ID: 69227 Digital Knee Osteoarthritis Mindset Intervention
NCT05698368
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Supplement 1.

Protocol: A Digital Mindset Intervention to Improve Pain and Exercise Participation in Individuals With Knee Osteoarthritis: A Randomized Clinical Trial

SPIRIT Checklist

Investigators

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Background and Significance

Osteoarthritis affects 7% of the global population and is a leading cause of disability globally. Physical activity improves health outcomes, weight management, and knee function for people with knee osteoarthritis and should be considered first-line treatment. Yet, physical activity levels in this population are low compared to those without knee osteoarthritis.

Emerging research has highlighted the powerful influence of mindsets about exercise on engagement in physical activity. Mindsets are core assumptions about a domain or category that orient individuals to a particular set of attributions, expectations, and goals (a "meaning system"). In individuals with knee osteoarthritis, mindsets about the appeal of physical activity relate to future physical activity levels and one's chosen symptom management strategy, and mindsets about osteoarthritis relate to knee symptoms.

We developed a digital mindset intervention to improve mindsets about exercise and osteoarthritis in individuals with knee osteoarthritis. We piloted the intervention on 21 individuals with knee osteoarthritis throughout the United States. Participants improved in exercise and osteoarthritis mindsets. However, this was a small sample size, a control group was not used, and it was cross-sectional; thus, not able to evaluate changes in physical activity and osteoarthritis symptoms. A large randomized trial is therefore needed to evaluate if our mindset intervention leads to improvements in

physical activity levels and osteoarthritis symptoms and, further, if these changes are due to more adaptive mindsets about exercise and osteoarthritis.

Supplement 1 Table 1. Study Meta-data

Data category	**Information**
Primary registry and trial identifying number	ClinicalTrials.gov: NCT05698368
Date of registration in primary registry	January 2023
Secondary identifying numbers	IRB-69227
Source(s) of monetary or material support	The Wu Tsai Human Performance Alliance at Stanford University and the Joe and Clara Tsai Foundation. The Stanford Catalyst for Collaborative Solutions; the Mobilize Center, which is supported by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) of the National Institutes of Health (NIH) under Grant P41EB027060; and the Center for Reliable Sensor Technology-Based Outcomes for Rehabilitation (RESTORE), which is supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) and the National Institute Of Neurological Disorders And Stroke (NINDS) of the National Institutes of Health (NIH) under Grant No. P2CHD101913.

Primary sponsor	Stanford University
Contact for public queries	*MB*, PHD Stanford University boswellm@stanford.edu
Contact for scientific queries	*MB*, PHD Stanford University boswellm@stanford.edu
Title	A Digital Mindset Intervention to Improve Pain and Exercise Participation in Individuals With Knee Osteoarthritis: A Randomized, Parallel-group Study
Countries of recruitment	USA
Health condition(s) or problem(s) studied	Knee osteoarthritis
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: Subjects not blind; outcomes assessor blind Primary purpose: Supportive Care
Date of first enrolment	April 2023
Target sample size	501

Choice of comparator

Education and exercise are recommended as first-line treatment for osteoarthritis, but often, “treatment as usual” is pain medication and, eventually, surgery. If patients want information about osteoarthritis, sometimes they are given a pamphlet about osteoarthritis by their doctor. Otherwise, they are left to research osteoarthritis on their own. Our comparator is education videos about osteoarthritis that one would typically find on the internet. While accurate, this information does not typically (or intentionally) target mindset and, as shown in the low physical activity levels and adherence to exercise, does not successfully support behavior change. As this does not put

participants at risk, we expect that it will neither improve nor worsen their physical or psychological states.

