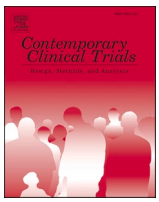
Contemporary Clinical Trials 141 (2024) 107523

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial



Protocol for a prospective, randomized, controlled trial of Mental Contrasting with Implementation Intentions (MCII) to enhance the effectiveness of VA's MOVE! weight management program: WOOP (Wish, Outcome, Obstacle, Plan) VA

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ARTICLE INFO

Keywords:
Behavior change
Mental contrasting
MOVE!
Obesity
Veterans
Weight loss
WOOP

ABSTRACT

Introduction: Intensive weight management programs are effective but often have low enrollment and high attrition. Lack of motivation is a key psychological barrier to enrollment, engagement, and weight loss. Mental Contrasting with Implementation Intentions (MCII) is a unique imagery technique that increases motivation for behavior change. We describe our study protocol to assess the efficacy and implementation of MCII to enhance the effectiveness of VA's MOVE! or TeleMOVE! weight management programs using a procedure called "WOOP" (Wish, Outcome, Obstacle, Plan) for Veterans. We hypothesize that WOOP+MOVE! or TeleMOVE! (intervention) will lead to greater MOVE!/TeleMOVE! program engagment and consequently weight loss than MOVE!/TeleMOVE! alone (control).

Method: Veterans are randomized to either the intervention or control. Both arms receive the either MOVE! or TeleMOVE! weight management programs. The intervention group receives an hour long WOOP training while the control group receives patient education. Both groups receive telephone follow up calls at 3 days, 4 weeks, and 2 months post-baseline. Eligible participants are Veterans (ages 18–70 years) with either obesity (BMI $\geq$ 30 kg/m2) or overweight (BMI $\geq$ 25 kg/m2) and an obesity-associated co-morbidity. At baseline, 6 and 12 months, we assess weight, diet, physical activity in both groups. The primary outcome is mean percent weight change at 6 months. Secondary outcomes include changes in waist circumference, diet, physical activity, and dieting self-efficacy and engagement in regular physical activity. We assess implementation using the RE-AIM framework.

Conclusion: If WOOP VA is found to be efficacious, it will be an important tool to facilitate weight management and improve weight outcomes.

Clinical Trial Registration: NCT05014984

1. Introduction

Approximately 40% of Veterans seen at the U.S. Veterans Health Administration (VHA) have obesity [1] with high chronic disease rates [2]. Modest clinically significant (≥5%) weight loss [3–5] via intensive behavioral programs can reduce the risk of type 2 diabetes in high-risk patients by 58% [6]. To achieve VHA and other key national care guidelines [6,7], the VHA systematically screens and offers eligible

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https://doi.org/10.1016/j.cct.2024.107523
Received 30 August 2023; Received in revised form 31 March 2024; Accepted 8 April 2024
Available online 10 April 2024
1551-7144/Published by Elsevier Inc.

Veterans a weight management program known as MOVE! program and another called TeleMOVE!. MOVE! is a national, intensive, evidence-based VA weight management program to improve the health and quality of life of Veterans [8,9]. MOVE! has been shown to be effective, resulting in weight loss of ≥5% among 20–25% of participants after one year [10]. The effectiveness of MOVE! and other lifestyle-based weight management programs is limited by both low uptake and high attrition rates. <5% of eligible Veterans participate in MOVE! nationwide [11] and only 3–7% of the participants attend at least one MOVE! visit [12]. The average MOVE! attendance was 4.6 visits for the first-time participants between 2004 and 2014 [13]. TeleMOVE! is a separate, but related program for Veterans who cannot attend MOVE! and/or may benefit from frequent reminders to stay on track with their weight management goals. TeleMOVE! has been shown to be as effective for weight loss as the MOVE! program [14].

Many Veterans with obesity find it difficult to initiate and sustain the behavioral changes necessary to promote long-term weight loss, which may discourage engagement in the program [15]. Poor motivation, negative thoughts/moods, and gaps in knowledge are known key internal obstacles to weight management program adherence [15–17] and participant dropouts [18]. In addition, behavior changes may be recommended by primary care providers (PCPs) without assessment of patients' willingness, reasons, or ability to make such changes [18], which highlights the importance of implementing approaches that are designed to enhance engagement and ongoing attendance at behavioral programs (e.g., MOVE!).

