





BMJ Open Peer-Assisted Lifestyle (PAL) intervention: a protocol of a cluster-randomised controlled trial of a health-coaching intervention delivered by veteran peers to improve obesity treatment in primary care

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ABSTRACT

Introduction Among US veterans, more than 78% have a body mass index (BMI) in the overweight (≥ 25 kg/m²) or obese range (≥ 30 kg/m²). Clinical guidelines recommend multicomponent lifestyle programmes to promote modest, clinically significant body mass (BM) loss. Primary care providers (PCPs) often lack time to counsel and refer patients to intensive programmes (≥ 6 sessions over 3 months). Using peer coaches to deliver obesity counselling in primary care may increase patient motivation, promote behavioural change and address the specific needs of veterans. We describe the rationale and design of a cluster-randomised controlled trial to test the efficacy of the Peer-Assisted Lifestyle (PAL) intervention compared with enhanced usual care (EUC) to improve BM loss, clinical and behavioural outcomes (aim 1); identify BM-loss predictors (aim 2); and increase PCP counselling (aim 3).

Methods and analysis We are recruiting 461 veterans aged 18–69 years with obesity or overweight with an obesity-associated condition under the care of a PCP at the Brooklyn campus of the Veterans Affairs NY Harbor Healthcare System. To deliver counselling, PAL uses in-person and telephone-based peer support, a tablet-delivered goal-setting tool and PCP training. Patients in the EUC arm receive non-tailored healthy living handouts. In-person data collection occurs at baseline, month 6 and month 12 for patients in both arms. Repeated measures modelling based on mixed models will compare mean BM loss (primary outcome) between study arms.

Ethics and dissemination The protocol has been approved by the Institutional Review Board and the Research and Development Committee at the VA NY Harbor Health Systems (#01607). We will disseminate the results via peer-reviewed publications, conference presentations and meetings with stakeholders.

Trial registration number NCT03163264; Pre-results.

Strengths and limitations of this study

- The Peer-Assisted Lifestyle (PAL) intervention was developed through rigorous formative work to provide evidence-based 5As (Assess, Advise, Agree, Assist, Arrange) counselling delivered by peer coaches in combination with brief counselling by primary care providers (PCPs).
- PAL was designed to serve as an adjunct or stand-alone intervention, providing more moderate intensity systematic obesity counselling, appealing to patients who do not have the time, ability or motivation to attend an intensive programme.
- The evidence gained from this study will inform a broader model for integrating peer-supported counselling within private and public healthcare settings.
- Assessment accuracy could be reduced because some of the study measures rely on self-report, which can be affected by recall and social desirability biases.
- Difficulties might arise regarding implementing a rigorous study protocol in a real-world setting due to factors such as PCP and peer coach turnover, which may affect counselling quality and frequency.

INTRODUCTION

The burden of obesity is substantial. In 2014, more than 78% of US veterans had a body mass index (BMI) in the overweight (≥ 25 kg/m²) or obese range (≥ 30 kg/m²)^{1–5} despite their access to care through the Veterans Health Administration (VHA), America's largest integrated healthcare system. Primary care providers' (PCP) obesity counselling can help promote behavioural changes and modest body mass (BM) loss.^{6–8} PCPs, however, often

do not counsel patients^{9 10} due to competing demands¹¹ and lack of training.^{11 12} The average number of PCP visits (3.6 visits/year) is too few to provide an intensive intervention as per clinical guidelines (≥ 6 sessions over 3 months¹³ or ≥ 12 sessions/year).¹⁴⁻¹⁶ Intensive lifestyle programmes such as the MOVE! programme offered through VHA can produce modest BM loss and decrease cardiovascular risk.¹⁷ Although the VHA provides access to obesity treatment through systematic screening and referral, in reality, fewer than 8% of eligible veterans attend MOVE!.^{18 19}

Peer coaching has the potential to improve obesity treatment for veterans. In other populations and settings, including primary care, peer coaches effectively delivered obesity interventions to support health behaviour change.²⁰⁻²⁷ The peer coaching approach may be appropriate for veterans given the strong communal identity and the camaraderie felt by those with shared military experience.²⁸⁻³⁰ Because peer coaches share a similar background, they can understand and help address barriers specific to veterans such as the change from leaving the highly structured military environment.³¹ Among female veterans, support from military friends after separation from service has been associated with better health outcomes.²⁸ Further, peer-led interventions among veterans with diabetes improved glucose control.^{32 33}

We developed a novel technology-assisted peer coaching intervention, called the Peer-Assisted Lifestyle (PAL) intervention, that uses the 5As (Assess, Advise, Agree, Assist, Arrange) counselling framework³⁴ and was adapted from our Goals for Eating and Moving (GEM) study.³⁵ A pilot study of the GEM intervention ($n=22$) showed modest BM loss when compared with control ($n=23$) for 6 months (-1.5 ± 3.1 kg vs 0.2 ± 3.6 kg, $p=0.08$).³⁶ The PAL intervention builds on our experience with GEM,³⁵ with the added focus on peer coaches to address the specific needs of veterans. The PAL study's aims are to (1) determine the impact of PAL on BM, clinical and behavioural outcomes; (2) identify predictors of BM loss related to PAL intervention components and goal-setting

processes; and (3) evaluate PAL's impact on PCP obesity-related counselling attitudes and practices.

METHODS AND ANALYSIS

Study design and overview

This cluster-randomised controlled study compares the PAL intervention to enhanced usual care (EUC). PAL includes an in-person peer coaching session, 12 peer coaching phone calls over 1 year and brief PCP obesity counselling during routine medical visits. In-person data collection occurs at baseline, month 6 and month 12 (figure 1).

Setting and participants

At the Brooklyn campus of the Veterans Affairs New York Harbor Healthcare System (Brooklyn VA), primary care teams have one to five PCP among other medical staff (eg, registered nurses). The Brooklyn VA has a diverse patient population. Patients enrolled in our study ($n=251$, as of 31 December 2019) were identified as African-American (59.5%), white (22.8%) and Hispanic/Latinx (79.3%).

PCP participants

We enrol PCP, including residents, with a panel of at least 250 primary care patients.

Veteran participants

Eligible patients are between the ages of 18 and 69 years (MOVE! eligibility criteria),¹⁸ under the care of a PCP with at least one prior visit in the past 2 years, have a BMI of ≥ 30 kg/m² or a BMI of ≥ 25 kg/m² with an obesity-associated condition (ie, hypertension, high cholesterol, sleep apnoea, osteoarthritis, metabolic syndrome or pre-diabetes),^{14 16} have access to a telephone and have the ability to travel to the Brooklyn VA. We exclude patients who are non-veterans, have a documented history of active psychosis or other cognitive issues via ICD-10 codes, have participated in more than four sessions of MOVE! in the past year, are pregnant, have a PCP stating that the patient should not participate, or have a self-reported

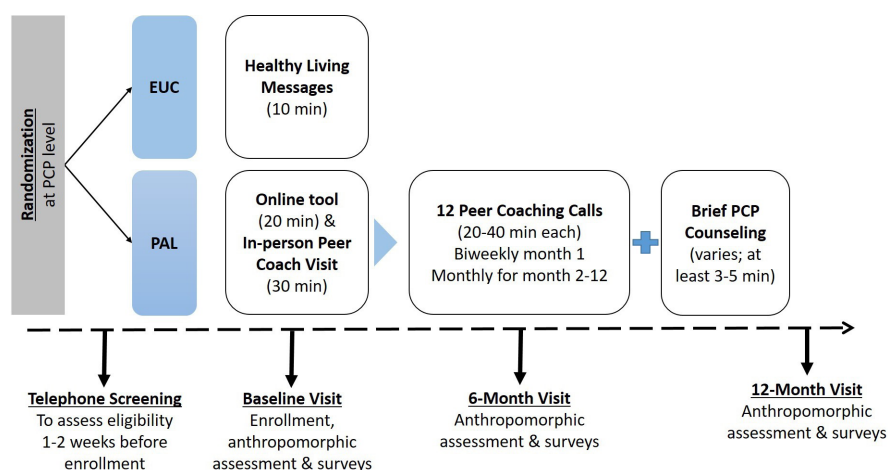


Figure 1 The Peer-Assisted Lifestyle (PAL) study design. EUC, enhanced usual care; PCP, primary care provider.

inability to read at a fifth grade level due to literacy skills or vision problems.

Recruitment and screening

Potentially eligible patients are identified using the Veterans Health Information Systems and Technology Architecture (VistA). PCP review patient lists to identify other contraindications to participating. Patients receive an invitation letter about the study. Research staff then calls patients to recruit, screen for eligibility and schedule the baseline visit. Enrolment began in January 2018 and has been suspended since March 2020 due to the COVID-19 pandemic.

Randomisation and blinding

In 2017, PCPs (n=17), along with their eligible patients, were initially randomised to either PAL (n=8) or EUC (n=9) using a random number generator. In 2018, five PCP left the VA, and in 2019, two new PCP joined the VA and were randomised so that 14 PCPs are currently active in the study (PAL=6; EUC=8). Patients of PCP that left were assigned new PCP by VHA. Those patients remained in the same study arm assigned at the time of enrolment due to the intention-to-treat methodology. As in other behavioural interventions, patients, peer coaches and PCP cannot be blinded to group assignment. We anticipate that the majority of research assistants (RAs) will not be blinded. While we take care not to divulge study arm assignment during measurement visits, our pilot study revealed that patients frequently reported health coach interactions to the RAs conducting outcome assessments. Thus, to minimise assessment bias, we use rigorous training protocols for RAs to standardise the collection of anthropomorphic measures and survey administration. Lastly, the data analyst is blinded to group assignment.

PAL intervention description

Peer coach training

Peer coaches have at least a bachelor's degree but no clinical degree or license and had to have served in one of five branches of the US military with honourable discharge. They receive a minimum of 20 hours of training delivered by the principal investigator (PI) and/or senior coaches based on a prior intervention.³⁷ Peer coaches learn techniques based on motivational interviewing (MI)³⁸ including brief action planning, review coaching manuals and use role-playing and audiotape review to practise counselling skills. MI materials are adapted from the Centre for Collaboration, Motivation, and Innovation (CCMI).³⁹ Peer coaches learn to promote small lifestyle changes, provide empathic care to minimise perceived obesity stigma, identify red flags and barriers (eg, binge eating, hypoglycaemic, untreated depression or pain). To ensure ongoing training, peer coaches meet biweekly with other coaches, the study coordinator and/or PI to discuss cases and share best practices.

Fidelity

We use a modified version of the VA ASPIRE health coach fidelity checklist⁴⁰ to monitor skill acquisition and quality of counselling. A random subset (minimum 10%) of peer coach sessions are audiotaped and reviewed by research staff using the fidelity checklist. Refresher training will occur periodically as needed. We also document reasons for missed sessions.

PCP training

PCP receive training during year 1 of the study (approximately 45 min) with at least one follow-up training by the PI. Similar to the peer coach training, this session is based on previously developed MI training protocols,³⁷ and other adapted MI materials through CCMI.³⁹ We educate PCP about the various MOVE! programmes (eg, in-person MOVE! or TeleMOVE!) and receive contact information for referrals. We provide an overview of the 5As, the intervention components, and practice brief MI (through role-play) to support patients' goals and address barriers to change. We scheduled either one-on-one or in small groups so as not to interfere with clinical or administrative duties.

Fidelity

We assess the quality of PCP counselling with patient surveys during in-person study visits (see the Aim 3: PCP counselling section and [table 1](#) for timing). Also, we use a chart abstraction tool to monitor how often PCP see patients and document goal-setting discussions during visits after enrolment. We evaluate the percentage of clinical reminders completed in the EHR to document counselling or reasons for not counselling.

PAL intervention arm

To deliver 5As-based obesity counselling, PAL uses in-person and telephone-based peer support, a tablet-delivered goal-setting tool and PCP training. [Figure 2](#) describes how the PAL intervention elements fit into the 5As model. Patients in the PAL intervention complete the following items. The estimated time to complete each step stem from pilot testing.

Online tool (20 min, baseline visit)

The development of the tool is described elsewhere.⁴¹ The tool is delivered via a tablet computer. It assesses healthy behaviours, barriers and facilitators related to BM loss (see online supplemental file A for questions), provides tailored advice and guides patients to set BM loss (5%–10%), diet and physical activity (PA) goals. It advises about intensive programmes and self-monitoring options. The tool generates an individualised patient report summary and tailored educational materials based on the patient's answers that are assembled into a personalised binder.

