Study Protocol and Statistical Analysis Plan

Tracking Physical Activity for Chronic Pain Management Among Older Adults in Detroit

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A. Background and Rationale

Improving function by increasing daily activity is a key goal of cognitive behavioral therapy (CBT) for pain. Incorporating wearable physical activity monitors into the design of cognitive behavioral pain self-management programs provides just-in-time data on patient progress that can be used to individualize behavioral messages and inform goal-setting. The 2016 National Pain Strategy encourages the use of wearable monitors as a pain self-management tool. Activity monitoring is likely to be most convenient for older adults when they can use accessible, commercial-grade monitors and cell phones. However, much remains unknown about how best to integrate these devices into behavioral interventions for specific groups of vulnerable older adults.

The goal of this study is to collect preliminary data regarding wearable monitor use by primarily African American older adults in Detroit in preparation for a trial of a community-based CBT intervention for chronic pain. Findings from the proposed study will inform the design of this future intervention, helping to ensure that it is effective and feasible in the Detroit community setting, and establishing a strong foundation for future competitive proposals. This is a high-priority population given the sharply disproportionate disease burden among older adults in Detroit and race disparities in pain treatment. Facilitators and barriers to activity monitor use in this population will be assessed and the feasibility and validity of various strategies for reporting daily step count data will be tested. This study is also known as the **STEPS (Seniors Tracking Exercise for Pain Self-management)**

B. Specific Aims:

1. Identify 50 adults, predominantly African American, age > 60 years with chronic musculoskeletal pain. Thirty of these participants will be randomly assigned to receive a FitBit ZipTM and instructions for reporting daily step-count data in 3 ways (2 weeks each of manual via Interactive Voice Response (IVR) telephone calls, manual via SMS (text messaging), automatic (via syncing the device with an app) (n=30); or to a control group (n=20).
2. After a six-week monitoring period: a) compare step data collection adherence (days provided/days anticipated) among the three intervention modes, within and across subjects; b) assess the validity of manual step reports by comparing them with device-stored data; and c) compare changes in functional outcomes between monitoring and control groups.

C. Methods

Inclusion criteria: Age $\geq$ 60 years, ambulatory with or without assistive device, community living; have a SMS-capable cell phone, Internet access (via smartphone, in-home or elsewhere); self-reported chronic musculoskeletal pain (pain in muscles or joints for $\geq$ 3 months); $\geq$4 (1-10 scale) average pain level over last week; $\geq$1 day/previous 30 when pain made it difficult to do usual activities. In addition, participants will have to be able to travel to a location in Detroit for a one-time study orientation session.

Exclusion criteria: serious acute illness or hospitalization in last month, planned surgery in next month or severe cognitive impairment.

Recruitment strategies: A total of 50 adults meeting above eligibility criteria will be recruited from the Healthier Black Elders Center Participant Resource Pool, an opt-in research registry available to UM researchers via the Pepper Center collaboration with Wayne State University. As of January 2017, the database included 1400 individuals with an arthritis diagnosis; many of these registrants are expected to meet pain-related study criteria. Secondary sources will include flyers and outreach at community locations serving Detroit seniors.

Randomization and data collection: After completing a baseline telephone survey, participants will be randomly allocated in a 2:1 ratio (intervention: control) using a computer-generated scheme to the monitoring condition or a no-monitoring control group. Participants in the intervention (monitoring) group will be invited to attend an orientation session in a central Detroit location where they will receive a FitBit Zip™ monitor and instructions in setting up their device and reporting data. A project hotline will be available for technical support. Participants will receive $10 for each questionnaire completed and can keep FitBits upon study completion (control participants will receive FitBits after follow-up survey).

Participants will be asked on the follow-up survey whether they would like to be contacted in the future to learn about opportunities to participate in studies on this topic. They will be told that they will receive all current study incentives whether or not they wish to be contacted in the future, and that they can remove themselves from the "contact" list at any time.

Intervention group: Intervention group participants will monitor and report step count data daily for six weeks, after which they will complete a telephone follow-up survey. For the first two-week period, a random half of the intervention group participants will receive IVR calls and half SMS messages; for the second two weeks these groups will 'switch'; and all intervention group participants will be asked to use the automatic sync feature for the final two weeks of the six-week period.

The commercially-available Fitbit Zip™ pedometer and activity tracker can be attached to the participant's waistband, belt, shirt, or stowed in his/her pocket. The Fitbit wirelessly syncs data from the tracker to the Fitbit software, or through an app compatible with most smartphones. The software is free for download on both Macs and PCs. Study staff will provide the activity tracker at an orientation session and assist with downloading the software including creation of a study-specific user name for downloading step count data. The participant will be asked to not add identifiable information to the Fitbit site during the course of the study.

