Published in final edited form as:

Circ Cardiovasc Qual Outcomes. 2021 February ; 14(2): e006760. doi:10.1161/CIRCOUTCOMES.120.006760.

Micro-Randomized Trial Design for Evaluating Just-In-Time-Adaptive-Interventions Through Mobile Health Technologies for Cardiovascular Disease

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Abstract

Smartphone and wearable device use is rising broadly and can be leveraged for chronic disease management. Just-In-Time Adaptive Interventions (JITAIs) promise to deliver personalized, dynamic interventions directly to patients through use of push notifications from mobile devices. While JITAIs are a powerful tool for shaping health behavior, their application to cardiovascular disease management has been limited as they can be challenging to design. Herein we provide a general overview and conceptual framework for micro-randomized trials, a novel experimental

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Disclosures: Dr. Nallamothu is a principal investigator or co-investigator on research grants from the NIH, VA HSR&D, the American Heart Association, Apple, Inc, and Toyota. He also receives compensation as Editor-in-Chief of Circulation: Cardiovascular Quality & Outcomes, a journal of the American Heart Association. Finally, he is a co-inventor on U.S. Utility Patent Number US15/356,012 (US20170148158A1) entitled "Automated Analysis of Vasculature in Coronary Angiograms" that uses software technology with signal processing and machine learning to automate the reading of coronary angiograms, held by the University of Michigan. The patent is licensed to AngioInsight, Inc., in which Dr. Nallamothu holds ownership shares (although it has yet to be funded). Disclosures provided by Brahmajee J. Nallamothu in compliance with American Heart Association's annual Journal Editor Disclosure Questionnaire are available at https://www.ahajournals.org/pb-assets/policies/COI_09_2020-1600719273583.pdf.

Dr. Jackson is a research investigator on grants from the NIH and Amgen. She also receives compensation from the American Heart Association for serving as an Editor. Additionally, she receives compensation from (1) the NIH for participating in study section grant reviews; (2) the American College of Cardiology, UpToDate, and McKesson for her role as consultant and/or author; and (3) DeBlase Brown Everly LLP for her role as an expert witness. Disclosures provided by Elizabeth A. Jackson in compliance with American Heart Association's annual Journal Editor Disclosure Questionnaire are available at https://www.ahajournals.org/pb-assets/policies/COI_09_2020-1600719273583.pdf.

study design that can be used to optimize JITAIs. Micro-randomized trials leverage mobile devices to sequentially randomize participants to types or levels of an intervention to determine the effectiveness of an intervention and time-varying moderators of those effects. Micro-randomized trials are an efficient study design that can be used to determine which intervention components to include in JITAI and to optimize their decision rules while maintaining the strength of causal inference associated with traditional randomized controlled trials.

Keywords

Mobile health interventions; Micro-randomized trials; Just-in-time adaptive interventions

Subject terms:

Echocardiography; Electrocardiology (ECG); Magnetic Resonance Imaging (MRI); Diagnostic Testing

Use of mobile health technology is expanding at an outstanding rate. More than 8 in 10 Americans owned a smartphone in 2019[1] with adoption rates increasing across the spectrum of age,[2] race,[3] and socioeconomic groups.[1] Nearly 70% of Baby Boomers own a smartphone,[2] and the proportion of users is largely equivalent across Black, Hispanic, and White adults.[3] This growth in mobile health technologies has clinical implications as an increasing number of American adults use smartphones and other wearable devices to digitally track at least one health behavior.[4]

Given such widespread adoption, there is great hope that mobile health technologies can deliver personalized, dynamic interventions directly to patients in real-time to assist with management of chronic diseases.[5-8] Just-In-Time Adaptive Interventions (JITAIs, pronounced as “Jedis”) use contextual information from mobile devices (location, calendar, etc.) to determine when to provide interventions to individuals.[9] Specifically, JITAIs aim to provide support at optimal times to shape health behaviors, such as sending a planning intervention when the user is cognitively available to engage in planning or a suggestion for low-sodium food options when the system detects the user has entered a fast-food restaurant.[6] Unlike static “pull” interventions—in-app feedback, psychoeducation, etc.—which require users to be aware of their need for support and to reach for an intervention, JITAIs use “push” notifications to deliver interventions when the system detects states of risk or opportunity, with the goal of modifying health behaviors in-the-moment and over time in a participant’s natural environment.[9] To determine when to intervene, JITAIs rely both on passively sensed data, such as step counts, location, and blood alcohol levels sensed via a transdermal alcohol monitor;[10] and data collected actively via short mobile questionnaires, termed ecological momentary assessments (EMAs), to assess psychosocial measures such as mood or anxiety.[6] Intervention components delivered as part of a JITAI may be based on any number of behavior change techniques such as goal-setting, feedback, and implementation intentions in order to promote long-term behavior change.[11-14] To date, JITAIs have been applied to states of physical inactivity;[15, 16] chronic medical conditions such as obesity,[17] alcohol abuse,[18] and nicotine addiction;[19] and mental health disorders.[20]