Computerised patient record system notes and clinical reminders

The online tool also creates a report that the peer coach enters into Computerised patient record system (CPRS),

**Table 1** Study measures and assessment points

| | Baseline | 6 months | 12 months |
|-------------------------------------------|----------|----------|-----------|
| Aim 1: Anthropomorphic measures | | | |
| Stature (cm) | X | | |
| Body mass (kg) | X | X | X |
| Waist circumference (inch) | X | X | X |
| Blood pressure | X | X | X |
| Aim 1: Behavioural outcomes | | | |
| Intensive programme attendance | X | X | X |
| Physical activity | X | X | X |
| Dietary changes | X | X | X |
| Self-monitoring and lifestyle behaviours | X | X | X |
| Aim 2: BM-loss predictors | | | |
| Motivational factors | X | X | X |
| Use of PAL intervention | | X | X |
| Aim 3: PCP counselling | | | |
| Quality and frequency | X | X | X |
| Competency and attitudes (PCP report) | X | | X |
| Other measures | | | |
| Sociodemographics | X | | |
| Technology use | X | | |
| Health literacy | X | | |
| Neighbourhood walkability | X | | |
| Discrimination due to race | X | | |
| Discrimination due to weight | X | | X |
| Alcohol (AUDIT-C) ⁷⁰ | X | | X |
| Food security | X | | X |
| Social support | X | X | X |
| Quality of life (PROMIS-29) ⁷¹ | X | X | X |
| Depression (CES-D-SF) ⁷² | X | X | X |
| BM-loss surgeries | X | X | X |

AUDIT-C, The Alcohol Use Disorders Identification Test Consumption; BM, body mass; BMI, body mass index; CES-D-SF, Centre for Epidemiologic Studies Depression Scale Short Form; PCP, primary care provider; PROMIS-29, Patient Reported Outcomes Measurement Information System-29.

the VA's Electronic Health Record (EHR). This clinical note summarises information about the peer coach session for the PCP and generates a clinical reminder. During the next visit, the reminder facilitates documentation about whether the PCP discussed goals and provided further counselling.

In-person peer coach visit (40 min, baseline visit)

After the patients complete the online tool, they meet with a non-clinician, peer coach. The peer coach works with patients to achieve health-related goals using MI³⁸ and SMART (Specific, Measurable, Attainable, Relevant, Timely) goal setting.⁴² The peer coach performs the following tasks:

- ▶ Use worksheets to turn goals into SMART goals⁴² and encourage participation in MOVE!, MOVE!TLC, or other programmes by providing brief MI with SMART Action Planning⁴³ to address barriers (20 min).
- ▶ Teach self-monitoring of BM, diet and PA behaviours via pedometer, food log and/or apps (eg, MOVE! Coach,⁴⁴ My Fitness Pal)⁴⁵ (10 min).
- ▶ Enter a report for the PCP into CPRS summarising the encounter to communicate patients' progress to the PCP (10 min).

Twelve telephone coaching calls (30–40 min each)

To achieve sufficient intensity according to clinical guidelines,¹⁵ PAL incorporates 12 telephone coaching calls by the peer coach over 1 year. Scheduled calls occur every 2 weeks (biweekly) for the first month and monthly for the remainder of the intervention. Patients receive a reminder call from the peer coach to self-monitor their BM, food intake and PA for at least 3 days before the coaching call. Studies suggest that episodes of short, consistent self-monitoring (for 3 days) lead to BM loss and may promote better adherence.⁴⁶ Peer coaches use self-monitoring data to determine goal adherence, counsel patients and encourage small changes.⁴⁷ They help patients create new goals when appropriate and use MI techniques to address barriers to behaviour change.

PCP counselling (3–5 min)

PCP in the PAL intervention arm are encouraged to provide brief MI to address barriers and discuss lifestyle goals, as needed, during regular medical visits. They document counselling with CPRS reminders (figure 3) and collaborate with peer coaches to discuss the patients' progress.

EUC control arm

Veteran patients in the EUC arm receive non-tailored healthy living handouts by RAs as well as information about the MOVE! programme including contact information to enrol. Patients follow up with their PCP for usual care.

Retention

Follow-up visits are scheduled at the baseline visit. One month prior to study visits, patients receive a reminder flyer in the mail. Additionally, 1 week and 1 day before their visits patients receive reminder phone calls from the RA. We also ask patients to provide contact information of a friend or family member to facilitate retention. To compensate for travel and time spent completing study measurements, veteran patients receive \$60 for the

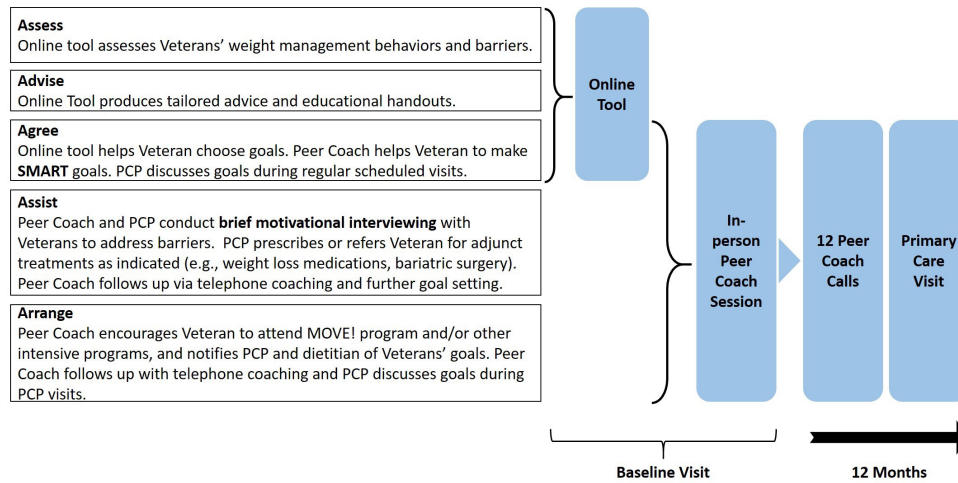


Figure 2 Integration of the Peer-Assisted Lifestyle (PAL) intervention components and the 5As (Assess, Advise, Agree, Assist, Arrange) counselling framework. PCP, primary care provider; SMART, Specific, Measurable, Attainable, Relevant, Timely.

baseline visit, \$45 for the 6-month visit and \$50 for the 12-month visit.

Quality control

The study team meets weekly to monitor recruitment, data collection procedures and unanticipated adverse events. Any serious adverse events are reported to the Institutional Review Board. A data safety monitoring board (composed of VA leaders from ambulatory care, biostatistics and health services research) meets every 6 months to evaluate the data quality and timeliness, recruitment, accrual and retention, and participant risk versus benefit. The board has the authority to halt the trial if it perceives that harm is occurring due to the intervention.

Study measures

In-person study visits to collect data occur in a private research office or clinic room at the Brooklyn VA at baseline, 6 months and 12 months (table 1). During each in-person study visit, an RA administers a survey and collects anthropometric measures.

Aim 1: anthropometric measures

BMI

Participants remove their shoes, heavy clothing, empty their pockets and undo interfering hairstyles. Participants

stand with heels, buttocks, shoulder blades and back of head positioned against the ruler. Stature is measured once, rounded up to the nearest 0.5 cm, using a SECA 213 Portable Stadiometer. BM is measured at least twice using a HealthOMeter 349KLX Digital Medical Scale and rounded to the nearest 0.1 pounds. If the first two measures differ by 0.5 pounds or more, RAs take a third measure, averaging the two closest values for data analysis.

Waist circumference

RAs measure at the high point of the iliac crest on bare skin at minimal respiration, rounding down to the nearest 0.25 inch. If the first two measures differ by 0.5 inches or more, RAs take a third measure, averaging the two closest values for data analysis.

Blood pressure

Using an automated sphygmomanometer (Omron HEM-907XL), RAs measure blood pressure at least 30 min into the survey administration. This delay ensures that the patient has not consumed any caffeine or participated in PA during this time. If the first two systolic or diastolic values differ by 5.0 mm Hg or more, RAs repeat the two measures, and take the average of the two closest values for data analysis.

Aim 1: behavioural outcomes

Intensive lifestyle programme attendance

To evaluate the attendance (number of sessions) to MOVE! programmes, we use electronic chart review. We also assess the self-reported use of intensive programmes via survey items.

Physical activity

The International Physical Activity Questionnaire–Short Form (IPAQ-SF)⁴⁸ is used to measure the intensity, frequency and duration of PA and walking. Participants also wear Actigraph Link accelerometers (model GT9X-BT) on the non-dominant wrist for 7 days after all in-person visits (figure 1). The data from the ActiGraph

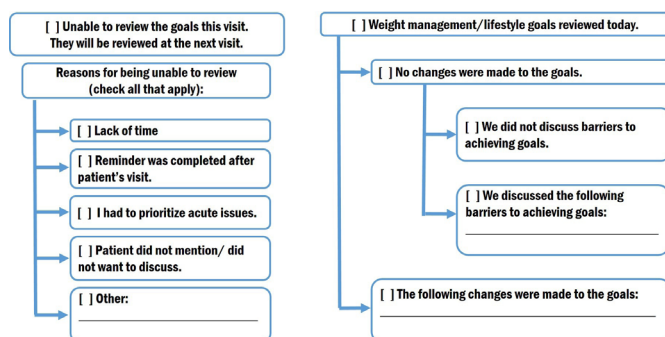


Figure 3 Logic model of the clinical reminder to facilitate weight management counselling.

monitor will be processed using ActiLife software. PA behaviour characterised will include total PA expressed as average daily vector magnitude units, time spent sedentary, and in light and moderate to vigorous intensity.

Dietary changes

We assess fruit and vegetable intake using a seven-item subscale of the validated Food Behaviour Checklist (FBC),⁴⁹ sweet and salty snack consumption using two items adapted from the Rapid Eating Assessment–Shortened Version (REAP-S),^{50 51} and dietary changes including portion sizes for processed foods and sugar-sweetened beverages using six items from the Latino Dietary Behaviours Questionnaire (LDBQ).⁵²

Self-monitoring and lifestyle behaviours

Patients report on how many days (scale: 0–7) during a typical week in the previous 6 months they have performed the following behaviours: weighing themselves, tracking their diet and PA, cooking a healthy meal at home and working out.⁵³

Aim 2: BM-loss predictors

Motivational factors

We assess self-efficacy for exercise⁵⁴ and for resisting overeating using the Weight Efficacy Lifestyle Questionnaire Short Form.⁵⁵ We also assess the stage of change for healthy diet^{56 57} and exercise,⁵⁸ and outcome expectations for changes due to participation in exercise.^{59 60} To assess intrinsic motivation for BM loss and self-monitoring, we use a subscale from the Treatment Self-Regulation Questionnaire^{61 62} (see online supplemental file B for questions).

Use of PAL intervention

We record the number and duration (in minutes) of phone coaching calls. During each telephone coaching session, patients report the attainment of their SMART goals.⁴² To assess improvement in BM loss, PA and dietary behaviours, we ask the patients about their use of pedometers and food logs (paper or via smartphone apps), and collect their recorded data. During study visits, the patients answer questions about their experience with their peer coach (eg, ‘How willing would you be to go back to your peer coach for further support?’ or ‘My peer coach seems to know what he/she is doing.’).⁶³ During exit interviews after the 12-month visit, the patients answer open-ended questions about any other health and lifestyle-related changes, and their experiences with PAL.

Aim 3: PCP counselling

Quality and frequency

To assess the use of 5As-based counselling, veteran patients report on their PCP use of 5As counselling practices (survey items that we have used previously).⁶⁴ Adapted from previous research,⁶³ the patients also report their satisfaction with their PCP treatment plan (eg, ‘My doctor is making good decisions about how to help me manage my weight problems’), their perception

of fairness of decision-making and treatment (eg, ‘My doctor listens to my views’) and their willingness to follow their PCP recommendations (eg, ‘I am trying very hard to follow my doctor’s recommendations’). EHR reviews and chart abstraction provide information on the frequency of counselling (eg, completion of clinical reminders).

Competency and attitudes

We survey PCP before receiving training about obesity counselling and again after at least 12 months to measure 5As-related counselling competency and attitudes about obesity (including self-efficacy, outcome expectancy, discomfort and bias) using validated survey items⁶⁵ (see online supplemental file C for the survey). PCP will participate in exit interviews to answer open-ended questions about their experiences with PAL.

