

# A web-based intervention to increase weight loss treatment initiation: results of a cluster randomized feasibility and acceptability trial

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## Abstract

Evidence-based behavioral weight loss treatment is under-utilized. To increase initiation of treatment, we developed a single-session, online, primary care-based intervention (“mobilization tool”). We evaluated the mobilization tool's acceptability for primary care patients with obesity, trial design feasibility, and signal of an effect of the tool on treatment initiation. In this cluster randomized feasibility trial, primary care providers (PCPs) were randomized to a mobilization tool or comparator tool arm. Patients with obesity and a scheduled appointment with a randomized PCP were assigned to complete the mobilization or comparator tool prior to their appointment. The online mobilization tool asks patients to answer questions about a variety of weight-related topics and then provides automated, tailored feedback that addresses psychosocial determinants of weight loss treatment initiation. The comparator tool provided a nontailored description of treatments. All participants were offered free enrollment in behavioral weight loss treatments. Sixty patients (57% female; 66% white; aged  $55 \pm 13$  years) participated in this study of 296 contacted for eligibility evaluation (20.2%). Six-month follow-up assessments were completed by 65% (22/34) of the mobilization and 73% (19/26) of comparator tool participants. Participants completing the acceptability survey reported that the mobilization tool was usable, enjoyable, informative, and useful. Weight loss treatment was initiated by 59% ( $n = 19$ ) of mobilization and 33% ( $n = 8$ ) of comparator tool participants. The mobilization tool shows promise for increasing treatment initiation among primary care patients, which may increase population weight loss.

Trial Registration: Clinicaltrials.gov identifier: NCT02708121.

## Keywords

Weight loss, Obesity management, Feasibility study, Primary health care, Web-based

## INTRODUCTION

Most adults with obesity report a desire to weigh less [1]. Weight loss is more likely to be achieved when individuals join a comprehensive, evidence-based behavioral weight loss treatment than when weight loss is attempted with more limited weight loss education or advice [2]. Accordingly, the American Heart Association and United States Preventive Services Task Force (USPSTF) recommend that

## Implications

**Practice:** A single-session online intervention delivered prior to a PCP appointment is acceptable to patients and has potential to increase initiation of evidence-based weight loss treatments.

**Policy:** In addition to funding patient access to evidence-based behavioral weight loss treatments, policymakers should consider strategies to increase uptake of these treatments.

**Research:** Researchers should test the intervention presented in a large, diverse sample of primary care patients to evaluate initial and sustained impacts on treatment utilization and weight.

adults with obesity be advised to join behavioral weight loss treatments [2,3]. Despite this, fewer than 10% of adults with obesity initiate any type of weight loss program [4], limiting these programs' public health impact.

Low population initiation of behavioral weight loss treatments may be partially attributable to these treatments' poor accessibility or affordability. Fortunately, several trends have converged to increase treatment access and affordability: (a) health care payers, including Medicare and some private insurers, are offering coverage of behavioral weight loss treatment, including comprehensive community-based or commercial programs; [3, 5–7] (b) some large employers are offering treatment at low costs; [8] (c) the Diabetes Prevention Program, a comprehensive behavioral weight loss treatment, is offered for free or at low cost across the country [9]; (d) web-based comprehensive weight loss treatments are increasingly available, providing options for individuals with barriers to in-person treatment [10].

Although increased access to treatment is an important step towards greater initiation of these treatments, increased access alone appears unlikely to

substantially increase treatment initiation. Studies conducted in real-world settings have found that even when weight loss treatments are offered at no cost in accessible locations, only a small portion of individuals enroll [11,12]. For example, when an employee wellness program was offered at no cost to employees at two large companies, 7.7% enrolled (in a sample where 92% of employees had overweight or obesity) [11]. Similarly, a free weight loss program offered in the Veterans Affairs (VA) Health System enrolled between 2.8% and 6.9% of patients with obesity, depending on region, in 2016 [12].

Approaches to increase initiation of weight loss treatments have been tested in two recent studies. One study, conducted in the VA healthcare system, examined the effects of receiving up to two motivational interviewing phone calls from health coaches focused on encouraging enrollment in preventive programs. In this study, participants could select among a variety of preventive programs, including weight loss, exercise, and smoking cessation programs. The authors found that participants who were randomized to receive the motivational interviewing phone calls were more likely to subsequently enroll in preventive treatment than those who were not (51% vs. 29%) [13]. Although informative, this study did not focus specifically on weight loss; only about half of the sample who choose to enroll in a program selected a weight loss program. A second study conducted in the United Kingdom found that randomizing adults with obesity to receive a referral from their primary care provider (PCP) to weight loss treatment resulted in greater treatment initiation than randomization to usual care [14]. This study shows the potential influence of providers on treatment initiation; however, this study was not designed to test a specific strategy for how to increase provider referrals. Most primary care providers do not emphasize weight counseling, in part due to barriers such as inadequate time, training, and confidence for delivering weight counseling [15–17]. Thus, strategies are needed that can address these barriers, for example, by delivering counseling outside of the primary care appointment or by giving providers tailored suggestions to guide a discussion with patients.