Participants will be instructed to wear their pedometer during waking hours, except showering, bathing, or swimming, every day throughout their enrollment in the study. At any time if the participant has questions regarding the use of the pedometer or problems uploading step counts, a study staff member can be contacted by phone to assist. Study staff will retrieve users' step

count data in three different ways, using each mode for a 2-week period (for a total of 6 weeks wearing the Fitbit and reporting data) as described below:

- *Manual upload*: Participants will be asked to use the display on their FitBit to view and then manually input daily step counts via daily IVR calls they will receive at evening times convenient to them. If the initial IVR call is missed, the system will try again 15 minutes and one hour later. For the SMS mode, participants will designate the time of evening they would like to receive their daily text. A second text will be sent one hour later if there is no response to the first.
- *Automatic upload*: As described above, the research assistant will instruct participants in how to set up the FitBit so that data *automatically uploads* to the intervention website. Note that during this set-up process, the devices will be paired with a study account, and the email address provided will belong to the study. The information provided to the Fitbit company during set-up will not be identifying. It will include a study username, a masked birthdate (01/01/birth year plus or minus a constant), and a height and weight that is the male or female average, as appropriate.

Control group: Control group members will not track their steps during the study period, but will participate in baseline and follow-up data collection, after which they will receive a FitBit to keep.

Data collection:
Data will be collected via telephone by a trained research assistant at baseline and following the 6-week intervention.

Measures:

Primary outcomes:

Adherence to reporting will be indicated by the proportion of days with successfully logged step-counts, i.e., reported days/14 total days for each of the three reporting modes.

Pain interference: 4-item subscale from the PROMIS-29 Adult Profile, measured at baseline and follow-up.

Secondary outcomes:

Physical functioning: 4-item subscale from the PROMIS-29 Adult Profile, measured at baseline and follow-up.

Social participation: 4-item subscale from the PROMIS-29 Adult Profile, measured at baseline and follow-up.

Validity of manually-reported step counts will be assessed by comparing up to one month of IVR or SMS- collected data to data collected by syncing the device. Validity of the data will also be

assessed by examining associations between step data and relevant baseline characteristics (e.g., functioning scores, comorbidities, and age).

Other baseline survey measures (to characterize sample and/or as potential moderators of adherence and outcomes): *Demographics and health*: age, gender, education, race/ ethnicity, marital status, health literacy, comorbidities, cognitive functioning, physical activity. *Pain-related*: pain duration, number and location of pain sites, pain treatments, pain centralization. *Technology-related:* attitudes toward technology, eHealth literacy, social support for technology use.

Staff burden: Number of participant calls to the study technical support line, time spent giving technical assistance, and difficulties encountered as described in staff notes.

Satisfaction/Acceptability. In the follow-up survey, intervention group participants will be asked a series of Likert scale items about their experience with the trackers and reporting modes.

Open-ended items for intervention participants will assess challenges and facilitators for device and reporting method use; identify environmental and individual barriers to using devices; and obtain feedback on how program implementation might be improved for this particular population.

Data security and management

Staff training to ensure confidentiality, security, and adherence to protocol

All members of the study team will be required to complete the University of Michigan's web-based Responsible Conduct of Research Training Program (PEERRS) and to sign a confidentiality document stating that they understand the procedures to be followed to ensure the integrity and confidentiality of the data and the consequences of disregarding them.

Research staff will sign a pledge of confidentiality and will understand that breach of confidentiality is reason for dismissal. Training of staff will include information about the importance of privacy and confidentiality and techniques to maintain confidentiality of all information.

Regular study team meetings will be used to ensure that all data quality and IRB policies and procedures are being followed. This will include ensuring that (1) all participants understand, agree to, and sign a written consent form before participating; (2) strict adherence is maintained to communication regarding the participants' right to withdraw or refuse to answer questions; (3) staff maintain confidentiality both by protecting hard-copy and electronic data collection forms and also by avoiding all unauthorized conversations about individual patients; (4) consent forms and identifying information are kept separately from study related information about patients' sociodemographics, clinical characteristics, disease self-care, service use, and outcomes; and (5)

all identifying information is kept locked at all times and sensitive computer files are maintained on a secured University of Michigan server.

Study participant information: REDCap

All study participant data will be collected, stored and managed in REDCap. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. It is HIPPAA compliant and supported by the University of Michigan. (See additional information below in *Data Management Protocol* section.)