Data analysis

Main outcomes will be analysed using intention-to-treat methodology. All the variables will be summarised using mean (SD) and median (IQR) for continuous variables and frequency tables for categorical variables overall and by study arms, respectively. Although the randomisation should balance the treatment arms, we will use Mann-Whitney tests for continuous variables and Fisher’s exact tests for categorical variables to explore if both patients’ and PCP baseline characteristics may differ between the two arms.

Aim 1: anthropometric measures and behavioural outcomes

The primary outcome is mean BM loss at 12 months. To compare outcomes between the two arms, we will use Mann-Whitney tests for continuous outcomes (eg, BM loss) and Fisher’s exact tests for categorical outcomes (eg, number of patients achieving $\geq 5\%$ BM loss). Unadjusted CIs will measure PAL’s effects on the outcomes compared with EUC. Also, repeated measures modelling based on mixed models will compare outcomes between study arms, using baseline and follow-up data to adjust for characteristics (eg, diabetes, gender), considering: (1) the correlation among patients within PCP and (2) the correlation among repeated measures within patients. Model-based adjusted CIs will be provided to demonstrate PAL’s effects on the outcome variables. These analyses combine the strength of both non-parametric tests, which are more powerful, and parametric tests, which are more robust, to justify our findings.

Aim 2: BM-loss predictors

Visualisation tools (eg, scatterplots) and descriptive analyses (eg, Spearman correlation coefficients) will display associations between BM change and potential BM-loss predictors (ie, motivational factors and use of PAL). Multivariate linear regression models for continuous variables and multiple logistic regression models for binary variables will further examine these predictors’ associations with BM loss. We will construct classification and regression trees (CARTs) to generate the variable importance for each intervention component.

Aim 3: PCP counselling

Mann-Whitney tests for continuous provider-level outcomes and Fisher's exact tests for categorical provider-level outcomes will be used to compare the study arms at each survey. CIs of the effects will be computed as well.

Missing data analysis

Although the repeated measures modelling can address missing data automatically under the assumption of missing-at-random, we will further analyse the missing data due to loss of follow-up or non-response using an inverse-probability-weighting approach and a multiple-imputations approach. These approaches adjust for response bias based on baseline characteristics. To conduct sensitivity analyses under the practical assumption of missing not at random, multiple-imputations procedures with pattern-mixture models will examine the robustness of our findings when considering the least-favourable scenario where missing data from the PAL and EUC arms follow the same pattern.

Sample size and power analysis

We based our sample size on within-person BM change from baseline to 12 months in each arm. As similarities in BM change within clusters should only stem from PCP potentially treating their patients in their unique way, we assume a small but conservative interclass correlation coefficient of 0.03⁶⁶ for patients of each PCP and a coefficient of variation of 0.25 for the cluster size, which was based on the data available at the Brooklyn VA. With eight physicians in the control group and six in the intervention group, we aim for 369 evaluable patients at 12 months to achieve 80% power and 5% type-I error for detecting a 2.4 kg (SD=6.0 kg) BM difference between the two arms. This amount of BM loss is consistent with findings from the ASPIRE VA study⁴⁷ and a systematic review of technology-assisted BM-loss interventions in primary care.⁶⁷ By incorporating a 20% dropout rate, PAL aims to recruit 461 patients.

Patient and public involvement

Feedback from patients and PCP enrolled in prior studies^{41 68} informed PAL's framework and intervention design. We assess the burden of the intervention among PAL patient and PCP participants during exit interviews (see the Study measures section). A summary of the results will be made available to the public after the study's conclusion and publication of the primary outcomes.

DISCUSSION

Developed through rigorous formative work, PAL provides comprehensive 5As counselling delivered by peer coaches in combination with brief counselling by PCP. Delivered by phone, PAL minimises patient travel and addresses logistical barriers like time and location, accommodating even hard-to-reach populations, such as those with lower income or who live in rural settings.

PAL can serve as an adjunct or stand-alone intervention, providing more moderate intensity systematic counselling, appealing to patients who do not have the time, ability or motivation to attend an intensive programme. To promote PCP counselling, PAL includes brief PCP training, peer coaching notes and clinical reminders. PAL is designed to fit into the workflow without overburdening the healthcare team, addressing important PCP barriers to counselling: lack of time and training.^{11 12} It requires 3–5 min of PCP time for brief counselling and documentation, which is a workload that was acceptable to most healthcare staff.^{41 68}

PAL may encounter challenges implementing a study protocol in a real-world setting. PCP and peer coach turnover may affect counselling quality and frequency. In anticipation of these challenges, patients are assigned a second back-up peer coach. The delivery of PAL may differ between patients as they may experience different barriers, prefer varying resources and set individualised nutrition and PA goals. To address these potential confounders, we assess these differences in implementation (eg, types of goals) as well as fidelity of counselling. These data will also help generate hypotheses about which components are most effective and fill a critical research gap; a systematic review on motivational interviewing in telehealth interventions finds that few trials (2 of 15) reported how engagement in different components and fidelity measures related to BM-loss outcomes.⁶⁹

Assessment accuracy could be reduced because some of the measures rely on self-report (eg, PA), which can be affected by recall and social desirability biases. Although RAs receive comprehensive training and follow rigorous protocols, the lack of blinding to participants' group assignment could result in measurement biases that inadvertently favour the intervention group. Lastly, while we aim to recruit a representative sample and have few exclusions for eligibility, patients who enrol in the study may feel more motivated than the average primary care patient, making the results less generalisable. Because PAL is investigated within a single VA site, future studies may test the implementation of PAL within different healthcare systems and populations.

This study emphasises the importance of incorporating obesity counselling in primary care and adds the innovation of using peer coaches, which addresses the specific needs of veteran patients and is cost-effective. The PAL intervention has the potential to improve obesity treatment within primary care and could serve as a model for integrating peer-supported evidence-based 5As obesity counselling within urban healthcare settings.

ETHICS AND DISSEMINATION

All study procedures have been reviewed and approved by the Institutional Review Board and the Research and Development Committee at the VA NY Harbor Health Systems (#01607). All participants are provided oral and written information on the study and asked to sign an

informed consent form (see online supplemental file D) and a Health Insurance Portability and Accountability Act (HIPAA) authorisation (see online supplemental file E). Only authorised study staff will have access to the study data.

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REFERENCES

- Rush T, LeardMann CA, Crum-Cianflone NF. Obesity and associated adverse health outcomes among US military members and veterans: findings from the millennium cohort study. *Obesity* 2016;24:1582–9.
- Nelson KM. The burden of obesity among a national probability sample of Veterans. *J Gen Intern Med* 2006;21:915–9.
- Noël PH, Copeland LA, Pugh MJ, *et al*. Obesity diagnosis and care practices in the Veterans health administration. *J Gen Intern Med* 2010;25:510–6.
- Das SR, Kinsinger LS, Yancy WS, *et al*. Obesity prevalence among Veterans at Veterans Affairs medical facilities. *Am J Prev Med* 2005;28:291–4.
- Breland JY, Phibbs CS, Hoggatt KJ, *et al*. The obesity epidemic in the Veterans health administration: prevalence among key populations of women and men veterans. *J Gen Intern Med* 2017;32:11–17.
- Tsai AG, Wadden TA. Treatment of obesity in primary care practice in the United States: a systematic review. *J Gen Intern Med* 2009;24:1073–9.
- Martin PD, Dutton GR, Rhode PC, *et al*. Weight loss maintenance following a primary care intervention for low-income minority women. *Obesity* 2008;16:2462–7.
- Bennett GG, Warner ET, Glasgow RE, *et al*. Obesity treatment for socioeconomically disadvantaged patients in primary care practice. *Arch Intern Med* 2012;172:565–74.
- Abid A, Galuska D, Khan LK, *et al*. Are healthcare professionals advising obese patients to lose weight? A trend analysis. *MedGenMed* 2005;7:10.
- Galuska DA, Will JC, Serdula MK, *et al*. Are health care professionals advising obese patients to lose weight? *JAMA* 1999;282:1576–8.
- Yarnall KSH, Pollak KI, Østbye T, *et al*. Primary care: is there enough time for prevention? *Am J Public Health* 2003;93:635–41.
- Huang J, Yu H, Marin E, *et al*. Physicians' weight loss counseling in two public hospital primary care clinics. *Acad Med* 2004;79:156–61.
- National Institute for Health and Care Excellence (NICE). *The grants register 2020*, 2019: 586–7.
- U.S. Department of Veteran Affairs and Department of Defense. *Management of obesity and overweight (OBE)*, 2014.
- Moyer VA, U.S. Preventive Services Task Force. Screening for and management of obesity in adults: U.S. preventive services Task force recommendation statement. *Ann Intern Med* 2012;157:373–8.
- Goodwin S. The practical guide to the identification, evaluation and treatment of overweight and obesity in adults. *Clin Nurse Spec* 2002;16:164.
- Knowler WC, Barrett-Connor E, Fowler SE, *et al*. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;346:393–403.
- Del Re AC, Maciejewski ML, Harris AHS. MOVE: weight management program across the Veterans health administration: patient- and facility-level predictors of utilization. *BMC Health Serv Res* 2013;13:511.
- VHA National Center for Health Promotion and Disease Prevention. *MOVE! weight management program for veterans fiscal year 2013 evaluation report: narrative summary*, 2013.
- Viswanathan M, Kraschnewski JL, Nishikawa B, *et al*. Outcomes and costs of community health worker interventions: a systematic review. *Med Care* 2010;48:792–808.
- Brace AM, Padilla HM, DeJoy DM, *et al*. Applying RE-AIM to the evaluation of FUEL Your Life : a worksite translation of DPP. *Health Promot Pract* 2015;16:28–35.
- a KJ, Vitolins MZ, Rosenberger EL. One-Year results of a community-based translation of the diabetes prevention program. *Diabetes Care* 2011;34:1451–7.
- West DS, Bursac Z, Cornell CE, *et al*. Lay health educators translate a weight-loss intervention in senior centers: a randomized controlled trial. *Am J Prev Med* 2011;41:385–91.
- Parikh P, Simon EP, Fei K, *et al*. Results of a pilot diabetes prevention intervention in East Harlem, New York City: project HEED. *Am J Public Health* 2010;100:S232–9.
- Lynch EB, Liebman R, Ventrelle J, *et al*. A self-management intervention for African Americans with comorbid diabetes and hypertension: a pilot randomized controlled trial. *Prev Chronic Dis* 2014;11:E90.