To address the need for strategies to increase initiation of weight loss treatment, we developed an online, primary care-based intervention, called the mobilization tool. The mobilization tool asks patients questions about their perspective on and experience with a variety of weight-related topics and then provides automated, tailored feedback that aims to address psychosocial determinants of treatment initiation. This mobilization tool is conducted prior to a primary care appointment and includes the PCP's endorsement in order to leverage provider influence. A first step towards evaluating the mobilization tool is conducting a feasibility trial

to determine the tool's acceptability, feasibility of a planned effectiveness trial protocol, and presence of a signal of an effect of the tool [18,19]. Thus, the aims of the current feasibility trial were to (a) characterize intervention acceptability by describing tool engagement and patient ratings of usability and acceptability; (b) characterize study recruitment and retention rates, including across study arms and across treatment initiators and noninitiators; and (c) determine if there is a signal of an effect of the tool on initiation of behavioral weight loss treatment.

## METHODS

### Design

The current study was a parallel group, two-arm, cluster randomized feasibility and acceptability trial with PCPs as the unit of randomization (1:1 allocation). Clustering at the provider-level instead of the patient-level was chosen in order to minimize the risk that provider behavior towards comparator arm patients could be influenced by contemporaneous exposure to mobilization tool arm patients. A second, patient-level randomization occurred, with patients randomized (1:1 allocation) to attend an in-person or a telephone-based baseline assessment. This was done in order to evaluate the feasibility of a remotely conducted baseline versus in-person baseline session on recruitment and retention to inform future trial design. Ethics approval was obtained by the Duke Health IRB for all research. All PCPs gave written informed consent, and all patients gave verbal informed consent via telephone during the recruitment call.

### Participants and recruitment

#### *Provider recruitment and randomization*

We sought to recruit six PCPs through a primary care-based research network. A sample size of six providers was anticipated to be sufficient to meet the feasibility goal of evaluating the strategy for recruiting providers [18]. Providers were recruited at a clinic staff meeting. Eligibility requirements for providers were practice  $\geq 20$  hr per week; have a majority adult patient panel; and have been employed at the clinic for one or more years. A statistician randomized providers to the mobilization tool arm or the comparator tool arm using a computer-generated sequence with block randomization. Providers were informed of their randomization arm by email before patients were enrolled.

#### *Patient recruitment and randomization*

The recruitment goal for patients was 60 (30 per randomization arm). This sample size was determined based on consideration of what would be sufficient to identify concerns with acceptability, recruitment approaches, treatment engagement, and study retention [18]. Patients who had an upcoming

appointment (“index appointment”) with an enrolled provider were recruited on a rolling basis. An electronic database of administrative and clinical health records was queried weekly to identify potentially eligible patients. Eligibility criteria evaluated at the database query included age 18–75, BMI  $\geq 30$  kg/m<sup>2</sup> recorded in EHR, scheduled appointment 21–28 days from query, presence of email address, and one or more prior appointments at the clinic in previous two years. Patients identified via database query were sent an invitation email. We sought to avoid recruiting a predominance of participants who were likely to initiate weight loss treatment in the absence of an intervention to increase initiation. Thus, the study was described to potential participants as involving the use a tool to help them decide if they wanted to change health behaviors, without explicit mention of the opportunity to join a weight loss program (see [Supplementary Material](#) for specific wording). If patients did not opt-out within a week, they were called to screen for eligibility until their eligibility window closed (10 days prior to index appointment). At phone screening, eligibility criteria were self-reported BMI  $\geq 29$  kg/m<sup>2</sup> (to account for under-reporting), email usage  $\geq 3$  times per week, ability to read websites without assistance, and absence of formal weight loss program participation in past year. The research assistant responsible for patient recruitment, screening, consent, and assessments was blinded to provider-level study arm.

Patient-level randomization to an in-person versus telephone-based baseline assessment was stratified by provider to ensure equal representation between arms. The randomization scheme was generated by a statistician using a uniform random-number generator and was loaded into a tracking database. Randomization occurred automatically via survey software during the telephone screening at the point that patients indicated interest in learning more about the study (and prior to consenting). Patients were informed that the study involved in-person assessment visits at baseline (“In-person assessment condition”) or that the study would include questions over the phone at baseline during the same phone call (“Phone-based assessment condition”). All patients were informed that an in-person assessment at 6 months post-enrollment was expected. Study personnel were not blinded to the patient-level randomization.

## Procedures

### *Mobilization tool arm*

The tool was designed to be integrated into the primary care setting in several ways. First, an email informed patients that their provider would like them to complete the tool prior to their appointment; this was intended to take advantage of the influence of the provider to motivate engagement with the tool. Second, the tool was sent to patients prior to their

primary care appointment so that a report could be sent to the provider before patients' appointments in order to support a weight-related discussion during their clinical visit. Offering the tool prior to the appointment also allowed patients to discuss with their provider any questions or concerns about weight loss or weight loss treatments that arose while using the tool. These approaches allowed patients to receive weight loss treatment advising via the mobilization tool even if there is insufficient time to discuss weight during the clinic visit.

