitForMe; and he has received consultant fees from FitForMe for acting as medical director and medical advisor. DE has received clinical supplies for his clinic MediZen, and financial support (but no speaker fees) for attending educational events and conferences, from Allurion Technologies; and he is a key opinion leader for Evolus Inc., DermaFocus, Cutera lasers, and Swift technologies. JWG is member of the executive board of the International Federation for the Surgery of Obesity (IFSO); he has received consultant fees from Morphic Medical (formerly GI Dynamics) for acting as member of its scientific advisory board and from Bariatric Solutions for teaching activities; and he has received payment from DEKRA for medical expert testimony and financial support from Bariatric Solutions to cover travel costs. IP-M has received consultant fees and financial support from Allurion Technologies for educational events, meetings, and/or travel costs. RC is an employee at Allurion Technologies, which includes receipt of financial support for attending meetings and to cover travel costs; he participates in the medical advisory board of Allurion Technologies; and he has stock and stock options in Allurion Technologies.

Abbreviations

ACT	acceptance and commitment therapy
AI	artificial intelligence
BBAQ	Barriers to Being Active Quiz
BCT	behavior change technique
BMI	body mass index
CBT	cognitive behavioral therapy
CCMO	Central Committee on Research Involving Human Subjects (Centrale Commissie Mensgebonden Onderzoek)
CDC	Centers for Disease Control and Prevention
CI	confidence interval
COM-B	capability-opportunity-motivation-behavior model
COVID-19	coronavirus disease
CRAN	Comprehensive R Archive Network
DBCCI	Digital Behavior Change Coaching Intervention
GEE	generalized estimation equation
GAD-7	Generalized Anxiety Disorder 7-item scale
IWQOL-Lite-CT	Impact of Weight on Quality of Life-Lite Clinical Trials Version scale
LOCES-Brief	Loss of Control Over Eating Scale-Brief version
NHS	National Health Service
PhD	Doctor of Philosophy
PIGB	procedureless intragastric balloon
PREVAIL	People Regulating Themselves to Achieve Weight Loss
SD	standard deviation
SEM	standard error of the mean
TBWL	total body weight loss
TDF	Theoretical Domains Framework
WEL-SF	Weight Efficacy Lifestyle questionnaire-Short Form
WEMWBS	Warwick-Edinburgh Mental Wellbeing Scale

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Supplementary Materials

Multimedia Appendix 1: Contraindications for the use of the Procedureless Intragastric Balloon System.

Contraindications [1]

Difficulty swallowing (dysphagia):

- Any abnormal swallowing mechanism from an esophageal motility disorder such as achalasia, scleroderma, or diffuse esophageal spasm
- History of any structural esophageal abnormality such as a web, stricture, diverticulum, or para esophageal hernia

Conditions that predispose to bowel obstruction:

- History of perforated appendicitis or any other perforated abdominal viscus
- Crohn's Disease
- Severe gastrointestinal (GI) motility disorder such as severe gastroparesis
- Any history of actual, or suspected, bowel obstructions or small bowel surgery
- Any history of intraperitoneal adhesions

Conditions that predispose to gastric perforation:

- History of any previous bariatric, gastric or esophageal surgery
- History of previous laparoscopic band ligation
- History of anti-reflux surgery

GI bleeding or conditions that predispose to GI bleeding:

- Recent history of inflammatory conditions such as esophagitis, gastritis, gastric ulceration, or duodenal ulceration
- History of vascular lesions such as esophageal varices, gastric or duodenal varices, or intestinal telangiectasias
- Benign or malignant gastrointestinal tumors
- Inability to discontinue use of non-steroidal anti-inflammatory drugs (NSAIDs) or other gastric irritants during the device period
- Patients receiving anticoagulants
- Severe coagulopathy
- Hepatic insufficiency or cirrhosis
- Inability or unwillingness to take prescribed proton pump inhibitor medications in preparation for and/or during device residence

Other conditions:

- Serious or uncontrolled psychiatric illness
- Diagnosed bulimia, binge eating, compulsive overeating, or similar eating-related psychological disorders
- Alcoholism or drug addiction
- Pancreatitis
- Symptomatic congestive heart failure, cardiac arrhythmia, or unstable coronary artery disease
- Pre-existing significant respiratory disease such as chronic obstructive pulmonary disease

