Increasing uptake of behavioral weight loss programs among primary care patients Protocol

NCT02708121

6/5/2017

Research Summary

1. **Protocol Title:** Your Wellness Prescription pilot trial

2. **Purpose of the Study:**

Aim 1: Determine feasibility of conducting a cluster randomized trial testing a treatment initiation intervention in a primary care setting, as indicated by provider recruitment, patient recruitment, and study assessment retention.

Aim 2: Determine intervention acceptability based on participant acceptability ratings and provider acceptability ratings.

3. **Background & Significance:**

Behavioral weight loss programs produce clinically meaningful weight loss, reductions in the severity and incidence of some obesity comorbidities, and improvements in patients' quality of life. Yet, behavioral weight loss programs are being initiated by only a small portion of adults with obesity (<10%). Important barriers to initiating programs are cost and availability; however, these barriers are diminishing as private and public health care payers have begun to offer evidence-based weight loss programs to insurees for free or at a low cost, a trend which is further supported by the 2010 Affordable Care Act. However, initial evidence indicates that the availability of affordable programs does not automatically translate into increased program uptake. This suggests that factors other than cost and availability are important contributors to initiation of weight loss programs. Observational data suggests that weight loss treatment initiation is determined in part by psychosocial factors identified in the Health Belief Model (i.e., perceived severity, susceptibility, barriers, benefits, and self-efficacy), which can be targeted to increase initiation of weight loss treatment.

An opportunity to increase initiation of weight loss treatment is present in the primary care encounter. Brief primary care weight counseling has been shown to increase patient motivation for weight loss. However, this rarely translates into significant weight reductions. It may be possible to achieve significant weight loss if this motivational opportunity was used to engage patients in evidence-based weight loss treatment. To do this, primary care weight counseling must address psychosocial determinants of treatment initiation. Given the limited time and other barriers to addressing these factors during the primary care appointment, it may be most effective and cost-efficient to target these factors with a web-based intervention that is completed by patients remotely, prior to their clinical visit. This intervention could target treatment initiation determinants and offer patients the opportunity to immediately enroll in weight loss treatment. For patients who are not responsive to initial intervention content (i.e., who do not immediately enroll in treatment), further content could be delivered to promote and assist patients in initiating an effective discussion about weight with their provider at their forthcoming clinical appointment. We are proposing a feasibility/acceptability pilot test of such an intervention.

4. **Design & Procedures:**

Design This is a parallel-arms pilot cluster randomized clinical trial. The unit of randomization is the primary care provider and the study arms are intervention and comparison. A 1:1 randomization allocation ratio will be used.

Procedures. Up to six primary care providers will be recruited (see below for details). Once consented, providers will be randomized to the intervention or comparison condition. Patients who have clinical visits (*index PCP visit*) scheduled with enrolled providers will be identified, recruited, and consented prior to their appointments (see additional details below). We will recruit up to 12 patients per provider, for up to 72 total participants (with an intent of enrolling 60 total participants). Participants will be recruited for and enrolled in the study arm that their provider was assigned to.

At the recruitment phone call, about half of the patients (determined by random assignment) will be informed that the study requires a baseline in-person assessment, and the other half will not be required to complete an in-person assessment. This is done to obtain important feasibility data about the impact on study enrollment of requesting an in-person baseline assessment session (in the context of a remotely delivered intervention). Having some participants attend an in-person session will also facilitate a comparison of clinically collected weight data and weight data collected by study research staff, which is also important for feasibility evaluation.

All enrolled participants (comparison condition and intervention condition) will receive an email 4 to 14 days prior to their index PCP visit (with the optimal aim of 7-9 days), which will contain either the intervention content or the comparison content (described in section 9 Study intervention).

The assessments during the intervention will be as follows:

Assessments

Baseline assessment (patient). Half of the participants will attend an in-person baseline assessment and the other half will answer baseline questions by phone only. Baseline questions will primarily focus on individuals' demographics and weight loss history. For individuals attending the in-person assessment, they will complete these questions in-person and we will obtain their height and weight (see Assessment Forms)

Post-intervention acceptability assessment (patient). At the end of the web-based intervention there will be a link that directs intervention participants to a brief survey to obtain their opinion of the acceptability of the intervention (see Assessment Forms).

Post-medical visit assessments (patient). The day of or day following participants' index PCP visit, participants will receive an email that includes a link to questions about their experience at the primary care visit as it relates to weight and (for intervention participants) the intervention (see Assessment Forms).

Provider interviews (provider). Within 1-2 weeks after each participant provider assigned to the intervention condition has completed all of his or her clinical appointment with all of the patient participants, intervention-condition provider participants will complete a 10-15 minute one-on-one phone interview to share their experience with the intervention. (see Assessment Forms for script)

In-person six-month follow-up assessment (patient). Patient participants will complete an in-person follow-up assessment 6 months after study enrollment. We will measure weight, treatment use, and other relevant psychosocial factors. (see Assessment Forms).