### *Weight loss treatment invitational email.*

Participants were sent an email from a study-specific email address 4 to 14 days prior to their index appointment that included a link to the mobilization tool, which was called “Your Wellness Prescription.” The body of the email stated that they had 4 months free access to weight loss treatments and informed them that they would learn more as they used the tool. The names and number of treatments available was not mentioned (see [Supplementary Material](#) for specific email wording).

### *Mobilization tool.*

Participants who clicked the mobilization tool link were immediately directed to the mobilization tool. The mobilization tool was hosted on a Qualtrics platform with a custom graphical appearance to make the experience visually engaging (see [Supplementary Material](#) for walkthrough video). The tool content was developed using a conceptual model of treatment initiation that was adapted from the Health Belief Model, chosen due to its strength in explaining one-time behaviors [20,21]. A data-informed adaptation of the Health Belief Model was developed that incorporated qualitative data from participants describing their reasons for choosing to initiate or not initiate treatment [22]. The adapted model (see [Fig. 1](#) columns B and C) includes perceived health threat of weight [21] and perceived psychosocial benefits of weight loss [23]. Together, these are hypothesized to influence desire to weigh less. The other components of this model are specific to a particular approach to weight loss and include (a) perceived effectiveness of an approach, (b) self-efficacy for engaging in an approach's prescribed behaviors, and (c) perceived barriers to approach [22].

[Figure 1](#), column A, shows the components of the intervention and how the components address the psychosocial determinants of treatment initiation identified in our adapted model of treatment initiation. The content of the tool is tailored via an algorithm created by the study team and programmed in to Qualtrics. Motivational interviewing concepts are included in the tool, such as emphasizing that participants have choices between treatment options or no treatment and highlighting discrepancies

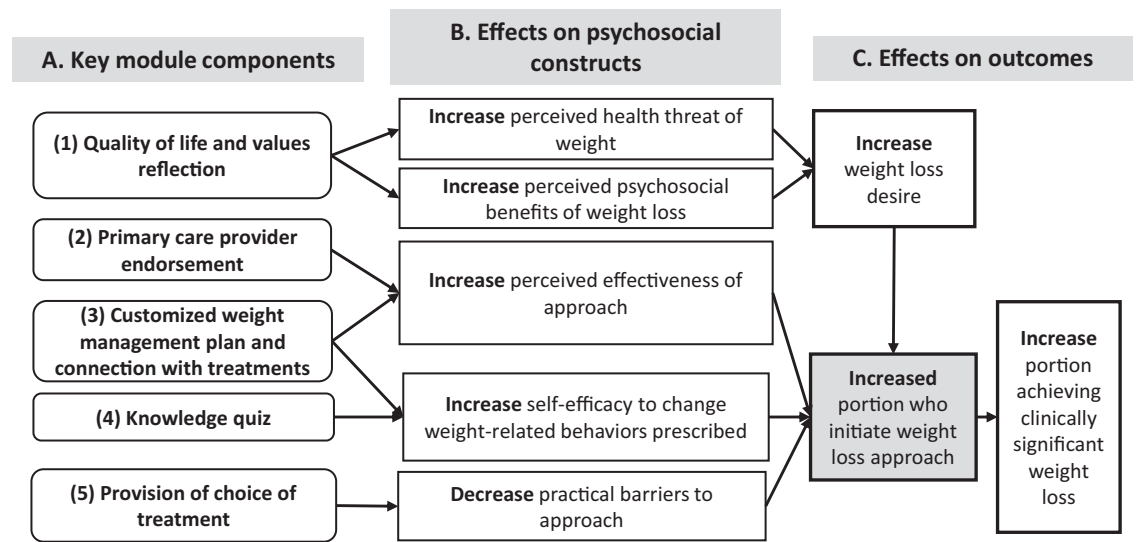


Fig. 1 | Conceptual model of treatment initiation and hypothesized effects of mobilization tool on treatment initiation.

between values and current behaviors [24]. The tool ranges from 24 to 35 brief web pages, depending on participants' responses, and is intended to take 5–15 min to complete. The quality of life and values reflection component asks participants to select the health and psychosocial outcomes that are most important to them (e.g., taking less medication, improved relationships) and then rate how these outcomes might differ if they made changes to diet, exercise, and weight loss. The customized weight management plan and connection with treatment component asks participants to select and rank from a list of 10 weight loss barriers which are most difficult for them. Participants are then presented with a tailored plan that suggests strategies to address the top barriers identified. Next, participants are presented with information about how the personal plan that is presented to them is consistent with comprehensive treatment that is being offered, thus conveying how treatment meets their specific needs. Near the completion of the tool, participants are informed that they can choose between treatments with differing characteristics and are given a description of each treatment, including the types of foods and exercise recommended, details on meetings or contact with coaches (e.g., modality, location, scheduling), a summary of what occurs at meetings or coaching calls, and details on any potential costs beyond the four months of free treatment (e.g., food). Participants who select not to enroll when offered treatment within the tool are provided additional tailored content focused on increasing future readiness to change.