Supplement 1 Table 2. Study Objectives

Primary Objectives	
Primary outcomes	Primary outcomes assessed at T2 (change from baseline): (i) Exercise mindset using the Mindset about the Process of Health -- Exercise scale. This one-factor scale was developed and validated[1] to assess mindset about the process of engaging in physical activity (e.g., physical activity is difficult/easy, unpleasant/pleasurable, boring/fun). The scale consists of 7 items and is measured on a 4-point scale and scored from 1 to 4, with a higher score reflecting a more appeal-focused mindset about exercise (ii) Osteoarthritis mindsets using the Illness Mindset Inventory. The Illness Mindset Inventory measures three mindsets about the nature and meaning of illness: that it is a catastrophe, manageable, or an opportunity. The scale consists of 20 items measured on a 6-point scale and scored from 1 to 6, with 10 of those questions capturing mindsets about chronic illness. The extent to which a participant endorsed each mindset was obtained by calculating the respective mean scores. A higher score indicates greater agreement with the mindset. This Illness Mindset Inventory is valid and reliable in individuals with knee osteoarthritis[2]. We adapted the scale to focus on mindsets about "knee osteoarthritis" as opposed to "chronic disease." Primary outcomes assessed at T3 (change from baseline): (i) Knee pain using the question, "*What was your average osteoarthritis-related pain over the past week?*" and measured on an 11-point Numeric Rating Scale (NRS) from 0 (no pain at all) to 10 (the worst pain imaginable) (ii) Physical activity using the Physical Activity Scale for the Elderly (PASE). The PASE asks respondents about the frequency of light, moderate, and strenuous work and leisure activities and is a validated measure of self-reported physical activity for individuals with osteoarthritis[3]. The scale is scored from 0 to 793 with higher scores indicating higher levels of physical activity.
Secondary Objectives	
Key secondary	Secondary outcomes assessed at T2 (change from baseline):

outcomes	(i) Knee osteoarthritis knowledge by the Knee Osteoarthritis Knowledge Scale[4]. The Knee Osteoarthritis Knowledge Scale is scored from 11-55 and measures knowledge about osteoarthritis in individuals with knee or hip osteoarthritis (ii) Body mindsets using the Illness Mindset Inventory. In addition to mindsets about chronic illness, the Illness Mindset Inventory measures three mindsets about the nature of the body in the context of a chronic illness: that it is adversarial, responsive, or resilient (iii) Activity adequacy mindsets using the Adequacy of Activity Mindset Measure[5]. This scale was developed to assess mindsets about the adequacy and benefits of one's physical activity as it relates to health. The scale consists of 5 items measured on a 7-point scale and scored from 1 to 7, with a higher score reflecting a more adaptive mindset about the benefits and risks associated with current levels of physical activity. Secondary outcomes assessed at T3 (change from baseline): (i) Knee pain and functioning using the Short version of the Western Ontario and McMaster Universities Arthritis Index (shortMAC). The shortMAC is a disease-specific 12-item measure of knee symptoms and has shown to be valid and reliable in patients with knee osteoarthritis[6]. We evaluated the measure divided into two subscales: pain and function (ii) Perceived need for surgery using the single question, "*How likely do you think you are of needing knee replacement surgery in the future?*" It was answered on the Likert scale from 1 (very unlikely) to 5 (very likely) (iii) Chosen symptom management strategies using the single question, "*Which of the following are ways in which you manage and/or improve your osteoarthritis symptoms? Please select all that apply*." It was answered via multiple choice with a multiple-selection option. The options available were the most commonly identified responses as determined by a previous study[7] (iv) Fear of movement using the Brief Fear of Movement Scale for Osteoarthritis[8]. The Brief Fear of Movement Scale for Osteoarthritis is a 6-item scale validated to assess fear of movement in individuals with osteoarthritis (v) Arthritis self-efficacy using the Arthritis-Self Efficacy Scale. This scale is scored from 1 to 10, with higher scores indicating greater self-efficacy, and was divided into the "pain" and "other symptoms" subscales (vi) Physical and Mental Health using the PROMIS v.1.1 Global Health Short Form[9]. This scale is a 10-item survey that measures overall physical function, fatigue, pain, emotional distress, and

	social health in healthy and clinical adult populations[10]. We evaluated the measure divided into its two subscales: physical health and mental health[11].

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Research Hypotheses

Hypothesis 1. A digital education and mindset intervention will significantly improve mindsets about the process of exercising and osteoarthritis among adults aged ≥ 45 years with knee osteoarthritis compared to an active comparison education intervention and no-intervention immediately post-intervention.

Hypothesis 2. A digital education and mindset intervention will significantly reduce knee pain and increase physical activity levels among adults aged ≥ 45 years with knee osteoarthritis compared to an active comparison education intervention and a no-intervention control group one-month post-intervention.