Mental Contrasting with Implementation Intentions (MCII) is a unique and practical strategy that was developed and tested through years of research by Dr. Gabriele Oettingen and others to promote motivation and to facilitate challenging behavior change [19]. MCII uses a 4-step mental tool called WOOP (Wish, Outcome, Obstacle, Plan). WOOP employs imagery to connect previously separate entities (i.e., future, reality, behavior to overcome reality) that then spurs behavior change. It allows individuals to mentally explore and identify important, personally feasible wishes and identify and imagine the best outcome and the main internal obstacle in the way of wish fulfillment. By vividly imagining the main obstacle, individuals develop instrumental behaviors to address the obstacle. People addressing wishes in various life domains including those geared toward lifestyle change by using WOOP increase their chances of wish fulfillment. WOOP changes behavior directly via non-conscious processes, bypassing the need to change attitudes or beliefs to achieve behavior change [20–23]. Three non-conscious processes including "cognition, motivation, and response to feedback" mediate the effects of WOOP on wish fulfillment and goal attainment [19,20]. For example, WOOP creates non-conscious mental links between the future and reality and between the reality and the behavior to overcome the reality. In addition, people engaged in WOOP non-consciously identify their personal obstacles in reality [20,21,24]. There is strong evidence to support the efficacy of WOOP for various behaviors (e.g., eating more fruits and vegetables, exercise) necessary for weight management in several healthy and at-risk populations [25–28].

While WOOP may help patients lose weight as a stand-alone intervention [19,28], we believe it is novel to combine it with intensive behavioral weight management programs, delivered in a real-world setting, potentially leading to a stronger impact. This is the first study to integrate an adaptation of WOOP for improving Veterans' engagement in the MOVE! or TeleMOVE! weight management programs. This paper describes our protocol to evaluate the efficacy and implementation of WOOP in primary care and to assess if WOOP+MOVE! (intervention) vs MOVE!/TeleMOVE! alone (control) can promote behavior change and weight loss. The objectives are to compare the impact of WOOP+MOVE!/TeleMOVE! vs. MOVE!/TeleMOVE! alone on 1) weight change and waist circumference; 2) MOVE!/TeleMOVE! attendance, physical activity (PA), and healthy eating at 6 and 12 months; and 3) to evaluate implementation barriers, facilitators, and outcomes of WOOP using the well-established Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework [29,30].

2. Methods and design

2.1. Overview of study design

WOOP VA is a randomized, controlled trial to test the efficacy of WOOP VA for weight management in primary care patients who have a Body Mass Index (BMI) in the obese or overweight ranges at the VA New York Harbor Healthcare System (NYHHS) in New York City, NY. All study procedures were approved by the Institutional Review Boards at VA NYHHS. Participants are randomized 1:1 to either intervention or control. Assessment time-points for both groups occur in person, with the option for remote data collection if needed (via video conferencing) at the following time-points: enrollment, baseline intervention (2 weeks post-enrollment), and 6- and 12-months post-baseline visits. At the enrollment visit, Veterans' socio-demographic and behavioral data and anthropometric measures are collected by trained research assistants (RAs). At the baseline visit, participants in both arms receive MOVE!/TeleMOVE! information and standard patient education. The intervention group receives an hour-long WOOP training, and 30-min follow-up calls at three time-points post-baseline. The control group receives baseline education, and three 30-min telephone follow-up calls for general support and education. At 6 and 12 months, participants' weight, diet and PA are assessed in both groups. Fig. 1 provides an overview of our study design and includes the frequency of intervention and follow-up visits. The trial design adheres to the CONSORT checklist, including an intention to treat analysis.

2.2. Setting

WOOP VA is conducted at the VA NYHHS, which serves diverse, urban Veteran populations; approximately 41% of patients identify as Hispanic/ Latino/a/x, and 49% as non-Hispanic Black. We anticipate that most of our sample will be men because female Veterans at the VA NYHHS only represent approximately 8% of VA healthcare users.