(COPD), severe sleep apnea, or cystic fibrosis
- Cancer
- Known or suspected allergies to polyurethane
- Inability or unwillingness to take prescribed antiemetic medications in preparation for and/or during device residence
- Women who are pregnant or nursing
- Children younger than 18 years
- An existing gastric balloon that is currently in the stomach

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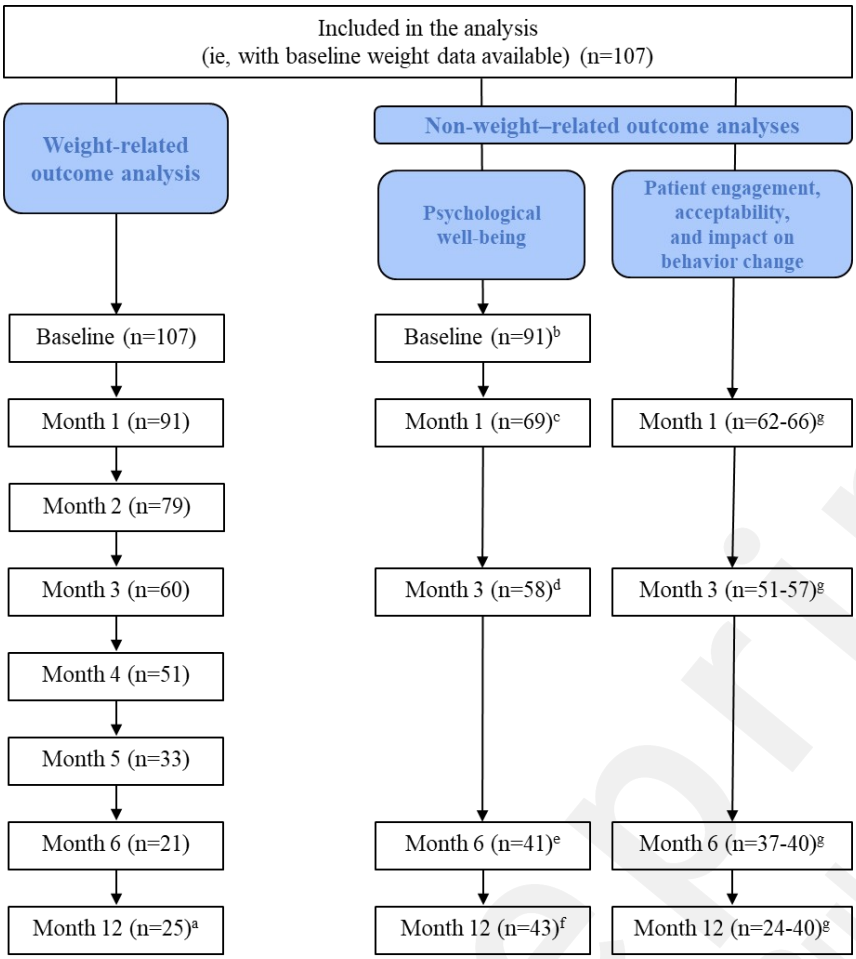
1. Allurion Technologies. Allurion Gastric Balloon System, Instructions for Use. April 2021.

Multimedia Appendix 2: Attrition Diagram.



Only the timepoints in which data were collected and included in the analyses are shown in the diagram.

[a]At Month 12, weight data were obtained via connected scale (n=11 participants) and via self-reporting through the participant-reported satisfaction survey (n=14 participants).

[b]Except GAD-7 (n=90), WEL-SF (n=83), and BBAQ (n=90).

[c]Except WEL-SF (n=68) and BBAQ (n=66).

[d]Except WEL-SF (n=57) and BBAQ (n=57).

[e]Except WEMWBS (n=42), GAD-7 (n=42), and BBAQ (n=40).

[f]Except IWQOL-Lite-CT overall and physical and psychological domains (n=42), LOCES-Brief (n=41); WEL-SF (n=40), and BBAQ (n=40).

[g]Range indicated due to space constraints; see Multimedia Appendix 3 for the number of participants with available responses for each item.

