Northwell Health

RESEARCH PROTOCOL

Protocol Title:	A Randomized, Controlled Trial to Test Behavior Change techniques (BCTs) to Improve Low Intensity Physical Activity in Older Adults.
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IRB Number:	20-1166

Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
- Do not use this template if:
  - Your study involves an FDA regulated product. In this case, use the *Clinical Trial Protocol Template.*
  - Your study has a protocol from a sponsor or cooperative group. In this case, use the *Protocol Plus*.
  - Your study is a registry or repository for data and/or samples, In this case, use *Protocol Template – Registry Studies.* .
- If a section of this protocol is not applicable, please indicate such.
- Do not delete any of the text contained within this document.
- Please make sure to keep an electronic copy of this document. You will need to use it, if you make modifications in the future.
- Start by entering study information into the table above, according to these rules:
  - Protocol Title: Include the full protocol title as listed on the application.
  - Investigator: include the principal investigator's name as listed on the application form
  - Date Revised: Indicate the date at which the protocol was last revised
  - IRB Number: Indicate the assigned IRB number, when known. At initial submission, this row will be left blank.
- Once the table information in entered, proceed to page 2 and complete the rest of the form.

↓ Continue to next page to begin entering information about this study ↓

1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain:

2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in **language intelligible to a moderately educated, non-scientific layperson**.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

The purpose of this pilot study is to determine the feasibility of using N-of-1 methods in a virtual research study with Northwell employees aged 45-75 years old to increase low-intensity walking by 2,000 steps per day/5 days per week using four behavior change techniques, provided in random order, and shown to have been effective in changing physical activity. This pilot will help determine if a Personalized Trial design can have widespread use in future research and clinical practice.

In preliminary phases, participants, via secure surveys delivered electronically and/or via interactive Microsoft Teams meeting(s) for focus groups and/or 1:1interviews, will finalize the content and design features used to deliver the study messaging.

Up to 60 participants will provide feedback on key aspects of study design, including BCT description, materials and electronic delivery methods, such as text messaging and email receipt. Focus group techniques, interviews and/or surveys may be used to elicit feedback concerning the clarity of instructions and convenience of messaging. At least 10 of these participants will engage with study materials and procedures as "mock participants," interacting remotely from their home or office, and providing feedback about the ease and acceptability of study procedures to further refine study materials and procedures. In the final, intervention phase of the study, up to 60 participants will be randomized to the 10 week personalized trial assessing the impact of 4 BCTs assigned in random order on their walking behavior.

Participants will be sent a Fitbit physical activity monitor that will track the number of steps taken per day. Depending upon the BCT assigned, the participant will

receive up to four text message prompts per day. They will complete a measure of self-efficacy (i.e. confidence in their ability to walk without stopping) and a 'satisfaction with BCT' survey once every two weeks. At the end of their trial, participants will receive a satisfaction survey and a summary of their observed data to help them learn more about their responses to the four behavioral change techniques and to inform investigators as to the feasibility of N-of-1 study design for future research and clinical applications.

3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

This study is a pilot project under the umbrella of the NIH-funded grant "Roybal Center for Personalized Trials: Physical Activity Promotion to Foster Healthy Aging." (Northwell IRB 20-0355) which is funded to test exercise promotion use cases appropriate for N-of-1 methodology and evaluate them for acceptability and scalability.

The overarching objective of our parent grant is to develop, test, and implement an innovative technology platform for conducting personalized trials that transforms precision therapeutics for exercise promotion in older adults. Right now, clinicians are engaging in clinical encounters in which they are trying to determine the best therapy for individual patients. Clinicians rely on the best available evidence (e.g., results from parallel group, phase III randomized clinical trials; RCTs) for recommending therapies to a patient. Yet, conventional, between-group RCTs only provide estimates of the effect of therapies on the hypothetical 'average' patient in those trials. Individual patients, however, often respond differently than the hypothetical average patient in the phase III RCTs, and thus, heterogeneity of therapy response plagues clinical decisions made for an individual patient every day.