2.3. Sample size and power analysis

Assuming 5% Type-I error rate and 80% power, we need 137 Veterans for each arm to detect a 2.1% (SD = 6.0%) difference in within-person weight change from baseline to 6 months between the groups with a Wilcoxon's rank-sum test. This amount of weight loss is consistent with findings from our prior WOOP study with stroke survivors [28], and similar results were found in a systematic review of technology-assisted weight management interventions in primary care [31]. We consider 2.1% weight loss difference to be conservative for 6-month outcomes and hypothesize the difference will be closer to 2.5% at 6 months. Assuming that the dropout rate at 6 months is about 25%, we plan to enroll 366 individuals to ensure that we have 274 evaluable participants. Details on power calculation for the primary outcomes are summarized in Table 1.

2.4. Participants

Eligible participants are Veterans 18–70 years of age, with either obesity (BMI ≥30 kg/m^2) or overweight (BMI ≥25 kg/m^2) and an obesity-associated co-morbidity (e.g., hyperlipidemia, hypertension, diabetes) [7,32], who have at least one prior visit with their primary care physician (PCP) in the prior 24 months, access to a telephone, and the ability to travel to Manhattan VA for in-person evaluations, and willing to lose weight and enroll in the MOVE! or TeleMOVE! programs. We exclude patients with conditions that may affect their participation or weight change including: 1) a documented current or past medical history of active psychosis or other cognitive issues, severe heart

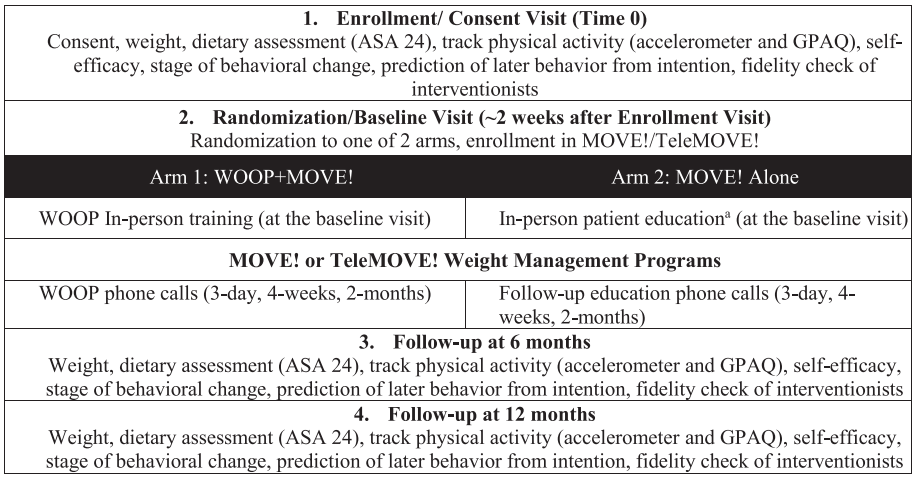

Fig. 1. Overview of the WOOP VA Study Design (Visits and Period).
WOOP: Wish, Outcome, Obstacle, Plan; GPAQ: Global Physical Activity Questionnaire.
[a] In-person education session consists of standard information about MOVE! or TeleMOVE!, diet, and physical activity delivered by the same lay educators (WOOP coaches).

Table 1
Sample Size Calculations for the WOOP VA Study[a].

Expected 6-month	WOOP+MOVE!/TeleMOVE! vs. MOVE!/TeleMOVE! alone	SD[c,d]	Power
Weight change differences between arms			
Pessimistic	2.1% difference[b]	6%	80%[c]
Likely	2.5% difference	6%	92%
Optimistic	3% difference	6%	97%
% of Veterans achieving ≥5% weight loss	20% MOVE!/TeleMOVE! alone 50% WOOP +MOVE!/ TeleMOVE!	30%	91%
MOVE! attendance (complete all 16 sessions)	20% MOVE!/TeleMOVE! alone 50% WOOP +MOVE!/ TeleMOVE!	30%	85%
Waist circumference	2.7-cm difference	7.7 cm	80%
Healthy Eating Index (HEI) score	4.9	14	80%
Moderate to vigorous physical activity	110.6 min	59.5 min	84%[e]

[a] Sample size calculation and power analysis were based on the expected within-person mean percentage weight change from baseline to 6 months (primary outcome).
[b] We consider 2.1% weight loss difference to be conservative for 6-month outcomes and hypothesize the difference will be closer to 2.5% at 6 months.
[c] difference in within-person weight change from baseline to 6 months between the WOOP plus MOVE!/TeleMOVE! vs. MOVE!/TeleMOVE! alone arms with a Wilcoxon's rank-sum test.
[d] Assuming a Type I error rate of 5%.
[e] to detect and increase by 20% in the intervention arm.