BBAQ, Barriers to Being Active Quiz; GAD-7, Generalized Anxiety Disorder 7-item scale; IWQOL-Lite-CT, Impact of Weight on Quality of Life-Lite Clinical Trials Version scale; LOCES-Brief, Loss of Control Over Eating Scale-Brief version; n, number of participants with available data; WEL-SF, Weight Efficacy Lifestyle questionnaire-Short Form.

Multimedia Appendix 3: Percentage of Participants who Scored Positively on Each Item of the Participant-Reported Satisfaction Surveys to Measure Engagement, Acceptability of the Intervention, and Impact on Behavior Change.

	Proportion of participants rating the item with a positive score, % (n/N)[a]				
	Month 1	Month 3	Month 6	Average Months 1, 3, 6 (during DBCCI)	Month 12 (6 months after end of DBCCI)
Items rated on a 5-point Likert scale					
"I have found the health coaching useful/helpful"	82.81 (53/64)	80.39 (41/51)	82.50 (33/40)	81.90	NA
"I feel supported by my health coach towards meeting my weight goals" (Months 1, 3) and "My study health coaches helped me to meet my weight goals" (Month 6)	85.71 (54/63)	82.14 (46/56)	76.92 (30/39)	81.59	NA
"My health coach has helped me develop strategies to lose weight"	69.35 (43/62)	69.64 (39/56)	80.00 (32/40)	73.00	NA
"I feel confident that I can reach my goal weight and maintain it" (Months 1, 3 only)	67.69 (44/65)	66.07 (37/56)	NA	66.88	NA
"I feel confident about making changes to help me lose weight" (Months 1, 3) and "I feel confident about maintaining my weight loss" (Months 6, 12)	90.91 (60/66)	91.23 (52/57)	57.50 (23/40)	79.88	45.00 (18/40)
"I have been able to put the information and actions from the articles (weight loss actions) into practice"	76.56 (49/64)	62.96 (34/54)	56.76 (21/37)	65.43	NA
"I have made a plan to change my eating habits"	92.42 (61/66)	87.72 (50/57)	85.00 (34/40)	88.38	77.50 (31/40)
"I have made a plan to change my physical activity habits"	83.33 (55/66)	81.82 (45/55)	82.50 (33/40)	82.55	65.00 (26/40)
"I have made a plan to change my sleep habits"	51.61 (32/62)	34.62 (18/52)	42.11 (16/38)	42.78	43.59 (17/39)

"I am aware of some of the barriers to me reaching my weight goals"	89.39 (59/66)	89.47 (51/57)	74.36 (29/39)	84.41	55.00 (22/40)
"My health coaching was personalized to my needs"	71.43 (45/63)	73.21 (41/56)	53.85 (21/39)	66.16	NA
"I have found the articles (weight loss actions) sent by the health coaches useful/helpful"	78.12 (50/64)	68.52 (37/54)	66.67 (26/39)	71.10	NA
Items rated on an 11-point Likert scale					
"How satisfied have you been tracking your weight, using the connected scales, on a scale from 0 (not at all satisfied) to 10 (completely satisfied)?"	89.39 (59/66)	84.21 (48/57)	82.50 (33/40)	85.37	95.83 (23/24)