- 26 Dutton GR, Phillips JM, Kukkamalla M, *et al.* Pilot study evaluating the feasibility and initial outcomes of a primary care weight loss intervention with peer coaches. *Diabetes Educ* 2015;41:361–8.
- 27 Leahey TM, Fava JL, Seiden A. A randomized controlled trial testing an Internet delivered cost-benefit approach to weight loss maintenance. *Prev Med* 2016;92:51–7.
- 28 Lehavot K, Der-Martirosian C, Simpson TL, *et al.* The role of military social support in understanding the relationship between PTSD, physical health, and healthcare utilization in women veterans. *J Trauma Stress* 2013;26:772–5.
- 29 Goldstein KM, Zullig LL, Oddone EZ. Understanding women veterans' preferences for peer support interventions to promote heart healthy behaviors: A qualitative study. *Prev Med Reports* 2018;10:353–8.
- 30 Mosack KE, Wendorf AR, Brouwer AM, *et al.* Veterans service organization engagement in 'POWER,' a peer-led hypertension intervention. *Chronic Illn* 2012;8:252–64.
- 31 Jay M, Mateo KF, Squires AP, *et al.* Military service and other socioecological factors influencing weight and health behavior change in overweight and obese veterans: a qualitative study to inform intervention development within primary care at the United States Veterans health administration. *BMC Obes* 2015;3:5.
- 32 Long JA, Jahnle EC, Richardson DM, *et al.* Peer mentoring and financial incentives to improve glucose control in African American veterans: a randomized trial. *Ann Intern Med* 2012;156:416–24.
- 33 Heisler M, Vijan S, Makki F, *et al.* Diabetes control with reciprocal peer support versus nurse care management: a randomized trial. *Ann Intern Med* 2010;153:507–15.
- 34 Glasgow RE, Emont S, Miller DC. Assessing delivery of the five 'As' for patient-centered counseling. *Health Promot Int* 2006;21:245–55.
- 35 Wittleder S, Ajenikoko A, Bouwman D, *et al.* Protocol for a cluster-randomized controlled trial of a technology-assisted health coaching intervention for weight management in primary care: the GEM (goals for eating and moving) study. *Contemp Clin Trials* 2019;83:37–45.
- 36 Viglione C, Bouwman D, Rahman N, *et al.* A technology-assisted health coaching intervention vs. enhanced usual care for primary care-based obesity treatment: a randomized controlled trial. *BMC Obes* 2019;6:4.
- 37 Jay MR, Gillespie CC, Schlair SL, *et al.* The impact of primary care resident physician training on patient weight loss at 12 months. *Obesity* 2013;21:45–50.
- 38 Miller W, Rollnick S. *Motivational interviewing: helping people change*. Guilford Press, 2013.
- 39 CCMI – Centre for Collaboration. Motivation and innovation. Available: <https://centrecmi.ca/> [Accessed 14 Jul 2020].
- 40 Damschroder LJ, Goodrich DE, Kim HM, *et al.* Development and validation of the ASPIRE-VA coaching fidelity checklist (ACFC): a tool to help ensure delivery of high-quality weight management interventions. *Transl Behav Med* 2016;6:369–85.
- 41 Mateo KF, Berner NB, Ricci NL. Development of a 5As-based technology-assisted weight management intervention for veterans in primary care. *BMC Health Serv Res* 2018;18:1–14.
- 42 Doran G. There's a S.M.A.R.T way to write management's goals and objectives. *Manage Rev* 1981;70:35–6.
- 43 Gutnick D, Reims K, Davis C. Brief action planning to facilitate behavior change and support patient self-management. *J Clin Outcomes Manag* 2014;21:17–29.
- 44 MOVE! Coach. MOVE! weight management program. Available: <https://www.move.va.gov/MOVE/movecoach.asp> [Accessed 14 Jul 2020].
- 45 MyFitnessPal. Available: <https://www.myfitnesspal.com/> [Accessed 14 Jul 2020].
- 46 Peterson ND, Middleton KR, Nackers LM, *et al.* Dietary self-monitoring and long-term success with weight management. *Obesity* 2014;22:1962–7.
- 47 Damschroder LJ, Lutes LD, Kirsh S, *et al.* Small-changes obesity treatment among veterans: 12-month outcomes. *Am J Prev Med* 2014;47:541–53.
- 48 Lee PH, Macfarlane DJ, Lam TH, *et al.* Validity of the international physical activity questionnaire short form (IPAQ-SF): a systematic review. *Int J Behav Nutr Phys Act* 2011;8:115.
- 49 Banna JC, Townsend MS. Assessing factorial and convergent validity and reliability of a food behaviour checklist for Spanish-speaking participants in US department of agriculture nutrition education programmes. *Public Health Nutr* 2011;14:1165–76.
- 50 Gans KM, Risica PM, Wylie-Rosett J, *et al.* Development and evaluation of the nutrition component of the rapid eating and activity assessment for patients (REAP): a new tool for primary care providers. *J Nutr Educ Behav* 2006;38:286–92.
- 51 Segal-Isaacson CJ, Wylie-Rosett J, Gans KM. Validation of a short dietary assessment questionnaire: the rapid eating and activity assessment for participants short version (REAP-S). *Diabetes Educ* 2004;30:774–81.
- 52 Fernandez S, Olendzki B, Rosal MC. A dietary behaviors measure for use with low-income, Spanish-speaking Caribbean Latinos with type 2 diabetes: the Latino dietary behaviors questionnaire. *J Am Diet Assoc* 2011;111:589–99.
- 53 Linde JA, Rothman AJ, Baldwin AS. The impact of self-efficacy on behavior change and weight change among overweight participants in a weight loss trial. *Heal Psychol* 2006;25:282–91.
- 54 Marcus BH, Selby VC, Niaura RS, *et al.* Self-efficacy and the stages of exercise behavior change. *Res Q Exerc Sport* 1992;63:60–6.
- 55 Ames GE, Heckman MG, Grothe KB, *et al.* Eating self-efficacy: development of a short-form WEL. *Eat Behav* 2012;13:375–8.
- 56 Prochaska JO, Velicer WF, Rossi JS. Multiple risk expert systems interventions: impact of simultaneous stage-matched expert system interventions for smoking, high-fat diet, and sun exposure in a population of parents. *Heal Psychol* 2004;23:503–16.
- 57 Prochaska JO, Velicer WF, Redding C. Stage-based expert systems to guide a population of primary care patients to quit smoking, eat healthier, prevent skin cancer, and receive regular mammograms. *Prev Med* 2005;41:406–16.
- 58 Sarkin JA, Johnson SS, Prochaska JO. Applying the transtheoretical model to regular moderate exercise in an overweight population: validation of a stages of change measure. *Prev Med* 2001;33:462–9.
- 59 Wilcox S, Castro CM, King AC. Outcome expectations and physical activity participation in two samples of older women. *J Health Psychol* 2006;11:65–77.
- 60 King AC, Taylor CB, Haskell WL, *et al.* Influence of regular aerobic exercise on psychological health: a randomized, controlled trial of healthy middle-aged adults. *Health Psychol* 1989;8:305–24.
- 61 Williams GC, Grow VM, Freedman ZR, *et al.* Motivational predictors of weight loss and weight-loss maintenance. *J Pers Soc Psychol* 1996;70:115–26.
- 62 Leahey TM, LaRose JG, Lanoye A, *et al.* Secondary data analysis from a randomized trial examining the effects of small financial incentives on intrinsic and extrinsic motivation for weight loss. *Health Psychol Behav Med* 2017;5:129–44.
- 63 Tyler T, Mentovich A, Satyavada S. What motivates adherence to medical recommendations? The procedural justice approach to gaining deference in the medical arena. *Regul Gov* 2014;8:350–70.
- 64 Rueda-Clausen CF, Benterud E, Bond T, *et al.* Effect of implementing the 5As of obesity management framework on provider-patient interactions in primary care. *Clin Obes* 2014;4:39–44.
- 65 Jay M, Kalet A, Ark T, *et al.* Physicians' attitudes about obesity and their associations with competency and specialty: a cross-sectional study. *BMC Health Serv Res* 2009;9:106.
- 66 van Breukelen GJP, Candel MJJM. Calculating sample sizes for cluster randomized trials: we can keep it simple and efficient! *J Clin Epidemiol* 2012;65:1212–8.
- 67 Levine DM, Savarimuthu S, Squires A, *et al.* Technology-assisted weight loss interventions in primary care: a systematic review. *J Gen Intern Med* 2015;30:107–17.
- 68 Jay M, Chintapalli S, Squires A, *et al.* Barriers and facilitators to providing primary care-based weight management services in a patient centered medical home for veterans: a qualitative study. *BMC Fam Pract* 2015;16:167.
- 69 Patel ML, Wakayama LN, Bass MB, *et al.* Motivational interviewing in eHealth and telehealth interventions for weight loss: a systematic review. *Prev Med* 2019;126:105738.
- 70 Bradley KA, DeBenedetti AF, Volk RJ, *et al.* AUDIT-C as a brief screen for alcohol misuse in primary care. *Alcohol Clin Exp Res* 2007;31:1208–17.
- 71 Cella D, Choi SW, Condon DM. PROMIS® adult health profiles: efficient short-form measures of seven health domains. *Value Heal* 2019;22:537–44.
- 72 Levine SZ. Evaluating the seven-item center for epidemiologic studies depression scale short-form: a longitudinal U.S. community study. *Soc Psychiatry Psychiatr Epidemiol* 2013;48:1519–26.

Question 1

How important is controlling your weight to you?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 1

How important is controlling your weight to you?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

**Managing your weight is important to you- that's great!
Let's get started.**

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 1

How important is controlling your weight to you?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

Many people feel that other things are more important. We can talk about what steps are possible for you right now.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 2

How much can you rely on family or friends for support and encouragement?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
At All

A lot



Question 2

How much can you rely on family or friends for support and encouragement?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
At All

A lot

Many people like you do not get a lot of support from family and friends. We're here to help you and talk about how we can best support you.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 2

How much can you rely on family or friends for support and encouragement?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
At All

A lot

It is great that you have people who are willing to support you! Talk to your friends and family about your goals.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 3

Which of the following make it hard to manage your weight?

(Select all that apply or none)

- | | |
|--------------------------------------------------|------------------------------------------------------------------|
| <input type="checkbox"/> Low self esteem/sadness | <input type="checkbox"/> Difficulty with self-control |
| <input type="checkbox"/> Stress or nervousness | <input type="checkbox"/> Hungry all the time |
| <input type="checkbox"/> Family Problems | <input type="checkbox"/> Smoking |
| <input type="checkbox"/> Boredom | <input type="checkbox"/> Medications |
| <input type="checkbox"/> No motivation | <input type="checkbox"/> Other (enter here) <input type="text"/> |
| <input type="checkbox"/> Loneliness | |

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 3

Which of the following make it hard to manage your weight?

(Select all that apply or none)

- | | |
|--------------------------------------------------|------------------------------------------------------------------|
| <input type="checkbox"/> Low self esteem/sadness | <input type="checkbox"/> Difficulty with self-control |
| <input type="checkbox"/> Stress or nervousness | <input type="checkbox"/> Hungry all the time |
| <input type="checkbox"/> Family Problems | <input type="checkbox"/> Smoking |
| <input type="checkbox"/> Boredom | <input type="checkbox"/> Medications |
| <input type="checkbox"/> No motivation | <input type="checkbox"/> Other (enter here) <input type="text"/> |
| <input type="checkbox"/> Loneliness | |

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 4

How often do you overeat?

- Never
- Less than once a week
- Once a week
- 2 - 4 times a week
- 5 or more times a week

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 4

How often do you overeat?

- Never
- Less than once a week
- Once a week
- 2 - 4 times a week
- 5 or more times a week

Congratulations! Portion control is an important aspect to weight control.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 4

How often do you overeat?

- Never
- Less than once a week
- Once a week
- 2 - 4 times a week
- 5 or more times a week

Portion control will help you maintain a healthy weight. We can help.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 5

Enter your weight and height so we can calculate your risk for weight-related health problems.

Weight

 lbs

POUNDS

KILOGRAMS

Height

 ft in

FEET/INCHES

CENTIMETERS

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 5

Enter your weight and height so we can calculate your risk for weight-related health problems.

Weight

 kgs

POUNDS

KILOGRAMS

Height

 cm

FEET/INCHES

CENTIMETERS

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Your Weight-Related Risk

Based on your height and weight, you are at a normal risk for health problems. Managing your weight can reduce these risks.

Your health care team is here to support you!

CREATE WEIGHT LOSS GOAL

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Your Weight-Related Risk

Based on your height and weight, you are at a high risk for health problems. Managing your weight can reduce these risks.

Your health care team is here to support you!

CREATE WEIGHT LOSS GOAL

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Create your weight loss goal

How much weight would you like to lose in the next 6 months?

0 lbs

POUNDS

KILOGRAMS

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Create your weight loss goal

How much weight would you like to lose in the next 6 months?

0 kgs

POUNDS

KILOGRAMS

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Create your weight loss goal

How much weight would you like to lose in the next 6 months?

 lbs

POUNDS

KILOGRAMS

**We recommend starting with a weight loss goal within X - Y pounds
(5-10% of your current weight)**

To change your weight loss goal, enter a new weight.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Create your weight loss goal

How confident are you that you can achieve this goal?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Confident

Very
Confident

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Create your weight loss goal

How confident are you that you can achieve this goal?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Confident

Very
Confident

CONTINUE TO SUMMARY

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Step 1 Summary

Here is your weight loss goal



In the next 6 months you would like to

lose 20 pounds

**We are here to support you and help you reach your goal!
Now let's move onto nutrition.**

CHANGE GOAL

CONTINUE TO NUTRITION

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 6

What do you think may get in the way of changing your eating habits?

(Select all that apply or none)

- | | | | |
|--------------------------|------------------|--------------------------|-----------------------------------------|
| <input type="checkbox"/> | Eating fast food | <input type="checkbox"/> | Feeling hungry |
| <input type="checkbox"/> | Unmotivated | <input type="checkbox"/> | Family/friends do not eat healthy |
| <input type="checkbox"/> | Not enough time | <input type="checkbox"/> | Eating too much |
| <input type="checkbox"/> | Not enough money | <input type="checkbox"/> | Other (enter here) <input type="text"/> |

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 6

What do you think may get in the way of changing your eating habits?