Hypothesis 3. A digital education and mindset intervention will significantly improve knee osteoarthritis knowledge and mindsets about activity adequacy and the body among adults aged ≥ 45 years with knee osteoarthritis compared to an active comparison education intervention and a no intervention control group immediately post-intervention.

Hypothesis 4. A digital education and mindset intervention will significantly improve knee pain and function, perceived need for surgery, symptom management, arthritis self-efficacy, fear of movement, physical health, mental health, among adults aged ≥ 45 years with knee osteoarthritis compared to an active-comparator education group and a no-intervention control group one-month post-intervention.

Key Personnel

Trial Coordinator
Dr. Melissa Boswell, boswellm@stanford.edu
Department of Bioengineering
Stanford University, Stanford, California, USA

Statisticians

Dr. Trevor Hastie
Department of Statistics
Stanford University, Stanford, California, USA

Disha Ghandwani
Department of Statistics
Stanford University, Stanford, California, USA

Trial Design

We will randomize 505 individuals aged ≥ 45 years with knee osteoarthritis into one of three groups with 1:1:1 group allocation: the Mindset Group (participants receive a digital mindset intervention to improve mindsets about osteoarthritis and exercise), the Education Group (Participants receive a series of osteoarthritis education videos and reflective questions that matches the digital mindset intervention in duration and attention), or the No-Intervention Group (participants take the same surveys as the other groups at the same time points, but do not receive any additional content). Participants will complete an initial baseline survey and be randomized one week later. Those randomized to the Mindset and Eduction Groups will have one week to complete the self-paced online programs. All groups complete osteoarthritis knowledge and mindset surveys at this timepoint. One-month later, participants will receive a follow-up questionnaire.

Study Setting

The study will be conducted entirely online.

Eligibility Criteria

Inclusion Criteria:

- Over 45 years of age
- Self-reported doctor's diagnosis of knee osteoarthritis OR meets the National Institute for - - Health and Care Excellence osteoarthritis clinical criteria (activity-related knee pain and no knee morning stiffness lasting ≥ 30 minutes)
- Knee pain for at least 3 months
- Ability to walk unaided
- Can read and write in English
- Consistent internet access
- Willingness and ability to comply with the study requirements

Exclusion criteria:

- Past total knee arthroplasty or scheduled surgical procedure on any back or

lower limb with osteoarthritis within the next 12 months
- Recent serious injury (within the past 2 months) on the knee(s) with osteoarthritis
- Any condition making it unsafe to participate in physical activity
- Intra-articular therapy within the past 6 months (e.g. injections such as corticosteroids and hyaluronic acid)
- Participates in physical exercise for 30 minutes or more 5 days per week

Interventions

Intervention(s)	Mindset Group: Participants receive a digital mindset intervention to improve mindsets about osteoarthritis and exercise. Education Group (active comparison): Participants receive a series of osteoarthritis education videos and reflective questions that matches the digital mindset intervention in duration and attention. No-Intervention (control): Participants take the same surveys as the other groups at the same time points, but do not receive any additional content.

Modifications

Discontinuation of the program due to psychological disturbance. We do not expect participants to have a psychological disturbance due to the mindset intervention or active comparator program. In the case that someone refuses to continue the study due to a psychological disturbance from participation, this should be reported as an adverse event.

Adherence

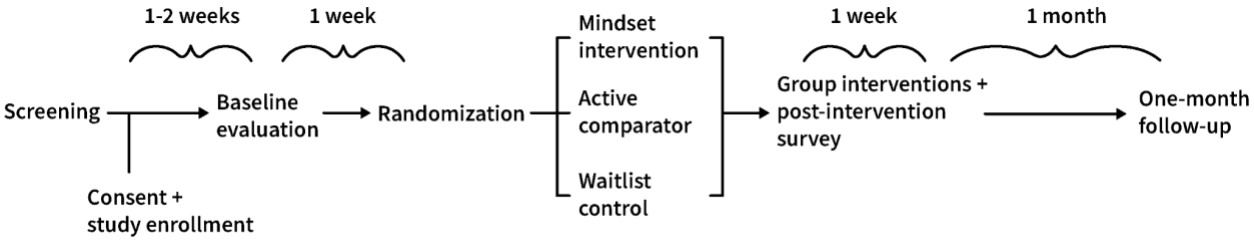
Adherence reminders will be in the form of emails. Three reminders will be sent out: once before the deadline, on the deadline, and the day after the deadline. Reminders will include the importance of completing the section in order to remain in the study. Reminders will also include a flow chart of the study timeline and components, with the relevant section highlighted. Participants will be able reply to the study coordinator with questions.

