Development and Proof-of-Concept Trial of a Meaning and Theory-Based Physical Activity Intervention

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1. **Summary**

Physical activity (PA) has numerous benefits, including reduced risk for chronic disease and cognitive impairment, improved mental health and well-being, and increased longevity. However, when measured objectively, only 5% of adults meet recommended PA guidelines of 150 min/week. Many interventions have been developed to increase PA among insufficiently active adults, yet the effects are modest, and many people return to inactive lifestyles after the intervention is completed.

Meaning in life, the sense that one's life matters, makes sense, and has purpose, has been shown to be a robust predictor of PA. To date, no PA interventions have thoughtfully incorporated meaning in life. A meaning-based approach is consistent with Self-Determination Theory (SDT), a theory of human motivation and behavior. The overall goal of this project is to systematically incorporate meaning in life and SDT principles into a web-based and text message intervention (Meaningful Activity Program ["MAP to Health"]) to increase PA among insufficiently active adults in midlife. The project will use Science of Behavior Change principles and the Obesity-Related Behavioral Intervention Trials (ORBIT) framework to conduct a Phase IIa proof-of-concept pilot study of MAP to Health.

The study has two aims: **(1) to develop and examine the acceptability of the technological and theoretical frameworks of MAP to Health** and **(2) to determine whether MAP to Health is related to changes in theoretically identified mechanisms of behavior change (meaning salience, basic psychological needs satisfaction, and internal motivation).** In an exploratory aim, we will assess how the intervention and mechanisms of change are related to changes in PA. Participants will be adults in midlife (ages 40-64) who are insufficiently active, are interested in increasing PA, do not have contraindications to engaging in PA, and are patients in a large healthcare system in the Midwest.

In Phase 1, we will develop the MAP to Health online web-based interview that will be used to explore what is particularly meaningful to participants, how PA is consistent with those goals, and what activities patients plan to engage in. Participants (*N*=12) will complete the interview and rate the ease of use, usefulness, intention to use, and theoretical fidelity of the intervention.

In Phase 2, we will conduct a proof-of-concept pilot trial using a double-pretest single group design. Participants (*N*=35) will complete a 4-week pretest monitoring period and an 8-week pilot trial of the intervention, with assessments of SDT mechanisms and meaning salience at pretest (-4 weeks), baseline (0 weeks), midpoint (4 weeks) and posttest (8 weeks). In addition, participants will wear accelerometers to assess PA during the 12 weeks.

2. Study Aims

Aim 1 (Development): To assess the acceptability of underlying theoretical and technological frameworks of the web-based MAP to Health interview.

H1a: Participants will rate the web-based interview as easy to use and useful and will report intentions to use the intervention.

H1b: The web-based interview will solicit data necessary to program theory-based, personalized text messages for participants.

Aim 2 (Proof-of-concept testing): To determine whether MAP to Health is related to changes in theoretically identified behavior change mechanisms.

H2: Participants will experience increases in the theoretically identified mechanisms of behavior change (i.e., meaning salience, internal motivation, and basic needs satisfaction) after receiving the MAP to Health intervention compared to a pre-test no intervention period.

Exploratory Aim: To assess whether the intervention and increases in the hypothesized behavior change mechanisms (meaning salience, internal motivation, and basic needs satisfaction) are associated with increases in PA compared to the pretest no intervention period.

3. Background, Rationale, Significance

A. Given its numerous benefits for physical and mental health, physical activity (PA) may be one of the most important behaviors for healthy aging. In particular, PA is known to be related to reduced risk of chronic disease, such as coronary heart disease and type 2 diabetes, improved mental health and well-being, improved cognitive functioning (and lower risk of Alzheimer's disease and other dementias), improved ability to engage in activities of daily living, and increased longevity.[1,2] The evidence that PA is beneficial for health is so overwhelming that some have argued that nearly everyone could benefit from PA.[3] However, 90% of US adults do not meet recommended guidelines of ≥150 minutes of moderate-intensity PA per week (or 75 minutes of vigorous PA);[4] when PA is objectively measured, this number rises to 95%.[5]

B. Given the importance of engaging in regular PA for health, there has been considerable effort to develop interventions to increase PA, with modest results.[6] Interventions to increase PA generally demonstrate short-term success but not long-term maintenance[7,8] and report varying attrition rates, with most participants dropping out in the first 6 months.[9,10] One potential explanation for this gap is the lack of systematic, mechanistic approaches to PA intervention development. In particular, despite the abundance of research examining theoretical psychosocial determinants of PA,[11] theory is often poorly applied to behavioral interventions.[12] *Consequently, it is clear that new and innovative interventions focused on psychological mechanisms known to predict PA adoption and maintenance are desperately needed.*

Table 1. *List of Abbreviations Used*

CESR	Center for Evaluation and Survey Research
EHR	Electronic health record
HP	HealthPartners
MI	Motivational interviewing
MAP	Meaningful Activity Program
MVPA	Moderate-to-vigorous physical activity
ORBIT	Obesity-Related Behavioral Intervention Trials
PA	Physical activity
SDT	Self-determination Theory
SOBC	Science of Behavior Change
TAM	Technology Acceptance Model

C. The theory-based, mechanism-focused approach to the research proposed herein is aligned with the NIH Science of Behavior Change (SOBC) program and Stage I of behavioral intervention development. The SOBC emphasizes basic research grounded in theory to identify targeted mechanisms and assessment of the degree to which those targets are engaged and lead to behavior change. In the current study, we respond to the SOBC call for an experimental approach to behavior change by constructing an intervention aligned with theory and targeted mechanisms and testing theoretical validity of the intervention and its initial ability to change hypothesized mechanisms. The proposed study falls within Phase IIa (i.e., proof-of-concept testing) as described in the Obesity-Related Behavioral Intervention Trials (ORBIT) Model for Developing Behavioral Treatments for Chronic Diseases.[13] The ORBIT model parallels the widely accepted drug development model.[14] In the proof-of-concept phase, the aim is to prove the concept that the intervention is effective at targeting theoretical mechanisms of change before advancing research to subsequent stages (efficacy and effectiveness trials). By employing SOBC and ORBIT frameworks, we will efficiently generate better understanding of the *how* and *why* of behavior change, enabling more precise future theory testing and development of effective interventions to increase PA.

D. Self-Determination Theory (SDT)[15] is a promising theory upon which to build innovative interventions to enhance long-term behavior change. SDT suggests that social environments that support the basic psychological needs of autonomy (feeling behavior is self-organized, accompanied by a sense of volition), relatedness (feeling connected to others), and competence (feeling capable of achieving goals) foster the internalization of motivation and facilitate behavior change. SDT posits that internally motivated behaviors are more likely to be maintained than behaviors that are extrinsically motivated. In SDT, motivation exists on a continuum from external regulation to internal regulation; research demonstrates that individuals who report more internally regulated motivation (i.e., motivated by

congruence with the self or enjoyment) also engage in more in PA and experience more positive psychological outcomes of exercise participation.[16-20] Exercise intervention research suggests that previously inactive exercise initiates experience a decrease in external regulations and an increase in more internalized motivations over time,[21] and that more self-determined motivations are associated with greater exercise persistence.[22] Three RCTs examining SDT-based interventions to increase PA[23] using motivational interviewing (MI)[24] frameworks demonstrated that increasing self-determined motivation increased PA.[25] These interventions used 1:1 (e.g., physician and patient) or group interventions to deliver intervention content; to our knowledge, none of the SDT interventions have used *ecological momentary interventions* to deliver SDT-based messages to encourage PA.