(Select all that apply or none)

- | | | | |
|--------------------------|------------------|--------------------------|-----------------------------------------|
| <input type="checkbox"/> | Eating fast food | <input type="checkbox"/> | Feeling hungry |
| <input type="checkbox"/> | Unmotivated | <input type="checkbox"/> | Family/friends do not eat healthy |
| <input type="checkbox"/> | Not enough time | <input type="checkbox"/> | Eating too much |
| <input type="checkbox"/> | Not enough money | <input type="checkbox"/> | Other (enter here) <input type="text"/> |

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 7

In an average week, how often do you eat meals from sit-down or takeout restaurants?

0 - 1 times
a week

2 - 3 times
a week

4 - 6 times
a week

7 or more
times a week

1

Weight Loss



2

Nutrition



3

Physical Activity



4

Resources



5

Report

Question 7

In an average week, how often do you eat meals from sit-down or takeout restaurants?



0 - 1 times
a week



2 - 3 times
a week



4 - 6 times
a week



7 or more
times a week

Cooking your own food is a great way to make healthy choices.

NEXT

1

Weight Loss



2

Nutrition



3

Physical Activity



4

Resources



5

Report

Question 7

In an average week, how often do you eat meals from sit-down or takeout restaurants?



0 - 1 times
a week



2 - 3 times
a week



4 - 6 times
a week



7 or more
times a week

Restaurant foods are often unhealthy or high in calories.

NEXT

1

Weight Loss



2

Nutrition



3

Physical Activity



4

Resources



5

Report

Question 8

How important is it for you to reduce the number of meals you eat from sit-down or takeout restaurants?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important



Weight Loss



Nutrition



Physical Activity



Resources



Report

Question 8

How important is it for you to reduce the number of meals you eat from sit-down or takeout restaurants?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

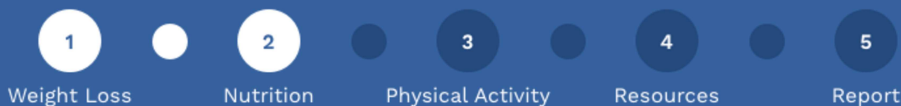
Question 9

How important is it for you to choose healthier foods from sit-down or takeout restaurants?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important



Question 9

How important is it for you to choose healthier foods from sit-down or takeout restaurants?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 10

How many servings of fruit do you eat a day?

(Not including fruit juice or smoothies)

1 SERVING =1 BASEBALL
SIZED FRUITor 1/2 CUP OF
FRUIT0 - 1
servings
a day2 - 3
servings
a day3 or more
servings
a day

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 10

How many servings of fruit do you eat a day?

(Not including fruit juice or smoothies)

1 SERVING =



1 BASEBALL
SIZED FRUIT



or
1/2 CUP OF
FRUIT



0 - 1
servings
a day



2 - 3
servings
a day



3 or more
servings
a day

You may not be eating enough fruit. Try to eat about 2 cups of fruit a day.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 10

How many servings of fruit do you eat a day?

(Not including fruit juice or smoothies)

1 SERVING =1 BASEBALL
SIZED FRUIT1/2 CUP OF
FRUIT0 - 1
servings
a day2 - 3
servings
a day3 or more
servings
a day**Congratulations! You eat enough fruit.**

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

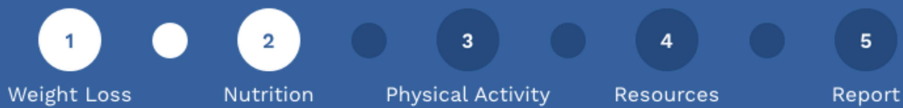
Report

How important is it for you to eat more servings of fruit each day?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important



How important is it for you to eat more servings of fruit each day?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 11

How many servings of vegetables do you eat a day?

1 SERVING =



1 CUP LEAFY
VEGGIES

or



1/2 CUP
OTHER VEGGIES



0 - 1
servings
a day



2 - 3
servings
a day



3 or more
servings
a day

1

Weight Loss

2

3

Nutrition

4

Physical Activity

5

6

Resources

7

8

Report

Question 11

How many servings of vegetables do you eat a day?

1 SERVING =



1 CUP LEAFY
VEGGIES

or



1/2 CUP
OTHER VEGGIES



0 - 1
servings
a day



2 - 3
servings
a day



3 or more
servings
a day

Vegetables are very healthy. Try to fill half of your plate with vegetables.

NEXT

1

Weight Loss



2

Nutrition



3

Physical Activity



4

Resources



5

Report

Question 11

How many servings of vegetables do you eat a day?

1 SERVING =



1 CUP LEAFY
VEGGIES



1/2 CUP
OTHER VEGGIES



0 - 1
servings
a day



2 - 3
servings
a day



3 or more
servings
a day

Congratulations! You eat enough vegetables.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

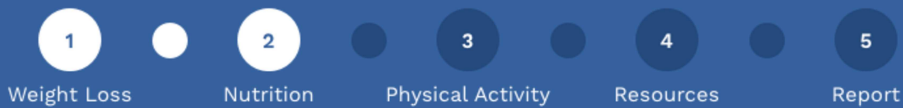
Report

How important is it for you to eat more vegetables?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important



How important is it for you to eat more vegetables?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 12

How many sugar-sweetened beverages like soda, juice, tea or coffee with sugar, do you drink per day?

- 0 beverages
- 1 - 2 beverages
- 3 or more beverages



Weight Loss



Nutrition



Physical Activity



Resources



Report

Question 12

How many sugar-sweetened beverages like soda, juice, tea or coffee with sugar, do you drink per day?

- 0 beverages
- 1 - 2 beverages
- 3 or more beverages

Sugary drinks have a lot of calories. Water is a healthy alternative.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 12

How many sugar-sweetened beverages like soda, juice, tea or coffee with sugar, do you drink per day?

- 0 beverages
- 1 - 2 beverages
- 3 or more beverages

Congratulations! Drinking water is a great way to avoid extra calories.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

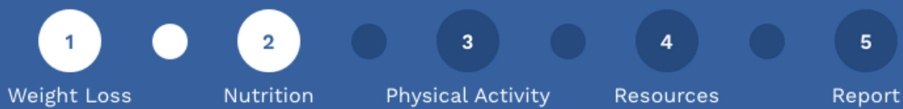
Report

How important is it for you to replace sugar-sweetened drinks with water?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important



How important is it for you to replace sugar-sweetened drinks with water?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 13

Do you drink alcoholic beverages such as beer, malt liquor, wine, etc?

Yes

No

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 13

Do you drink alcoholic beverages such as beer, malt liquor, wine, etc?

Yes

No

Alcohol is high in calories; limiting alcohol can be an important step in achieving weight loss goals.

[NEXT](#)

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 13

Do you drink alcoholic beverages such as beer, malt liquor, wine, etc?

Yes

No

That's great. Keep it up!

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

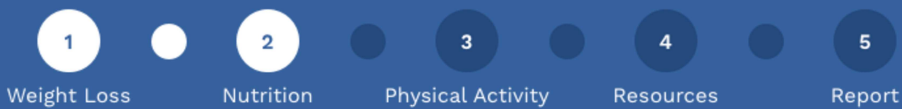
Report

How important is it for you to reduce the amount of alcohol that you drink?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important



How important is it for you to reduce the amount of alcohol that you drink?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 14

How often do you eat sweets or unhealthy snack foods?



DONUTS
CAKE
CANDY
COOKIES

or



CHIPS
PRETZELS
BUTTERY
POPCORN



0 - 1
times
a day



2 - 3
times
a day



3 or more
times
a day

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 14

How often do you eat sweets or unhealthy snack foods?

| | | | | | |
|-----------------------------------------------------------------------------------|----|-----------------------------------------------------------------------------------|--------------------------|--------------------------|-------------------------------------|
|  | or |  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| DONUTS CAKE CANDY COOKIES | | CHIPS PRETZELS BUTTERY POPCORN | 0 - 1 times a day | 2 - 3 times a day | 3 or more times a day |

These are often high in calories, sugar, and fat. Try snacking on fruits, veggies or nuts instead.

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 14

How often do you eat sweets or unhealthy snack foods?



DONUTS
CAKE
CANDY
COOKIES

or



CHIPS
PRETZELS
BUTTERY
POPCORN



0 - 1
times
a day



2 - 3
times
a day



3 or more
times
a day

That's great, keep it up! Fruit, vegetables, or nuts can be great snacks.

NEXT

1

Weight Loss

●

2

Nutrition

●

3

Physical Activity

●

4

Resources

●

5

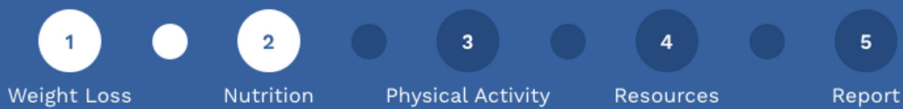
Report

How important is it for you to eat fewer sweets and snack foods?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important



How important is it for you to eat fewer sweets and snack foods?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

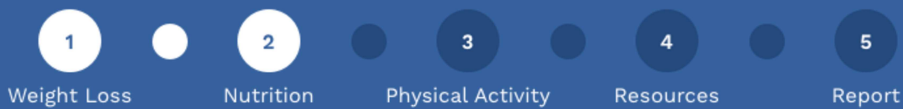
Report

How important is it for you to eat smaller portions or limit second helpings?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important



How important is it for you to eat smaller portions or limit second helpings?

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

Not
Important

Very
Important

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Please select 1 or 2 nutrition goals to focus on

- Eat less takeout
- Order healthier at restaurants
- Eat more fruit a day
- Eat more vegetables a day
- Drink fewer sugary drinks
- Drink less alcohol
- Eat less sweets and snacks
- Eat smaller portions
- Other (Write in your own goal here)



Weight Loss



Nutrition



Physical Activity



Resources



Report

Please select 1 or 2 nutrition goals to focus on

- Eat less takeout
- Order healthier at restaurants
- Eat more fruit a day
- Eat more vegetables a day
- Drink fewer sugary drinks
- Drink less alcohol
- Eat less sweets and snacks
- Eat smaller portions
- Other (Write in your own goal here)

NEXT

1

Weight Loss



2

Nutrition



3

Physical Activity



4

Resources



5

Report

Step 2 Summary

Here is your nutrition goal



In the next 6 months you would like to

Eat more vegetables
Eat fewer sweets and snacks

CHANGE GOAL

CONTINUE TO PHYSICAL ACTIVITY

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 15

What do you think may get in the way of you being more physically active?

(Select all that apply or none)

- | | | |
|---------------------------------------------|-------------------------------------------------|------------------------------------------------|
| <input type="checkbox"/> Not enough time | <input type="checkbox"/> Not enough money | <input type="checkbox"/> No place to be active |
| <input type="checkbox"/> No transportation | <input type="checkbox"/> Don't like to exercise | <input type="checkbox"/> Daily habits |
| <input type="checkbox"/> Pain | <input type="checkbox"/> Back problems | <input type="checkbox"/> Muscle/joint issues |
| <input type="checkbox"/> Heart/lung disease | <input type="checkbox"/> Too tired | <input type="checkbox"/> Other (enter here) |

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 15

What do you think may get in the way of you being more physically active?

(Select all that apply or none)

- | | | |
|---------------------------------------------|-------------------------------------------------|------------------------------------------------|
| <input type="checkbox"/> Not enough time | <input type="checkbox"/> Not enough money | <input type="checkbox"/> No place to be active |
| <input type="checkbox"/> No transportation | <input type="checkbox"/> Don't like to exercise | <input type="checkbox"/> Daily habits |
| <input type="checkbox"/> Pain | <input type="checkbox"/> Back problems | <input type="checkbox"/> Muscle/joint issues |
| <input type="checkbox"/> Heart/lung disease | <input type="checkbox"/> Too tired | <input type="checkbox"/> Other (enter here) |

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

How many days a week do you engage in moderate or vigorous activity?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|

Moderate Physical Activity



- Light sweating
- Small increase in heart rate/breathing
- Talking is difficult
- 150 min/week recommended

Vigorous Physical Activity



- Heavy sweating
- Large increase in heart rate/breathing
- Talking is very difficult
- 75 min/week recommended

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

How many days a week do you engage in moderate or vigorous activity?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|

Moderate Physical Activity



- Light sweating
- Small increase in heart rate/breathing
- Talking is difficult
- 150 min/week recommended

Vigorous Physical Activity



- Heavy sweating
- Large increase in heart rate/breathing
- Talking is very difficult
- 75 min/week recommended

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

How many minutes do you engage in physical activity per week?

| | | | | | |
|----|----|----|----|----|-----|
| 15 | 30 | 45 | 60 | 75 | 150 |
|----|----|----|----|----|-----|

Moderate Physical Activity



- Light sweating
- Small increase in heart rate/breathing
- Talking is difficult
- 150 min/week recommended

Vigorous Physical Activity



- Heavy sweating
- Large increase in heart rate/breathing
- Talking is very difficult
- 75 min/week recommended

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

How many minutes do you engage in physical activity per week?

| | | | | | |
|----|----|----|----|----|-----|
| 15 | 30 | 45 | 60 | 75 | 150 |
|----|----|----|----|----|-----|

Moderate Physical Activity



- Light sweating
- Small increase in heart rate/breathing
- Talking is difficult
- 150 min/week recommended

Vigorous Physical Activity



- Heavy sweating
- Large increase in heart rate/breathing
- Talking is very difficult
- 75 min/week recommended

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Question 16

What kind of physical activity do you currently do?