Personalized trial designs provide a method for tailoring interventions to individual patients and then evaluating the efficacy of these interventions. In many ways, **Personalized Trials are the foundational design for a truly patient-centered approach by serving as a clinical decision tool for patients.** Historically, in introducing evidence-based medicine, Guyatt and others have described Personalized Trials as the pinnacle of the evidence-based design pyramid. Personalized Trials are specifically designed to help patients and their clinicians make healthcare decisions that are informed by high-integrity, evidence-based information uniquely relevant to the outcomes and values important to them.

Yet, clinicians and patients do not routinely engage in this type of scientific endeavor because they lack the tools and resources to implement efficiently. In post-mortem assessments as to why Personalized Trials had yet to become commonly employed, proponents concluded that they were insufficiently appealing to patients or clinicians to justify the cost and effort needed to design and implement them. Specifically, Personalized Trial design specifications had mostly been driven by clinicians or researchers with little input from patients.

Rationale for Selecting Four Behavioral Change Interventions as a Personalized Trial for Increasing Low Intensity Physical Activity in Older Adults

Guidelines and recommendations focus on increasing physical activity for older adults, but adherence to recommendations remains low. This is despite the fact that any increase in physical activity is associated with benefit (LIFE trial). Increasing physical activity meets all of our criteria for selection as a use case as outlined in our umbrella grant: it has high public health burden, high heterogeneity of therapy response, and is high priority for a Personalized Trial approach as determined by previously interviewed clinicians and patients. This instance will adapt our personalized, virtual trial platform to testing the efficacy of four behavioral change techniques consistent with theory (Lally & Gardner, 2013) and randomized clinical trials (Lally et al., 2010). This pilot test will enable us to expand our personalized, virtual trial platform of behavioral interventions. Of note, it is possible that personalized trials of behavioral change techniques could eventually be conducted at the direct-to-consumer level.

Without development of innovative platforms for conducting Personalized Trials, with within-participant randomization to eligible wellness management options, patients and clinicians cannot obtain the objective data they need to empirically choose the optimal precise therapy. Scientists may be able to use Personalized trials to better understand the uniqueness of responders versus non-responders. Should this study demonstrate scalable implementation, acceptability and satisfaction with this methodology amongst participants, it will be a critical step in broadening the application and utilization of this methodology to promote wellness behaviors.

4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

The specific aims of the study include:
-Eliciting and incorporating participant feedback in the development of required content and study procedures for implementation of a personalized, virtual

interventional trial to enhance low-intensity walking using behavioral change techniques
-Determine the feasibility of conducting a virtual, randomized control trial using participant selected behavioral change techniques
-Examine the novel individual-level heterogeneity of treatment effect made possible by the crossover, personalized trial design, and pool results across patients to efficiently estimate the overall efficacy of the four behavioral change techniques in increasing low-intensity walking by 2,000 steps, 5 days per week.
-Assess the relationship between individual behavior change techniques and walking self-efficacy.
-Elicit participant attitudes and opinions toward using Personalized Trials to help inform their personal wellness strategy

5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

Northwell Health employs over 72,000 employees, a vast number of whom are between the ages of 45-75 years. As an organization committed to the promotion of wellness as a means of decreasing disease and disability, our colleagues in both the Employee Wellness Department and Occupational Health Services have agreed to support promotion of this study. Northwell social media groups and electronic communications remain a rich resource for research participant recruitment. Our team has demonstrated exceptional success in virtual, personalized trial recruitment using these employee recruitment pathways, and boasts high levels of participant satisfaction with virtual participation in personalized trials.

