Just In Time: Increasing physical resilience in older adults with osteoarthritis pain: Feasibility and acceptability of a brief behavioral physical activity intervention

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Purpose of the Study

The pilot feasibility study is a small randomized trial (N=50) with an intervention group receiving a brief Engage protocol that focuses on physical activity (Engage-PA; n=25) as compared to treatment as usual plus personal fitness-tracker control (TAU+; n=25) for older adults with OA-pain. The intervention group will receive two 45 minute sessions over the course of three weeks, receiving a novel combination of three theoretically critical elements: 1) personal feedback from physical activity monitoring using wearable fitness-tracker device, 2) increasing motivation through linking physical activity goals to deeply held personal values for living a meaningful life, and 3) a form of pacing called the Activity Rest Cycle which involves setting physical activity goals using strategic cycles of timed activity and ever-shortening rest periods designed to prevent episodes of severe pain while also increasing stamina. Physical activity will be measured by personal fitness tracker, Garmin VivoFit 4.0 for all participants throughout the study.

Aim1: Examine the feasibility and acceptability of Engage-PA in a sample (N=50) of adults ≥ 65 with OA-related pain. Feasibility will be measured by meeting ≥75% study accrual (H1a) and ≤ 20% attrition (H1b), and adherence will be measured by use of fitness-tracker for 75% of days participating in the study (H1c). Acceptability will be measured by ≥ 80% participant satisfaction (H1d) on a standardized self-report measure utilizing both qualitative and quantitative assessment (i.e., Client Satisfaction Questionnaire-8).

Aim 2: Examine indicators of improvement over time (baseline and post-treatment) and between groups via patterns of daily steps (H2a), self-reported pain-related disability (H2b) and psychological well-being (H2c). We anticipate that Engage-PA participants will show patterns of improvement at follow up as compared to those in the TAU+ group (H2a-c).

Background & Significance

Osteoarthritis (OA) is one of the most common age-related problems facing older adults, often leading to reductions in recommended physical activity. Physical activity has been shown to prevent disability across large samples of older adults and is safe for even vulnerable older adults. Yet, there are often significant barriers to regular physical activity for older adults with OA, including persistent pain and numerous psychosocial factors. For older adults, OA is often a progressive, degenerative condition, and as such physical functioning is often on a trajectory of decline. Older adults with persistent OA-related pain are at particular risk for more complications and poorer functional outcomes from joint replacement surgery, and the rate of complications and mortality from problematic opioid therapy (e.g., chronic, high dose) in older adults is increasing.

Physical resilience can slow the concomitant decline in function and activity related to OA. Physical resilience for older adults with OA pain can be defined as increasing physical mobility and decreasing pain-related disability. A trajectory of physical resilience is critical for ongoing independence in older adults with OA because decreased mobility and persistent pain are associated with worse outcomes for living independently and lack of exercise can exacerbate other common health conditions. Given the prevalence of OA, the often degenerative course of OA, and the specific risks with medical treatment approaches for older adults, there is much enthusiasm for the development and testing of innovative behavioral approaches to improving physical resilience in this population.

Our team has developed an enhanced pain coping skills protocol (i.e., Engage) to better meet the needs of older adult populations. Engage is brief, and counselors teach participants behavioral pain coping skills (such as strategic use of activity pacing for increasing physical activity) along with additional psychological coping skills such as linking behavior change to deeply held personal values. Previous work testing the Engage protocol demonstrated improvements in pain-related disability for patients with advanced cancer, many of whom were older adults. We propose to extend previous work by increasing our focus on physical activity within the Engage protocol for adults ≥ 65 with persistent OA-related pain. Specifically, we will integrate the behavioral physical activity component of Engage with physical activity monitoring using wearable technology and tailor it for older adults with OA. This critical step will provide important data to support the testing of a brief, adapted protocol for this population.