Six-month data obtained from weight loss programs. Data will be obtained by study staff on patient attendance for participants who enroll in the Track weight loss programs that (see Intervention section for details on this program, and Data Plan for data sharing information).

Six-month data from clinical records. A pull of data from Epic (either via Deduce or manually) will be conducted at six months to obtain weight data (up to 6 months prior to

study enrollment and 2 years after study enrollment) and number of primary care appointments attended. Progress notes from encounters with PCPs from time of study enrollment to up to 1 year will be examined to abstract any documentation of weight-related discussions.

5. Selection of Subjects: Selection criteria for *provider* participants is provided in Table 1. Selection criteria for *patient* participant entry into study are listed in Table 2.

Table 1. Inclusion and exclusion criteria: Providers

Inclusion criteria	Exclusion criteria
• Employed by Duke PCRC clinic as primary care provider at least ½ FTE. • Has a primary adult panel • Has worked at Duke PCRC clinic for at least one year	• none

Table 2. Inclusion and exclusion criteria: Patients

Inclusion criteria determined by record review	Exclusion criteria determined by record review
• BMI ≥ 30 kg/m^2 as measured at any clinic in previous 24 months. • Age 18-75. • Clinical appointment (well visit or chronic care visit) in next 4-6 weeks. • At least one prior appointment with the provider they are scheduled to see at target clinical appt. • Has a valid email address in Epic.	• None
Inclusion criteria determined by phone	**Exclusion criteria determined by phone**
• English speaking • BMI ≥ 29 kg/m^2 by self-report (to allow for under-reporting) • Regular email usage, defined as accessing email 3 or more times per week (on home or work computer or cell phone)	• In weight loss treatment program in past year • Unable to read content on websites without any assistance

6. Subject Recruitment & Compensation:

Provider recruitment.

Clinic leadership at several Duke PCRC clinics will be contacted to determine willingness to allow recruitment of their physicians. We will request to attend a provider meeting to describe the study and enroll eligible providers (see recruitment script). Interested providers who meet eligibility criteria (see Table 1) will be consented by PI or the project coordinator in a private room. Providers will be paid $100 for their time at the end of the study after completing the phone interview. We will recruit up to 6 providers.

Patient recruitment.

A DEDUCE search will be used to identify potentially eligible patients. Individuals who appear eligible based on record review using DEDUCE (see Table 1 for criteria) will be emailed a recruitment letter that is signed by the patient's primary care provider. The email from the providers will be sent using the study-specific email (wellnessprescription@duke.edu). The letter will include a number to call to opt-out. If individuals do not opt out within one week, we will call them to determine if they are eligible and interested (we have proposed one week, given that we will be recruiting by email and thus there is not the typical delay of a mailed letter). Participants who are eligible and interested will be consent by phone (see phone script). We will recruit up to 12 patients per provider, for a total of up to 72 patient participants (with an intent of enrolling 60 total participants).

Participants will be compensated $15 for completing the baseline questions (on phone or in-person, depending on assignment). They will be compensated $5 for answering the questions immediately after their medical visit, and $40 for attending the 6 month outcome session, for a total possible compensation of $60.

7. Consent Process – This study does not involve any risks that are outside those encountered in everyday life, and is thus considered minimal risk. We will not be meeting in-person with study participants before the intervention is delivered (for half the participants, a baseline in-person visit will occur but will occur after the intervention is delivered; for the other half no in-person visit occurs until the 6 month follow-up session). Thus, we have requested a waiver of written consent. Participants will consent by phone. Approved research staff will describe the study to the participants by phone, including all elements required for informed consent (see phone script). Patients will be asked questions to ensure that they understood the study description and key elements of consent. They will be given option to take time to think about consent, or to consent immediately. After consenting (or, if they request more time to review before consenting), participants will be sent an email that includes a written description of all of the elements of consent. Additional details are provided in Section 14 of the e-IRB submission form and in the waiver of informed consent form.

8. Subject's Capacity to Give Legally Effective Consent: Ability to give consent will be assessed in the recruitment call (for patients) and in-person meeting (for providers). We will not enroll participants unable to provide consent.