E. SDT interventions can be enhanced by integrating meaning salience. Meaning in life is the sense that one's life matters, makes sense, and has purpose.[26] Meaning and existential literatures explicate the basic human need to live a meaningful life. Research shows that people who engage in intrinsically meaningful life activities experience greater life satisfaction and well-being.[27] *Although previous SDT intervention studies[23,28,29] assessed personal life goals and values, they did not deliberately integrate them with behavior change techniques or enhance awareness of meaning in life during the intervention.* We hypothesize that **meaning salience**, or the extent to which individuals live with awareness of their sense of personal life meaning, is key to enhancing behavior change. This hypothesis is an implicit, but essentially ignored, aspect of SDT that suggests that integrating or directly linking new behaviors with important and salient aspects of meaning in life increases the likelihood of long-term maintenance of the new behaviors.[30-32] Moreover, Ryff and Singer[33] suggest that individuals who *live with awareness of a sense of meaning in life (i.e., meaning salience) may be more motivated to engage in healthier behaviors*.[34] Research supports this claim and observational findings show that greater meaning is *related* to greater engagement in PA.[35-39] Further, a recent meta-analysis[40] found that possessing a high sense of meaning in life was associated with reduced risk for all-cause mortality and cardiovascular events. Additional evidence suggests that meaning is associated with improved health measured in a variety of ways, including subjective (e.g., self-rated health) and objective (e.g., biomarkers) health indicators.[41,42] Nevertheless, there are many reasons individuals fail to act in ways congruent with their sense of meaning, including the lure of short-term hedonic pleasures (e.g., watching a favorite TV show) and demanding environmental stimuli (e.g., peer/work pressure) that transfer their attention from what is meaningful toward what is immediate or comfortable. Thus, meaning salience is considered a state that can vary over the course of a day. We *hypothesize* that behaviors explicitly integrated within one's life meaning are more likely to be maintained, particularly when the meaning salience is accentuated daily.

F. Midlife (ages 40-64) may be an important time to harness meaning and establish a healthy behavior pattern to improve health in later life. Evidence suggests that PA tends to decline as individuals age,[43,44] even though engaging in health behaviors during this time may be more important than ever to prevent development of chronic disease and enhance healthy aging. Indeed, midlife PA levels are related to longer telomeres (a biological indicator of healthy aging) and improved cognition in old age.[45,46] Further, although midlife is a time when risk factors such as high blood pressure emerge,[47] physical fitness in midlife is associated with delayed onset of chronic disease.[48] However, midlife is also a time in human development when meaning becomes more salient.[49] Thus, adults in midlife may be a particularly apropos group in which to test the hypothesis that pairing meaning with PA enhances PA engagement.

G. Preliminary Studies

Development of Colorado MAP (COMAP). Dr. Hooker and her colleagues systematically developed a smartphone intervention to increase PA in inactive healthy adults that was based on SDT and meaning and serves as the prototype for the present study.[50] Focus groups of previously inactive adults provided feedback on the feasibility, utility, and usability of the COMAP app as well as general feedback regarding the initial interview, length of the program, and overall impressions. The team then modified the intervention based on the focus group feedback and recruited 10 inactive adults to participate in COMAP for 2 weeks. Participants gave feedback regarding their experience with COMAP and the response was overwhelmingly positive, with all participants reporting increased PA. Participants were particularly positive about the initial interview and personalized push notifications. Despite the initial success of the smart phone app, major challenges of using this platform include the need to develop multiple versions to reach a

wider audience (iOS and Android) and maintenance of the app(s) after development due to continual operating system updates. Thus, for this project, we chose to use a web platform plus text messages to be able to disseminate the intervention more easily.

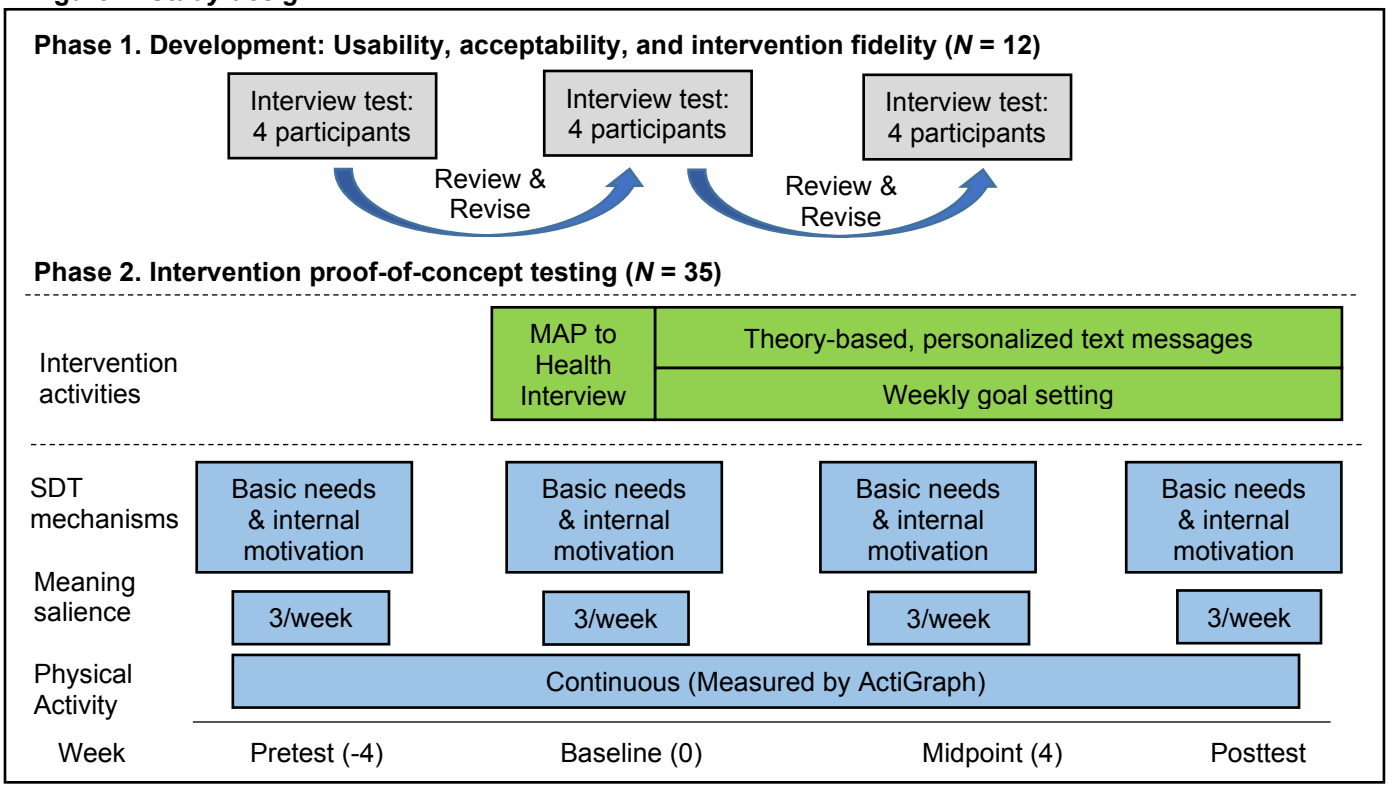
Observational studies of meaning and PA. Dr. Hooker led a study wherein 100 community members completed a self-report measure of meaning and then wore accelerometers for three consecutive days.[37] Meaning was significantly and positively related to total activity counts and self-reported PA, and it was marginally related to minutes of moderate-to-vigorous PA (MVPA). A second study, supported by the American Heart Association, examined the associations of SDT, meaning, and PA in a group of 160 previously inactive adults starting new PA programs.[51,52] Meaning was significantly and positively related to basic psychological needs satisfaction and internal motivation. Meaning, needs satisfaction, and internal motivation at baseline were significantly and positively related to PA at 4-weeks. In a second aim, 80 participants recorded meaning salience, mood, and PA daily for 4 weeks. Meaning salience was significantly and positively associated with daily PA duration and intensity and a greater likelihood of attending the fitness center.

4. Approach

a. Study Design

This study will use a pilot study design with two phases (see Figure 1). In Phase 1, an iterative, rapid development approach to assess intervention usability, acceptability, and intervention fidelity. In Phase 2, we will use a double-pretest single group pilot study to assess the effects of the intervention on proposed intervention mechanisms and physical activity.