(Select up to 3 or none)

- | | |
|-------------------------------------------|----------------------------------------------|
| <input type="checkbox"/> Walking | <input type="checkbox"/> Swimming |
| <input type="checkbox"/> Running | <input type="checkbox"/> Sports |
| <input type="checkbox"/> Bicycling | <input type="checkbox"/> Housework/Gardening |
| <input type="checkbox"/> Aerobic exercise | <input type="checkbox"/> Weightlifting |
| <input type="checkbox"/> Dancing | <input type="checkbox"/> Other (enter here) |

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

The American Heart Association recommends



150 minutes
of moderate
exercise
per week



75 minutes
of vigorous
exercise
per week



You said you exercise

XX minutes per week

Physical activity is important for keeping your metabolism active, strengthening your heart, and decreasing pain!

CREATE A NEW PHYSICAL ACTIVITY GOAL

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

The American Heart Association recommends



150 minutes
of moderate
exercise
per week



75 minutes
of vigorous
exercise
per week



You said you exercise

XX minutes per week

Congratulations!

CREATE A NEW PHYSICAL ACTIVITY GOAL

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

How many days a week do you want to engage in physical activity?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|

Moderate Physical Activity



- Light sweating
- Small increase in heart rate/breathing
- Talking is difficult
- 150 min/week recommended

Vigorous Physical Activity



- Heavy sweating
- Large increase in heart rate/breathing
- Talking is very difficult
- 75 min/week recommended

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

How many days a week do you want to engage in physical activity?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|

Moderate Physical Activity



- Light sweating
- Small increase in heart rate/breathing
- Talking is difficult
- 150 min/week recommended

Vigorous Physical Activity



- Heavy sweating
- Large increase in heart rate/breathing
- Talking is very difficult
- 75 min/week recommended

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

How many minutes do you want to engage in moderate or vigorous activity?

| | | | | | |
|----|----|----|----|----|-----|
| 15 | 30 | 45 | 60 | 75 | 150 |
|----|----|----|----|----|-----|

Moderate Physical Activity



- Light sweating
- Small increase in heart rate/breathing
- Talking is difficult
- 150 min/week recommended

Vigorous Physical Activity



- Heavy sweating
- Large increase in heart rate/breathing
- Talking is very difficult
- 75 min/week recommended

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

How many minutes do you want to engage in moderate or vigorous activity?

| | | | | | |
|----|----|----|----|----|-----|
| 15 | 30 | 45 | 60 | 75 | 150 |
|----|----|----|----|----|-----|

Moderate Physical Activity



- Light sweating
- Small increase in heart rate/breathing
- Talking is difficult
- 150 min/week recommended

Vigorous Physical Activity



- Heavy sweating
- Large increase in heart rate/breathing
- Talking is very difficult
- 75 min/week recommended

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Step 3 Summary

Here is your physical activity goal



In the next 6 months you would like to engage in moderate or vigorous physical activity

3 days per week
30 minutes per day

CHANGE GOAL

CONTINUE TO RESOURCES

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in?

- VA MOVE! ?
- VA TeleMOVE! ?
- Weight Watchers ?
- VA MOVE! Coach Mobile ?
- VA Healthy Teaching Kitchen ?
- Gym Membership (non-VA) ?
- VA MOVE! Telephone Lifestyle Coaching ?
- Shape Up NYC ?
- Other programs/resources (non VA) ?

NEXT

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

VA MOVE!

is a program that supports Veterans to lose weight and improve health. Twelve in-person meetings provide teaching, access to dietitians, physical therapists, health psychologists, and other Veterans.

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

VA TeleMOVE!

is a program that supports Veterans to lose weight and improve health. It is a telehealth program that lets you participate from home, when it is most convenient for you.

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

Weight Watchers

is a program that can be helpful for weight loss. This program provides information regarding healthy eating habits, and group support. You can join online or in-person.

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

VA MOVE! Coach Mobile

is a weight loss app for smart phones developed by the MOVE! staff at the VA Hospital. It is a 19-week program that guides participants to lose weight through education and use of interactive tools.

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

VA Healthy Teaching Kitchen

offers in-person cooking demonstrations and healthy recipe prep for Veterans and their families.

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

Gym Membership (non-VA)

Your Health Coach can help you locate a convenient and affordable gym for you to exercise and participate in sports.

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

VA MOVE! Telephone Lifestyle Coaching

is a telephone-based program that supports Veterans to lose weight. The program provides pedometers and weight scales to aid you in your weight-loss journey.

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

Shape Up NYC

offers fitness classes open to everyone in New York. The classes are free!

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Management Programs and Resources

Which of the following are you interested in enrolling in or getting

Other programs/resources (non VA)

Losing weight can be challenging. There are many options for increasing exercise and changing your eating habits. Please let us know how we can help you!

BACK

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Tracking Your Progress

Keeping track of your diet and physical activity can help you reach your new goals. Would you like to track your progress by paper or with an electronic device?

Electronic devices

Wearables, mobile apps or websites

Paper Journal

Food diary or exercise log

Other

CHANGE RESOURCES

CONTINUE TO SUMMARY

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Step 4 Summary

Here are additional resources to help you achieve your goals



Weight Watchers
Gym

Electronic devices
Journal

CHANGE RESOURCES

FINISH

1

Weight Loss

2

Nutrition

3

Physical Activity

4

Resources

5

Report

Weight Efficacy Lifestyle Questionnaire Short Form[1]

How confident are you that you can resist overeating in each of the following situations?

On a scale of 0 (not at all confident) to 10 (completely confident), choose ONE number that reflects how confident you feel now about being able to successfully resist overeating.

I am confident I can resist overeating when:

1. When I am anxious or nervous.
2. On the weekend.
3. When I am tired.
4. When I am watching TV or using the computer.
5. When I am depressed.
6. When I am in a social setting (or at a party).
7. When I am angry or irritable.
8. When others are pressuring me to eat.

| | | | | | | | | | | |
|----------------------------|---|---|---|---|-------------------------|---|---|---|---|-------------------------|
| Not At All Confident | | | | | Moderately Confident | | | | | Completely Confident |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Self-Efficacy For Exercise[2]

How confident are you that you can participate in regular physical activity or exercise in each of the following situations?

On a scale of 0 (not at all confident) to 10 (completely confident), choose ONE number that reflects how confident you feel now about being able to successfully participate in regular physical activity or exercise.

I am confident I can participate in regular physical activity or exercise when:

1. I am tired.
2. I am in a bad mood.
3. I feel I don't have the time
4. I am on vacation
5. It is raining or snowing.

| | | | | | | | | | | |
|----------------------------|---|---|---|---|-------------------------|---|---|---|---|-------------------------|
| Not At All Confident | | | | | Moderately Confident | | | | | Completely Confident |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Intrinsic Motivation (Subscales Of The Treatment Self-Regulation Questionnaire)[3,4]

There are many reasons why people try to lose or control their weight. How true is each reason for you?

I try to lose weight or control my weight because...

1. I feel that it would improve my health.
2. Being overweight makes it difficult to do many things.
3. I feel that it would improve my physical appearance.
4. I find weight-loss to be an exciting, personal challenge.

| Not True for Me | Rarely True for Me | Sometimes True for Me | True for Me | Very True for me |
|-----------------|--------------------|-----------------------|-------------|------------------|
| 1 | 2 | 3 | 4 | 5 |

I do things like weigh myself and keep track of what I eat and my physical activity or exercise because...

1. I feel it helps me stay motivated.
2. I believe that it helps me stay focused on my weight-loss efforts.
3. I find that it helps me stay under my calorie goal and exercise more.
4. I find it rewarding to track and view my personal progress.

| Not True for Me | Rarely True for Me | Sometimes True for Me | True for Me | Very True for me |
|-----------------|--------------------|-----------------------|-------------|------------------|
| 1 | 2 | 3 | 4 | 5 |

Stage Of Change For Healthy Diet[5,6]

Each of these statements represents where various people are in their thinking about changing their eating or eating more healthily. Which statement best indicates where you are now? Have you made changes to your eating habits?

| Yes, I have been for more than 6 months | Yes, I have been but for less than 6 months | No, but I intend to in the next 30 days | No, but I intend to in the next 6 months | No, and I do not intend to in the next 6 months |
|-----------------------------------------|---------------------------------------------|-----------------------------------------|------------------------------------------|-------------------------------------------------|
| 5 | 4 | 3 | 2 | 1 |

Stage Of Change For Exercise[7]

Each statement represents where various people are in their thinking about changing or increasing their physical activity. Have you made changes to or increased your physical activity?

| | | | | |
|-----------------------------------------|---------------------------------------------|-----------------------------------------|------------------------------------------|-------------------------------------------------|
| Yes, I have been for more than 6 months | Yes, I have been but for less than 6 months | No, but I intend to in the next 30 days | No, but I intend to in the next 6 months | No, and I do not intend to in the next 6 months |
| 5 | 4 | 3 | 2 | 1 |

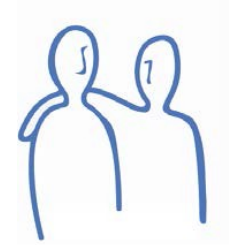
Outcome Expectations For Changes Due To Participation In Exercise[8,9]

| | | | | | | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|----------------------|---|---|---|---|---------------------|
| We would like to know how the following factors have changed, if at all, over the past 6 months due to participation in physical activity or exercise? | | | | | | | | | | |
| <ol style="list-style-type: none"> 1. Physical Shape and Appearance 2. Quality of Sleep 3. Body Weight 4. Physical Fitness 5. Mood 6. Confidence and Well-being 7. Stress | | | | | | | | | | |
| Not At All or N/A | | | | | Moderate Improvement | | | | | Extreme Improvement |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

- [1] G.E. Ames, M.G. Heckman, K.B. Grothe, M.M. Clark, Eating self-efficacy: Development of a short-form WEL, *Eat. Behav.* 13 (2012) 375–378. <https://doi.org/10.1016/j.eatbeh.2012.03.013>.
- [2] B.H. Marcus, V.C. Selby, R.S. Nlaura, J.S. Rossi, Self-efficacy and the stages of exercise behavior change, *Res. Q. Exerc. Sport.* 63 (1992) 60–66. <https://doi.org/10.1080/02701367.1992.10607557>.
- [3] G.C. Williams, V.M. Grow, Z.R. Freedman, R.M. Ryan, E.L. Deci, Motivational Predictors of Weight Loss and Weight-Loss Maintenance, *J. Pers. Soc. Psychol.* 70 (1996) 115–126. <https://doi.org/10.1037/0022-3514.70.1.115>.
- [4] T.M. Leahey, J.G. LaRose, A. Lanoye, J.L. Fava, R.R. Wing, Secondary data analysis from a randomized trial examining the effects of small financial incentives on intrinsic and extrinsic motivation for weight loss, *Heal. Psychol. Behav. Med.* 5 (2017) 129–144. <https://doi.org/10.1080/21642850.2016.1276460>.
- [5] J.O. Prochaska, W.F. Velicer, J.S. Rossi, C.A. Redding, G.W. Greene, S.R. Rossi, X. Sun, J.L. Fava, R. Laforge, B.A. Plummer, Multiple risk expert systems interventions: Impact of simultaneous stage-matched expert system interventions for smoking, high-fat diet, and sun exposure in a population of parents, *Heal. Psychol.* 23 (2004) 503–516. <https://doi.org/10.1037/0278-6133.23.5.503>.