9. Study Interventions: All intervention and comparison condition materials are provided in this eIRB application.

Intervention. The Your Wellness Prescription intervention is a single session, web-based intervention that involves questions and tailored motivational feedback aimed to help individuals decide what changes, if any, they want to make to their diet, exercise, or weight, and to increase their likelihood of initiating weight loss treatment. This intervention was created by the study PI, Megan McVay, PhD, in collaboration with her mentors on this project. Dr. McVay contracted a freelance web-developer to assist in designing the intervention. We conducted user testing on this intervention and made adjustments to it as part of a prior project (Pro00059364). A complete copy of the intervention is included in this submission. The intervention is delivered on the Duke licensed Qualtrics survey software. Intervention participants will be sent an email 4 to 14 days prior to their medical appointment that contains introductory comments and a unique link to the intervention. The intervention includes questions about patients' motivations and barriers to make changes in diet, physical activity, and weight, and their perceptions of weight loss treatments. Based on their responses, participants will be

provided tailored feedback that aims to motivate them to lose weight and join a weight loss program. They will be informed that they are receiving 4 months free access to a weight loss program as part of this study (see Weight Loss Programs section, below). At the end of the intervention, participants are given the option to enroll in one of three weight loss programs for free (see description below). They will also be given the option to share a summary of their results with their provider. The intervention is anticipated to take 15 minutes to complete. Intervention participants who do not complete the intervention by two days prior to their clinic visit will be sent a reminder email.

After completing the web-based intervention, participants will be sent an email summary of their tailored intervention feedback. Their provider will be made aware that the patient completed the intervention (via EPIC messaging) and will be provided a summary of their tailored feedback and suggestions for discussing weight with patient (if patients agree) via EPIC messaging and through entry of a progress note in to their medical records. After their primary care visit, patients will be emailed a link again offering them the chance to sign up for one of the weight loss programs.

Comparison Condition. Participants in the comparison condition will receive an email informing them that they have free access to the available weight loss programs. It will also include a link that leads to information about the available weight loss programs (included in submitted IRB materials) and provide information about how to sign up for the programs.

Weight Loss Programs. All participants will be offered 4 months of free enrollment in one of three evidence-based weight loss programs: Weight Watchers, Jenny Craig, and Track. Weight Watchers is a commercial program that includes in-person group educational/support sessions focused on assisting individuals in changing their diet to improve diet quality and achieve calorie reduction and weight loss. Session content also includes nutritional education as well as behavioral skills training. The program also encourages increased physical activity tailored to individual's level of ability/skill. Jenny Craig is a commercial weight loss program that offers one-on-one coaching focused on dietary change to achieve weight loss, increasing physical activity (as appropriate to individuals ability/skills), and behavior change techniques. Jenny Craig also involves prepackaged foods that individuals are responsible for purchasing from Jenny Craig (participants are informed of this added cost as part of the Your Wellness Prescription Planning Tool). Track is an academically based program that was developed by Dr. Gary Bennett (Professor, Duke Department of Global Health) and has been tested in an IRB-approved clinical trial (Duke University IRB #B0033). Track is completely remotely delivered and mobile phone-based. It involves setting 4 personalized goals related to changes in diet and physical activity (e.g., no sugary drinks) and self-monitoring of these goals. Participants also have regular phone coaching sessions (weekly at first, then every other week, then monthly). Track will be run as a research protocol headed by Dr. Bennett (a key personal on this study) under this study. Additional details about Track are included in an appendix.

Participants will enroll in each program with the following strategy.

1. If they select Track, they will be sent an email from Your Wellness Prescription that asks a few screening questions and includes a consent for the study (see the approved Track amendment and the Track consent (Qualtrics) document). For participants who consent, they will be asked to provide their phone number. Track intervention personnel will then call patient to initiate the treatment.
2. If they select Weight Watchers, they will be emailed a unique promo code, a link to a website to sign up for Weight Watchers, and instructions for how to enroll.
3. If they select Jenny Craig, they will be emailed a letter that they will be asked to bring to one of two local Jenny Craig facilities (letter provided). This will assist the

Jenny Craig staff in recognizing that they qualify for free enrollment. Study staff will receive a periodic bill for services.

10. Risk/Benefit Assessment: There are few potential risks associated with study participation. The intervention itself may result in participants feeling uncomfortable answering questions. However, they can discontinue the intervention at any time by closing their web-browser. There is the potential risk of loss of confidentiality. However, we are minimizing this risk via efforts to secure data, including keeping data stored on a secure server accessed only by authorized study staff. The primary benefit to participants is free access to weight loss programs.

11. Costs to the Subject: There will be no direct cost to subjects. If subjects decide to join a weight loss program at the end of this study, they may have to pay for the cost of the food they eat during the program.