While JITAIs hold promise, their application to cardiovascular disease management has been limited by the lack of experimental methods that can empirically inform their design: decisions on which components to include in a JITAI and rules (termed decision rules) for when and how often those components should be delivered to maximize their effectiveness. We highlight limitations of commonly used experimental designs for informing JITAI design and then present micro-randomized trials as a unique approach for optimizing JITAIs.

Challenges with Designing JITAIs

Traditional randomized controlled trials (RCTs) refer to an experimental design in which participants are randomized to one of two or more groups, an experimental group and a control group in which participants received placebo or the prior standard of care, and then are compared on one or more outcomes. These, however, have three key shortcomings as a method for JITAI optimization. First, due to resource constraints, RCTs typically have a limited number of study arms and are thus best suited for determining the efficacy of an intervention rather than the efficacy of individual components in a multi-component intervention.[9] Second, given that intervention assignment is randomized at baseline, RCTs cannot rigorously assess the effect of intervention components moderated by time-varying factors such as changing levels of patient motivation or self-efficacy, or the context (e.g., location) in which an intervention component is delivered. Such information is essential for determining decision rules for the provision of JITAIs. And third, analyses of RCTs are traditionally based on a relatively small number of pre-specified time points (e.g.,1 and 3 years). JITAI design provides detailed information about how the effectiveness of an intervention component changes over time. For example, the effect of a reminder to go for a walk may rapidly decrease over a few weeks, making such a component a poor match for a JITAI designed for long-term behavior modification. RCTs provide no rigorous ways of studying such issues empirically.

A key limitation of RCTs—namely the inability to efficiently study the efficacy of individual intervention components—can be addressed through the use of factorial experiments. Factorial experiments are a study design in which participants are randomized to different combinations of a multicomponent intervention and the efficacy of each component is assessed, averaging across the other intervention components. Like RCTs, however, factorial designs are limited in their ability to study the effect of time-varying moderators on the intervention effectiveness.

Overview of micro-randomized trials.

The micro-randomized trial is an experimental design to aid in constructing empirically-based JITAIs through the serial randomization of participants to different types of interventions and/or different levels of an intervention. Researchers can use micro-randomized trials to decide whether to include a time-varying component in a multi-component intervention and in which contexts delivering a component is most effective. These trials are not confirmatory studies designed to evaluate an intervention package; instead, they are focused on selecting and optimizing intervention components for use in a JITAI. For the remainder of this paper, we focus on the development and execution

of micro-randomized trials, providing a general overview of the design, illustrating key concepts through a case example, and closing with important statistical considerations.

Micro-randomization refers to the process of sequential randomized assignment to one or several intervention components throughout the conduct of the trial.[21] Micro-randomized trials are unique with respect to the time scale over which they operate, potentially randomizing a single individual at multiple time points—termed decision points—over the course of a day (Figure 1). Decision points are guided by tailoring variables, which are individual-level or contextual characteristics used to determine when a participant is most likely to benefit from an intervention component. In a micro-randomized trial with multiple intervention components (e.g., medication reminders and planning of activity), each component will be associated with its own decision points and decision rules that operationalize intervention delivery.

At each decision point, participants are randomized to levels of an intervention component: to receive or not receive the intervention, or to receive different forms of the intervention (e.g., framing of a motivational message). When provided, interventions are typically delivered through push notifications. In a micro-randomized trial, intervention effectiveness is assessed via repeated short-term assessments of near-term outcomes, termed the proximal outcome. By repeatedly randomizing participants, micro-randomized trials can interrogate the dynamic effects of intervention components and investigate psychosocial, temporal, and contextual factors that moderate effectiveness. By leveraging within-person contrasts over time (i.e, instances in which a participant receives vs. does not receive an intervention component), micro-randomized trials are a statistically and temporally efficient study design that can add to our understanding of causal effects.[22] Table 1 lists the types of research questions that micro-randomized trials can help answer.[22, 23] A JITAI that was optimized based on the data from a micro-randomized trial can then be tested for overall efficacy in a confirmatory trial, such as a standard RCT.