conditions, cancer treatment, bariatric surgery or planning to have weight loss surgery in the next year, hospitalization within 90 days prior to enrollment; 2) diagnosis with Parkinson's disease, severe arthritis that might require joint or knee replacement in the next year, or another condition that would greatly impact mobility; 3) participating in a weight management study or seeing a dietitian or MOVE!/TeleMOVE! program attendance more than three times (indicating meaningful engagement in weight management) [33,34] in the past year. Patients taking medications for weight loss and those who are pregnant or breastfeeding, become pregnant during the intervention period, or whose PCP states that they should not participate in the study, are excluded.

2.5. Identifying and recruiting patients

Enrollment of participants began in February 2022 and is expected to conclude in August 2025. Enrollment is done through the Veterans Health Information Systems and Technology Architecture (VistA) or PCP and MOVE! provider referrals. Potential participants are sent invitation letters and study flyers describing the WOOP VA study with an offer to opt out of being contacted. After at least a week, trained study staff make a follow-up phone call to invite Veterans to participate in the study. All eligible participants are consented at the enrollment visit before any study procedures commence.

2.6. Randomization, allocation concealment, and blinding

Randomization is performed using a random number generator in blocks of four and stratified by gender (male/female/other). The MOVE! dietitians or research staff assigned to the control arm are blinded to the intervention arm. Outcome assessors and the study team are blinded. Given the nature of the intervention (i.e., behavioral) [35], WOOP coaches and participants cannot be blinded.

2.7. Study procedures common to both groups

At the baseline visit, all eligible participants (control and intervention) are enrolled in the MOVE! or TeleMOVE! programs [36]. MOVE! is offered at the VA NYHHS as individual telephone and/or in-person and remote group visits consistent with the national MOVE! program guidelines [37]. MOVE! dietitians deliver a 16-module MOVE! Veteran Workbook and the MOVE! facilitator guide to help patients make healthy lifestyle changes [36]. Participants review handouts on weight management, diet, and PA with a dietitian. The TeleMOVE! option was added for study participants in 2024 based on Veteran preference and due to intermittently limited MOVE! program availability. TeleMOVE! includes home weight monitoring, frequent interaction (at least 5 days per week) with in-home messaging technologies (such as a phone or computer) to receive health education messages, and clinician contact as needed. We help schedule the first MOVE! visit using standard VA procedures and/or enroll them in TeleMOVE! based on Veteran preference. While enrollment in MOVE! or TeleMOVE! is a requirement for study participation, the expected range of number of sessions attended by each Veteran will be between 0 and 16 at 6 months. Some Veterans may take longer to finish the program.

2.8. Control arm (MOVE! alone)

During the baseline visit, Veterans randomized to the control arm receive an in-person education session, which consists of standard education about MOVE!/TeleMOVE!, diet, and PA delivered by the same lay educators (WOOP coaches) that deliver the WOOP VA intervention described below. Control arm participants also receive three 30-min telephone follow up calls for general support and education at approximately 3 days, 4 weeks, and 2 months after the baseline visit to check in about how the Veterans have been doing since their last follow up, their experiences with MOVE! or TeleMOVE! and provide general weight management support.

2.9. Intervention arm (WOOP + MOVE!)

At the baseline visit, the WOOP coach teaches the 4-step WOOP technique in-person using protocols adapted from our prior work [26]. WOOP coaches are lay educators that have or are receiving an undergraduate degree in psychology, health sciences, or a related field. All receive the WOOP VA manual and are trained by senior investigators (GO and SW) and the lead WOOP (RC) coach until they demonstrate proficiency (approximately 3–5 h per week over two months). A lead WOOP coach (RC) is responsible for overseeing the training sessions and intervention delivery. WOOP coaches meet regularly as a group for ongoing feedback and training, and fidelity is monitored via audio recording playback. WOOP coaches are also trained to deliver the control arm intervention, described above.