All study personnel are fully trained in Human Subjects Protections and HIPAA/Privacy protections. All engaged staff members are listed on the IRB and compliant with trainings and attestations as required by the Northwell Health Human Research Protection Program. Additionally, staff will be required to participate in weekly meetings with the Principal Investigator, and an additional weekly meeting with the Project Manager, in order to stay informed about the study protocol, staff duties and functions, and to answer any questions that come up within the group. Staff will have daily access to the Project Manager, Director of Clinical Research, and Principal Investigator to answer any protocol questions they may have outside these established weekly meetings.

6. RECRUITMENT METHODS

- *Describe the source of potential subjects*

- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

Since the proposed study will take place virtually, potential participants may be recruited from any Northwell facility.

Potential participants may be recruited via the following avenues:
-Email advertisement through employee communication channels, within the Northwell Health network.
-E-mail advertisements through existing email lists from those who previously expressed an interest in participation in a Personalized Trial with the Center for Personalized Health
-Flyers, shared within the Northwell Health network.
-Northwell Health employee social media (Facebook) site.

Potential participants will be Northwell Health employees who are community-residing, 45-75 years old, healthy, report that they walk regularly without health/safety issues, and express an interest in participating in a Personalized Trial to increase their walking by a minimum of 2000 steps five to seven days each week. Study activities are divided into phases. Participants in the first four preliminary phases (non-interventional) will receive 5,000 points credited to their "Northwell My Recognition" account. In the 5th or intervention phase, involving ten weeks of study participation, participants will receive a pay card valued at $100 for completing all study requirements. Additionally, they will be able to keep their Fitbit valued at $150.

7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*
- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

Inclusion Criteria: Northwell Health employee
-At least 45 years of age

-Able to speak and comprehend English
-Community dwelling
-Report they are in good general health, walk regularly and have never been informed by a clinician that it was not advisable/safe to participate in a low intensity walking program
-Owns and can regularly access a smartphone capable of receiving text messages
-Owns and can regularly access an email account

Exclusion Criteria:
-Not employed by Northwell Health
-Less than 45 years of age or greater than 75 years of age
-Unable to speak/comprehend English
-Have self-reported poor health, limited mobility and/or have been advised by a clinician not to increase their low-intensity walking
-Pregnancy
-Previous diagnosis of a serious mental health condition or psychiatric disorder such as bipolar disorder

8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

We expect to pre-screen and enroll up to 180 potential participants in this study. Up to 60 participants will be recruited across the four preliminary (brief duration) phases. Up to 60 participants will be randomized to the 10 week personalized trial, first undergoing a 2 week baseline monitoring of their walking behavior, followed by 8 weeks of monitoring their walking in response to each of the four behavioral change techniques (2 weeks per technique).

9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

The initial phases of study participation will involve either a single session via a virtual interaction (electronic meeting, 1:1 interview or electronic correspondence) or remote evaluation of study message content and frequency over the course of five days The last study phase will involve a total of 10 weeks of study participation: activity tracking using a Fitbit activity monitor for 10 weeks, and

responding to behavior change strategy prompts and surveys delivered via text message to a secure link for 8 weeks. At the end of the 10 week intervention period, a report containing the individual's responsiveness to each BCT will be sent to the participant, along with a satisfaction survey.

10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

This study is a feasibility pilot whose primary objective is to assess the acceptability, scalability of implementation and participant satisfaction with a personalized trial methodology using behavior change techniques to promote low-intensity physical activity. Secondary endpoints include pooling personalized trial results to assess efficacy of BCTs utilized to promote walking behavior.

11. PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*
- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

Potential participants will self-identify as Northwell employees who are 45-75 years of age, community-dwelling, are in good general health, report walking regularly, and have never been advised by a clinician that it is unsafe/not advisable for them to increase low-intensity walking, and are interested in increasing their low-intensity walking by a minimum of 2000 steps 5 out of 7 days each week. Those who are interested in participating in this pilot study will be directed to an initial screening survey that includes questions pertaining to inclusion and exclusion criteria. Those who are determined to be eligible will receive a secure message with a link to an electronic participant information sheet (preliminary study phases) or the electronic informed consent form (Personalized Trial participants). Before being able to sign and submit the consent form, potential personalized trial participants must demonstrate understanding of the protocol by correctly answering 4 questions pertaining to the information presented in the consent form. Contact information (name, age, Northwell email, cell phone number and service provider) will be obtained from all consented participants.