Engage-PA will leverage technology, strategic activity pacing and goal setting, and linking physical activity goals (i.e., average daily steps walked) to meaningful personal values clarification (e.g., enhancing the quality of time spent with grandchildren) to increase physical resilience via physical activity in older adults. The integration of these particular physical activity components for this population is novel. While existing protocols for enhancing physical activity in this population may utilize activity pacing types of interventions along with other psychological coping strategies, none to date have incorporated such a strategic focus on deepening personally meaningful values as a means of increasing motivation with those methods. Further, we are integrating these behavioral strategies while also providing participants with ongoing direct feedback on their physical activity from their personal fitness tracker that can be discussed with a provider as an additional source of positive accountability for physical activity goal setting. Such technology extends the intervention by bringing it into participants' daily life, maximizing the potential for positive behavior change from even brief counseling support.

Both qualitative and quantitative data will assist us in learning about the acceptability of this brief Engage-PA protocol that is designed in a way that is likely highly implementable. This critical step will provide important data to support further testing of an optimized Engage-PA

protocol for improving physical resilience via increases in physical activity and decreases in pain-related disability in older adults with OA-pain. The current study is in line with our long term goal of disseminating brief, accessible, evidence-based interventions to improve physical resilience in older adults through increases in physical activity, reduced pain-related disability, and reduce reliance on opioid pain medications.

Design & Procedures

This small randomized study will assess the feasibility and acceptability of a brief intervention to increase physical resilience in older adults with OA pain. Participants will engage in baseline and post-treatment assessments.

Measures. Age, race/ethnicity, marital status, medical comorbidities, exercise patterns, medical care utilization, height and weight, use of pain medications, and COVID-19 impact will be collected via self-report and electronic medical record review. Screening: Recruitment Screening phone script uses items from the Physical Activity Readiness Questionnaire Plus (January, 2020 version) tailored for this study to assist in assessing for eligibility and safe participation, and assist staff in determining if participants need to discuss exercise with their medical team prior to enrolling in the study. Folstein Mini-Mental Status Exam will be utilized to determine if participants have more than mild cognitive impairment that could prevent safe participation in the study. A cut off score of 19 will be used, which is the lower bound of mild cognitive impairment. Clinical Tool: Rating of Perceived Exertion scale. This is a 0-10 scale with anchors for personally-determined exertion levels as participants engage in activity. Primary Outcomes. Feasibility will be measured by recruitment rate, at least 75% accrual (N=50), retention (≤ 20% attrition), and adherence as measured by use of fitness-tracker for ≥ 75% of days participating in the study. Acceptability will be measured by ≥ 80% of participants reporting being “very satisfied” with the program using a standardized measure, the Client Satisfaction Questionnaire. Secondary outcomes will be collected at baseline, post-treatment, and 1 month follow up. Physical resilience will be measured via Garmin fitness tracker daily steps tracked for 7 consecutive days at each timepoint and continuously throughout the study. Pain-related disability will be assessed with the self-reported Arthritis Impact Measurement Scale (AIMS) which assesses functioning across several areas such as physical mobility, social activity, and activities of daily living. Psychological well-being will be measured by 1) the AIMS Mood and Tension subscales, which measure depression and anxiety, 2) Bulls-Eye Values Survey where participants are asked to rate how successful they have been in living consistent with personal values across life domains of health, relationships, work/community, and leisure, and 3) The Acceptance and Action Questionnaire-II, which is a 7-item questionnaire assessing psychological flexibility, which is a common measure used to assess psychological well-being. The Coronavirus Impact Scale will rate the impact of the COVID-19 pandemic, and was developed to widely cover types of adversities individuals’ experienced secondary to the pandemic. The scale is used commonly in numerous large studies in response to clinical and

research needs from the COVID-19 pandemic. The COVID changes to exercise and sitting questionnaire contains 3 items to assess changes of individuals' activity levels from COVID-19.

Screening procedures. After DEDUCE query identifying older adults with osteoarthritis diagnosis served in Duke Clinics, potential participants will be a) emailed a link to take the Pre-Screen Survey in Redcap and research staff will follow up by phone using Recruitment Phone Script to finalize eligibility, or b) mailed a Recruitment Letter and interest and eligibility will be confirmed in a follow up phone call by study staff using the Recruitment Phone Script. The Recruitment Phone Script reviews inclusion and exclusion criteria, and also asks several questions about unmanaged medical conditions that might contraindicate safe participation; in which case study members will directly contact potential participants' medical teams for confirmation that their patient's health is managed and gain approval to enroll in the study that would require the physical activity of walking. Potential participants will be encouraged to discuss walking and/or other exercise with their medical team prior to enrolling in the study as well.