- [6] J.O. Prochaska, W.F. Velicer, C. Redding, J.S. Rossi, M. Goldstein, J. DePue, G.W. Greene, S.R. Rossi, X. Sun, J.L. Fava, R. Laforge, W. Rakowski, B.A. Plummer, Stage-based expert systems to guide a population of primary care patients to quit smoking, eat healthier, prevent skin cancer, and receive regular mammograms, *Prev. Med. (Baltim)*. 41 (2005) 406–416. <https://doi.org/10.1016/j.ypmed.2004.09.050>.
- [7] J.A. Sarkin, S.S. Johnson, J.O. Prochaska, J.M. Prochaska, Applying the transtheoretical model to regular moderate exercise in an overweight population: Validation of a stages of change measure, *Prev. Med. (Baltim)*. 33 (2001) 462–469. <https://doi.org/10.1006/pmed.2001.0916>.
- [8] S. Wilcox, C.M. Castro, A.C. King, Outcome expectations and physical activity participation in two samples of older women, *J. Health Psychol.* 11 (2006) 65–77. <https://doi.org/10.1177/1359105306058850>.
- [9] A.C. King, C.B. Taylor, W.L. Haskell, R.F. DeBusk, Influence of regular aerobic exercise on psychological health: a randomized, controlled trial of healthy middle-aged adults., *Health Psychol.* 8 (1989) 305–324. <https://doi.org/10.1037/0278-6133.8.3.305>.

PAL – Peer Assisted Lifestyle



PAL – The Peer Assisted Lifestyle Intervention is a VA-funded and IRB-approved research study (MIRB #1607) to assess the effectiveness of a technology-assisted intervention to promote weight loss, behavior change, and participation in intensive weight management programs among our patients. We also hope to learn whether the program promotes primary care provider weight counseling for patients to make healthier lifestyle choices.

The purpose of this before and after survey is to assess the impact of the intervention so research staff can understand implementation issues. We will follow up with you in 1 year with a similar survey. Your survey participation is entirely voluntary; you can choose not to complete this survey or participate in the trainings if you are invited. Your decision will not impact your employment or status at the Department of Veterans Affairs in any way. **Completing the survey implies your consent to allow us to use your responses in this study.** If you participate now, you can choose to withdraw your participation at any time.

Your decision to participate and your individual responses will not be viewed by anyone other than the PAL Study staff. The main risk of participating is a slight chance of the loss of confidentiality; however, we take steps such as storing files in locked cabinets and using password-protected computers, to minimize this risk. Once your responses are entered into a study table, we will replace your name with a study ID number. Only one PAL Study staff member will retain access to the file linking your study ID number and your name. Your data will only be reported in the aggregate, without any personally identifying information. If you have any questions about this survey, please contact Laura Wong at laura.wong1@va.gov or 212-686-7500 x5098 or the New York Harbor VA Research Compliance Officer, Marna Abarientos at marna.abarientos@va.gov or 212-686-7500 x7443.

We know how busy you are and we appreciate you taking the time to complete this questionnaire. Thank you in advance for your participation and valuable insight.

Melanie Jay, MD, Principal Investigator

Melanie.Jay@va.gov

Part I

Please choose the response that best characterizes your CURRENT ABILITY TO PERFORM (OR TEACH) each of the following 5A recommended tasks.

| | Know very little about it and NOT ABLE TO PERFORM IT AT ALL | Know something about it and SOMEWHAT ABLE TO PERFORM IT | ABLE TO PERFORM IT WELL | ABLE TO TEACH OTHERS HOW TO DO IT | Decline to Answer |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------|--------------------------|-----------------------------------|--------------------------|
| Obtain diet history (e.g., 24-hour recall, food record, or food frequency). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Assess and interpret body mass index (BMI) from weight and height measurements. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Assess diet for common unhealthy behaviors associated with obesity (e.g., sweetened beverages, nutritional quality of snacks, frequent meals from fast food restaurants, etc.). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Assess current level of physical activity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Assess each patient's readiness and ability to work on weight loss according to health beliefs and stage of change. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Discuss the effect of obesity on present and future health and personalize risk to each patient. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Advise patients on ways to improve diet. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Advise patients on ways to improve physical activity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Address patients' concerns and answer questions regarding treatment options for obesity including medications and bariatric surgery. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Describe the MOVE! Program to my patients and answer questions. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

PAL Study

| | Know very little about it and NOT ABLE TO PERFORM IT AT ALL | Know something about it and SOMEWHAT ABLE TO PERFORM IT | ABLE TO PERFORM IT WELL | ABLE TO TEACH OTHERS HOW TO DO IT | Decline to Answer |
|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------|--------------------------|-----------------------------------|--------------------------|
| Assist patients in setting realistic goals for weight loss. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Work with patients to agree on sustainable behavioral / lifestyle goals (e.g., diet and physical activity). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Work with patients to agree on goals for health outcomes (e.g., improve mood). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Help make patients' weight management goals into SMART goals (specific, measurable, attainable, relevant, and timely). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Use motivational interviewing skills to activate patients to change behavior. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Provide brief counseling intervention to help patient lose weight. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Address patient barriers to weight management. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Prescribe medications for weight loss. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Choose medications that are less likely to cause weight gain in individuals at risk for obesity or who are already obese. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Recognize which patients should be sent for a bariatric surgery evaluation based on the NIH Conference Criteria. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Counsel patients about the risks and benefits of the different procedures for weight loss surgery. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Refer to clinic-based weight management programs (e.g., MOVE! Program). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

PAL Study

| | Know very little about it and NOT ABLE TO PERFORM IT AT ALL | Know something about it and SOMEWHAT ABLE TO PERFORM IT | ABLE TO PERFORM IT WELL | ABLE TO TEACH OTHERS HOW TO DO IT | Decline to Answer |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------|--------------------------|-----------------------------------|--------------------------|
| Refer patients to community-based weight management programs and weight management resources. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Refer patients with obesity to the appropriate ancillary healthcare provider for care (e.g., mental health worker, dietician, exercise specialist, bariatric specialist). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Collaborate with registered dietitians and other providers to support weight management. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Monitor patient's progress with regards to weight management. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Part II

| | Disagree Strongly | Disagree Somewhat | Agree Somewhat | Agree Strongly | Decline to Answer |
|--------------------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| I feel uncomfortable when examining a patient with obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| It is difficult for me to feel empathy for a patient with obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I have negative reactions towards the appearance of patients with obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I feel qualified to treat patients with obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I have been successful in treating patients for obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| The best role for a physician in weight management is to provide treatment rather than referral. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Most obese patients could reach a normal weight (for height) if motivated. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

PAL Study

| | Disagree Strongly | Disagree Somewhat | Agree Somewhat | Agree Strongly | Decline to Answer |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Obesity is primarily caused by behavioral factors. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Obesity is a treatable condition. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Most patients with obesity will not lose a significant amount of weight. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Treating patients with obesity is very frustrating. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Most patients with obesity are well aware of the health risks of obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Bariatric surgery is a SAFE option for weight loss in patients with class III (extreme) obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I feel comfortable referring patients for bariatric surgery. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| When there are alternatives available, it is important to choose medications that are less likely to cause further weight gain in individuals with obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Medications can play a significant role in a patient's risk of developing obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Providing weight management counseling is a priority when I am caring for a patient with obesity. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I receive adequate support from other members of the Primary care team (e.g. nurses, dietitians, health coaches) to provide weight management to patients. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I have a personal desire to counsel patients about weight management. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If a patient is overweight/obese, I feel awkward discussing his/her weight. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I feel confident treating overweight/obese patients. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

PAL Study

| | Disagree Strongly | Disagree Somewhat | Agree Somewhat | Agree Strongly | Decline to Answer |
|----------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| I feel effective in helping overweight/obese patients manage their weight. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I have a personal desire to counsel patients about exercise. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I have a personal desire to counsel patients about nutrition. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I find it rewarding to talk to someone about nutrition. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Counseling about nutrition does not change behavior. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Part III

Your Name: _____

Do you identify as:

- female
- male
- other
- decline to answer

What is your degree:

- MD
- NP
- RN
- LPN
- decline to answer

How many years have you been practicing at this site? _____

How many years have you been with the VA? _____



Department of Veterans Affairs
VA New York Harbor Healthcare System

RESEARCH CONSENT FORM

Please type or print legibly: Last name, First name M.I.

Subject Name:

Study Title: The Peer Assisted Lifestyle (PAL) intervention protocol: A technology-assisted weight-loss intervention within Patient Aligned Care Teams at the VA

Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

Participants full SSN:

INTRODUCTION

You are being asked to volunteer to participate in a VA-approved research study at **the VA New York Harbor Healthcare System** (VA NYHHS). It is important that you read and understand the information on this form and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide.

BACKGROUND AND PURPOSE

Purpose of the study: To pilot test a weight management intervention among Veterans in order to improve weight management counseling within VA primary care.

Expected enrollment: Up to 520 VA patients and 30 VA health providers/staff are expected to enroll. You are being asked to participate in this study because you have been identified as a patient who could gain a health benefit from personalized behavior change information in the area of diet and exercise to lose weight.

Study conducted by Principal Investigator: Melanie Jay, MD MS (VA New York Harbor Healthcare System, NYU Langone Medical Center) as part of a VA-funded grant to explore feasibility of a cluster randomized controlled trial at the VA New York Harbor Healthcare System.

DURATION OF THE RESEARCH

Expected research study length: 1 year (with potential monitoring of weight for an additional year)

Your individual participation requires 3 in-person study visits:

- Baseline study visit (~1-3 hours), Follow-up study visits at 6 and 12 months (1-2 hours)

Your individual participation may require additional participation in 10-12 brief (<30 minutes) phone conversations with a health coach over 1 year as part of the intervention study. To be eligible to participate, you need to have a cellular or traditional telephone.

FOR IRB USE ONLY:

IRB Approval Date: 11/04/19

MIRB ID: 1607

VA Form **10-1086**
As modified on 02/05/15

VA NYHHS IRB-APPROVED INFORMED CONSENT DOCUMENT

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Department of Veterans Affairs
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RESEARCH CONSENT FORM

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Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

STUDY PROCEDURES

Baseline study visit: You will be asked to come to the Brooklyn VA for 1-3 hours and you will be randomly assigned to one of two intervention groups. You will complete a questionnaire with several questions to provide information about your dietary and exercise habits, your attitudes about your health, and your experiences with the healthcare system. Basic physical measurements (i.e. height, weight, waist circumference, blood pressure) will also be taken. You may also be asked to complete a routine blood draw at the Diagnostics Center to measure HbA1c and lipid levels. Depending on your group assignment, you may have the opportunity to use an online weight management and goal-setting tool to discuss these topics more in detail with a research team member and set behavior change goals and/or receive educational materials. Afterwards, you may be asked to complete an exit questionnaire.

Follow-up study visits: You will be asked to come back to the Brooklyn VA for 2 follow-up study visits at 6 and 12 months after the Baseline study visit. Each follow-up study visit (1-2 hours), you will be asked to complete follow-up questionnaires, basic physical measurements, and a routine blood draw at the Diagnostic Center.

Data Collection: Your interactions with research staff and health providers may be recorded for research purposes. In addition, research staff may share important information related to your care with your primary care provider. Additional data will be collected via paper/online questionnaires and study visits notes.

If you decide to take part in this study, you will also need to do the following to the best of your ability:

- Keep your study visit appointments. If it is necessary to miss an appointment, please contact the investigator or research study staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- Tell the investigator or research staff about anything that may affect your participation in the study.

FOR IRB USE ONLY:

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Department of Veterans Affairs
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Subject Name:

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Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

POSSIBLE RISKS OR DISCOMFORTS

Any intervention has possible risks and discomforts and rare, unknown, or unforeseeable (unanticipated) risks also may occur. However, there are no more than minimal risks to your health or well-being from participation in this study.

For Participants with Diabetes Only: If you have diabetes, increasing physical activity and changing your diet can cause hypoglycemia (low sugar). While the risks of hypoglycemia happening as a result of this study are small, hypoglycemia can be life threatening. By agreeing to participate in this study, you accept this risk. You must be familiar with the symptoms of hypoglycemia and how to manage it. Symptoms of hypoglycemia include sweating, confusion, irritability, headaches, feeling shaky, and/or heart palpitations. Having sugar (glucose tablets or juice) immediately will improve the symptoms. If you experience an episode of hypoglycemia, you must notify your doctor and our study team. Also, if you are prescribed insulin during the study period, please let the study team know since this could increase the risks of hypoglycemia.