Concomitant Care

Participation is at the discretion of the participants. Thus, the other option for participants is to not participate in the study.

Prohibited Concomitant Treatment. Additional physical therapy treatment is not permitted during the study as it would interfere with the main outcomes of our study.

Study Flow and Timeline



Supplement 1 Figure 1. Study flow and timeline.

Sample Size

The efficacy of the mindset intervention will be deemed successful if enhancements in either or both key outcomes, namely pain intensity (NRS) or physical activity levels (PASE), are observed. Anticipating modest effect sizes between the mindset and educational cohorts, we conducted a preliminary power analysis, similar to prior online education studies for knee osteoarthritis[12,13], using G*Power 3.1 with a presumed effect size of 0.3 (see below). This analysis involved comparing the mindset group against both the education and no-intervention groups, leading to four distinct comparisons. These assessments are planned to be executed at a 5% significance level, aiming for an 80% probability of discerning a noticeable improvement in delta. Based on Boswell et al.[7], we estimated the standard deviations for PASE and pain at 70.28 and 1.67, respectively. A 26-point difference in PASE was selected as the target delta. While no clinically significant benchmarks for PASE has been established, the intervention's focus on promoting walking and moderate exercise led us to define this delta as the equivalent shift in walking and light exercise frequency from “seldom” (<1 hour per day) to “sometimes” (1-2 hours per day), as per the PASE scale, giving a goal of 26 points. This determination necessitates a sample size of 139 participants per group, totaling 417. To compensate for an anticipated 20% dropout rate, we plan to enroll 501 participants. This sample size is adequately powered to detect a clinically relevant difference of 2 points in NRS pain[14].

A priori power analysis

Disha Ghandwani

11/29/2022

Let, y_i^b represents outcome at baseline and y_i^f represents outcome at follow-up for i^{th} person in treatment group, and $\bar{y}^b$ and $\bar{y}^f$ represents respective means. Similarly, x_i^b represents outcome at baseline and x_i^f represents outcome at follow-up for i^{th} person in control group, and $\bar{x}^b$ and $\bar{x}^f$ represents respective means.

Assumption: Let $x_i^f - x_i^b \sim \mathcal{N}(\Delta_1, \sigma^2)$ and $y_i^f - y_i^b \sim \mathcal{N}(\Delta_2, \sigma^2)$.

Let's say $\Delta = \Delta_2 - \Delta_1$, we want to test the hypothesis

$$H_0 : \Delta = 0$$

$$\text{v/s } H_1 : \Delta > 0$$

Under H_0, $T = (\bar{y}^f - \bar{y}^b) - (\bar{x}^f - \bar{x}^b) \sim \mathcal{N}(0, 2\sigma^2/n)$. We reject H_0 if $\frac{T}{\sqrt{2\sigma^2/n}} > z_{1-\alpha}$. We want n so that power at Δ is $1 - \beta$, i.e.,

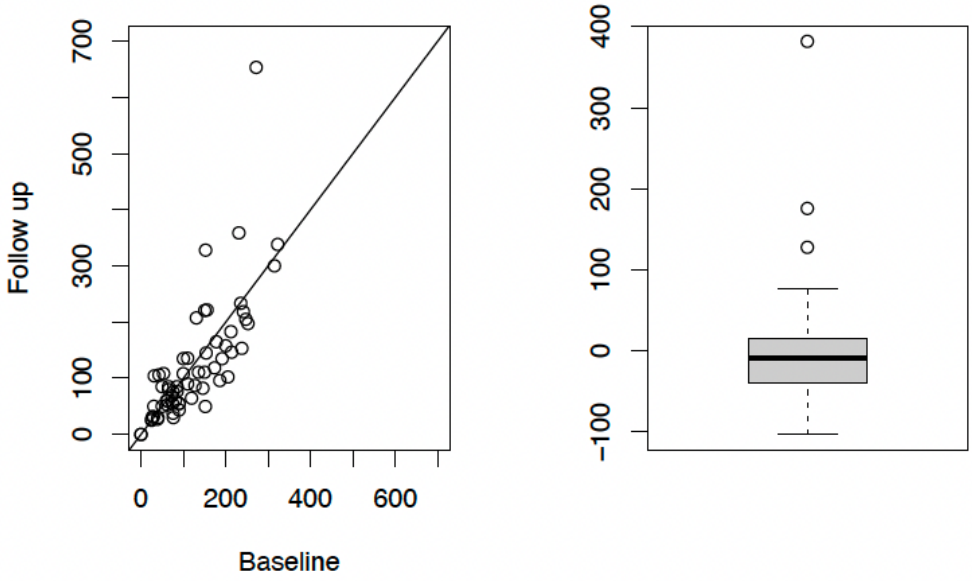
$$P_\Delta\left(\frac{T}{\sqrt{2\sigma^2/n}} > z_{1-\alpha}\right) \geq 1 - \beta$$