Near completion of the tool, all participants are given the option to share a summary of their data with their provider by having their results placed in the electronic health record (EHR). If they agree, a note is placed in EHR that includes: (a) participant's top four weight loss motivators; (b) participant's top

four weight loss barriers; (c) participant's decision to enroll in treatment or make other changes (e.g., see a nutritionist); and (d) suggested statements for the provider to tell the participant, which were written by the study team and selected according to an algorithm developed by study team. For example, if participants signed up for weight loss treatment, providers were encouraged to provide a statement supportive of treatment engagement, whereas if participants expressed interest in changing weight behaviors but were not interested in joining a treatment, they were suggested to ask a question about how they can offer support. A direct message is also sent to providers via the EHR messaging system 1–2 days prior to the participants' appointments informing them that the summary is available. Participants received standard appointment reminders that are part of usual care, such as text messages or phone calls (depending on what they have selected at previous clinic visits); no extra reminders were sent about appointments as part of this study. The mobilization tool was subject to user testing with nine patients with obesity prior to this trial. Their responses informed changes to the function, appearance, and content of the tool to improve user experience and intervention acceptability.

#### *Weight loss treatments and treatment enrollment process.*

All participants were informed that they could enroll in the selected treatment up to 2 months after completing the tool, and that they had 4 months of free treatment access. The three treatments offered were Track, Jenny Craig, Weight Watchers meetings (now known as WW). Track is an evidence-based, remotely delivered weight loss treatment designed and administered by a University laboratory [25]. It includes 12 possible phone-based health coaching sessions, weekly goal setting, and monitoring of goals via

Interactive Voice Response or text messaging. Jenny Craig is a commercial program that includes weekly counseling sessions and the provision of prepackaged prepared foods [26]. Although Jenny Craig offers both in-person and phone counseling, participants in our study were offered the phone-based program. Participants were informed that the study did not pay for food, only for coaching. Weight Watchers is a program that offers both in-person and remotely delivered services; for the current study, participants were offered access to the in-person group sessions. The program focuses on health eating, calorie reduction, and increasing physical activity. It uses a variety of evidence-based behavior change strategies (e.g., self-monitoring). Weight Watchers generally encourages participants to attend weekly meetings until they meet their goal weight. These programs were selected because they met criteria as evidence-based behavioral programs that have potential for scalability [25,27]. Multiple program options were offered in order to increase the experience of choice for participants and to provide options that may overcome barriers to treatment use.

#### *Comparator tool.*

In line with the mobilization tool arm participants, comparator tool arm participants received an email 4–14 days prior to their PCP appointment informing them of free access to weight loss treatment and providing a link to follow in order to learn more information. In this email, the names and number of treatments available were not mentioned. If they clicked on the link, participants were directed to a webpage containing the same basic information about the weight loss treatments that was provided in the mobilization tool (e.g., types of foods and exercise recommendations). They were then given the option to select a treatment to begin the treatment enrollment process. There was no mention of their providers in the comparator tool or email, as that was considered an active element of the mobilization tool arm. The weight loss treatments offered and the process for initiating treatments were the same for comparator tool and mobilization tool participants.

#### Data sources and measures

##### *Recruitment and retention*

Recruitment and follow-up activities were managed through an internally developed participant tracking web application. Each contact with participants (e.g., calling to schedule follow-up appointment) was logged in the tracking application by study staff. These data were used to calculate percent patient recruitment and study retention rates.

##### *Baseline characteristics*

The research assistant asked participants to self-report demographics, health conditions, and weight history at baseline.

##### *Mobilization tool acceptability*

Data on participants' progression through the mobilization tool were available on the Qualtrics platform. These data were used to report on participant initiation and completion of the tool, as this is an indicator of acceptability. After completing the mobilization tool, participants were presented with a 12-item survey of their perceptions of the tool's acceptability. This survey was developed by the research team and covered common domains of acceptability for a web-based intervention, such as ease of use, enjoyment, perceived learning, trustworthiness, usefulness, and appropriateness of length [28,29] (see Table 2 for specific items). Response options ranged from 1 (strongly disagree) to 5 (strongly agree). Participants were also provided an open text box to write feedback.

##### *Treatment initiation and sustained use*

Treatment initiation was defined as attending at least one treatment session by phone or in-person within 2 months of being sent the tool. Sustained treatment use was defined as attended  $\geq 8$  sessions, as this represents attending at least half of the recommended sessions for all treatments included. Data on attendance at weight loss treatments were provided to the study team by two of the three treatment programs offered (two participants who selected the treatment that did not provide data were excluded from analyses of these data). Additionally, participants self-reported if they initiated treatment, i.e., if they attended at least one in-person group session or one phone meeting with their coach.