The researchers understand that exploration of these topics and a persons' individual struggle with their weight can be emotionally charged for many people, particularly considering the stigma placed on obesity in our society. The researchers have been trained in order to effectively facilitate conversations on this sensitive topic and will seek to minimize any emotional discomfort you may feel during the study. Additionally, any potential behavior changes related to diet or exercise will be assessed and approved by properly trained individuals including select research staff, the Primary Investigator, and health professionals. All research study procedures will be completed in a private setting.

Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers about risks of usual care.

POTENTIAL BENEFITS

By participating in this intervention study, you will have the opportunity to receive weight management information. Talking about these topics with trained researchers could serve as support or motivation for the difficult task of diet and exercise behavior change. In addition, you may also be able to discuss weight management behaviors and use individualized techniques to improve diet and exercise and set health behavior change goals. This could help you with motivation and give you tangible methods for weight loss.

FOR IRB USE ONLY:

IRB Approval Date: 11/04/19

MIRB ID: 1607

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VA NYHHS IRB-APPROVED INFORMED CONSENT DOCUMENT

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Department of Veterans Affairs
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Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

ALTERNATIVE PROCEDURES

Your participation in this weight management intervention study is voluntary and completely optional. You may choose not to participate in this study. A decision to not participate in this study will not impact your normal medical care. You may discuss other weight management options with your doctor.

CONFIDENTIALITY

Taking part in this intervention study will involve collecting some private data about you via questionnaires, discussions, research notes, and a review of your medical record.

This data will be protected in the following ways:

- All written data will be kept in locked filing cabinets and electronic data (including survey responses, audio files, and responses to online tool) on secure VA servers and only accessible on VA password protected computers. Original audio files will be removed from recorders.
- Data will be accessed by research team members.
- For transcription of audio files, files will be sent as encrypted files through the secure server to the VA-contracted transcription company, Transcription Outsourcing, LLC. Transcripts will be de-identified by leaving all identifiable information out of the transcript and using only a unique coded identifier generated by the Principal Investigator. This unique identifier will not use any identifying information (i.e. it will not be generated using the subject's social security number, name, etc.) Recorded information will be transferred to Transcription Outsourcing via a HIPAA-compliant web portal using a VA computer. The transcripts will then be stored and analyzed on a VA secure server.
- The online weight management and goal-setting tool uses a web-interface to ask health questions and collect the data in order to deliver tailored advice. This website will be hosted on an NYU server. Data Use Agreements have been setup with both parties and the VA to protect ownership and use of collected coded data. Data will be regularly migrated from NYU's server to the VA server via encrypted USB drive.
- Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study.
- Except when required by law, study information shared with persons and organizations outside of the VA will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

FOR IRB USE ONLY:

IRB Approval Date: 11/04/19

MIRB ID: 1607

VA Form **10-1086**
As modified on 02/05/15

VA NYHHS IRB-APPROVED INFORMED CONSENT DOCUMENT

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Department of Veterans Affairs
VA New York Harbor Healthcare System

RESEARCH CONSENT FORM

Please type or print legibly: Last name, First name M.I.

Subject Name: _____

Study Title: The Peer Assisted Lifestyle (PAL) intervention protocol: A technology-assisted weight-loss intervention within Patient Aligned Care Teams at the VA

Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

- When your study information will be disclosed outside of the VA as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. The VA will not disclose the code key, except as required by law.
- Your data will be combined with data from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you. We will not share your records or identify you unless we have to by law.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants: There will be no costs to you for any of the treatment or testing done as part of this research. However, medical care and services provided by the VA that are not part of this study (e.g. normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services. There will be no cost to you to be involved in this study other than transportation costs you may incur in getting to the Brooklyn VA.

Payment Offered for Participation:

For time and inconvenience to complete study-related questionnaires, you will be given:

- \$60 cash voucher at the end of the Baseline study visit
- \$45 cash voucher at the end of the 6 month study visit
- \$50 cash voucher at the end of the 12 month study visit

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

We do not expect there will be a risk of injury, but all forms of medical (or mental health) discussion – whether routine or experimental – involves some risk. In addition, there may be risks associated with this study that we do not know about.

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

- DURING THE DAY or AFTER HOURS
 - Dr. Melanie Jay at 212-263-4169 or 212-686-7500 x5097
 - Laura Wong, Research Coordinator at 212-686-7500 x5098 or 718-836-6600 x1304

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

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Department of Veterans Affairs
VA New York Harbor Healthcare System

RESEARCH CONSENT FORM

Please type or print legibly: Last name, First name M.I.

Subject Name:

Study Title: The Peer Assisted Lifestyle (PAL) intervention protocol: A technology-assisted weight-loss intervention within Patient Aligned Care Teams at the VA

Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study: If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are otherwise entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff and it will not affect the usual care that you receive as a patient.

If you do decide to withdraw your consent: please contact Dr. Melanie Jay and let her know that you are withdrawing from the study. Written requests to withdraw must be sent to her mailing address at VA New York Harbor Healthcare System, 423 East 23rd Street, 15 North, New York, NY 10010. Remember that withdrawing your authorization only affects the uses and sharing of information after your written request has been received, and you may not withdraw your authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research. The Principal Investigator or another research team member will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study and may be asked to return for a final check-up.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The Principal Investigator may decide to withdraw you from the study for certain reasons, including:

- worsening health or other conditions that might make it harmful for you to continue participating
- failure to keep appointments or follow directions as instructed
- termination or cancellation of the study by the VA

FOR IRB USE ONLY:

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VA Form **10-1086**
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VA NYHHS IRB-APPROVED INFORMED CONSENT DOCUMENT

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Department of Veterans Affairs
VA New York Harbor Healthcare System

RESEARCH CONSENT FORM

Please type or print legibly: Last name, First name M.I.

Subject Name:

Study Title: The Peer Assisted Lifestyle (PAL) intervention protocol: A technology-assisted weight-loss intervention within Patient Aligned Care Teams at the VA

Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

PERSONS TO CONTACT

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study drug or procedure, please contact the Principal Investigator Dr. Melanie Jay at 212-263-4169 or 212-686-7500 x5097.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA NYHHS IRB Office at 212-686-7500 Ext. 4455. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Research Administrative Officer if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input. At the NY campus call 212-686-7500 x 7474. At the BK campus call 718-836-6600 x 3838. Or you may contact the Research Compliance Officer at 212-686-7500 x 7443.

SIGNIFICANT NEW FINDINGS

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.

If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

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VA Form **10-1086**
As modified on 02/05/15

VA NYHHS IRB-APPROVED INFORMED CONSENT DOCUMENT

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Department of Veterans Affairs
VA New York Harbor Healthcare System

RESEARCH CONSENT FORM

Please type or print legibly: Last name, First name M.I.

Subject Name:

Study Title: The Peer Assisted Lifestyle (PAL) intervention protocol: A technology-assisted weight-loss intervention within Patient Aligned Care Teams at the VA

Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

I authorize the principal investigator and her co-investigators to contact me about future research on **Primary Care Weight Management in Veterans** provided that this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol. If I agree, then someone from Dr. Jay's research staff might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

- I agree to be contacted by the Principal Investigator or Co-Investigators for
 I **do not** want to be contacted by the Principal Investigator or Co-Investigator

Signature of participant or legal representative

Date

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The research study has been explained to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

I agree to participate in this research study as has been explained in this document.

| SIGNATURE | PRINTED NAME | DATE SIGNED |
|---------------------------|--------------|-------------|
| Subject: | | |
| Person Obtaining Consent: | | |

FOR IRB USE ONLY:


IRB Approval Date: 11/04/19

MIRB ID: **1607**

VA Form **10-1086**
As modified on 02/05/15

VA NYHHS IRB-APPROVED INFORMED CONSENT DOCUMENT

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|  Department of Veterans Affairs | | Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Subject Name (Last, First, Middle Initial): | | Subject SSN (last 4 only): | Date of Birth: |
| VA Facility (Name and Address): NY Harbor Healthcare System - Brooklyn Campus 800 Poly Place, Brooklyn, NY 11209 | | | |
| VA Principal Investigator (PI): Melanie Jay, MD MS | | PI Contact Information: Melanie.Jay@va.gov | |
| Study Title: The Peer Assisted Lifestyle (PAL) intervention protocol: A technology-assisted weight-loss intervention within Patient Aligned Care Teams at the VA | | | |
| Purpose of Study: The purpose of this study is to test the impact of the PAL intervention on weight change and behavior in Veterans who are enrolled. The PAL intervention is a technology-assisted, weight management intervention in primary care settings at the Brooklyn VA campus. The study lasts 12 months, and requires 3 in-person visits. | | | |
| USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI): Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and /or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care. Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization. Your individually identifiable health information used for this VA study includes the information marked below: | | | |
| <input checked="" type="checkbox"/> Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings, etc. <input type="checkbox"/> Specific information concerning: <input type="checkbox"/> alcohol abuse <input type="checkbox"/> drug abuse <input type="checkbox"/> sickle cell anemia <input type="checkbox"/> HIV <input checked="" type="checkbox"/> Demographic Information such as name, age, race, etc. <input type="checkbox"/> Billing or Financial Records <input checked="" type="checkbox"/> Photographs, Videotapes, and/or Audiotapes of you <input checked="" type="checkbox"/> Questionnaire, Survey, and/or Subject Diary <input type="checkbox"/> Other, as immediately described below: | | | |

| Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------|
| Subject Name (Last, First, Middle Initial): | Subject SSN (last 4 only): | Date of Birth: |
| <p>USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (This section must only be completed when banking is a required component of this study. When banking is an optional component of this study complete page 5 of this form in lieu of this section.)</p> <p><input checked="" type="checkbox"/> Not Applicable - No Data or Specimen Banking for Other Research</p> <p>An important part of this research is to save your</p> <p><input type="checkbox"/> Data</p> <p><input type="checkbox"/> Specimen</p> <p>in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.</p> <p>DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you. Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons outside the VA/VHA as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information. These non-VA/VHA institutions or persons include the entities marked below:</p> <p><input type="checkbox"/> Non-VA Institutional Review Board (IRB) at _____ who will monitor the study</p> <p><input type="checkbox"/> Study Sponsor (name): _____ Person or entity who takes responsibility for and initiates a clinical investigation</p> <p><input type="checkbox"/> Academic Affiliate (institution/name/employee/department): _____ A relationship with VA in the performance of this study</p> <p><input type="checkbox"/> Compliance and Safety Monitors: _____ Advises the Sponsor or PI regarding the continuing safety of this study</p> <p><input type="checkbox"/> Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO): _____ _____</p> <p><input type="checkbox"/> A Non-Profit Corporation (name and specific purpose): _____ _____</p> <p><input type="checkbox"/> Other (e.g. name of contractor and specific purpose): _____ _____</p> | | |

| Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------|
| Subject Name (Last, First, Middle Initial): | Subject SSN (last 4 only): | Date of Birth: |
| <p>Note: Offices within VAVHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VAVHA job duties.</p> | | |
| <p>Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you</p> <p><input type="checkbox"/> will have access to your research related health records</p> <p><input checked="" type="checkbox"/> will not have access to your research related health records</p> <p>This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.</p> | | |
| <p>REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:</p> <p>Melanie Jay, MD MS 423 East 23rd Street, Room 15161N New York, NY 10010</p> <p>If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.</p> | | |
| <p>EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:</p> <p><input type="checkbox"/> Expire at the end of this research study</p> <p><input type="checkbox"/> Expire on the following date or event: _____</p> <p><input checked="" type="checkbox"/> Not expire</p> <p><input type="checkbox"/> Expires at the end of this research study unless you have: (1) provided additional permission to store your data and/or biological specimens in a research data repository or (2) when further optional analysis of your specimens has been completed</p> | | |

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------|
| Subject Name (Last, First, Middle Initial): | Subject SSN (last 4 only): | Date of Birth: |
| TO BE FILLED OUT BY THE SUBJECT | | |
| <p>Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.</p> <p>I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.</p> | | |
| _____ Signature of Research Subject | | _____ Date |
| _____ Signature of Legal Representative (if applicable) | | _____ Date |
| To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law) | | |
| _____ Name of Legal Representative (please print) | | _____ Date |