which is equivalent to

$$n \geq \frac{2\sigma^2(z_{1-\alpha} + z_{1-\beta})^2}{\Delta^2}$$

For our analysis, we choose $\alpha = 0.05$, and try four different values of β,0.05,0.10, 0.15, and 0.20. We estimate σ from pilot data.

Outcome variable, PASE

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## sigma =  70.27939
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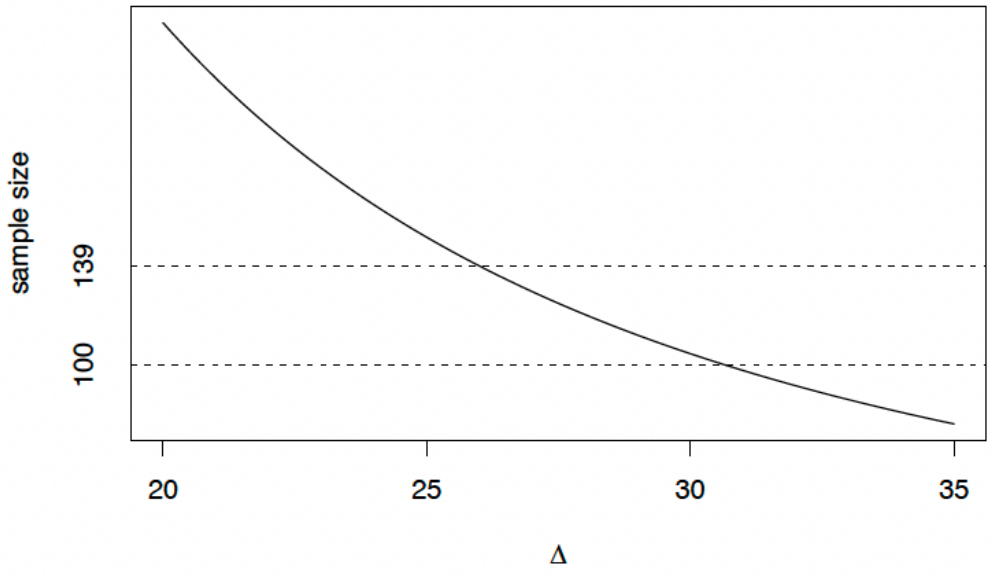
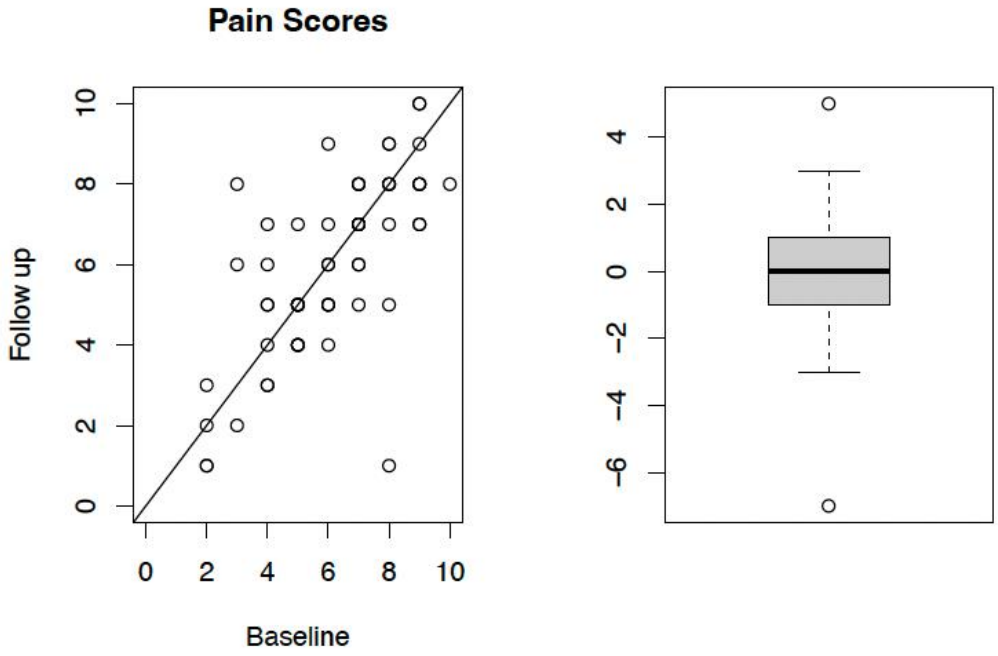
A priori sample size analysis for outcome variable, PASE