##### *Weight*

To determine the feasibility of obtaining weight data from EHR, we obtained weight measurements available from EHR at the index visit and at any clinical visit within the health care system occurring 20 to 32 weeks after baseline (i.e., a 2 month window around 6 month follow-up). We also obtained study-measured weight at baseline for participants who were assigned to an in-person visit and at 6 month assessments. Participants attending in-person assessments were weighed on a digital scale (Health O Meter 349KL) in light clothing with shoes removed by a blinded, trained research assistant. Height was obtained using a stadiometer.

##### *Analyses*

Analyses were conducted using SAS software versions 9.4. Descriptive data are presented in means and standard deviations for continuous variables or portion for count variables. Data are presented separately for the mobilization and comparator study arms.

## RESULTS

### *Provider recruitment and characteristics*

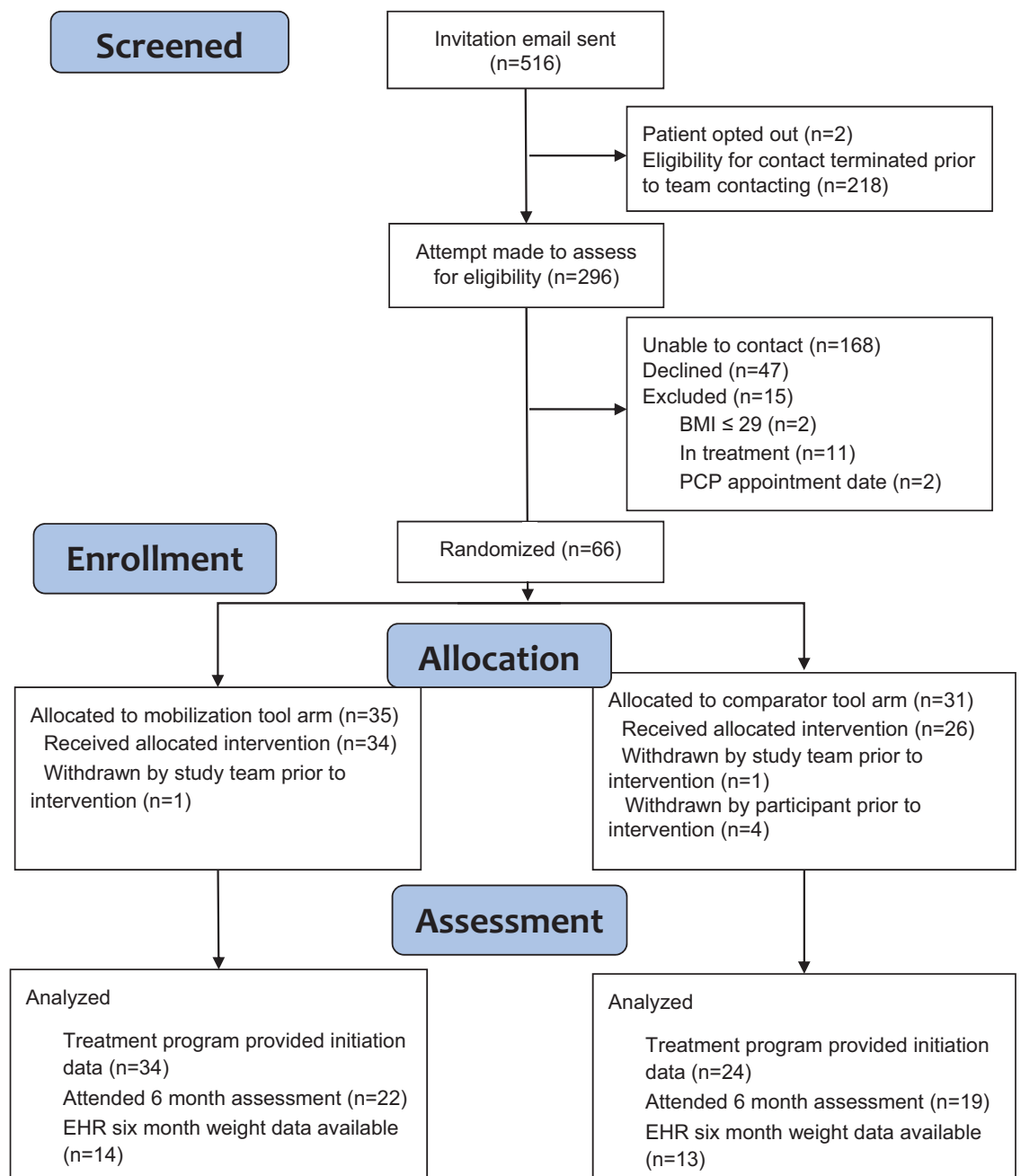
Study staff attended a PCP meeting in February 2017. All six providers present were eligible and

consented to participate. All enrolled providers had doctorates of medicine, with an average of 11 years since completing their medical training. Four providers were women and two were men. Three providers identified as white, two as Black, and one as Asian.