Case study.

To date micro-randomized trials have been leveraged for primary cardiovascular disease prevention, such as the promotion of physical activity,[15] weight loss,[24] and smoking cessation, though applications to secondary cardiovascular disease prevention are lacking.[25] To illustrate how micro-randomized trials could be used for cardiovascular disease management and provide a framework by which to present important design concepts, we describe a hypothetical study, termed The Heart failure with preserved ejection fraction diEt and Activity micro-Randomized Trial (HEART).

The HEART study would be a micro-randomized trial for patients with heart failure with preserved ejection fraction (HFpEF) in which participants would receive a smartwatch and a mobile application that delivers micro-randomized notifications (Figure 2). The application would allow for tracking of activity parameters, such as step count and distance walked, but also proximity to fast food restaurants through geofencing, a location-based smartphone feature which tracks crossings of defined geographical boundaries. The study would have two synergistic intervention components designed to promote weight loss and improve

functional capacity through (1) promotion of physical activity and (2) avoidance of fast food restaurants.

The first goal of the HEART study would be to encourage participants' to be more physically active (Figure 2a). Participants on enrollment would identify 5 times of day[15] in which they are typically sedentary. At each of these time points (i.e. decision points), their activity level would be assessed. If sedentary, as determined by their step count in the prior 30 minutes, participants would be randomized, with 60% probability, to receive a notification promoting physical activity, or to no notification (at 40% probability). The probabilities chosen are arbitrary and would be selected by the investigators based on their clinical knowledge of the setting. Messages would be selected from a message bank and tailored to contextual factors such as season, weather, and day of the week. Short-term intervention effectiveness would be determined through step count over the one hour following randomization (the proximal outcome) (see Table 2 for this and other key terms).

The second goal of the HEART study would be to support participants in minimizing consumption of high fat foods through avoidance of fast food restaurants (Figure 2b). Close proximity to a fast food restaurant, determined through geofencing, would trigger an EMA containing two questions on stress and anxiety, capturing information on the user more difficult to measure passively.[9] With 50% probability, participants would receive a notification promoting a low-sodium diet, tailored to stress and anxiety scores. The other 50% of times, participants would receive a generic notification not tailored to their current state. Fifteen minutes after a decision point, participants would receive a survey to ascertain whether they entered the restaurant and what they ordered. The proximal outcome would be entry into the restaurant .[18, 26] After 1-month, percent weight loss (the distal outcome) would be assessed.

Design considerations for micro-randomized trials.

Proximal and distal outcomes.

A micro-randomized trial design requires selecting a long-term clinical outcome, termed the *distal outcome*,[13, 14] which guides the intervention design and is analogous to the primary outcome in an RCT (Table 2). The distal outcome also serves to guide the choice of *proximal outcomes*, a short-term version or hypothesized mediator of the distal outcome.[13] A proximal outcome should capture short-term progress towards adopting and maintaining a target behavior. It should be measurable passively or actively at a low burden to the participant after each decision point.[27] For example, exercise minutes is a measurable outcome and clear mediator in an intervention designed to promote weight loss. For an intervention component designed to reduce addiction, proximal outcomes may include reduction in cravings or an increase in sobriety motivation. The proximal outcome should also be one that can be measured consistently and with sufficient temporal granularity to link it to an intervention component. In the HEART study, both intervention components would be assessed within an hour of randomization, linking them temporally to the intervention (Table 2). Both also represent intermediates in the weight loss pathway (i.e., increased activity and decreased consumption of high fat foods).

Decision points and decision rules.

Decision points denote times at which an intervention component may be delivered and are chosen based on the dynamics (anticipated or actual) of the state that the intervention component is targeting (e.g., sedentary behavior or fast food consumption). These may be pre-specified time points or may arise rapidly and ecologically in response to the interaction between dynamic and static factors. Fixed decision points afford greater control over the frequency with which notifications are delivered, ensuring alignment between the time frame over which the tailoring variable and proximal outcome are expected to change.[12] In contrast, this lack of flexibility may lead to missed opportunities for facilitating behavior change, and notifications may be delivered at times when participants are unreceptive, such as activity notifications during vacations or illness. While dynamic decision points avoid many of these limitations, they require high frequency monitoring and wearable device signals which can be measured with sufficient reliability and fidelity to ensure intervention components are appropriately timed. Dynamic decision points are also analytically more complex[28] and afford less control over the frequency of decision points.