12. Data Analysis & Statistical Considerations: Our primary outcomes are feasibility and acceptability outcomes and are mostly descriptive. Our data analyses plan is as follows:

1. **Recruitment:** Descriptive data on recruitment rate (number of eligible patients identified and proportion of eligible patients who consent), reasons for ineligibility, and reasons for declined enrollment. We will use chi-square analyses to compare recruitment of participants who are informed that a baseline study visit is required vs. participants who are no required to attend a baseline visit.
2. **Intervention use:** We will present descriptive data on 1) the portion of participants initiating the "Your Wellness Prescription Planning Tool" intervention, 2) portion of intervention participants completing the intervention, 3) average and range of page clicks on feedback report (as an indicator of engagement). This data will be obtained
3. **Intervention acceptability and clinical visit experience**. Descriptive data on the acceptability questions and on questions about medical visit experience will be presented.
4. **Provider acceptability**: Qualitative interviews with providers will be recorded and transcribed and analyzed using direct content analyses.
5. **Study retention**. Completion rates for 6-month assessments will be presented for entire sample and will be presented by study condition and demographics (age, race/ethnicity, gender). These will be compared against the goal of 80% retention.
6. **Weight loss enrollment, sustained engagement, and weight change**: Although the study is underpowered to make conclusions on weight loss enrollment, we will present descriptive data on treatment enrollment, sustained treatment use, and weight change, including presenting it by study condition.

13. Data & Safety Monitoring: This is a minimal risk study so the potential for serious adverse events related to the study is low. The study PI (Megan McVay, PhD) will be responsible for monitoring participant safety during the study. Study participants will be asked to contact the PI to report any concerns or adverse events. Additionally, staff will collect information on adverse events when they are volunteered by study participants, and this information will be immediately reported to Dr. McVay. (Because this is a single session intervention with only one follow-up visit, additional proactive monitoring would be burdensome to participants). All serious adverse events will be reported to the IRB according to local IRB requirements (within 5 days of event) and will be reported to NIH on the progress report. A Data Monitoring Committee will be formed consisting of the

study PI, William Yancy, MD (primary care physician and obesity expert) and one additional faculty member who is independent from the study team. The team will convene yearly or more often as needed. The team will also look at data as the study progresses, including adverse events and any serious unrelated adverse events.

The study PI, Megan McVay, PhD, will be leaving her position at Duke and beginning a position as Assistant Professor at University of Florida in January 2018. In order for her to oversee the study after she leaves Duke, as well as to be able to analyze the data from this study for purpose of publication, she is requesting a transfer of data including PHI to University of Florida.

14. Privacy, Data Storage & Confidentiality – Paper documents that will be collected will be the payment form, which includes SSN, and patient assessment forms. This will be kept in kept in a locked filing cabinet belonging to the PI or Co-Is in room 520 in Legacy Tower. During the active enrollment, paper data will be temporarily kept in a locked cabinet in the study coordinator's office in room 9054 in Hock plaza. The key will be in custody of the PI or study coordinator. Only authorized study staff will have permission to access to paper data.

Electronic data will be stored on the server \\duhsnas-pri\dusom_psych\private\irb\mcvay\ wellness pilot and subfolders, maintained by the IT support staff.

Research data will also be collected through REDCap database and Qualtrics. That data will be securely stored on a server hosted by Duke Health Technology Services (DHTS).

Study tracking data (e.g., data on participants' progress through the study, on their status as enrolled/completed/etc) will be stored on Duke General Internal Medicine Divisions' Microsoft SQL Server running on a Windows Server maintained by DHTS. Access to the SQL Server data is managed via Active Directory Groups. Permissions is only granted to documented study personnel authorized to access the data. Access to the Study Tracking application is managed by Aviel Alkon who built and manages the Study Tracking System.

DEDUCE reports used for identifying eligible patients will be saved on the study server.

The subject payment forms will be stored on the psychiatry server \\duhsnas-pri\dusom_psych\private\Exper Subject-BehMed.

We will receive information about the attendance and weight information for subjects who joined the Weight Watchers program. Data will be obtained through Weight Watchers personnel providing us the data on attendance and weight that are linked to the promotional codes that Weight Watchers will provide us for our participants to sign up for the program. We will not provide any PHI to Weight Watchers. They will create an excel file that includes data on program attendance linked to promotional code number. This file will also not have PHI. They will share this data via email.

Study staff will enter all participant information into the study web application, which is hosted and maintained in a remote data center (Heroku and Amazon S3). All software and servers are reachable only via logging in using multi-factor authentication. All

communication between our software's application programming interface (API) and third-party software is encrypted using a protocol called Secure Sockets Layer (SSL). As described above, physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all databases are encrypted and access from the public Internet is precluded; all software and servers are reachable only via a virtual private network (VPN) or multi-factor authentication; and all communication between our software's application programming interface (API) and third-party software is encrypted using SSL. Only research staff who have received CITI Certification and are listed on the Duke University Institutional Review Board protocol will have access to the study database. Information in the database will not be shared with anyone outside the research team.
In the Track consent, we inform participants that we do collect identifying information and that we take all appropriate measures to minimize the risk of unintentional breach of confidentiality.

eGRC exception was submitted (EXC-1204).