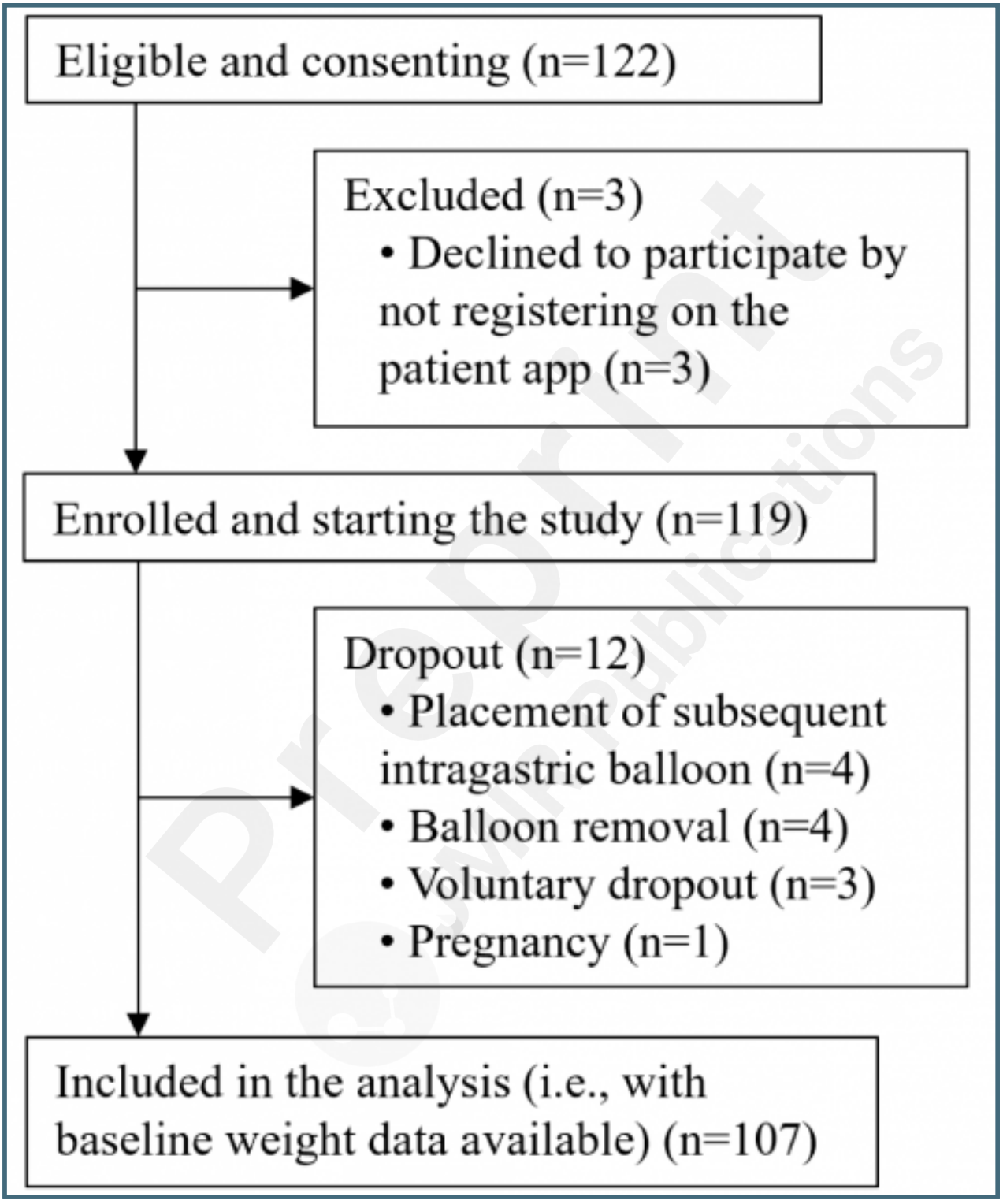
[a]A positive score was defined as a score ≥3 (ie, "slightly agree" or "strongly agree") for items rated on a 5-point Likert scale (0-4), or score ≥5 for items rated on an 11-point Likert scale (0-10; see Methods).

n, number of participants who scored positively; N, total number of participants with available responses; NA, not assessed.