In the four preliminary phases (with up to 10 participants each in phase 1,3, 4 and up to 30 participants in Phase 2), virtual focus groups and/or 1:1 discussions will be held to answer questions and elicit feedback about the comprehensibility of behavior change strategy descriptions, special study website content and videos, the ability to receive "sample" study messages in home and work settings, the virtual informed consent process, and study tools with attention toward for clarity and ease of use.

Potential participants for the Personalized Trial Participants will be sent a secure message with the start date of their baseline period, as well as a review of what to expect during onboarding to the study. They will be mailed an initial study kit including a Fitbit device. A PDF copy of their electronically signed consent form will be made available to all participants via N1Thrive/REDCap secure messaging. Potential participants will be asked to download the Fitbit app to their smart phone. No more than 20 participants will be permitted to begin on the same day.

The baseline period will take place over the course of two weeks. During the baseline period, potential participants will be asked to wear their Fitbit for 10 ours per day and also while they are sleeping, as tolerated and to acknowledge receipt of a daily text message that is not an activity prompt. Baseline participants will be instructed to sync their Fitbit device by opening the Fitbit app on their phone at least every two days.

Individual adherence to Fitbit wear and to survey responses will be assessed in order to determine which individuals progress to intervention. Adherence to Fitbit wear will be defined as recorded activity of greater than 10 hours a day. Text message adherence will be defined as responding to a given text message. Baseline participants that do not achieve at least 80% adherence of Fitbit wear and text responsiveness the baseline period will be withdrawn from the study. Those that maintain at least 80% adherence will be randomized to one of their selected behavior change techniques to begin their pilot personalized trial. Participants who are randomized to receive intervention sequences will receive email confirmation including their protocol timeline. Enrollment will continue until up to 60 participants have been randomized.

Intervention Delivery

This pilot study will use text messages to deliver four behavioral change techniques identified in Michie et al.'s (2011) paper which identified those BCTs associated with influencing change in physical activity behavior. These BCTs were updated to align with current BCT definitions using Michie et al.'s (2013) Taxonomy of Behavioral Change Techniques. A list of BCTs is provided as an appendix to this protocol. Participants will also receive bi-weekly surveys to assess their satisfaction with the given BCT and walking self-efficacy. BCTs will be provided to participants in a randomized crossover design with each BCT delivered individually in one of four 2-week blocks. The order in which participants receive BCTs will be randomized with the randomization order determined by the study

statistician. Prior to BCT delivery (i.e. every two weeks) participants will be sent information/BCT descriptions the day before they start their new BCT so that they understand the differences between the four BCTs for their personalized trial. For instance, BCT descriptions may include:

BCT Name	Definition	Sample Text Message Prompt
Goal Setting Behavior	Set or agree on a goal defined in terms of behavior to be achieved	*Set the goal of being more active today. Record your goal*
Action Planning	Prompt detailed planning of performance of behavior (must include a setting frequency, duration, and intensity)	*"It's Tuesday. Walk 2,000 steps from 10am -11am this morning."*
Self-Monitoring of Behavior	Establish a method for person to monitor and record their number of active periods based on their Fitbit	*"It's time to check your FitBit dashboard and view how active you have been today."*
Feedback on Behavior	Monitor and provide informative or evaluative feedback on performance of the behavior (e.g. form, frequency, duration, intensity)	*"You met your goal yesterday. You walked 2,000 steps more than baseline."*

Participants may receive additional text messages to those outlined above with important reminders to sync their data as needed.

Upon completion, participants in the personalized trials phase will receive an individual report that demonstrates their walking responses in relation to their assigned BCTs and a satisfaction survey to obtain feedback about their personalized trials experience.