Figure 1. ***Study design.***

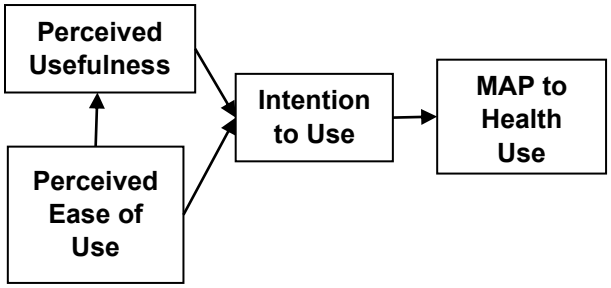


i. Phase 1: Development of web-based MAP to Health Intervention

Phase 1 consists of alpha and beta testing to examine the usability and acceptability of the technological and theoretical frameworks. During the first phase, the in-person interview designed during the COMAP pilot study will be translated into an interactive, web-based interview to determine how participants derive meaning and how that might be connected to reasons they want to be more physically active. Then, participants will be guided in setting small, realistic goals to be active in the next two weeks and will plan when they will be active.

In Phase 1, we will use the Technology Acceptance Model (TAM; see Figure 2) as a framework for evaluation, as it has been widely used to examine the usability and acceptability of interventions using technology.[53-57] Based on the Theory of Reasoned Action, the TAM proposes that attitudes about perceived ease of use and perceived usefulness predict intention to use the technology, which then predicts actual technology use. We will use the TAM framework to ensure that the technological interface is acceptable to participants prior to moving to a proof-of-concept pilot trial.

Figure 2. ***Technology Acceptance Model.***



After internal testing of software fidelity, 12 patients will be recruited to test the interview to determine the acceptability and usability and whether the interview appropriately gathers information needed to program theory-based, personalized text messages (see Figure 1). Participants will complete an e-consent form, the web-based interview, and Phase 1 measures.

After completing the measures, a list of text messages for that participant will be generated and displayed to the participant for review. Participants will review the text messages and rate the extent to which the messages are personalized to their sense of meaning and goals. Intervention modifications will be made iteratively; four participants will complete the web-based interview and review text messages. After each round of testing, the intervention will be modified to increase below-threshold ratings on the TAM constructs or intervention fidelity to theory. The process will repeat for at least three rounds, until the team is confident the interview is ready for preliminary testing in Phase 2.

ii. Phase 2: Intervention Proof-of-Concept Testing

Aim 2 will use a single-group, double pretest design to examine change in theoretical mechanisms prior to and during participation in MAP to Health (see Figure 1 for details). After completing the baseline measures, participants (N = 35) will begin the intervention by completing the web-based interview. For the next 8 weeks, they will receive personalized, theory-based text messages at times that they identify as opportune for PA, 2 times per day. After week 2, patients will receive a weekly link, via text message, to the calendar in the web-based application to set new goals for planned PA. At the four main assessments (pretest -4, baseline 0, midpoint 4, posttest 8), participants will complete SDT mechanism measures (needs satisfaction and internal motivation).

Because meaning salience is a state, participants will be asked to report on meaning salience on 3 random days during the same weeks. Participants will be given ActiGraph wGT3X-BT accelerometers to wear over the course of the 12 weeks; data will be automatically uploaded to the cloud and research staff will monitor wear compliance, reaching out to participants after 2 consecutive days of no wear. At the end of the study, participants will rate the acceptability of the intervention using the same measures from Aim 1 and complete open-ended questions asking for qualitative feedback on intervention components and the use of accelerometers.

b. Population

i. Inclusion/Exclusion Criteria

The eligibility criteria were chosen to identify a sample of insufficiently active midlife adults, without serious medical or psychiatric conditions, who are interested in increasing PA. Insufficiently active adults (individuals who engage in PA between 10 and 149 min/week)[43] were chosen because they have indicated interest in engaging in PA but not yet made PA a regular habit. This group represents one quarter of adults[43] who could use support to meet PA guidelines.

Inclusion Criteria

- Midlife (ages 40-64 at enrollment)
- Able to read and understand English
- Insufficiently active (engaging in ≥10 and ≤149 min of PA/week)
- Intention to increase PA in the next 30 days

- Has consistent access to a smartphone with text-messaging capability
- Able to access internet through phone or computer (to participate in intervention activities)

Exclusion Criteria

- Greater than minimal risk to starting a PA program (Physical Activity Readiness Questionnaire score > 0)
- BMI ≥ 40
- Currently pregnant
- Has opted out of research
- Diagnosis of metastatic cancer or cardiovascular disease
- Residing in a nursing home or long-term care facility
- Cognitive or psychiatric conditions that preclude completion of questionnaires, including dementia diagnosis
- Diagnosis of severe psychiatric disorder (e.g., Bipolar Disorder, Schizophrenia)
- Diagnosis of substance use disorder or AUDIT-C[62] >7

ii. Sample size

To identify potential participants, we will use electronic health records (EHRs) of patients from HealthPartners, Park Nicollet, and Stillwater Medical Group clinics who meet eligibility criteria. Then the Programmer Analyst will randomly select potential participants to recruit and screen. Recruitment samples will be stratified on sex and race/ethnicity; specifically, we will oversample racial and ethnic minorities to ensure adequate representation.

Because some eligibility criteria are not available in EHR, potential participants will be further assessed for eligibility during the phone screening process. Estimating a 2-3% participation rate, we will pull a recruitment sample of 2250 patients: 250 in Phase 1 and 2,000 in Phase 2.

For Phase 1, we will recruit up to 20 participants for usability testing. We anticipate that we will recruit a minimum of 12 participants, with three rounds of 4 participants. This sample size was chosen because it is the industry standard for this type of usability testing (~10 participants). We have included an additional 8 participants in case we need to conduct additional rounds of usability testing.

For Phase 2, we will recruit up to 45 participants for the proof-of-concept pilot trial. Our power analysis indicates that a minimum of 35 participants is needed to detect a meaningful change in the hypothesized mediators (see Phase 1 Power Analysis for details).

c. Data collection process

i. Identifying Participants

Potential participants will be identified EHRs by a Research Informatics Programmer Analyst. The Programmer Analyst will use available inclusion/exclusion criteria above to identify potentially eligible patients, stratify on sex and race/ethnicity, apply a random selection algorithm to that list, and check the research opt-out list. Once the list of potentially eligible participants has been narrowed to the appropriate sample size, the analyst will then pull demographics and contact information.

For Phase 1, we may also offer the study to employees of HealthPartners who believe they meet the study inclusion exclusion/criteria.

After Phase 1 is complete and the intervention is ready to move to Phase 2 proof-of-concept testing, another EHR recruitment batch will be gathered. Prior to starting the next recruitment batch, each newly generated list will be checked against the research opt-out list, and then reviewed to eliminate patients who have already had direct CESR staff contact (e.g., enrolled in the study, did not meet full eligibility criteria, opted out from further study contact).

In Phase 2, we will partner with the HP Communications team to use social media and other communication strategies to advertise the study. Interested individuals will be directed to a self-screening link in REDCap to see if they are eligible. If so, the CESR team will reach out to screen and confirm eligibility.

ii. Recruitment

Recruitment, consent, and study assessments will be conducted by the Center for Evaluation and Survey Research (CESR) at HP. Patients in the recruitment sample will be sent a letter informing them of the research opportunity; CESR staff will make follow-up phone calls to conduct eligibility screening. In Phase 1, the recruitment process will be 'batched' to recruit patients on a rolling basis. For example, 4 patients will be recruited at a time for 3 consecutive rounds.

CESR study staff will mail an introductory letter with study description and elements of informed consent to potential participants. The letter will include next steps for interested individuals to complete an online self-screener in REDCap or call CESR staff using a study-specific phone line for more information, opt out of further contact, or wait for a follow-up call from CESR staff. Up to three follow-up calls will be made. Call-management software will ensure that calls are made at different times of day and days of the week, including evenings and Saturdays, to maximize likelihood of contact.

Upon successful contact, CESR staff will explain the study, gauge patient interest, complete eligibility screening, and collect required study participant information (i.e., cell phone number, email address). Participants who provide verbal consent for participation will be sent a study confirmation e-mail with a link to the MAP to Health web-based platform. For Phase 1, if participants have not completed the study within 2 business days, one reminder email will be sent.

For Phase 1 only, we will also offer the study through email and huddle meetings to HealthPartners employees. Interested individuals can reach out to the study team via email to be screened and determine eligibility.