Enrollment and assessment procedures. Interested participants will meet with study staff to conduct informed consent and complete the baseline assessment, and then be randomized to either Engage-PA or TAU+. All participants will complete self-report questionnaires at baseline and post-treatment. Self-report data using measures as listed above will be collected online using RedCAP or paper/pencil. All participants will be given a personal fitness-tracker (ie., Garmin ViVoFit) at baseline for use throughout the study, with instructions on how to write down daily steps for 7 consecutive days at baseline and post-treaatment assessments, as well as continuous measures of daily steps in the intervening period. Number of daily steps as read by the Garmin will be collected via paper and pencil and sent to study staff via telephone, text, email or participants can come to the research staff offices for syncing and daily steps data will be recorded directly from the Garmin devices and devices then returned to participants. All daily steps data will be de-identified and coded using a Study ID. Data will be collected on Duke servers and managed by Duke study staff. This data will be collected and stored using a unique Study ID, and will not include PHI. Participants will be compensated for their time completing both assessments ($30 each, for up to $60).

Engage-PA Intervention. Engage-PA participants will attend two 45-minute sessions with a study therapist two weeks apart. Session 1. Participants will learn to apply the Activity-Rest Cycle for strategic pacing of physical activity while also avoiding extreme pain, and this practice is graded to increase stamina over time. Participants will select a physical activity (e.g., walking), and set a specific physical activity goal (e.g., walk for 10 minutes two times per day) for practice between sessions. Participants may choose to walk or exercise in their homes or communities at times and places of their choosing. Participants will be coached on the use of the Rating of Perceived Exertion Scale for rating how intense they experience walking or other exercise. Participants will be encouraged to keep their perceived exertion level at or below 5 on

a 10 point scale (10 being the max exertion), unless they had previously engaged in a vigorous activity program or have discussed initiating a new physical activity (other than walking) with their doctor. They will also be encouraged to continue monitoring any medical conditions using at-home monitoring devices as recommended by their treating medical team (e.g., blood pressure cuff, glucose monitors) if they had previously been using those monitoring devices. They will also identify and clarify deeply meaningful personal values (e.g., connection with loved ones) as motivation for increasing physical activity. Participants will link their personal values to their physical activity goals either directly (e.g., playing with grandchildren, walking the dog) or indirectly (e.g., being healthier furthers such activities as helping others, spending quality time with friends, being less dependent on others and increased financial stability, etc.). Session 2. Participants will review their personal exercise goal using their personal fitness monitor data with the study therapist, troubleshoot issues using the Activity-Rest Cycle, further clarify personal values for increasing physical activity, and set longer term physical activity goals. Participants may choose to walk or exercise in their homes or communities at times and places of their choosing. Study sessions will be audio recorded using a Duke issued tablet device.

TAU Plus Personal Fitness Tracker condition. The treatment as usual group will be monitoring only. They will continue to receive standard care throughout the study, and there will be no intervention. They will be given a personal fitness monitor as a continuous monitoring device for the steps walked. They will be given basic instructions on the device's use and data from the device will be collected (only during the study period). They will not be asked to engage in any particular form of exercise, or specifically be asked to increase their walking. However, they will be given the Ratings of Perceived Exertion Scale, and informed that study members will contact their medical team before they initiate a new exercise program to gain permission of enrolling in a study that will increase or start physical activity, and participants will be encouraged to talk to their doctor if they plan to engage in activity above a 5/10 on the RPE Scale. They will also be encouraged to continue monitoring any medical conditions using at-home monitoring devices as recommended by their treating medical team (e.g., blood pressure cuff, glucose monitors) if they had previously been using those monitoring devices. They will not receive the 2 session intervention protocol, and no specific goals for steps or other activity will be set by the study staff.