The steps for WOOP include Wish: The Veteran is guided to generate a personal wish for a specific timeframe that is feasible for them but challenging (e.g., "I wish to go to the gym twice a week") that they feel passionate about realizing, and that they are confident they will be able to realize within the timeframe. Outcome: The Veteran identifies the most desired outcome related to the wish that he/she named (e.g., "I will feel proud") and vividly imagines this outcome. Obstacle: The Veteran identifies the main internal obstacle to fulfilling the wish and experiencing the outcome. Then the Veteran imagines this internal obstacle as vividly as possible (e.g., "I feel nervous working out with other people around me"). Plan: The Veteran identifies an action they can take or a thought they can tell themselves to overcome the obstacle. Finally, the Veteran creates an if–then plan according to the following format: If… [Imagine the obstacle in its place and time], then I will… [Imagine performing the behavior to address the obstacle] (e.g., "If I feel nervous working out with other people around me, then I will put my earbuds and music on tuning out the people around me").

After explaining the WOOP steps and showing a brief video about the scientific background of WOOP, the WOOP coach encourages each participant to create two WOOPs related to weight management or another area of their life, one focused on a long-term goal over a 4-week period and one focused on a short-term goal over a 24-h period. The WOOP coach shows a standardized instructional video from the WOOPmylife.org website [38], pausing the video at each step and answering questions along the way. This 13-min video guides patients through WOOP step by step to create their first WOOP for the 4-week period. This increases standardization of the delivery and patients can then use this video at home or at the VA Learning Resource Center. The WOOP coach then guides the Veteran to create the second 24-h wish, outcome, obstacle, and plan using the WOOP app or the paper WOOP diary. The Veteran then completes the 24-h WOOP steps independently, with the WOOP coach providing guidance as needed. If requested by the Veteran, the WOOP coach may guide the Veterans to identify outcomes or obstacles or help them with creating a plan for fulfilling their wish or another WOOP if they prefer. Lastly, The WOOP coach schedules three follow-up telephone check-ins with the Veteran at 3 days, 4 weeks, and 2 months after the baseline visit and encourages them to practice WOOP steps daily and record their WOOPs. Practicing WOOP daily means to practice a short (about 5–10 min) WOOP exercise daily. We encourage them to at least practice a few days a week if daily practice is not possible.

2.9.1. Follow up calls

The WOOP coaches review any personal WOOPs the participants have attempted, address any questions that may have arisen during their WOOP practice and inquiries about the outcomes of their previous WOOPs. If the Veteran would like additional practice, the coaches also guide the Veterans to create another WOOP.

2.10. Data collection

At enrollment, 6-month, and 12-month visits RAs administer all surveys, conduct measurements, and enter the data directly into REDCap. Core measures and their timing are listed in Table 2. To compensate for travel and time for study measurements, Veterans are given 25 US dollars (USD) for the enrollment, 30 USD for the baseline, 40 USD for the 6-month, and 50 USD for the 12-month visits. To facilitate retention, during enrollment we use motivational interviewing techniques and ask Veterans their preferred contact method and information. At the enrollment visit, we collect self-reported socio-demographic information including but not limited to age, gender, race/ethnicity, education level, marital status, employment status, household composition; use of technology; health literacy (two-item screen); chronic conditions; and physical, mental, and social domains of quality of life (PROMIS-29) [39].

Table 2
Variables, data source, and time of assessment for outcomes with the WOOP VA study visit time points.

Variable	Data Source	E	B	6M	12M
Anthropomorphic Measurements					
Weight and BMI	Scale, Stadiometer	✓		✓	✓
Waist circumference	Inelastic tape measure	✓		✓	✓
Health Behaviors					
Dietary outcomes	ASA 24 (24-h recall) [43]	✓		✓	✓
Physical activity	Accelerometer, GPAQ [44,48]	✓		✓	✓
MOVE! program attendance	Service dates from EHR			✓	✓
Motivation and Goal Setting					
Dieting and exercise self-efficacy	DIET-SE [49] and exercise self-efficacy [50][a] scales	✓		✓	✓
Prediction of later behavior (i.e., eating and physical activity) from intention[b]	Theory of Planned Behavior Questionnaire [51]	✓		✓	✓
Readiness and stage of change for eating and physical activity	Stages of change scales [52–54]	✓		✓	✓
Fidelity Measurement					
Frequency of using WOOP	Self-reported WOOP diary and app			✓	✓
Fidelity check of interventionists	Audio recordings, checklist scores			✓	✓
Other Measures					
Demographics	Survey	✓			
Quality of life	PROMIS-29 [39]	✓		✓	✓
Adverse events	Self-reported adverse events			✓	✓