12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

The sample size of 60 participants for testing the Personalized Trial was chosen to have a sufficient number of participants to obtain a preliminary assessment of the feasibility of Personalized Trials of the four behavioral change techniques as

compared to baseline. The numbers of prompts and reports were based on expert recommendations and estimations about maximal duration of the trial to maintain patient engagement. Data will be reported transparently so that individual level heterogeneity can be assessed.

Means and standard deviations of step scores for baseline versus behavioral change strategy treatment period will be visualized using a column graph. The statistical significance of differences will be adjusted for time interval. The effects of treatment on number of steps will be assessed using generalized estimating equations (GEE) with an unstructured variance-covariance matrix for measures on the same day. This model accounts for possible autocorrelation and linear trends between steps across time.
Data from the four small sample preliminary phases will be considered as descriptive data/information and will not be statistically analyzed.

13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

N/A

14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*
  - *Who will have access to the data?*
  - *Who is responsible for receipt or transmission of data and specimens?*
- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

Data management in this study varies according to phase of study participation. Individuals who are participating in preliminary study phases will engage with the study team through secure Northwell emails via Northwell's Office 365 Microsoft Teams application or by phone. Email communication and documentation of feedback shared during Teams meetings will be retained in a Sharepoint folder on the Northwell network, accessible only to IRB approved study personnel.

Electronic informed consent and demographic information will be retained in the study database (N1Thrive/REDCap).

Fitbit

This pilot study uses Fitbit devices to remotely monitor participant activity and sleep. All enrolled participants will be provided with a study account that has been created by the research team with no identifying information to the participant. The email address of the study account contains a unique identifier (e.g. northwellf25). Data collected by the activity monitor may include daily steps, floors climbed, activity intensity, heart rate, sleep duration, and estimated minutes in sleep stages. A file linking the Fitbit identifier to the study participant will be housed in a Northwell-approved drive to store PHI, and be accessible only by members of the study team listed in the IRB application. Coded data from Fitbit will remain stored in a Northwell-approved drive indefinitely, but the file linking the Fitbit identifier to the study participant will be destroyed upon completion of an individual's participation with the study.

Fitabase

The Personalized Trial Study will use Fitabase to retrieve Fitbit data from participant activity tracking devices. Fitabase is a secure, online portal. The Fitbit study account provided to the participants will be linked to an identification number in the Fitabase system (e.g. FLT01). No information that could be used to identify a participant will be stored on Fitabase. Only the research team will have access to data that will be able to connect a research participant to their Fitabase ID. Data collected may include last sync date, battery charge status, daily steps, floors climbed, activity intensity, heart rate, sleep duration, and estimated minutes in sleep stages. Fitabase will stop tracking participant data at the trial end date selected by the research coordinator. As an added measure, participants will be instructed to remove the Fitbit study account from their device if they plan to keep the Fitbit.

Personalized Trial Consent, Fitbit data, Study Messages and Surveys

This study will utilize a technology platform to support the delivery of Personalized Trials. To achieve this goal, we are partnering with a company called N-1 Thrive, a Northwell approved system for collecting and storing research data, including PHI that was formed specifically for the development of technology to support Personalized Trial methodology. Informed consent, study messages and surveys (BCT & satisfaction surveys) will be delivered via a text-message link to a secure, HIPAA compliant web browser through N-1 Thrive/REDCap. In addition, the Personalized Trial portion of the study will use N1Thrive to retrieve Fitbit data from participant activity tracking devices. Coded data using unique generic participant IDs will be shared with 4Peacocks in order to assist with analyzing the individual reports and to pool of N-of-1 results across all projects using the N1Thrive platform. This analysis will be done by unique identifier. Coded reports will be given back to the study team, who will identify the document before

sending to the participant via encrypted email. Pooled N-of-1 results will be used to assess gaps in phenotypic understanding to empirically determine if modeling precise therapy is feasible.