In Phase 2, CESR staff will schedule participants for an initial study orientation visit with the project manager, either virtually (phone or Microsoft Teams) or in-person, based on the participants' preference and in compliance with COVID-19 infection control guidelines. The CESR team will send a study confirmation e-mail with a link to the MAP to Health web-based platform, including details about how to register and complete the pre-test survey, and their scheduled study orientation visit.

See Appendix A for Phase 1 recruitment materials. See Appendix D for Phase 2 recruitment materials.

iii. Consent

We are requesting a waiver of informed consent from the HealthPartners IRB to access patient data needed to determine potential eligibility and contact potential participants.

During phone screening, participants will be given a description of the study activities and informed about the voluntary nature of the study. They will be given opportunities to ask questions before providing verbal consent to participate. After providing informed consent, staff will send study confirmation email to interested participants with instructions for study activities and link to the MAP to Health web-based platform, which will contain an e-consent form (both Phases). Participants will be required to consent to the study using the e-consent form before participating in any future study activities.

iv. Data Sources

HealthPartners Electronic Health Record (Epic/Clarity). EHR data will be extracted by the Programmer Analyst to identify a sample of potentially eligible HP patients to invite to participate. These data will include identifying information (name, address, phone number, email), demographic characteristics (sex, race, ethnicity, DOB), and clinical characteristics (diagnoses, vitals [BMI], visits).

Self-Report Surveys and Screening Questionnaires. Self-report surveys and screening questionnaires will be stored in REDCap, a secure database management software. CESR staff will use REDCap to store data related to phone recruitment scripts, eligibility screening, and consent information. Participants will directly answer self-report survey questions in REDCap software that they receive through a link in a text message or email.

MAP to Health Intervention Web-Based Platform. The web-based MAP to Health intervention is an interactive tool to guide participants through identifying reasons to engage in physical activity and scheduling those activities. As part of the intervention, participants will be prompted to respond to questions about physical activities, meaning, values, and barriers. This platform will be developed by

programmer from HPI's Software & Engineering Team. These data will be collected and stored on a secure HPI server and will be used to generate personalized text-messages.

ActiGraph Accelerometers. Participants in Phase 2 will wear ActiGraph accelerometers for 12 weeks to monitor physical activity. These data will be uploaded directly to a cloud-based software provided from ActiGraph (CentrePoint) and accessed by our study team. The project manager will introduce the ActiGraphs and procedures to participants during the study orientation visit and will monitor use and remind participants to charge and wear the ActiGraphs throughout the study.

v. Process steps for data acquisition

Phase 1:

1. Identifying Eligible Patients:

   Potential participants will be identified through either (1) HP EHR by a Research Informatics Programmer Analyst or (2) by advertisements among HP employees. For the first method, the Programmer Analyst will use the inclusion/exclusion list to determine potentially eligible participants. The Programmer Analyst will exclude participants who have opted out of research at this phase. For HP employee recruitment, we may offer the study through email or announce the availability of the study at Huddles.

2. Recruitment & Screening:

   Potential participants identified through the EHR will be mailed a letter that describes the study and invites them to participate. Interested individuals will have the option to call the study team if they are interested, or they can wait for a phone call from CESR staff. For individuals who express interest from advertisements, they will reach out to study staff to schedule an eligibility screening call. For participants recruited through both sources, a CESR survey specialist will talk with potentially eligible participants via phone to screen for additional eligibility requirements. Specifically, they will ask questions about recent physical activity, interest in increasing activity, readiness for physical activity (Physical Activity Readiness Questionnaire), alcohol use (AUDIT-C), consistent access to a phone with text-messaging capability, and access to internet (through phone or computer). If individuals are eligible, CESR staff will send participants a study confirmation email with a link to the web-based platform, which will contain an e-consent form.

3. MAP to Health Web-Based Interview:

   Participants in Phase 1 will use the MAP to Health web-based platform to complete the MAP to Heath Interview, further described below in Section 4dii. **See Appendix B: Phase 1 Intervention Tools** for an outline of the interview.

4. User Experience and Feedback:

   Immediately after completing the MAP to Health interview, participants will be directed to a REDCap survey to evaluate the usability and theoretical fidelity of the interview. They will also provide feedback using open-ended questions. **See Appendix C: Phase 1 Survey Measures**.

5. Text Message Review and Ratings:

   After completing the measures rating the acceptability and theoretical fidelity of the interview, participants will review a list of generated text messages. They will rate the extent to which the messages are personalized to their sense of meaning and goals. **See Appendix B: Phase 1 Intervention Tools** for templates of text messages.

6. Incentives:

   The Project Manager will confirm that the participants have completed the web-based interview and survey measures. The Project Manager will send a $25 gift card to the participant as a thank you for their time.

Phase 2:

1. Identifying Eligible Patients:

   Potential participants will be identified through HP EHR by a Research Informatics Programmer Analyst. The Programmer Analyst will use the inclusion/exclusion list to determine potentially eligible participants. The Programmer Analyst will exclude participants who have opted out of research as well as anyone who was involved in Phase 1. Additional recruitment may be conducted in collaboration with the HP Communications team through social media posts or press releases.

2. Recruitment & Screening:

   Potential participants identified through the EHR will be mailed a letter that describes the study and invites them to participate. Interested individuals will have the option to complete an online screener to determine if they are eligible or call the study team if they are interested, or they can wait for a phone call from CESR staff. A CESR survey specialist will talk with potentially eligible participants via phone to screen for additional eligibility requirements. Specifically, they will ask questions about recent physical activity, interest in increasing activity, readiness for physical activity (Physical Activity Readiness Questionnaire), alcohol use (AUDIT-C), consistent access to a smartphone with text-messaging capability, and access to internet (through phone or computer). If individuals are eligible, CESR staff will schedule participants for a study orientation visit with the Project Manager and send them a study confirmation email with a link to the web-based platform, which will contain an e-consent form, and a detailed list of study activities. **See Appendix D for Phase 2 recruitment materials.**

3. Outcome Assessments:

   Participants will complete survey measures at 4 time points: pre-test (-4 weeks), baseline (0 weeks), midpoint (4 weeks), and posttest (8 weeks). To improve retention, we will send regular text and email reminders to complete study activities (up to 3 per assessment). If participants have not completed surveys after email and text prompts, the Project Manager may make one follow-up phone call to encourage completion.

   a. Pretest (-4 weeks): After reviewing the e-consent form, participants will complete the Pretest survey measures in REDCap through the MAP to Health web-based platform. Participants will complete measures of the hypothesized intervention mechanisms (basic psychological needs satisfaction and internal motivation) as well as demographic and physical activity history measures that will be used to describe the sample. During the study orientation visit, the Project Manager will confirm that participants have completed the Pretest survey and will mail participants the accelerometer. During the orientation visit, the Project Manager will review instructions for the accelerometer, including instructions on how to wear it, charge it, and ensure that the data are synced to the cloud-based data management software (CentrePoint). The Project Manager will follow-up with the participants within 2-3 business days by phone to ensure the participants received the accelerometer and understand how to use it. The Project Manager will monitor ActiGraph data collection and will contact to participants if data have not been uploaded for more than 2 consecutive days to encourage charging and/or wear. The Project Manager will schedule the remaining assessment surveys in REDCap for the participants. In the week following the Pretest surveys, participants will complete measures of meaning salience and mood on three random days (2 weekdays and 1 weekend day).

   b. Baseline (0 weeks): In the week leading up to baseline, participants will be sent the measures of meaning salience and mood on three random days (2 weekdays and 1 weekend day). They will be prompted to complete the baseline surveys that assess hypothesized mechanisms (basic needs satisfaction and internal motivation). Once the baseline survey measures are complete, the web-based platform will prompt participants to complete the MAP to Health web-based interview and start the intervention.

   c. Midpoint (4 weeks): In the week leading up to the midpoint assessment, participants will be prompted to complete the measures of meaning salience and mood on three random days (2 weekdays and 1 weekend day). They will be prompted to complete the midpoint surveys that assess hypothesized mechanisms (basic needs satisfaction and internal motivation).

d. Posttest (8 weeks): In the week leading up to the posttest assessment, participants will be prompted to complete the measures of meaning salience and mood on three random days (2 weekdays and 1 weekend day). They will be prompted to complete the posttest surveys that assess hypothesized mechanisms (basic needs satisfaction and internal motivation). Participants will provide feedback on intervention and study procedures using the measures from Phase 1 (usability and intervention fidelity).