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## sigma =  1.670426
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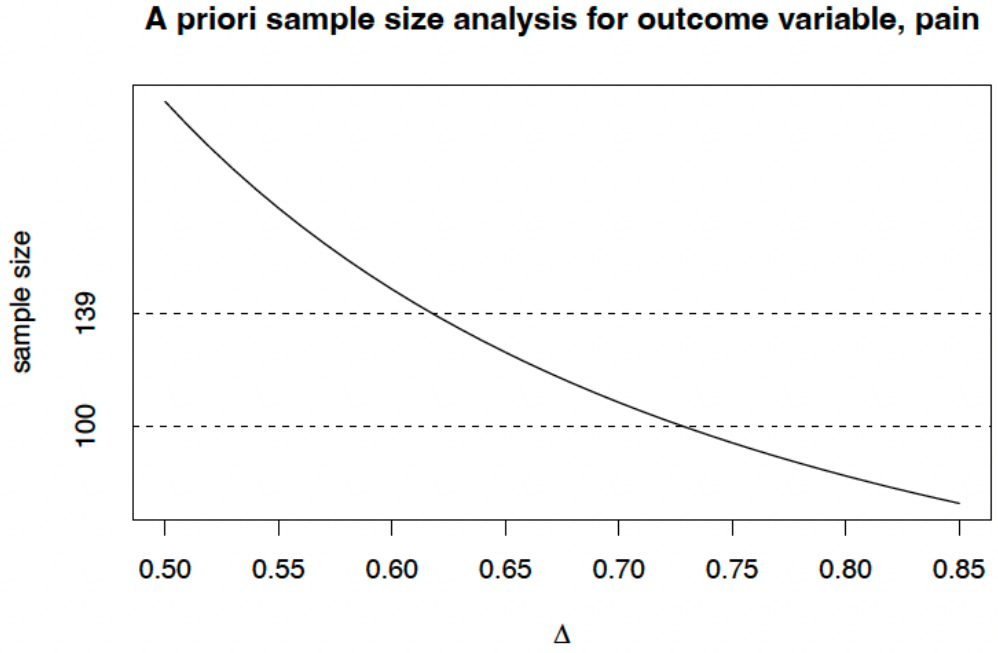

Recruitment

Participants will be recruited through paid online and social media advertising and local flyer postings.

Allocation

We will use the randomizer function in Qualitrics to randomize participants into one of three groups (1:1:1): the Mindset Group, the Education Group (active comparison), or the No–Intervention Group (control).

Blinding (Masking)

During the informed consent process, participants will be informed that the purpose of the study is to understand the effect of a new online osteoarthritis program and that they will be randomized to either a no-intervention group or one of two different sets of videos and reflective questions. Participants will be aware of whether they are randomized to an online program; however, the differences in content between the two programs and the hypotheses of the study will not be revealed. The biostatistician performing the data analysis will be blinded to the group labels.

Data Collection, Management, and Access

All data will be collected through the Qualitrics online survey software. Qualitrics encrypts all transmitted data using Transport Layer Security and hosts data on data centers that are independently audited using the industry standard SSAE-18 method. Stanford University has a Qualtrics license for research use, and data obtained from the Qualitric platform can only be accessed through a secure login. Data will be exported to Microsoft Excel and securely stored for use by the research team. Only after de-identification may the data be shared outside of the research team.