Decision points are paired with *decision rules* to operationalize the provision of support, establishing levels, ranges, or thresholds for treatment delivery;[13] these may be modified over time in response to participant behavior. When selecting decision rules, researchers must balance the complex interplay between participant engagement and intervention fatigue in order to maintain adherence and retention.

For the dietary intervention in the HEART study, decision points would arise once participants crossed a virtual fence surrounding a fast food restaurant. In contrast, for the activity intervention, decision points would be pre-selected with the decision rule specifying that participants would be randomized if they walked < 200 steps in the 30 minutes prior to a decision point. Fixed time points ensure that participants would receive notifications with sufficient frequency to promote weight loss though not so frequently as to lead to burn-out in this relatively inactive population. The burden to participants could be reduced by decreasing the overall frequency of notifications delivered, either by altering the decision rules or by reducing the probability of receiving a notification at each decision point. Minimizing the burden to participants by increasing the threshold for notifications must be balanced, however, against the risk of decreased intervention effectiveness. Additionally, in this study design, the least active individuals would receive the greatest number of activity notifications yet their response burden would be greatest. As an alternative design, participants could be stratified on baseline activity levels and different decision rules implemented for each activity quartile. These decision rules could then be modified over time as participants become more active.

Tailoring variables.

Tailoring variables are individual-level and contextual characteristics used to identify conditions in which a participant may benefit from an intervention component, denoting periods of opportunity or vulnerability.[12] Tailoring variables are used as part of decision rules to operationalize the intervention provision protocol. Tailoring variables can be measured passively by sensors, such as step count, or actively via EMA. These actively or

passively collected measures may be intrinsically informative (i.e. step count for identifying states of inactivity) or may require aggregation with other variables to form composite scores for intervention-relevant states.[12, 13] For example, in patients with opioid use disorders, a machine-learning model was trained to predict heroin and cocaine cravings using GPS data and participant-level demographic characteristics.[29] Such predictors can be used as tailoring variables to determine when to intervene (e.g., when the risk of heroin use is above a threshold). Tailoring variables should be able to be assessed reliably and with sufficient granularity to identify meaningful changes in states of interest (e.g., risk of drug use).[12, 13]

In the HEART study, the tailoring variables in the activity intervention would be time of day and step count prior to decision points; in the dietary intervention, stress and anxiety scores and distance from a fast-food restaurant. The latter leverages stress-vulnerability theory which reflects the transient tendency of individuals to experience adverse health outcomes or to engage in maladaptive behaviors during periods of heightened anxiety or stress.[11, 13] Step count, in contrast, is designed to leverage the impact of shaping on attainment of the target behavior.

Participant availability.

Participant availability to receive an intervention at each decision point encapsulates rules for when it is safe and appropriate to deliver an intervention. Participant availability may change from one decision points to another, and the rules governing availability will differ based on the target behavior. For example, activity notifications are inappropriate when a participant is driving or is currently physically active and, potentially, for a certain period thereafter. Definitions of unavailability may significantly impact how frequently a component of an intervention can be delivered and should be considered during the study design phase given its impact on sample size calculations. Participant availability may also change systematically over the course of a study. An effective physical activity intervention may lead to greater unavailability if participants can only receive treatment when sedentary.[21] During times of both availability and unavailability, the same participant data should be collected to allow interrogation of sources of unavailability during the analytic phase of the study.[21]

For the dietary intervention in the HEART study, participants would be considered unavailable only when they lacked an internet connection. More complex rules could be incorporated to determine exactly when participants are available though these would come at the cost of increased burden to participants. One could imagine a trial in which participants would only be considered available to receive a notification if they had already exceeded their daily recommendations for trans and saturated fat consumption.

Intervention options.