4. Exit Interview

After Week 12, the Project Manager will call each participant to conduct an exit interview over the phone. The interview will consist of open-ended questions about the participant's experience with the study. After the interview, the Project Manager will confirm that the participant has returned the accelerometer to the study or provide instruction on how to complete the return.

5. Incentives

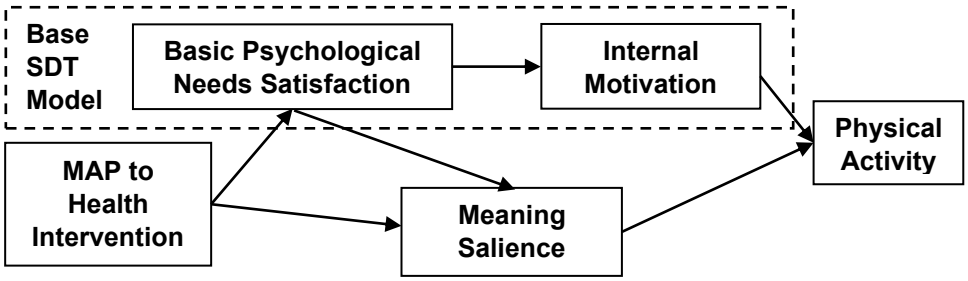
Participants can receive up to $250 for their participation. Incentives will be paid out based on the activity schedule (**see Appendix D: Phase 2 Activities and Incentives Schedule**). Incentives will be distributed every 4 weeks. The Project Manager will upload the final incentive disbursement at the end of the study, prorated based on the return of the accelerometer.

d. MAP to Health Intervention

i. Intervention Overview

The Meaningful Activity Program (MAP to Health) intervention is a theory-driven mobile health (mHealth) intervention that has the goal of helping adults in midlife increase physical activity. Specifically, MAP to Health uses theory (see Figure 3) and mHealth technology to increase ***meaning salience*** and support ***basic psychological needs*** (support autonomy in PA activities, encourage setting small goals to increase competence, and encouraging relatedness through promoting PA activities with important others), which will, in turn, enhance ***internal motivation*** to engage in PA. By explicitly addressing meaning, the intervention will overtly integrate PA with key life values, and therefore increase the likelihood that PA will become internally motivated and maintained. The intervention will be ***individualized*** by first having participants complete a web-based, interactive interview, using an MI framework, to explore what is particularly meaningful to them and how PA is consistent with those goals. After obtaining personalized information about meaning and PA goals, the web-based app will generate personalized messages that will be delivered as ***ecological momentary interventions*** to patients via text. A recent meta-analysis shows that text messages are an effective and flexible intervention strategy to increase PA.[58] MAP to Health's web-based interview plus text message modality (a) can flexibly deliver ecological momentary interventions to enhance meaning salience, (b) is resource-sparing, and (c) can be scaled up to a large audience without requiring interventionists or continued software maintenance (like smartphone apps).

Figure 3. ***Conceptual Model Integrating SDT and Meaning to Increase PA.***



ii. Web-based Interview

The intervention begins with a web-based interview that guides participants through a structured behavior change clinical interview. Participants will log in to a web-based portal with a unique login and password. The interactive interview will: (1) provide an overview of the program; (2) gather information about past physical activity experience; (3) provide a rationale for connecting physical activity to meaning; (4) guide participants through a life values assessment to rank values in order of meaningfulness and gather details about the top 3 most meaningful areas; (5) make the explicit

connection between health and meaning; (6) identify how current behavior does not match with meaning or physical activity goals; (7) identify opportunity for physical activity; (8) guide participants in setting SMART goals for activity (Specific, Measurable, Attainable, Realistic, Timely); (9) elicit barriers and spur problem solving; and (10) summarize lessons learned and preview next steps. The initial interview will be designed to last 30 to 45 minutes. The information gathered from the interview will be used to program the personalized text messages (see next section).

iii. Text Messages

For 8 weeks after the initial interview, participants will receive text messages on their personal phones. The texts are designed to be delivered at times participants previously noted they will have an opportunity to be active (up to twice per day) and will incorporate personalized messages about meaning (e.g., For a person who derives meaning from work; "Good morning! Ready to go to the gym? Remember that being more active can help you take care of your health and be more efficient at work."). These "just-in-time" messages will pair meaning with PA to (1) increase PA; (2) increase meaning salience; and (3) support basic psychological needs satisfaction to, in turn, internalize motivation to engage in PA.

iv. Weekly Activity Scheduling

Each week, participants will be prompted to log in to the web-based platform to update their physical activity schedule in the calendar for the coming week. Participants will have the option of carrying forward the previous week's schedule and modifying it as they see fit. Weekly scheduling ensures that participants continue to actively plan for physical activity and that text messages are sent at appropriate times.

e. Outcome and Variable Definitions

i. Eligibility Screening

1. EHR screening data. Data will be collected from the EHR to determine eligibility for a pool of potentially eligible individuals. This will include information on demographic characteristics (e.g., age, race, ethnicity, sex), most recent height and weight (BMI), diagnoses (e.g., cancer, cardiovascular disease, dementia, mental health and substance use disorders), and residential information (e.g., residing in a nursing home or long-term care facility). Individuals who are recruited through emails or huddle announcements will complete a self-report survey that will assess the same information.
2. Self-reported Physical Activity. In the screening process, potentially eligible individuals will be asked to complete Godin's Leisure Time Exercise Questionnaire (GLTEQ)[59] to assess recent moderate to vigorous physical activity (MVPA). Individuals are asked to think about a typically 7-day period (week) and how many times they exercise for more than 15 minutes per time for each type of activity (strenuous, moderate, or mild exercise). Individuals then estimate the total number of minutes per week they engage in each type of exercise. Individuals who exercise between 10 and 90 minutes per week of MVPA (mild exercise does not count) will be eligible for this study.
3. Intentions to be Physically Active. In the screening process, potentially eligible individuals will answer one question about intentions to increase physical activity: "Do you intend to increase your physical activity in the next 30 days?" Individual who answer "yes" will be eligible for this study.
4. Physical Activity Readiness. The Physical Activity Readiness Questionnaire (PAR-Q)[60] will be used to assess medical or physical contraindications to participate in physical activity. The PAR-Q has 6 questions that assess situations in which it may be unsafe to start a physical activity program without the supervision of a physician (e.g., Do you feel pain in your chest when you do physical activity?). If individuals answer "yes" to any one of the questions, they will not be eligible for the study.
5. Alcohol Use Disorders Screening. The Alcohol Use Disorders Identification Test – Consumption (AUDIT-C)[61] is a 3-item screener that assesses whether someone may be engaging in problematic alcohol use. Individuals answer the frequency and volume of alcohol that they

typically drink on a scale from 0 to 4, with higher scores corresponding to greater frequency or volume of consumption. Items are summed for a total score. Individuals who score above the cut-point (>7) will be ineligible for this study.[62]

ii. Measures Used in Both Phase 1 and Phase 2

1. Demographic questionnaire. Participants will complete self-report measures of demographic characteristics, including gender, age, race, ethnicity, marital status, employment status, education, and annual income.
2. Technology Acceptance. Participants will answer 10 questions rating the extent to which they found the MAP to Health intervention easy to use (4 items) and useable (4-items) and their intentions to use the intervention in the future (2 items). Items were based on previous research[53,57] and modified for the purposes of this study. Participants will rate each item on a scale from 1 (strongly disagree) to 5 (strongly agree). Items will be averaged within each subscale (ease of use, useability, and intentions to use).
3. Intervention Fidelity to Theory. The Intervention Fidelity to Theory (IFT) questionnaire is a 14-item questionnaire that assesses the extent to which the MAP to Health intervention adheres to the theoretical foundations of supporting autonomy, competence, and relatedness and prompts meaning salience.[50] Participants rate the extent they agree with each item on a scale from 1 (strongly disagree) to 5 (strongly agree). Items will be averaged within each subscale for a total score.
4. Intervention Acceptability and Feedback. In both phases, participants will be asked to respond to a series of open-ended questions asking about their experiences with the intervention (either the interview alone or the interview plus text messages) and the research process.