#### Patient recruitment and characteristics

Patient recruitment occurred over 16 weeks (May 2017 to August 2017) and is summarized in Fig. 2. Notably, 218 patients were not able to be proactively contacted by the study team prior to their window of eligibility running out (10 days prior to their PCP

appointment). Among those for whom a proactive attempt to reach was made, 66 (22.3%) consented. Of the 66 patients consented, six withdrew prior to learning their provider-level randomization assignment; four chose to withdraw for no stated reason; one was withdrawn by the study team due to being in treatment; and one was withdrawn by the study team due to canceling their index appointment. The final patient analytic sample was 60 participants (34 mobilization tool arm and 26 comparator tool arm; see Table 1). The patient sample had a mean age of 55 ( $SD = 12.7$ ) years, with slightly more females ( $n = 34$ ; 57.6%) than males and a majority of



**Fig. 2** | Participant flow chart following Consolidated Standards of Reporting Trials guidelines. BMI = body mass index. PCP = primary care provider. EHR = electronic health record. Participants who did not complete the 6 month assessment were lost to follow-up.

**Table 1** | Baseline characteristics of patient sample by provider-level randomization study arm

	Total patient sample <sup>a</sup> ( <i>n</i> = 60)	Mobilization arm ( <i>n</i> = 34)	Comparator arm ( <i>n</i> = 26)
Age, <i>M</i> ( <i>SD</i> )	54.6 (12.7)	54.4 (14.0)	54.9 (10.9)
Female	34 (57.6)	19 (55.9)	15 (57.7)
Male	26 (44.1)	15 (44.1)	11 (42.3)
Race/ethnicity, <i>n</i> (%)			
White, Non-Hispanic	39 (66.1)	23 (67.7)	16 (64.0)
African American	19 (32.2)	10 (29.4)	9 (36.0)
Other or multiple races	1 (1.7)	1 (2.9)	0 (0.0)
Marital status, <i>n</i> (%)			
Married or partnered	35 (59.3)	18 (52.9)	17 (68.0)
Divorced/never married/widowed	24 (40.7)	16 (47.1)	8 (32.0)
Education level, <i>n</i> (%)			
Bachelor's degree or higher	33 (55.9)	18 (52.9)	15 (60.0)
Some college or tech school	23 (39.0)	14 (41.2)	9 (36.0)
High school or lower	3 (5.1)	2 (5.9)	1 (4.0)
Work status, <i>n</i> (%)			
Employed full/part time	36 (61.0)	20 (58.8)	16 (14.0)
Other	23 (39.0)	14 (41.2)	9 (36.0)
Self-reported weight (kg), <i>M</i> ( <i>SD</i> )	110.5 (26.8)	110.4 (24.1)	110.7 (30.4)
Measured weight <sup>b</sup> (kg), <i>M</i> ( <i>SD</i> )	103.1 (15.37)	101.2 (9.8)	107.0 (23.3)
Self-reported BMI, <i>M</i> ( <i>SD</i> )	37.1 (6.4)	37.3 (6.2)	36.9 (6.7)
Self-reported BMI class, <i>n</i> (%)			
Overweight/normal (<25)	1 (1.7)	0 (0.0)	1 (3.9)
Obese class I (30–34.9)	28 (46.7)	15 (44.1)	13 (50.0)
Obese class II–III (>35)	31 (51.7)	19 (55.9)	12 (46.2)
Diabetes diagnosis, <i>n</i> (%)	14 (23.7)	8 (23.5)	6 (24.0)
Pre-Diabetes diagnosis, <i>n</i> (%)	13 (22.0)	8 (23.5)	5 (20.0)
Arthritis diagnosis, <i>n</i> (%)	20 (33.9)	13 (38.2)	7 (28.0)
High blood pressure diagnosis, <i>n</i> (%)	33 (55.0)	17 (50.0)	16 (64.0)
High cholesterol diagnosis, <i>n</i> (%)	26 (44.1)	15 (44.1)	11 (44.0)
Sleep apnea diagnosis, <i>n</i> (%)	17 (28.8)	8 (23.5)	9 (36.0)
GERD diagnosis, <i>n</i> (%)	13 (22.0)	10 (29.4)	3 (12.0)
No obesity-comorbidity diagnosis <sup>c</sup> , <i>n</i> (%)	9 (15.3)	6 (17.6)	3 (12.0)

<sup>a</sup>One patient in comparator arm did not complete baseline session and thus for some characteristics *n* = 59.

<sup>b</sup>Measured weight available only for those participants randomized to the in-person baseline assessment.

<sup>c</sup>Patients were considered to have no obesity comorbidity if they did not select any of the available comorbidities.

white individuals (*n* = 39; 66.1%). Mean BMI based on self-report was 37.1 kg/m<sup>2</sup>, and 84.7% of participants reported at least one obesity-related medical comorbidity diagnosis.