ASA 24, Automated Self-Administered 24-h; B=Baseline visit (2 weeks after E); BMI; Body Mass Index; DIET-SE, Dieting Self-Efficacy Scale; E = Enrollment visit; EHR, Electronic Health Record; GPAQ, Global Physical Activity Questionnaire; M = months post-baseline; PROMIS-29, Patient-Reported Outcomes Measurement Information System; WOOP, Wish, Outcome, Obstacle, Plan.

[a] A five-item measure to represent "Precontemplation", "Contemplation", "Preparation", "Action", and "Maintenance".

[b] As a general rule in the Theory of Planned Behavior, the more favorable the attitude and subjective norm, and the greater the perceived control, the stronger should be the person's intention to perform the behavior in question.

2.10.1. Anthropomorphic outcomes

RAs obtain weight measurements using a standardized protocol and a Patient Aid Medical Heavy Weight 550 lb. capacity scale, taking the average of two weights in lbs. rounded to the nearest 0.10 lb. Using a stadiometer, RAs measure the Veteran's height once in cm rounded up to the nearest 0.10 cm. The RA use an inelastic tape to measure the Veteran's waist circumference twice at the peak of the iliac crests, taking an average of two measures rounded down to the nearest 0.25 in. All measurement procedures are adapted from National Health and Nutrition Examination Survey [40].

2.10.2. Behavioral outcomes

We assess dietary behaviors as changes in overall Healthy Eating Index (HEI)-2015 [41] score, a diet quality index that measures alignment with the 2015–2020 Dietary Guidelines for Americans guidelines [42]. To measure dietary intake (one weekday and one weekend measurement) at each time-point, we use the web-based Automated Self-Administered 24-Hour Recall (ASA24) [43]. We use the ActiGraph Link (GT9X) accelerometer to measure PA during a 10-day period to ensure 7 days of full data collection. During an initial enrollment visit and at 6- and 12-month assessments, RAs place the Link monitor on the participant's non-dominant wrist and instruct the participant to wear it for 24 h daily for 10 days continuously, except when swimming and bathing. This 24-h protocol increases compliance [44]. Since our main PA measure is total weekly moderate and vigorous PA (MVPA) [45], on valid days of wear [46], we classify activity counts into metabolic equivalencies using established cut-points for moderate and vigorous intensities in adults [47]. We also use the Global Physical Activity Questionnaire (GPAQ) to capture PA constructs related to the participant's purpose for being active, including for work, transportation, and recreation [48].

2.10.3. MOVE! or TeleMOVE! attendance

MOVE!/TeleMOVE! attendance is recorded as a date of service in the EHR. We review the EHR data at the VA as well as receive attendance reports from MOVE!/TeleMOVE! dietitians to obtain attendance data. In addition, we ask participants about their perceived involvement in the MOVE! or TeleMOVE! programs during each of the three 30-min follow up calls for both groups.

2.10.4. Predictors of weight loss pertaining to motivation and goal setting processes

We assess the following measures via established scales (Table 2) to determine whether they are predictive of behavioral changes within the WOOP VA intervention: 1) dieting self-efficacy [49]; 2) self-efficacy to exercise in relation to stages of change for exercise [50]; 3) prediction of later behavior (i.e., eating and PA) from intention [51]; and 4) readiness and stage of change for eating [52,53] and PA [54].

2.10.5. Implementation measures

Using the RE-AIM framework [29,30], we plan to collect quantitative and qualitative data on WOOP VA implementation (Table 3). More specifically we will evaluate: Reach: Using Veteran recruitment data, the reach of the intervention is evaluated as the number (proportion) of individuals who are eligible for the study, exposed to recruitment, initially respond, enroll, and complete $\geq$1 visit. To evaluate barriers to participation, we survey those who decline participation. Factors associated with participation are evaluated by comparing the clinical and demographic characteristics of Veterans reached vs. those not reached. Efficacy: Potential outcome differences in subgroups (e.g., women, African Americans and Latino/a/x Veterans, Veterans with a mental health diagnosis, and Veterans that self-referred to MOVE! or were referred by their provider) are assessed. Adoption: Willingness to adopt the intervention including, key stakeholders (e.g., dietitians, PCPs) and barriers/facilitators toward future adoption is assessed. Implementation: The acceptability and feasibility of the WOOP intervention among Veterans and key stakeholders as well as how well WOOP integrates with the MOVE! program is evaluated. Maintenance: We assess long-term maintenance of primary clinical outcomes (weight maintenance at 24 months post-baseline via EHR). We also assess the intention of local leadership and operations to maintain the intervention once the trial ends, as well as maintenance barriers/facilitators.