iii. Measures Used in Phase 1 Only

1. Text Message Acceptability. Participants will rate each one of a list of generated text messages (up to 14 messages) on whether they are a good fit for them (Yes/No). If participants say "No" to any message, they will be prompted to give feedback on how that message could be improved.

iv. Measures Used in Phase 2 Only

1. Physical Activity History. Physical activity history will be assessed at pre-test to describe the sample. Specifically, participants will be asked to note when they were last physically active, how many times they have stopped being active, and what were the reasons for stopping activity.
2. Meaning Salience. Meaning salience is a primary outcome for Aim 2. The Meaning Awareness Scale (MAS) is a 6-item measure that assesses meaning salience.[63] Participants rate the extent to which they were aware of meaning over the past day (e.g, "I was aware of the meaning in my life" on a 7-point Likert type scale ranging from 1 (*rarely*) to 7 (*very often*). Items are summed for a total score. Participants will complete the MAS on three random days during each of the four assessment periods and total scores will be averaged across those three days.
3. Basic Psychological Needs Satisfaction. Basic needs satisfaction is a primary outcome for Aim 2. The Psychological Needs Satisfaction in Exercise Scale (PNSE)[64] will be used to measure satisfaction of needs of autonomy (e.g., "I feel free to exercise in my own way"), competence (e.g., "I feel confident in my ability to perform exercises that personally challenge me"), and relatedness (e.g., "I feel attached to my exercise companions because they accept me for who I am") in exercise contexts. The PNSE has 18-items that participants rate on a 6-point Likert-type scale ranging from 1 (false) to 6 (true). Items are averaged within and across the subscales for total scores. Previous research has demonstrated that the PNES has strong internal consistency reliability (αs ≥ .90), construct validity, and convergent validity.[64]
4. Internal Motivation. Internal motivation is a primary outcome for Aim 2. Motivation internalization will be measured using the Behavioral Regulations in Exercise Questionnaire, version 4 (BREQ-4).[65-67] The 28-item BREQ-4 assesses motivations for exercise on the SDT continuum. There are 7 subscales with 4 items each: amotivation (e.g., "*I don't see why I should have to exercise.*"); external regulation (e.g., "*I exercise because other people say I should.*"); introjected regulation-avoidance (e.g., *"I feel guilty when I don't exercise."*); introjected regulation – approach (e.g., *"I*

feel proud of myself when I persist."); identified regulation (e.g., *"It's important to me to exercise regularly."*); integrated regulation (e.g., *"I exercise because I value the benefits it gives me."*); and intrinsic motivation (e.g., *"I exercise because it's fun."*). The subscales will be combined using a bifurcation approach[68] and scored into two subscales: autonomous and controlled motivation. Autonomous regulation will be the average of the intrinsic, integrated, and identified scales whereas controlled regulation will be the average of the external and introjected scales. The BREQ-2 has been shown to have good psychometric properties, including good internal consistency (αs range from .78 - .93).[65,67]

5. Mood. Positive and negative mood will be measured using a positive and negative affect scale previously used in a study of daily meaning and daily mood.[27] Eight items will measure positive affect (relaxed, proud, excited, appreciative, enthusiastic, happy, satisfied, and curious) and five items will measure negative affect (sluggish, afraid, sad, anxious, and angry). Participants will rate their mood using a 5-point Likert-type scale ranging from 1 (*very slightly or not at all*) to 5 (*extremely*). Sums of the positive and negative affect scales have been shown to be positively correlated with their respective scales on the Positive and Negative Affect Schedule (PANAS)[69] (*r*= .55 - .57) and to have very high internal consistency (α = .97 - .98). Participants will complete the mood scale on three random days during each of the four assessment periods and total scores will be averaged across those three days. Mood will be a covariate for Aim 2.

6. Psychological Well-Being. Psychological well-being will be assessed as an exploratory outcome. Well-being will be measured using two scales: The Subjective Vitality Scale (SVS)[70] and The Satisfaction with Life Scale (SWLS).[71] The 6-item SVS measures feeling active, alive, enthusiastic, and energetic (e.g., *"I feel alive and vital"*). Participants will rate the extent they generally feel this way on a 7-point Likert-type scale ranging from 1 (*not at all true*) to 7 (*very true*). Items will be summed for a total SVS score. Previous psychometric studies have demonstrated that the SVS correlates positively with other positive measures of well-being (e.g., self-esteem, self-actualization, satisfaction with life) and negatively with poor psychological well-being (e.g., depression, anxiety, psychopathology), and was internally consistent (α = .84-.86).[70] On the SWLS, participants will rate their agreement with five statements on a 7-point Likert scale ranging from 1 (*strongly disagree*) to 7 (*strongly agree*). Responses will be summed so that higher scores correspond with greater satisfaction with life. Diener and colleagues[71] conducted a thorough assessment of the SWLS's reliability and validity. Previous assessments of reliability indicated that this measure is internally consistent (α = .87) and had good two-month temporal stability (*r* = .82). Evidence for construct validity indicates that the SWLS correlated positively with other measures of subjective well-being and negatively correlated with measures of personality psychopathology. Evidence for criterion validity indicates that the measure correlated highly with interviewer's rating of the individual's satisfaction with life.[71]

7. Text Message Acceptability. Participants will rate the extent to which the text messages reflected what they found meaningful to them and their plans for physical activity. They will also report on the acceptability of the timing and frequency of the text messages at the end of the study. Participants will rate the extent to which they agree with each statement on a scale from 1 (strongly disagree) to 5 (strongly agree). Item responses will be analyzed separately.

8. Physical Activity. Participants will be given ActiGraph wGT3X-BT accelerometers[72] to wear over the course of the 12 weeks; data will be automatically uploaded to the cloud (using CentrePoint software). Participants will be asked to wear the accelerometer on their non-dominant wrists during waking hours. Accelerometers will measure total activity counts and minutes of MVPA over a 7-day period at 6-months after the index visit. A valid assessment week will consist of four monitored days (at least one weekend day and three weekdays), each with 10 hours minimum wear time (determined by the best currently available wear-time algorithms.[73] Data will be analyzed in 60-second epochs; epochs with at least 2020 activity counts per minute will be classified as MVPA and summed per week for each participant. The weekly sum of minutes of MVPA will be the primary measure for the exploratory aim. For the purposes of this study, weekly summaries of physical activity (MVPA) at each of the four assessment time points will be used for the main exploratory analyses. Research staff will monitor wear compliance, reaching out to participants after 2 consecutive days of no wear.

f. Statistical Analysis Plan

Aim 1 Analysis. Descriptive statistics will be used to examine the ratings of TAM constructs (perceived ease of use, perceived usefulness, and intention to use) and intervention theory fidelity. Average ratings will be considered sufficient to move to the second phase if the mean reaches the threshold of satisfactory agreement for each construct (i.e., $M \geq 4$ on a 5-point Likert-type scale with 4 corresponding to "Agree").

Aim 2 Analysis. The goal of Aim 2 is to determine whether the intervention satisfactorily impacts the hypothesized theoretical mechanisms. As an exploratory outcome, we will also assess PA. Participant ratings of meaning salience (average of 3 measures across the week), basic psychological needs satisfaction, and internal motivation will each be compared across four time points (weeks -4, 0, 4, 8) using multilevel linear modeling with time points nested within participants to control for repeated measures variance. A fixed time effect will estimate participant ratings at each time point relative to baseline, and a series of linear contrasts will test our hypotheses about the pattern of change in ratings over time. Without intervention, we do not expect to see change in hypothesized mechanisms so that a week -4 vs. week 0 contrast will be close to zero. Following intervention implementation, however, we expect participants to report increases in the theoretical mechanisms so that contrasts comparing weeks 4 and 8 to baseline will each be positive. Furthermore, we expect to see the greatest change in the first 4 weeks post-intervention so that a week 8 vs. week 4 contrast will be close to zero.