Finally, when designing a micro-randomized trial, one must consider the form of intervention delivery (e.g., smartwatch notifications, text messages, or phone calls) and which treatments or actions should be randomized. Participants may be randomized to receive or not receive an intervention, or to receive one of two or more forms

of an intervention, as in the dietary intervention of the HEART study. Intervention components should be selected which actuate the psychosocial mechanisms mediating behavior change with the amount, type, and source of support guided by prior digital health research, behavioral health theory, and technical and logistical considerations. Intervention components should be randomized if there is uncertainty as to the (1) best intervention or combination of interventions; (2) appropriate intervention "dose"; or (3) how context of delivery impacts intervention effectiveness.[9, 22]

Statistical considerations for micro-randomized trials.

We now detail several important statistical considerations when designing and analyzing micro-randomized trials. While we focus herein on sample size calculations, the same techniques can be applied when analyzing micro-randomized trial data to determine causal effects. The following section focuses on estimating the time-varying effects of an intervention component on the proximal outcome. While the study could be powered based on the distal outcome, this is typically avoided as micro-randomized trials focus on the selection and optimization of time-varying intervention components and are not confirmatory studies. Sample size calculations are thus designed to assess the proximal effects of the time-varying component. An intervention package containing the time-varying components from a micro-randomized trial can subsequently be evaluated in a confirmatory trial. Herein, we demonstrate sample size calculations for the HEART study. For ease of demonstration, we focus on the activity intervention in which decision points are fixed and opportunities to receive an intervention component are the same for all participants, contingent on availability. In this example, the intervention would be notifications promoting low-level physical activity and the proximal outcome would be step count in the hour after a randomization. Moreover, we may be only interested in the effect if the participant is currently sedentary.

Generally, let $t = 1, \ldots, T$ index the decision points with $A_t = 1$ if the participant is sent a push notification and $A_t = 0$ otherwise. These decision points may be fixed (e.g., every minute or hour during the day), as in this example, or patient-dependent (e.g., patient chooses exact timing of decision points within pre-defined 2-hour windows). Let Y_{t+1} denote the proximal outcome after decision point t. The effect of treatment at decision point t is the expected difference in Y_{t+1} between participants who receive the push notification and those who do not. Let $I_t = 1$ if the participant is sedentary at time t and $I_t = 0$ if not. A micro-randomized trial aims to test a particular treatment effect denoted:

$$\beta(t) = E[Y_{t+1} \mid A_t = 1, I_t = 1] - E[Y_{t+1} \mid A_t = 0, I_t = 1]$$

See Dempsey et al. for a full derivation of $\beta(t)$ using causal inference notation.[28] Of note, the proximal effect is defined with respect to treatment at decision point t. This is distinct from traditional longitudinal analyses in which the time-varying effect is with respect to a single treatment administered at baseline.

The next step is to calculate the study's sample size, for which we can leverage the publically available calculator at https://CRAN.R-project.org/package=MRTSampleSize.[30]

We wish to calculate a sample size with sufficient power to detect alternatives to our null hypothesis that notifications have no effect on our proximal outcome, defined as $H_0 : \beta(t) = 0$ for every decision point $t = 1, \ldots, T$. Sample size calculations for micro-randomized trials require five inputs: (1) study duration, (2) number of decision points per day, (3) randomization probability, (4) expected availability, and (5) standardized proximal treatment effect. In the HEART study, the study duration would be 1-month (30 days), the number of decision points 5 per day, and the probability of receiving a notification 60%. Expected availability at decision point $E[I_t]$ is the fraction of users available for treatment at each decision point t. As participants in the HEART study would only be available if sedentary (i.e., $I_t = 1$), availability may vary over the course of the study. For simplicity, we assume here a constant fraction of sedentary participants at each decision point. We consider several plausible values of expected availability as follows: 0.3, 0.5, 0.5, and 0.6 (Table 3). See Klasnja et al.[9] and Liao et al.[30] for a further discussion of participant availability.

Finally, calculating expected power requires estimates of the standardized proximal treatment effect, which depends on (1) the proximal treatment effect $\beta(t)$ and (2) the population standard deviation of Y_{t+1} denoted $\sigma(t)$. Technically, the standardized effect at each decision point is

$$d(t) = \frac{\beta(t)}{\sigma(t)}.$$

The standardized effect measures the magnitude of effect relative to the standard deviation and is equivalent to Cohen's d.[31] For the numerator, we assume a simple functional form which can be constant, linear, or quadratic based on the predicted response to treatment. If, for example, we suspect that the treatment effect will decrease with time due to habituation than a linear form would be appropriate.[28] Alternatively, a quadratic form may be selected if the intervention's effectiveness is predicted to be low at the start of the study, increase as participants become familiar with the intervention, and then decrease with time due to habituation. While a less complex form has the advantage of requiring a smaller sample size, it may not reflect the true alternative. We thus suggest sizing a study using the least complex realistic alternative. Since in the HEART study we would be interested in detecting linear trends in treatment effect, we size the study where the alternative is linear based on day-in-study with treatment effect, $\beta(t)$, decreasing with time t.