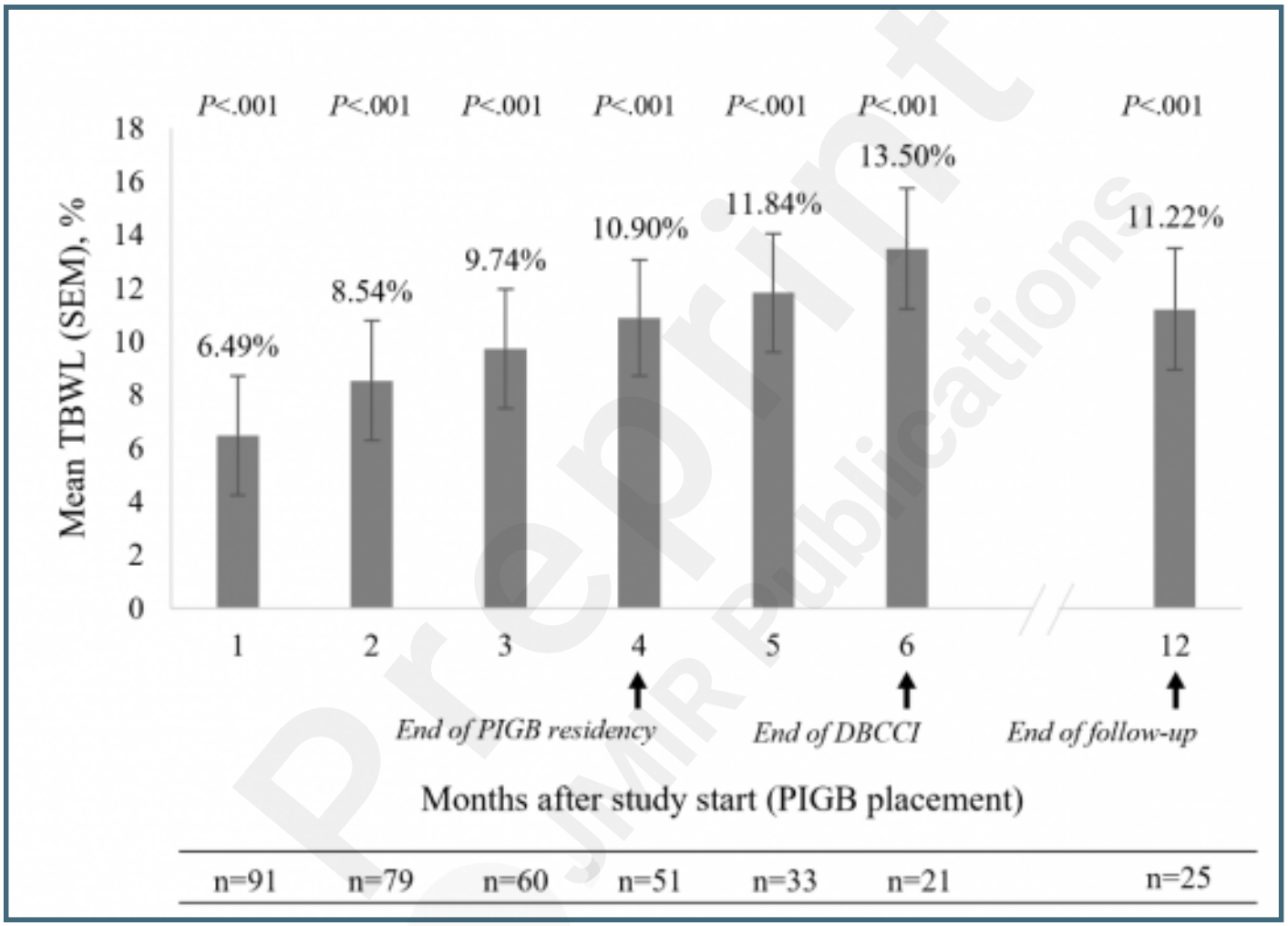
Supplementary Files

Figures

Participant flow diagram. Footnotes: n, number of participants.



TBWL over the study period. Footnotes: Note: at Month 12, weight data were obtained via connected scale (n=11 participants) and via self-reporting through the participant-reported satisfaction survey (n=14 participants). A multiple imputation method was used to handle missing weight data. TBWL was estimated using GEE models adjusting for age, visit, and country. Error bars represent SEM. P values for the comparison versus baseline. DBCCI, Digital Behavior Change Coaching Intervention; GEE, generalized estimation equation; n, number of participants with available data at that timepoint; PIGB, procedureless intragastric balloon; SEM, standard error of the mean; TBWL, total body weight loss.



Multimedia Appendixes

Contraindications for the use of the procedureless intragastric balloon system.
URL: http://asset.jmir.pub/assets/e95a1e7f7f0eb7fb981e6401ae0b7b2f.docx

Attrition Diagram.
URL: http://asset.jmir.pub/assets/e4e93f104386e1ff1737a99e531f5ab2.docx

Percentage of Participants who Scored Positively on Each Item of the Participant-Reported Satisfaction Surveys to Measure Engagement, Acceptability of the Intervention, and Impact on Behavior Change.
URL: http://asset.jmir.pub/assets/9ff7b9136bc04c9ca334b5e8ec02d87e.docx