Exploratory Aim Analysis. In exploratory analyses, we will use this same approach as Aim 2 to examine changes in PA and whether the hypothesized mechanisms are related to PA over time (i.e., pre-intervention, early intervention, and late intervention stages). First, we will examine whether the difference in PA slope during the active intervention phase (week 0 to week 8) is significantly greater than the change observed during the pre-intervention phase. Additionally, we will examine whether changes in hypothesized mechanisms (meaning salience, needs satisfaction, and internal motivation) from week 0 to week 4 are associated with changes in PA from week 0 to week 8 using growth curve modeling. Although this pilot study will not be powered to determine statistical significance, the effect sizes will be calculated to assess the extent to which the intervention is impacting the hypothesized mechanisms.

g. Power analysis

Aim 2 Power. In this pilot, the aim is not to determine statistical significance but rather to assess whether MAP to Health is likely to increase the hypothesized mediators enough to elicit meaningful change in PA (Cohen's $d \geq 0.30$). Based on our previous observational study,[52] the strength of the observed relationships in Figure 1 are expected to be $\beta = .55$ (needs satisfaction to internal motivation), $\beta = .30$ (internal motivation to PA), $\beta = .16$ (needs satisfaction to meaning salience), and $\beta = .10$ (meaning salience to PA). Therefore, if half of the total intervention effect ($d = .30/2 = .15$) is mediated through the pathways in Figure 1, then the intervention will need to increase both needs satisfaction (estimated $\beta = .50$) and meaning salience (estimated $\beta = .60$) by $d > 0.55$. The remaining $d \approx 0.15$ of the total effect would be represented as a direct effect on PA and could be obtained at least in part via unmeasured mediators. If the week -4 vs. week 0 comparison yields a difference of approximately 0, the week 4 vs. week 0 comparison is similar in power to a paired *t*-test. A paired *t*-test with a sample size of $N = 35$ is powered (0.80, $\alpha = 0.05$) to detect differences of $d \geq 0.49$. As such, the planned analyses may be sufficiently powered to detect meaningful within-person changes in the hypothesized mediators.

h. Strengths and Limitations

This study has several strengths, including building off a previously developed prototype intervention that used a psychometric approach to intervention development (COMAP), using a systematic approach to developing and testing the intervention (using the ORBIT and SOBC models), and building off a solid base of observational and interventional research based on SDT and meaning. Further, we have a strong interdisciplinary team with the resources to carry out the proposed work.

The study is designed as a proof-of-concept pilot trial. Participants will serve as their own controls instead of being compared to a no-intervention control group and our sample size is small. These design choices were made to ensure the intervention was related to changes in the hypothesized

mechanisms; however, we will be limited in our abilities to state that the intervention was related to changes in physical activity.

There are two potential biases that we will be sure to address during the project. First, in longitudinal studies, there is always data loss due to participants not completing assessments. To reduce data loss, we will use multiple reminders to encourage participants to complete follow-up assessments (up to 3 reminders per assessment). Further, we will provide compensation for participants to complete each of the assessments to encourage continued participation. Finally, multilevel modeling allows for use of all available data, so participants will not be completely dropped from analysis if they miss any of the assessments.

Second, objectively measured PA using accelerometers has the advantage over self-report PA in reducing measurement bias.[74] However, it also requires that participants' wear the devices and can be subject to data loss due to hardware malfunction. Participants will be encouraged to wear devices on their wrist during daytime hours and data will be uploaded to a cloud-based data management system. Research staff will call participants and remind them to wear or charge the device if needed.

6. Setting/Environment/Organizational feasibility

This study will be conducted at HealthPartners Institute (HPI). HPI is a particularly appropriate setting because we have the research infrastructure and staffing capacity to build the MAP to Health intervention (SET team), serve hundreds of thousands of midlife adults who may benefit from this intervention in care group and health plans, and have experience designing and evaluating technological innovations. During the development of this proposal, we sought the support of the health plan's Health Promotion department (Joel Spoonheim, leader) in the potential of integrating MAP to Health in the Be Well offerings should it be funded. We will continue to engage the Health Promotion team to ensure we are developing an intervention that will fit with their product offerings.

7. Risks and Benefits

a. Potential Risks

In terms of procedures, measurements, and data collection methods, this is a low risk study. Many adults attempt to start physical activity programs on their own every year; this study would not impose a specific plan or program for activity but would rather capitalize on participants' motivation to change and encourage free choice of activities. As with any physical activity, there is a slight risk that participants could get injured during the study. A second risk is the risk of loss of confidentiality. HealthPartners Institute has procedures to ensure that confidentiality will always be protected and that potential risks are systematically minimized.

b. Potential Benefits

There are no direct benefits to participating in this research study to the participant. As a result of participating in the proof-of-concept trial, some participants may increase physical activity, which has been shown to have many health benefits. The major benefit of this study is the knowledge gained about how the intervention impacts the hypothesized mechanisms of behavior change and physical activity.

c. Protection Against Risks

To reduce risks of injuries as a result of engaging in physical activity, we will encourage participants to engage in activities that are consistent with their current levels of physical fitness and to rest when needed.

To reduce the risk of breach of confidentiality, we will access and employ only the minimally necessary EHR data to identify and screen potentially eligible participants and to contact them for recruitment. We will maintain the confidentiality of all study data by assigning an arbitrary and unique subject identification number to each participant. We will maintain study data on computerized databases on username- and password-protected file servers at HPI to which only staff and researchers involved in the study will have access. No participant data will be individually identified or released to anyone other than the study investigators without specific written permission from the study participant. All procedures will be reviewed in advance, approved, and monitored on an ongoing basis by the HealthPartners IRB.

8. Data Confidentiality and Privacy

The study team has extensive experience in health services research and clinical research with human subjects, with procedures to safeguard privacy and personal information. Data will be retained in secure storage following the completion of the study in accordance with Minnesota and federal law. We guard against the potential for breach of subject confidentiality through a multi-layered system of data protection policies, processes, staff training, software safeguards and physical security measures for both paper and electronic data involved in research.

The following measures will be taken to protect subjects from the risk of breach of confidentiality:

1. All data collected in the study will be identified by using an arbitrary and unique study ID number to each patient.
2. A file containing a link between the study ID and individually identifying information will be maintained by a study team programmer.
3. A crosswalk table linking the study ID to a patient identity will be destroyed within 6 months after the linked databases needed to complete study analyses are completed.
4. All electronic study data will be maintained in a computerized database residing on a username- and password-protected fileserver to which only the study team members will have access.
5. All study-related paper documents containing individually identifiable information will be maintained in locked file cabinets.

To protect the confidentiality of any clinic or organization employee participating in a survey, we will not allow anyone outside of the research team to know the identity of those respondents. All of the protection to electronic data sources, described above, also apply to survey collection.

9. Timeline: Key Milestones

Phase 1: Development
Oct – Dec 2021: *Intervention Development*
Finalize MAP to Health online assessment Develop text messages Develop outcome surveys Determine process for ActiGraph delivery & set up and monitoring
Oct 2021 – Jan 2022: *Programming*
Programming for MAP to Health online assessment Build REDCap survey for usability testing Build CESR Recruitment REDCap Develop modality for sending surveys
Feb – Apr 2022: *Recruitment & Usability testing*

Phase 2: Proof-of-Concept Trial
Feb – Apr 2022: *Intervention Modifications*
Revise text messages Revise MAP to Health online assessment Revise survey measures
Feb – Jun 2022: *Programming*
Updates and modifications
Jun – Nov 2022: *Intervention Delivery*
Recruitment (rolling) Participant Outreach (start up and reminders)

Survey Data Collection ActiGraph data collection (using CentrePoint cloud-based software)

Analysis & Dissemination
Dec 2022 – May 2023 Data preparation & cleaning Data analysis Manuscript preparation

10. Dissemination/Sharing Results/Integration and Impact

A. Reporting on ClinicalTrials.gov

Upon funding, we will register our study protocol with ClinicalTrials.gov in accordance with NIH policy no later than 21 calendar days after enrollment of the first participant. We will enter study results no later than one year after the trial's primary completion date. All participant consent forms will include specific language indicating that the study information will be registered with ClinicalTrials.gov, including the final results. The HealthPartners Institute, as part of internal policy and in compliance with federal regulations, registers all of its clinical trials on ClinicalTrials.gov.