We examined the effects of in-person versus telephone baseline assessment assignment. Among patients who were eligible for the study at screening (*n* = 69), consent was obtained by 31 of 32 (97%) of those assigned to in-person assessment and 35 of 37 (95%) assigned to phone assessment. Among those who enrolled, four individuals randomized to the in-person assessment withdrew prior to attending the baseline assessment and prior to learning of provider-level arm allocation. No participants withdrew from the phone assessment arm. In the final sample, 34 participants were in the phone-based and 26 in the in-person baseline assessment arm.

#### Mobilization tool acceptability

Among the 34 mobilization tool participants, 28 (82%) progressed past the tool's introductory page, and 27 (79%) completed all elements of the tool. The acceptability survey was completed by 20 of the 28 participants who started the tool (72%; or 58.8% of the 34 participants assigned to the mobilization tool arm). All positively worded items had a mean score greater than 4 ("agree"; see Table 2). For the open-ended question, three comments were made. One comments reported dissatisfaction about how the tool functioned on their phone, one reported desire for more information on what to expect after completing the tool, and one reported concern that information requested by the tool did not fully capture dietary habits. Twenty-six of the intervention participants selected to share their results from the tool with their providers.

**Table 2** | Range, mean, and standard deviations in responses of acceptability items for mobilization tool arm participants at completion of tool ( $n = 20$ )

Item	Observed range	M	SD
1. I enjoyed completing <i>Your Wellness Prescription</i>	3–5	4.15	0.67
2. I learned new things from <i>Your Wellness Prescription</i>	2–5	4.05	0.83
3. The <i>Your Wellness Prescription</i> website was easy to use	3–5	4.25	0.72
4. I trusted that the information I entered into <i>Your Wellness Prescription</i> was secure and would stay private	3–5	4.30	0.73
5. <i>Your Wellness Prescription</i> was interesting	3–5	4.10	0.72
6. The information I received during <i>Your Wellness Prescription</i> could be trusted	3–5	4.15	0.75
7. I had enough time to complete <i>Your Wellness Prescription</i> before my doctor's appointment	3–5	4.15	0.75
8. The instructions given on <i>Your Wellness Prescription</i> were easy to understand	4–5	4.35	0.59
9. It was easy to navigate through <i>Your Wellness Prescription</i>	3–5	4.40	0.50
10. <i>Your Wellness Prescription</i> was useful	3–5	4.15	0.67
11. The amount of time it took me to complete <i>Your Wellness Prescription</i> was too long	1–5	2.45	1.39
12. <i>Your Wellness Prescription</i> gave me enough information about the weight loss programs to make a decision about joining them	3–5	4.10	0.64

Response options ranged from 1 = strongly disagree to 5 = strongly agree.

#### Retention at 6 month follow-up assessment

Six month in-person follow-up assessment was attended by 41 of the 60 enrolled participants (68%), including 22 of 34 (65%) in the mobilization tool arm and 19 of 26 (73%) in the comparator tool arm. Considering assessment attendance as it relates to treatment initiation status, 6 month assessment was attended by 21 of 31 participants (68%) who choose to initiate treatment, and 20 of 29 participants (69%) who did not initiate treatment.

#### Treatment initiation and sustained treatment use

##### *Treatment initiation*

Per weight loss program-provided data, 20 of 34 (59%) mobilization tool and 8 of 24 (33%) comparator tool participants initiated weight loss treatment (two

**Table 3** | Weight change from baseline to 6 month follow-up among all study-enrolled participants with weight data

Outcomes	Mobilization tool arm		Comparator tool arm	
	Sample size	Weight change	Sample size	Weight change
Weight change measured by study team (kg), <i>M</i> ( <i>SD</i> )	11	-4.3 (5.9)	7	-0.9 (8.0)
Weight change using EHR reported weight (kg), <i>M</i> ( <i>SD</i> )	13	-4.6 (5.3)	11	-2.3 (6.4)

comparator arm participants were excluded from this comparison due to absence of program-provided data). Per self-report among those with available data, treatment was initiated by 14 of 22 mobilization tool participants (64%) and 8 of 19 comparator tool arm participants (42%; out of all randomized, 41% mobilization arm vs. 31% comparator arm reported initiating).

##### *Sustained treatment use*

Program-provided attendance data showed that the mean number of sessions attended by participants who initiated treatment in the mobilization tool arm was 7.2 ( $SD = 3.3$ ) and in the comparator tool arm was 7.5 ( $SD = 4.2$ ). Eight or more treatment sessions were attended by 11 of 20 (55%) mobilization tool arm participants who initiated treatment and by 5 of 8 (63%) of comparator tool arm participants who initiated treatment.

##### Weight change

Weight change data were available from EHR for 24 participants and from study-assessed weight for 18 participants. **Table 3** shows mean weight loss in both study arms across all participants (regardless of treatment initiation) based on both EHR and study-measured weight. Weight loss of 5% or more of baseline weight (using study-measured weight) was achieved by 2 mobilization participants (5.9% of the 34 participants randomized, or 18.2% of the 11 participants with available weight data) and 2 comparator tool arm participants (7.7% of the 26 randomized, or 28.6% of the 7 participants with available weight data).