Missing Data

Participants who did not complete a survey entirely were removed from the study and not sent the follow-up survey. Each question of each survey was “force response,” meaning that if a participant completed the survey, no answers would be missing from the response. Thus, no methods for missing data were implemented.

Statistical Methods

Statistical analysis will be carried out in R[15] by a blinded statistician, Disha Ghandwani, with no knowledge of group allocation.

Standard descriptive statistics will be presented for all participant characteristic measures at baseline. Prior to analysis, t-tests for continuous variables and chi-square ($\chi 2$) tests for categorical variables will be conducted to test the equality of means of baseline characteristics. Additionally, baseline characteristic comparisons between participants who completed the study and those who dropped out will be reported.

Changes in primary and secondary mindsets post-intervention will be compared among the mindset intervention group versus the active attention control (education group) and the no-intervention control group. We will present standard descriptive statistics of and calculate changes from baseline to post-intervention for the mindsets and knee osteoarthritis knowledge and from baseline to one-month follow-up for all other outcome variables. Changes will be presented as the mean change with 95% confidence intervals, along with Cohen d, using the following formula:

$$cohen\ d\ = \frac{\bar{x_2} - \bar{x_1}}{s}$$

where $\bar{x_2}$ denotes the mean of variable after intervention, $\bar{x_1}$ denotes the mean of variable before intervention, and s denotes the standard deviation of the change in the variable due to intervention.

We will perform the t-test to compare the change in outcome variables post-intervention and at follow-up between the mindset group and the education and no-intervention groups. We assume the equality of variance for the changes. The t-statistic is given by:

$$\frac{\bar{X} - \bar{Y}}{s_{pooled}\sqrt{\frac{1}{m} + \frac{1}{n}}},$$

where $\bar{X}$ is the mean of changes in the first group and $\bar{Y}$ is the mean of the changes in the second group, s_{pooled} is the pooled standard deviation from the two groups. We assume that there were m people in the first group and n people in the second group. After calculating the t-statistics, the p-values will be computed to estimate the statistical significance of differences in changes between groups. We will perform Bonferonni correction for the four comparisons (e.g., the mindset group vs. the education group and the mindset group vs. the no-intervention group for pain and physical activity at one-month follow-up), which adjusts the significance threshold to *P* = 0.0125. The comparison of the education group to the no-intervention group will not be a primary comparison.

Data Monitoring

The trial coordinator will provide ongoing project oversight and will meet regularly with the senior investigators throughout the project period to provide study feedback including recruitment, retention, and adverse events. During the study, participants have access to email the study coordinator at any time to report adverse events.

Harms

The potential harms associated with this study include psychological complications resulting from the assessments or mindset and education programs or medical risks due to increasing physical activity levels. There is a small risk that individuals completing psychological questionnaires may become distressed, but there is no evidence of resulting psychological dysfunction. We performed pilot testing of the program and questionnaires in which there was no evidence of psychological complications or the risk of such complications. Further, while the program presents the benefits of physical activity, no specific programs are requested for participation and participants are encouraged to go slow and listen to their bodies.

Therefore, no harm or adverse events are foreseen in this study. However, if a complaint or adverse event arises, the research team will discuss and take appropriate action to manage the issue. Any serious adverse event or harm reported by participants will be recorded and reported.

Research Ethics Approval

The study protocol, consent form, and recruitment material will be approved by the Stanford University Research Compliance Office Institutional Review Board.

Protocol Amendments

Protocol amendments will be documented and reported.

Consent Or Assent

Participants will be directed from recruitment materials to a RedCap survey. The survey will first be provided with information on the purpose of the study and the requirements for participation. After that, participants will be given a survey to determine whether they can participate. If participants pass the qualifying survey, they will be directed to the online consent form, where they have the option to consent to participate in the study digitally.

Confidentiality

Personal or identifiable information obtained during this study is considered confidential. Participant confidentiality will be ensured by using identification code numbers corresponding to data across time points. Identifiable data will not be included in the dissemination of the manuscript and its accompanying data. See Data Management for additional information on the security of personal data.

Declaration Of Interests

None of the investigator team has any financial or other competing interests to declare.