The study team takes data confidentiality very seriously. The participant will be made aware of all data collected and the companies/technology employed to collect the data via the consent process. All data will be maintained on a Northwell-approved drive to store PHI. Data collected for this study will be maintained in its original and unaltered source data state in a Northwell-approved SQL database on a Northwell-approved drive to store PHI indefinitely. Data collected under this research may be used for future research in coded format without additional consent as per the consent form participants sign and with appropriate IRB approval as required. Any additional data that must be shared will be done so according to the consent form participants signed. Only research staff listed within this IRB submission will have access to identifiable information. Anonymized data may be stored indefinitely for reference following the conclusion of the study. All members of the research team with access to directly identifiable data will be trained and included on the IRB submission for approval. Regular meetings will take place with the PI and other members of the study team to ensure protocol adherence and data accuracy.

15. DATA AND SAFETY MONITORING PLAN

A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the Guidance Document *on the HRPP website.*

Part I – this part should be completed for all studies that require a DSMP.
Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*
- *Where applicable, describe rules which will guide interruption or alteration of the study design.*
- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*

- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

Given that study activities involve no more than risks encountered in daily life (increased time spent walking by healthy, working individuals), the study has received approval from the NIA for a safety monitor. Dr. Zenobia Brown has been approved to provide safety monitoring for this pilot. Dr. Brown is a family medicine clinician and oversees Northwell's Health Solutions programs.

Although it is not anticipated that increased low-intensity walking by healthy employees poses greater risk than daily life, participants will be advised to report any potential adverse events such as increased fatigue or muscle soreness related to increased walking. Dr. Brown will be immediately informed of any serious adverse events along with the study PI. Events will be reported to the IRB according to local policy and NIA as indicated. Additionally, Dr. Brown will review participation and attrition from the personalized trial on a monthly basis.

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

Given that study activities involve no more than risks encountered in daily life (increased time spent walking by healthy, working individuals), the study has not convened a DSMB.

16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

Concern for withdrawal of study participants is likely only relevant to participants engaged in the 10-week personalized trial. Circumstances under which participants will be withdrawn from the research without their consent include failure to maintain protocol adherence, repeated failure to respond to text prompts or self-reported adverse side effects of increased walking. A participant will not be randomized to receive the (8-week) intervention protocol until he/she has demonstrated at least 80% adherence to Fitbit monitoring (activity recorded at least 10 hours/day during the two-week baseline period of the personalized trial.

Participants will be notified in the informed consent of the possibility of being removed from the study before the 8-week intervention period due to adherence issues.

Participants who fail to maintain protocol adherence or who deviate from the protocol will be contacted by a member of the study team with a reminder of the study protocol, and warning that this may impact their continued study eligibility. Once a protocol deviation has been repeatedly recorded, the Principal Investigator will determine the participant's continued eligibility in the study, with consultation of the safety monitor if needed. If it is determined that the participant will be withdrawn from the study, the participant will be notified by the research team via email and phone call. The participant will stop receiving notifications and BCT prompts, and will be sent instructions to un-link their Fitbit device. Participants who are withdrawn due to low adherence during the intervention portion will be able to keep their Fitbit.

Should a participant choose to withdraw from research, they will be instructed temail the study email address (walkingstudy@northwell.edu), an e-mail account monitored by IRB-approved members of the research team. Participants will be contacted by a member of the research team confirming their study withdrawal, and to answer any questions they may have. The participant will stop receiving notification and survey prompts, and will be sent instructions to un-link their Fitbit device. Data collection will stop the business day the letter or email is received. All data up until the receipt date of the letter will be included in the research study.

17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*
- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to results*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

The study poses low risk of physical harm to subjects as participants are community dwelling employees, report themselves as healthy, walk regularly and have never been advised by a clinician that increasing low intensity walking would be unadvisable/present a safety issues. It is possible that participants may experience muscle soreness or fatigue related to increasing their walking. Completion of validated questionnaires and text message delivery of BCTs has not been shown to increase risk to study participants.