Table 3
The RE-AIM Framework Data Collection Steps and Timeline.

Implementation Factors	Baseline	6M	12M	24M	RE-AIM Steps
Veteran Recruitment Data[a]	✓				R
Key Informant Interviews[b]			✓		A, I, M
Weight Measurements	✓	✓	✓		E
Veteran Surveys[c]	✓	✓	✓		E
Veteran Interviews[d]			✓		E
Chart Abstraction/Review		✓	✓	✓	E, I, M
Audiotapes of WOOP visits	✓				I

M = months post-baseline. The RE-AIM framework, developed by Glasgow, et al. (1999) [29,30], provides a comprehensive evaluation tool for assessing the public health impact of health promotion interventions, focusing on Reach (R), Effectiveness (E), Adoption (A), Implementation (I), and Maintenance (M).

2.10.6. Fidelity measurements

We monitor the fidelity of intervention delivery using audio recordings of visits and a WOOP coach fidelity checklist adapted from the Aspiring to Lifelong Health in VA study [55]. For 15 WOOP visit recordings, or more if needed, GO and SW (Co—I) review recordings and complete the checklists to confirm inter-rater reliability ($\kappa > 0.8$). Once this is deemed sufficient, they run fidelity checks on a random subset (minimum 20%) of visits. We collect data on the frequency and quality of WOOP VA practice. We obtain participant-level data on frequency of performing mental WOOPs and using the WOOP app or paper diaries from self-report. For quality of WOOP, we use content analysis to code variables such as the type of wish (e.g., diet or PA wish) and the presence and quality of all four WOOP steps.

We use semi-structured qualitative interviews to capture rich information on perceptions of the intervention to inform the development of a future implementation manual. SL (Co—I, qualitative expert) has developed a semi-structured interview guide and trained an interviewer to assess Veteran satisfaction with the intervention, barriers to adherence, and recommendations to improve the intervention. At 6 and 12 months, in-person or telephone interviews are conducted with 30 participants in the intervention arm who completed at least one follow-up call. We also will interview up to 20 key informants (e.g., PCPs, nurses, MOVE! staff, coaches) whose patients participate in the study. All interviews are audio-recorded using a digital recorder and downloaded as WAV files. Audio-taped interviews are transcribed verbatim. Under the guidance of SL, transcripts will be double-coded. The coding team will meet frequently to discuss discrepancies in coding and to iteratively refine the codebook. Analysis of data from transcriptions use a "constant comparison" analytic approach [56], which is a method of explanation-building in which the findings of an initial case are compared to a provisional category, property, or proposition and revised as necessary.

2.10.7. Statistical analysis

Before analyses, we will assess whether participants were equitably randomized by comparing each arm's baseline characteristics using Wilcoxon's rank-sum test for continuous variables or Fisher's exact test for categorical variables. All analyses will be intent-to-treat. Regression models will be used to quantify the effects of intervention on outcome variables while controlling for key potential confounders. Generalized linear mixed effects models based on a linear link function will be used for continuous outcomes, while those based on a logistic link function will be used for binary outcomes. Although mixed effects modeling can address missing data internally, assuming data are missing at random,

we will further use a multiple imputation procedure to conduct sensitivity analyses under the assumption of missing not at random [57]. SAS v.9.4 and R v.4.3.1 [57] software will be used to analyze data. All interview transcripts will be double-coded, and discrepancies will be resolved by consensus discussion. The coded transcripts will be analyzed with Atlas.ti v.8.

3. Discussion

WOOP VA is a novel study that integrates WOOP within an established intensive behavioral weight management program in a real-world primary care setting, potentially leading to improvements in the MOVE!/TeleMOVE! program engagement, addressing barriers to sustained motivation, and consequently in weight management and healthy behavioral changes. WOOP can support existing VA weight management performance measures. If WOOP increases Veteran engagement in weight management, it will help the VA meet weight management performance measures.