Ancillary And Post-Trial Care

Participants who agree to be contacted for future research during the consent process may be contacted for ancillary studies. Any ancillary studies will be submitted to the Institutional Review Board for approval.

After study completion, all participants will be offered the mindset intervention program.

Dissemination Policy

The study will be submitted to peer-reviewed journals for publication. The results will be presented at national and international conferences. The results may also be shared in news outlets, such as online articles, newspapers, and magazines. Participant identity will not be disclosed when publishing or presenting the results. Participants will be informed of the results if requested.

Informed Consent Materials

FOR QUESTIONS ABOUT THE STUDY, CONTACT:
Melissa Boswell
Email: boswellm@stanford.edu

Are you participating in any other research studies? _____ Yes _____No

DESCRIPTION: You are invited to participate in a research study on the use of digital osteoarthritis management programs. The purpose of the study is to understand the effect of a new online osteoarthritis program.

PROCEDURES: If you choose to participate, you will be randomized to either a waitlist group or one of two different sets of videos and reflective questions. You have a one in three (33.3%) chance of being assigned to each group. Each group is equally important for the study. Regardless of which group you are assigned to, you will be asked to fill out surveys, watch videos, answer reflection questions, and provide feedback on the program content. You will also be given the option to perform a functional assessment consisting of moving from a seated position to standing 5 times, which you can record and upload within the online survey.

DURATION OF STUDY INVOLVEMENT: Each participant will be actively enrolled in the study for the one-month duration of the study.

Enrollment will occur throughout the United States. Stanford University expects to enroll 501 research study participants in this research study.

Identifiers might be removed from identifiable private information, and videos will be de-identified with face-blurring. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

RISKS AND BENEFITS: The risks associated with this study are minimal, but there is a small risk of injury consistent with increasing daily physical activity and performing the sit-to-stand movement. Such injuries are temporary and minor (i.e., muscle fatigue and soreness). We will do everything possible to maintain your confidentiality during the study, but there is the potential risk of breach of confidentiality in which your video and survey results may be linked to your name. Study data, including videos, will be stored securely, in compliance with Stanford University standards, minimizing the risk of a confidentiality breach. Again, we will do our best to keep your data confidential.

The benefits which may reasonably be expected to result from this study are that you will contribute to improving the program for other people with osteoarthritis in the future. You may also benefit from an increased understanding of knee osteoarthritis. We cannot and do not guarantee or promise that you will receive any benefits from this study.

TIME INVOLVEMENT: Your participation will take approximately 4 hours over the course of five weeks. It will take around 30 minutes for the initial survey. You then may be asked to complete a program that will take around 3 hours over the course of one week. There will also be a follow-up survey one month after the start of the study at which you will be asked to take another 30-minute survey.

PAYMENTS: You will receive up to a total of $50 in gift cards as payment for your participation, split into three payments:

- $10 after the first survey
- $10 after the second survey
- $30 after the third and final survey

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is

voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Your decision not to participate will not have any negative effect on you or your medical care. You have the right to refuse to answer particular questions. The alternative to participation in this study is to not participate.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Authorization To Use Your Health Information For Research Purposes
Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this study is to evaluate digital osteoarthritis management programs for individuals with knee osteoarthritis. Health information will be evaluated over the course of the study and the results may be published in a conference and/or research journal. As this is a clinical trial, the information provided will, in some form, be submitted to the sponsor and other federal agencies as required.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Melissa Boswell (boswellm@stanford.edu).

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: name; email; self-reported health and demographic information including age, height, weight, sex, gender, ethnicity, state of residence, education, employment status, marital status, medical issues, osteoarthritis status, physical activity level, mental health, and physical health; physical activity; video of the sit-to-stand test.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Melissa Boswell
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

You give consent for your video recordings to be used for (describe proposed use of the recordings and what will happen to the recordings, e.g., shown at scientific meetings; and describe the final disposition of the tapes).(Please note, this option is also applicable if the recordings are used for purposes that are not part of this research project, e.g. future analysis, professional presentations, etc)

Please initial your choice: ___Yes ___No

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

WITHDRAWAL FROM STUDY: The Protocol Director may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

SPONSOR:
Stanford University is providing financial support for this study.

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Melissa Boswell. You may contact her now or later at [phone number].

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Melissa Boswell, at [phone number].

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;

- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

Please download the copy of your signed consent form below.

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