Selection of Subjects

We plan to enroll a maximum of 50 adults age 65 or older with a diagnosis of OA in the knee or hip who are currently served by Duke clinics. Letters will be mailed to potentially eligible patients identified through electronic health records (i.e., DEDUCE) and follow up phone calls will assess participant interest and conduct eligibility screening. Our study team has successfully recruited using these methods in large, NIH funded behavioral pain management trials.

Eligible participants:

- age 65 or older
- English speaking
- diagnosis of osteoarthritis in knee or hip (as verified by medical record review)
- able to ambulate even if assisted with walker or cane
- endorse worst pain AND pain interference as ≥ 3 out of 10 within the last week

Exclusion criteria:

- planned surgery during study duration that would limit mobility (e.g., due to recommended rehabilitation or recovery period) for more than 3 weeks
- current enrollment in cardiac rehabilitation
- myocardial infarction in the past 3 months
- major surgery requiring limited movement or mobility for recovery within the past 3 months
- presence of a serious psychiatric condition (e.g., schizophrenia, suicidal intent) indicated by medical chart, treating medical provider or other staff, or study staff interactions that would contraindicate safe study participation
- Medical provider indicating that exercise (even walking) should only be medically supervised; as determined by medical record review or patient reported
- fall or falls within the last 3 months that led to immediate medical treatment/hospitalization
- reported or suspected moderate or severe cognitive impairment (i.e., due to dementia) subsequently informed by a Folstein Mini-Mental Status Examination of <19

Subject Recruitment and Compensation

We plan to enroll a maximum of 50 adults age 65 or older with a diagnosis of OA in the knee or hip who are currently served by Duke clinics. Potential participants will be identified using electronic medical record from the PACE-DEDUCE query. Duke clinics will be included as a search variable along with other inclusion criteria per protocol. Once identified, potential participants will be emailed to inform them of the study and sent a REDCap Pre-Screening link to the study Pre-Screening survey and asked to provide their contact information if eligible and interested in learning more. The Pre-Screening Redcap Survey asks potential participants items 1-9 from the Recruitment Phone Script (dated 6/10/2020). Study staff will follow up with potentially eligible participants via email, telephone, or postal mail, and they will be invited to enroll if they are interested and fully eligible based on the Recruitment Phone Script questions. Depending on recruitment response, we will also send Recruitment Letters via USPS, and finalize eligibility with the Recruitment Phone Script. Responses to unmanaged health conditions assessed from the Recruitment Phone Script, may result in study members

contacting potential participants' medical teams for confirmation that their patient's health is managed and gain approval to enroll in the study that would require the physical activity of walking. Primary care teams will be contacted first, and if needed, specialty care providers will be contacted. DEDUCE pulls organized by Duke Primary Care clinics will be used to identify potential participants with OA, and as such, all potential participants shall have seen a Duke PCP. If a provider requests a release of information, patients will be provided one to sign to permit the discussion of their health information solely for the purpose of determining eligibility if they so choose.

Informed consent procedures will be conducted either in person, online using REDCap or via phone. Once informed consent has been received, participants will be scheduled for a study appointment either to happen at that time or a time convenient for them in the future. A member of the study team will conduct the appointment. If a participant declines study participation at any point during these procedures, the information provided to the study team through DSR/DEDUCE/Maestro will be immediately de-identified. At this first study appointment, the study team member will explain all study procedures and administer the baseline assessment. After the patient has consented and completed the baseline assessment, they will be randomized to either receive: 1) Engage-PA or 2) Treatment As Usual plus use of personal fitness tracker.

Based on previous work with this population, we expect that approximately 50% of the sample to be male and 50% female. Based on the ethnic make-up of patients coming to Duke clinics, we anticipate that the ethnic make-up of the sample will likely include Caucasian (75%), African-American (15%), Asian (5%) and Hispanic (5%). Recruitment efforts will focus on actively seeking to attract an ethnically diverse sample representative of demographics of the local recruitment area.

Participants will be compensated $30 for their time when they participate in baseline and post-treatment assessments, for a total of up to $60 per participant.