The magnitude of the standardized proximal effect may be informed by prior data[32] if available. The numerator can be estimated by taking the difference between those who received treatment at decision point t and those who did not, $(\hat{\beta}(t) = \bar{Y}_{t+1,1} - \bar{Y}_{t+1,0})$; the denominator can be calculated using standard pooled variance calculations at each decision point. This is in line with Cohen's d which calculates the standard deviation pooled over treatment groups.[32] If prior data is unavailable, we may choose standardized effect sizes that are in line with prior sample size calculations. In Liao et. al, the average effect sizes $\bar{d} = \frac{1}{T}\sum_{t=1}^{T} d(t)$ ranged from 0.05 to 0.10 (Table 3).[30] Due to minimal prior data, we consider the same range in the HEART study.

Data from a micro-randomized trial can also be used to assess moderation of a treatment effect given a time-varying covariate. In the HEART study, for example, scientists may be interested in assessing the intervention effect based on self-reported stress S_t. The moderated effect of treatment at decision point t is the expected difference in Y_{t+1} between participants who receive a tailored push notification while at stress level s and those who don't receive a notification at stress level s. Mathematically, the moderated treatment effect can be denoted[33]:

$$\beta(t;s) = E[Y_{t+1} \mid A_t = 1, I_t = 1, S_t = s] - E[Y_{t+1} \mid A_t = 0, I_t = 1, S_t = s].$$

Similarly, one may be interested in assessing treatment effect only at *at-risk times*, as determined by the tailoring variables. In the HEART study, for example, the dietary intervention is only provided when a participant is within the virtual fence surrounding a fast food restaurant. Let L_t denote a binary indicator that the individual is within the virtual fence at decision point t (i.e., $L_t = 1$ if true and 0 otherwise). Then the effect of interest using the above notation is $\beta(t; 1)$ where L_t replaces S_t as the time-varying covariate. Note that in settings where the primary aim is assessment of effects at at-risk times, the randomization probabilities are often complex functions of participants' histories. When this occurs, the corresponding analytic methods and sample size calculations are more complex.[28]

Opportunities and challenges.

As micro-randomized trials enrich our understanding of digital behavioral interventions through the provision of longitudinally dense data, additional questions in the field may be broached. Should decision rules change over time once goals are achieved?[27] What factors dictate the timing over which new behaviors are developed? How are users' experiences impacted by their mobile interactions and by the form of goal attainment? Additional questions exist with respect to how best to analyze this data. These include how to (a) assess delayed effects under JITAI policies that differ from the micro-randomization protocol, (b) handle missing data in the primary analysis, (3) evaluate proposed JITAIs using the micro-randomized trial data, and (4) update intervention components in real-time for future study participants.

Finally, while not unique to micro-randomized trials, we must consider how we are keeping participant data safe. While digital data collected as part of a research study remains protected under the Health Information and Privacy Protection Act (HIPAA) Privacy Rule, that same information collected by non-study applications can be sold to commercial entities.[34] There are numerous publications that discuss this issue in detail and readers are referred to those sources.[34-36] It remains to be seen, however, whether these challenges to privacy will be addressed at the consumer level or through greater regulation of health-related information.

Herein, we presented micro-randomized trials as a novel experimental design that can aide in optimizing JITAIs while maintaining the strength of causal inference associated with traditional randomized controlled trials. By leveraging evolving mobile technology and behavior change strategies, JITAIs promise to deliver interventions to users when and where

they are most needed, helping them to implement behavior changes in their daily lives. Such an approach, we hope, will allow mobile health technologies to achieve their potential of facilitating long-term change and help users with cardiovascular disease manage their condition more effectively.

Acknowledgments

Sources of Funding: This work is supported by grant number T32-HL007853 from the NIH (JRG). This word was additionally supported by grant numbers R01HL125440, U01CA229445, and R01LM013107 from the NIH (PK).