## DISCUSSION

Most adults with obesity do not initiate behavioral weight loss treatments, even in settings where evidence-based behavioral weight loss treatments are accessible [11,12]. To extend the reach of these treatments, we developed a single-session, primary care-based, online tool aimed at increasing initiation of evidence-based weight loss treatment. In the current study, we found that the study design



was successful in recruiting providers and patients and that the mobilization tool showed promise for increasing initiation of treatment, with 59% of mobilization tool participants initiating treatment compared to 33% of comparator tool participants. A larger cluster randomized trial across a range of primary care clinics is warranted to test the effectiveness of this tool for increasing initiation of evidence-based treatment and promoting population-level weight loss.

The mobilization tool was rated as being easy to use and understand, informative, and useful by those completing the acceptability measure. We also observed other indicators of high acceptability, including excellent rates of tool completion among those who initiate the tool and high rates of sharing data from the tool with provider. However, given lower than desired response rate to the acceptability measure, the subsequent trial should further assess tool acceptability among a larger sample of participants. Participants' comments in this trial suggest that modest changes may improve the tool, including offering more detailed information about the process of intervention enrollment and addressing concern that the tool is not sufficiently comprehensive. The high acceptability reported by those who completed the acceptability questionnaire in the current study may be attributed in part to our development process, which included user testing with the target population and iteratively refining the tool content and interface design [30].

A larger trial is warranted to determine whether there is evidence of a meaningful effect on treatment initiation that can be observed with adequate power to detect statistical significance across a range of primary care clinic settings. Higher treatment initiation, if achieved by use of this tool, should translate to an increase in weight loss in a population; this is consistent with intention-to-treat data from clinical trials showing that individuals who initiate weight loss treatment lose more weight than those who do not [2]. However, it is possible that increasing treatment initiation as a result of the mobilization tool may not translate into meaningful weight loss if, for example, there is greater drop out or poorer adherence among users of this tool than among individuals who enter treatment without this tool. Contrary to this concern, in this study, we observed similar levels of sustained treatment use in both study arms.

Study procedures were effective for recruiting health care provider participants, potentially due to the minimal time demands on the providers with this intervention and study design. This suggests that the mobilization tool has implementation potential. There was concern that patient recruitment would yield a sample that was highly interested in initiating treatment, which would limit the ability to detect an effect of the tool and generalizability to the target population. However, only 33% of the comparator

tool arm participants initiated treatment, suggesting that procedures were successful in recruiting a population who would not likely initiate treatment in the absence of an intervention. Differences in retention between treatment initiators and noninitiators of the two study arms would also limit validity of results; however, similar retention between these groups was observed. A smaller than desired retention in the overall sample suggests that strategies are needed to improve retention in the future trial.

A limitation of this study is that we had acceptability ratings from only a portion of mobilization tool participants. Another potential limitation of this study is that we only collected weight data on a subset of participants. However, this was by design, in order to inform the future trial. Another potential limitation is that in this study we provided participants free treatment access; such a design may not generalize to settings where free treatment is not available. However, free and low-cost treatment appears to be increasingly common [3,5–10]. This study is limited in that the providers in our study were part of a primary care research network, possibly making them more willing than other providers to participate in research or to incorporate innovative processes into practice. Another potential limitation of this study is that our participants were likely more active internet users than the general primary care population. Finally, the current study does not provide information on how widely the mobilization tool intervention would be used in a real-world setting, as the decision to decline study enrollment in this study could be due to the intervention itself or to the research protocol. If proven effective, future research will need to determine strategies to ensure maximal engagement with the tool.

In summary, the results of this feasibility cluster randomized trial provide initial support for the acceptability of the mobilization tool, the feasibility of the design used in this study, and the potential of the tool to increase treatment initiation. Results provide guidance for a future trial to test mobilization tool efficacy. If effectiveness of the tool is demonstrated in a larger trial, it could provide a new, efficient, and cost-effective approach to increasing initiation of comprehensive weight loss treatment leading to meaningful population weight loss.

## SUPPLEMENTARY MATERIAL

Supplementary material is available at *Translational Behavioral Medicine* online.

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#### Compliance with Ethical Standards

**Conflict of Interest:** Author Gary Bennett holds equity in Coeus Health, LLC, serves as a scientific advisor to Nutrisystem and Interactive Health, is a member of the board of directors at Girl Trek. Authors McVay, Yancy, Levine, Seung-Hye Jung, Soyeon Jung, Anton, and Voils declare that they have no conflicts.

**Authors' Contribution:** MAM, WSY, GGB, and CIV: Study conceptualization and design; interpretation of data, and drafting of manuscript. EL: Study conceptualization and design. S-HJ: acquisition of data. SJ: analysis and interpretation of data. SA: interpretation of data. All authors: critical revisions.

**Ethical Approval:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Duke University IRB. This article does not contain any studies with animals performed by any of the authors.

**Informed Consent:** Informed consent was obtained from all individual participants included in the study.

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