The primary risk to participants is the potential risk of loss of privacy of information pertaining to research material collected by the study, we will take precautions, described below, to minimize these risks.

We will emphasize to subjects involved in all study phases that they can stop and withdraw from the preliminary phases and/or the N-of-1 trial completely at any point.
The study team plans to protect privacy by only sharing necessary information about participants with those who receive IRB approval to join the study team
All participants will be informed that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation, and that such action will not affect their future interactions with their employment, ability to receive health care or to participate in other research studies. The risk of loss of confidentiality will be minimized by securely storing data including PHI in a Northwell-approved platform and minimizing the use of PHI. To ensure confidentiality, all data containing personal identifiers, and used to track contact with participants will be kept in a secure, password-protected, encrypted Northwell-approved platform (REDCap, Sharepoint and/or N1Thrive). No paper documents with personal identifiers will be kept. The PI will be responsible for ensuring that the confidentiality of the data is maintained at all times. All data will be obtained specifically for research purposes.

Personal or identifiable information is not stored on any of the study devices used in this study. No information about the participants or the participants' health history will be shared with Fitbit, except for the information the participants directly share themselves should they choose to use the device for personal use at the conclusion of the study. There is no additional risk with using Fitbit as part of this research study as compared to using the device as a consumer, including mild skin irritation (i.e. contact dermatitis) which occurs among a small proportion of users. Participants will be instructed via the consent form on methods to reduce irritation (i.e. keep the band clean and dry) and that they can remove the band for a short period of time.

18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

Should a participant experience an adverse event, they will be advised to notify a study coordinator and contact their primary care provider. The study will immediately notify the safety monitor, Dr. Brown, the PI, and the IRB according to timelines established in the study's manual of operations. Should a participant report emotional distress in responding to survey questions, the research coordinators will refer to a licensed clinical psychologist in our center, who will recommend follow-up.

19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

Individuals may have no direct benefit from participating in this study. Participants randomized to the intervention may gain a better understanding of how following certain behavioral change techniques (e.g., goal-setting, self-monitoring) personally affects them. This may result in their being more satisfied with their walking regimen and in achieving benefits of increased walking. Through pooling personalized trial data, a greater understanding of the effectiveness of systematic use of self-regulatory behavioral change techniques to promote walking may be obtained. This knowledge may contribute to the incorporation of personalized trials into health promotion. Additionally, the information collected from participant involvement will inform the development of future Personalized Trials to help other research participants and eventually patients discover which treatment options are best for them as an individual.

20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

Participants in this study will be self-referred in response to advertisements aimed at employees within the Northwell Health network. Names and email addresses from potential study participants will not be collected until participants have read through web information explaining the research study and protocol, filled out pre-screening data, and indicated their interest in the study. This information will be stored in a Northwell-approved platform (REDCap, Sharepointand/or N1Thrive) and it will only be accessible to research staff listed on the approved IRB protocol. Names or other identifying information will not be shared with those outside the

research team. Phone numbers and email will only be used for study-related communications, and employees will only be contacted outside the study if they indicate interest in participating in a future Personalized Trial

21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

The study uses text messaging to deliver notifications, reminders and study questionnaires. Standard message and data rates from the participant's carrier may apply to the study participant. Study participants will not be compensated for any costs related to data usage or sending and receiving text messages by the study or members of the study team.

22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

All participants in preliminary study phases (30-60 minute commitment) will receive 5,000 points added to their Northwell "My Recognition" account. Participants in the Personalized Trial will receive $100 upon completion of study and a custom report of their personal responses to the selected BCTs. Additionally, participants will be able to keep the Fitbit tracker (value $150)

23. CONSENT PROCESS

If obtaining consent for this study, describe:

- *Who will be obtaining consent*
- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

Potential participants in the focus group phases of the study will be directed through a series of web pages that summarize the study, and ask them to confirm that all of the following are true: they currently work at Northwell Health, are between the ages of 45 -75 years old, have never been told by a health care provider that it is not advisable/unsafe to increase their walking, they read and understand English, own a smart phone capable of receiving text messages and accessing the internet, are not pregnant and have never been diagnosed with a severe mental illness or psychiatric disorder such as bipolar disorder. Participants will not identify their specific exclusion to better protect their privacy.