B. Disseminating and implementing the results of this research in other settings

Regular physical activity is a key behavior for healthy aging and wellbeing. In the Healthy People 2030 goals, physical activity was named a leading health indicator, and increasing the proportion of adults who are engaging in physical activity is a core objective. Despite significant efforts to increase the proportion of physically active adults, the high rates of insufficient physical activity have not improved. MAP to Health is a resource-sparing, theory-based intervention for encouraging regular physical activity. The intervention harnesses a person's personal sense of meaning in life to increase internal motivation to engage in regular physical activity, with the goal of increasing the likelihood that physical activity will become a part of that person's regular routine. The proposed study will further develop and provide proof-of-concept testing for the intervention; if successful, we will seek additional funding for a Phase III efficacy trial to compare MAP to Health to a physical activity reminder intervention.

To ensure that the intervention can be easily disseminated within our system, we will work closely with the HealthPartners Health Promotion department, who maintains and offers several digital health promotion products to HealthPartners insurance members. We will meet with their development team prior to, during, and after intervention development to make sure the product we develop could be integrated within their health promotion package.

Because MAP to Health is an entirely digital product, it has the potential to be widely disseminated and offered to individuals across the country. There is no staffing requirement beyond regular maintenance of the digital tools. We will be open to discussing implementation of the intervention in other health systems and health plans as part of their health promotion packages. We posit that taking a systematic approach to behavioral intervention development will increase the probability of intervention success and will facilitate the likelihood that the final product will be useful to adults attempting to increase their physical activity.

Beyond these considerations, we will also promote dissemination by communicating results of this study in many ways, including through publications in peer-reviewed professional journals, communications in lay and professional media, and presentations to patients, clinicians, and health care leaders. In addition, we are willing to engage in any dissemination activities that may be suggested by the funding agency during or after the project period.

Our preliminary communication strategy for dissemination includes the following components:

- Communicate findings internally to leaders of the HealthPartners medical group and HealthPartners insurance plan
- Communicate findings to other health systems that collaborate with HealthPartners on research and care improvement initiatives (e.g., Health Care Systems Research Network)

- Publish study methods and results in peer-reviewed journals
- Present findings at scientific and professional meetings

The research team will evaluate the success of the dissemination plan iteratively in a long-term partnership with NIH, end users, dissemination partners, and stakeholders.

C. Disseminating study results to study participants after completion of analyses

Participants who are interested in learning the results of the study will indicate so on their baseline study questionnaire. Our team will develop a one-page description of the results of the study in lay language, with information about study publications, that will be distributed to participants in their preferred mode (e.g., via email or mail). We will work closely with the HealthPartners Communications team to include information about study results in HealthPartners publications that are sent to staff, physicians, patients, and members.

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Appendix A: Phase 1 recruitment materials

MAP to Health Phase 1 recruitment letter v1.0

MAP to Health Phase 1 recruitment email to HPI employees v1.0

MAP to Health Phase 1 phone scripts v1.0

Screening Questionnaire v1.0

Screening Questionnaire_HPI employees v1.0

MAP to Health Phase 1 FAQs v1.0

MAP to Health Phase 1 confirmation and reminder emails v1.0

MAP to Health Phase 1 e-consent v1.0

MAP to Health Phase 1 thank you message

Appendix B: Phase 1 Intervention Tools

Map to Health online assessment v1.0

Map to Health example messages

Appendix C: Survey Measures

Phase 1 Measures v1.0

Phase 2 Measures v1.0

Appendix D: Phase 2 recruitment materials

Phase 2 Activities and Incentives Schedule v1.0

Consent to Participate in a Research Study

Title of Study: Development and Proof-of-Concept Trial

of a Meaning and Theory-Based Physical Activity Intervention

"MAP to Health"

We are inviting you to take to be part of a research study. We have developed an online program called "MAP to Health," which is designed to help people be more physically active. The program takes place over 12-weeks during which you will be asked to track your physical activity, complete online survey measures, participate in the MAP to Health program (including the initial assessment, weekly scheduling of activities, and receive text messages) and provide feedback on study activities.

Please review the information below and ask any questions before you decide if you want to participate.

Why is this study being done?

Physical activity has many benefits, including reducing the risks for certain medical conditions, improved mental health and well-being, and living longer. However, many adults are unable to regularly meet the recommended activity of 150 minutes per week. This study aims to support people who want to increase their physical activity by offering an online program to enhance motivation, assist with planning, and offer encouraging text message reminders.

What will I be asked to do?

If you choose to participate in this study, you will be asked to complete the following activities:

- Complete online survey measures 4 times (every 4 weeks). These surveys should take between 15-30 minutes. During each of these 4 weeks, you will also be asked to do short surveys on your mood 3 times (12 short surveys total; < 5 minutes each).

- Wear an accelerometer to track your activity for the duration of the study. As part of this, we will have you download an app on your phone to sync the accelerometer to the database. You will be asked to regularly charge and sync the accelerometer.

- After 4 weeks, you will start the MAP to Health program. As part of this program, you will:
    - Complete the **MAP to Health online assessment**. This assessment takes 20-30 minutes. In this assessment, you'll be asked questions about the types of physical activity you enjoy and the things you find meaningful in your life.
    - Schedule physical activities each week (8 weeks total) using the **activity scheduler**. This should take about 5-10 minutes a week.
    - Receive **personalized text messages** designed to increase your motivation for activity. These messages are based on your initial assessment and scheduled at times based on your activity calendar. Text messaging rates may apply.

- After finishing the intervention, provide feedback on your study experience in an exit interview. This interview will be 15-20 minutes long.

You will be eligible to receive up to $250 for your participation. The total you receive depends on how many study activities you complete.

Can being in this study help me?

Physical activity has many known benefits, including improving energy and mood, reducing risks for chronic diseases, and helping people live longer. The aim of this program being tested in this study is to increase physical activity among participants. However, these benefits are not guaranteed as part of your participation. This study will help us learn if this program could be helpful for future participants.

What are the risks?

There are minimal risks to participating in this study. There is a risk of injury as individuals participate in exercise. However, you will not be asked to participate in any specific exercise activities as part of this research study. You may also feel some fatigue from completing the online assessment and study measures. However, you can do them at your own pace and take breaks if needed.

How is my information protected?
Survey responses will be stored on a secure web server with access limited to study staff. The following groups may inspect these records: National Institutes of Health, the HealthPartners Institutional Review Board, the United States Food and Drug Administration (FDA), or other applicable regulatory authorities.

Any information that can identify you will be removed before analysis. The results of the study may be published. Your name or other personal information will **never** be used.

Do I have to participate?
Your participation is voluntary. Your decision whether or not to participate will not affect your regular medical care or health care benefits in any way. At any point if you decide that you do not want to participate, please call 952-967-5389.

What if I have questions or problems?
The researcher ("Principal Investigator") conducting this study is Stephanie Hooker, PhD, MPH. You may ask any questions you have by contacting her at 952-967-5056 or emailing Stephanie.A.Hooker@HealthPartners.Com.

If you have questions about your rights as a research participant, you may contact the HealthPartners Institutional Review Board (IRB) via phone at 952-967-5025 or by mail at 8170 33rd Avenue South, Mail Stop 21112R, Bloomington, MN 55440-1524. Refer to study A20-287.

Statement of Consent:

I have read the consent form and I understand:

- What I am being asked to do, and

- The risks and benefits of participating in this research

I understand that clicking the "submit" button indicates:

- I have read this consent form,
- I have no outstanding questions, and
- I am agreeing to participate.

You may print or retain a copy of this consent for your records.

☐ I consent. [Skip to End of Survey if not checked]

☐ (Optional) I would like to receive a copy of the study results when the study is complete.