Strengths of the study include delivery of WOOP in the VA primary care setting in a potentially cost-effective way. WOOP can be integrated with MOVE!, TeleMOVE!, and/or other weight management services and treatments (e.g., pharmacotherapy, bariatric surgery). WOOP is also easy for patients to practice on their own using the WOOP app, videos, and/or paper diaries, with each session requiring <10 min. This provides flexibility and increased reach for Veterans. WOOP can be taught across all levels of education and literacy.

We acknowledge limitations to this study. Patients are Veterans, mainly male from Hispanic and non-Hispanic Black populations. Therefore, findings may not be generalizable to other genders, race/ethnicities, and populations in primary care. Since this is a pragmatic study utilizing existing clinical weight management services, Veterans may not receive the same MOVE! or TeleMOVE! programs; however, they receive the same MOVE! materials over 16 sessions regardless of the program type. In addition, lay educators have high job turnover, which can limit continuity of care. To address this barrier, all research staff work in teams with trained backup personnel. The quality, fidelity, and continuity of the intervention and research team are monitored throughout the study. Finally, our focus on using WOOP to increase adherence to lifestyle-based weight management may be a limitation given the recent advent of highly effective medications [58] and our decision to exclude Veterans on these medications. However, lifestyle remains a core pillar of obesity treatment [58], and future studies can explore the use of WOOP to increase adherence to anti-obesity medications.

Despite these limitations, our study will provide important insights to improve weight management, even if we do not see a positive impact of WOOP VA. Through rigorous evaluation of implementation using the RE-AIM framework [29,30], we will inform future implementation and accelerate the potential impact of this intervention. If WOOP VA is efficacious, this intervention can be tested in and disseminated to other health systems and patient populations.

Funding

This trial is funded in through the Veterans Affairs Health Services Research and Development Service [1I01HX003264-01A1; IIR 20–153 – HSR&D Study]. The funding sources had no role in study design, data collection, data analysis and interpretation of data, in the writing of the report, and in the decision to submit the article for publication.

Dr. Jay also receives support from the NIH (k24HL165161, R01DK127916, R01DK137135–01) and has consulted with Laekna Therapeutics. Dr. Moin also receives support from the NIH/NIDDK (R01DK124503, R01DK127733, R18DK122372), NIDDK/CDC (U18DP006535), CDC (U18 DP006708), UCLA, UCOP, and the Department of Veterans Affairs (QUE20–028, CSP#2002 and CSP NODES0017).

Credit authorship contribution statement

Sarvenaz Vandyousefi: Methodology, Writing – original draft, Writing – review & editing. **Gabriele Oettingen:** Conceptualization, Investigation, Supervision, Writing – original draft, Writing – review & editing. **Sandra Wittleder:** Conceptualization, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. **Tannaz Moin:** Methodology, Writing – original draft, Writing – review & editing. **Victoria Sweat:** Funding acquisition, Project administration, Writing – review & editing. **Adrian D. Aguilar:** Methodology, Project administration, Writing – original draft. **Andrea Ruan:** Project administration, Writing – original draft, Writing – review & editing. **Gina Angelotti:** Project administration, Writing – review & editing. **Laura Wong:** Project administration, Supervision, Writing – review & editing. **Stephanie L. Orstad:** Methodology, Writing – original draft, Writing – review & editing. **Nicholas Illengberger:** Methodology, Writing – original draft, Writing – review & editing. **Andrew Nicholson:** Methodology, Writing – original draft, Writing – review & editing. **Sahnah Lim:** Methodology, Writing – review & editing. **Rachel Cansler:** Project administration, Supervision, Writing – review & editing. **Dilara Portelli:** Project administration, Writing – review & editing. **Scott Sherman:** Methodology, Writing – review & editing, Conceptualization. **Melanie R. Jay:** Conceptualization, Funding acquisition, Project administration, Supervision, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

Acknowledgments

We express deep gratitude to our research staff and research interns for their many contributions to the project. We thank the staff at the VA New York Harbor Healthcare System (Manhattan campus) Medical Group for their support. Not least of all, we would like to especially thank all the patients and providers participating in the WOOP VA study.

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