If a prospective participant is ineligible, they will be notified immediately and thanked for their interest. If the potential participant is deemed eligible, they will proceed to read the information sheet (preliminary phases) and provide their basic contact information to be scheduled for focus group activities. The clinical research coordinator will confirm participant understanding when scheduling focus group sessions.

For participants in the personalized trial phase of the study, consent will be obtained electronically. A PDF copy of the electronically signed form will be made available to the participants via N1Thrive/REDCap. Potential participants will be directed through a series of web pages that summarize the study, and ask them to **confirm that all of the following are true**: they currently work at Northwell Health, are between the ages of 45 -75 years old, have never been told by a health care provider that it is not advisable/unsafe to increase their walking, they read and understand English, own a smart phone capable of receiving text messages and accessing the internet, are not pregnant and have never been diagnosed with a severe mental illness or psychiatric disorder such as bipolar disorder. Participants will not identify their specific exclusion to better protect their privacy.

If a prospective participant is ineligible, they will be notified immediately and thanked for their interest. If the potential participant is deemed eligible, they will receive a secure message with a link to acknowledge either the information sheet (preliminary phases) or electronically sign the informed consent form (intervention phase) within 2 business days of the initial completion date of the screening. In order for the consent form to be signed and submitted successfully, potential participants will need to correctly answer 4 questions about the protocol to demonstrate their understanding. PDF versions of signed consent forms will be maintained electronically on a HIPAA-compliant, Northwell Health-approved share drive, accessible only to members of the research team listed on the IRB protocol.

We are requesting a waiver of a witness to the consent process as consent is being obtained remotely. As such, we are also requesting a waiver of investigator signature.

In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*
- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

Not applicable

If the study involves cognitively impaired adults, additional information should be provided to describe:

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

Not applicable

If the study will enroll non-English speaking subjects:

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*

- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

Not applicable

24. WAIVER OR ALTERATION OF THE CONSENT PROCESS

No N/A

Complete this section if you are seeking an alteration or complete waiver of the consent process.

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *Explain why it is not possible to conduct this research without using the information or biospecimens in an identifiable form*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

We request a waiver of documentation of consent for preliminary study phases eliciting feedback about study materials and procedures via focus group participation or 1:1 feedback discussions. For these participants, the only record linking the subject to the research would be their signature on the informed consent form, and the principal risk to these individuals is the potential harm resulting from a breach of confidentiality. In addition, the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. We will provide an information sheet to each individual that describes the nature of the research and informs them that they are free to skip any question/refrain from any part of the discussion that they do not want to answer.

Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

SUBSECTION 1

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

Not applicable

SUBSECTION 2

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

Not applicable

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25. WAIVER OF HIPAA AUTHORIZATION ☒ N/A

Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*
- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

Not applicable

Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)*
- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

Not applicable

26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☐ *Cognitively impaired*
- ☐ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☒ *NSLIJ Employees, residents, fellows, etc*
- ☐ *poor/uninsured*
- ☐ *Students*
- ☒ *Minorities*
- ☐ *Elderly*
- ☐ *Healthy Controls*

If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.

Potential participants will be asked to self-identify based on their interest from existing employee communications and Northwell employee resources, as well as social media groups. All potential participants will be informed that their decision to participate or not participate in the study has no impact on their employment or their ability to receive care from Northwell providers. Participants are free to terminate study participation at any time without any impact on their position or health care services.

27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.

Not applicable

28. REFERENCES/BIBIOGRAPHY

Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.

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