IVR/SMS platform security

Secure servers (virtual machines) at Michigan Medicine will host the IVR/SMS platform, store the participants' contact data and responses, and send out automated IVR calls and SMS messages to patients. Information stored on the participants includes first and last name, a telephone number, date of birth, and a study ID. An instance of Microsoft Dynamics CRM 2016 (industry standard CRM) will store the patient information, schedule and execute phone calls/SMS sessions, and store participant responses which will be retained until the end of the study. All information passing in and out of the IVR system is encrypted using SSL. We understand that SMS is inherently unsecure; to mitigate this, we will only collect step counts and will not use identifying language in the SMS questions.

CRM access control is managed through LDAP using Level-2 accounts from the University of Michigan. Outside vendors do occasionally access the system to perform upgrades or troubleshooting, using Level-2 UM accounts and Remote Desktop Protocol. These servers cannot be accessed from outside the Michigan Medicine network – off-site connections require use of a VPN. They are backed up daily to allow for quick system recovery with minimal data loss in case of disaster. They are separate from Electronic Health Records, and the CRM website is the only place at which patient information can be directly accessed. All Michigan Medicine servers are actively monitored to detect attacks, potential attacks, and unauthorized use.

Information about Fitbit data accessed

Per the FitBit Terms of Service and Privacy Policy, Fitbit accesses height, weight, gender and age to estimate calories; and contact information. Note that in our study, when we are setting up participants' devices, we will provide a study email, not the participant's personal email. We will not be providing a name; we will use a study identifier. To mask birth year, we will provide the same birthday – 1/1- for everyone and will add or subtract a constant from the birthyear. We will input an average male or female height and weight with the permission of the participant. In sum, no personally identifying information will be provided to the company.

Note that all data collected from the FitBit device belongs to the user, not Fitbit. Upon user request, they will deactivate the account and all data associated with that account will be deleted, including backups.

Data Management Protocol

A REDCap database will be set up to contain all participant data, including identifying information. After training regarding issues of confidentiality, only specially designated research staff will be authorized to have password-secured administrative access to the master list of names and original participant data. All other research staff and health educators will only have access to specific and select information on an "as needed" basis in order, e.g., to collect interview data, conduct the intervention or mail gift card incentives. This level of access will also be password secured to just those few individuals who need the data. Otherwise, participants' data records will have only a sequential code number necessary for identification.

Data management personnel will prepare the data entry software, and will set up the logical and range checks. This software will store the data, together with the date of entry, in a data entry set that will be maintained in the research office at the School of Public Health.

Written documentation of data collection, storage, and transmission procedures will be maintained by the data management personnel.

Statistical Analysis Plan

Descriptive statistics will be calculated for baseline variables, comparing intervention and control groups using independent-sample t tests for continuous variables and chi-square tests for categorical variables, and on survey items related to satisfaction, acceptability, and adherence to step count reporting.

Step data collection adherence: (Days provided/14 days anticipated) among the three intervention modes, within and across subjects;

Validity of manual step reports: Proportion of days/21 days that manually-collected (SMS and IVR) and FitBit-stored counts are within 50 steps of each other will be calculated.

Functional outcomes

Per the recommended scoring algorithm (see https://www.healthmeasures.net/explore-measurement-systems/promis), items in each PROMIS-29 subscale of Pain Interference, Physical Function, and Social Participation were summed and converted to a subscale T score, a standardized score with a population average of 50 and a standard deviation of 10. Means at baseline and follow-up of each subscale per treatment condition will be calculated.

Repeated measures analysis of variance (ANOVA) will be used to assess treatment effect: A time-by-treatment interaction term, indicating differential pre–post change by group, was the main predictor of interest.

We used chi-square tests to evaluate differences in the proportion of participants in intervention vs control groups who achieved the minimally important difference—that is, the smallest clinically relevant difference—of 3 T-score points in the PROMIS Pain Interference measure and in the proportion who increased the frequency and duration of their low-intensity walks from baseline to follow-up (vs decreased or stayed the same).

Qualitative data on satisfaction, barriers, and facilitators from open-ended survey responses will be compiled and detailed notes made from recordings of postprogram interviews and technical support logs. These were reviewed and coded, and all meaningful statements were placed by two researchers (MRJ, VS) into conceptual categories under the broad a priori themes of challenges/disadvantages and facilitators/advantages. In place of specialized software for qualitative analysis, we used standard word processing and spreadsheet apps.