Risk/Benefit Assessment

Include a thorough description of how risks and discomforts will be minimized (per 45 CFR 46.111(a) (1 and 2)). Consider physical, psychological, legal, economic and social risks as applicable. If vulnerable populations are to be included (such as children, pregnant women, prisoners or cognitively impaired adults), what special precautions will be used to minimize risks to these subjects? Also identify what available alternatives the person has if he/she chooses not to participate in the study. Describe the possible benefits to the subject. What is the importance of the knowledge expected to result from the research?

Potential medical risks and discomforts: We do not anticipate any significant medical risks or discomforts for participants in the study. Older adults with OA-related pain are frequently encouraged to increase their exercise and physical mobility (e.g., walking) as a means of improving health and wellness; physical activity is recommended for all older adults by the World Health Association (WHO, 2020) and is associated with positive health outcomes such as pain reduction and improved overall health and wellbeing in OA populations (Kanavaki et al, 2017; Pahor et al 2014; Singh, 2002). The addition of behavioral pacing strategies in the protocol is aimed at providing participants with a way to strategically increase walking/exercise without creating severe pain, though some pain may be present with physical movement. There is some minimal risk of exercise-related injuries or falls if participants choose to walk or exercise at home or in their own community environments. The potential benefits of increased walking or other forms of exercise for older adults outweigh such risks. Participants may choose not to walk at any time, and may cease participating at any time for any reason. All participants will continue to receive standard health care throughout the study. No participant will be asked to change or decline any strategies for pain management based on their participation in this study.

Psychological risk and discomfort: The study is not targeting treatment of psychiatric illnesses, and as such we do not anticipate that the participants will be at increased risk of suicidality, self-harm, or harm to others. The PI is a licensed clinical psychologist and supervisor currently in practice here at Duke with the expertise to manage clinical issues related to imminent safety if they arose. A situation in which a study participant is at imminent risk of harming him/herself or others may necessitate involuntary reporting and intervention. This risk of loss of confidentiality will be discussed and disclosed to potential participants at the time of consenting. Some of the questions asked during the assessments or issues addressed during the intervention may make some participants uncomfortable. Participants will be told that they may refuse to answer any of the questions and that they may stop participation in this study at any time. If a participant reports high levels of emotional distress or psychological symptoms (depression, anxiety), a licensed clinical psychologist (Dr. Plumb Vilardaga) will provide patient consultation and referral for appropriate treatment.

Other risks: The other risks of this study are those associated with confidentiality. In any research project of this type, there is some risk attendant to confidentiality of self-report data. To ensure confidentiality of data, all records will be identified by the participant's identification number, not by name. All raw data will be kept in a locked file cabinet. Protocols and completed measures will be coded by number only, for the purpose of data tabulation and analysis. Data will be stored in protected research computer servers /systems at Duke which employ strict procedures to ensure subject confidentiality. All data will be entered into the computer by study staff only, utilizing code numbers only for subject identification. All information given by the participants will be kept confidential unless otherwise required by law to disclose such information.

Potential Benefits of Proposed Research to Human Subjects and Others.
Participants may gain strategies and skills to help them improve their physical resilience (defined as increased physical mobility and decreased pain-related interference) and psychological wellbeing as a result of participating in the intervention. The information gained from this study will provide much needed information for future work disseminating brief, accessible protocols for improving physical resilience in response to a chronic health condition such as persistent pain from OA in older adult populations.

Data Analysis & Statistical Considerations

Sample Size and Power: Sample size of N=50 has been chosen based on effect sizes estimated from previous studies using similar behavioral approaches for these outcome variables, and after accounting for a maximum 20% attrition rate, resulting in N=40 effective number of participants.

Analysis: Descriptive statistics will be used to characterize the primary feasibility and acceptability outcomes. To identify types of physical activity are trending toward change, mixed model analyses or functional data analysis in line with current data analytic recommendations will be used to assess changes average daily steps over time. Missingness of data will be examined and accounted for using recommended models, including intent-to-treat, where appropriate for secondary outcomes such as the self-report psychological outcome variables.