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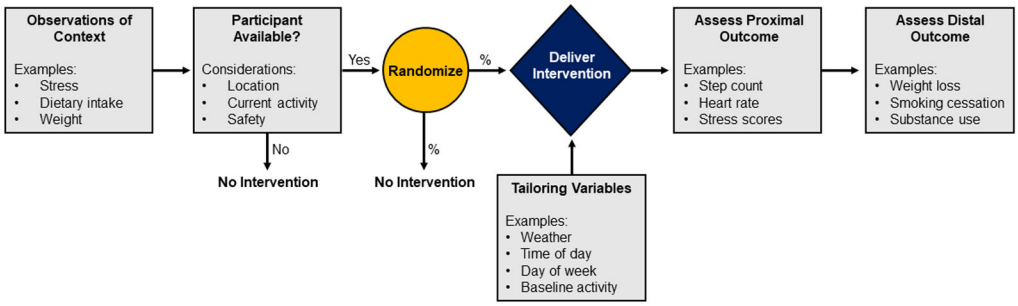

Figure 1: Sample micro-randomized trial design.

In this example, participants would be randomized to receive the intervention or no intervention based on pre-specified probabilities. In an alternative study design, participants could be randomized to different forms or levels of an intervention.

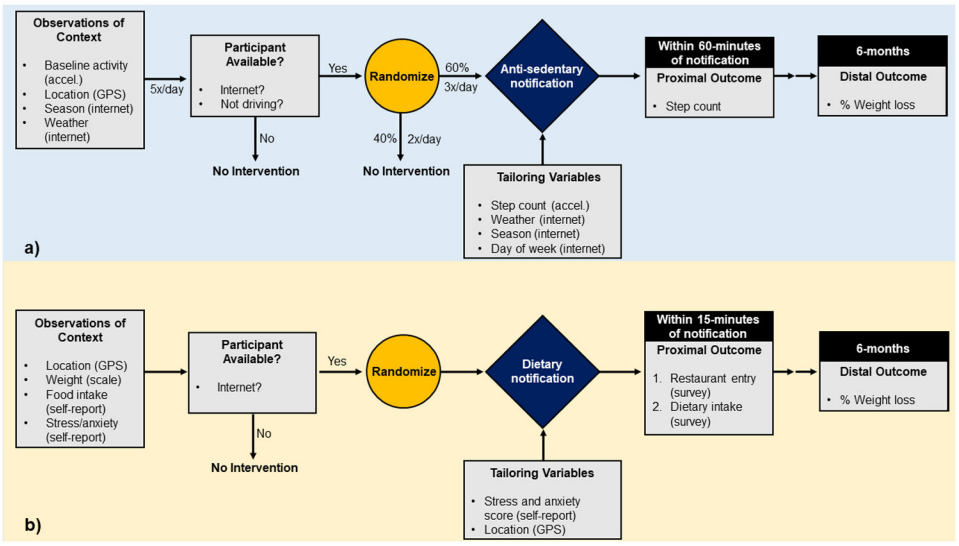

Figure 2: Visual representation of the HEART (a) activity and (b) dietary interventions.
Key: accel = accelerometer; GPS = global positioning system.

Table 1:

Sample research questions that can be answered by a well-designed micro-randomized trial.

[22, 23] Key: MI = myocardial infarction; PAD = peripheral arterial disease.

Study Questions	Example
1. Does an intervention component impact its intended proximal outcome?	Does receiving a notification encouraging walking result in more steps in an hour following the randomization than not receiving a notification?
2. How is the effect of an interaction component impacted by other intervention components?	Are patients more likely to act on notifications encouraging a low sodium diet by choosing a low-sodium meal when they receive a morning reminder of their commitment to their heart health?
3. Is treatment effectiveness context-dependent?	In participants with PAD, are notifications encouraging them to walk more effective when received at home or at work?
4. How does the effect of an intervention component change over time?	Do participants become less responsive over time to notifications reminding them to choose low-sodium meals?
5. How frequently should an intervention component be delivered?	For secondary MI prevention, are walking notifications more effective for increasing step count if delivered one or three times per day?

Table 2:

Key terms in micro-randomized trial design and their application to the HEART study.

	Definition	HEART Study: Activity Intervention	HEART Study: Dietary Intervention
Proximal outcome	Short-term impact of an intervention component	Step count in the 60 minutes following a decision point	Entry into fast food restaurant
Distal outcome	Target behavior	Percent weight loss	Percent weight loss
Tailoring variable	Participant-level and contextual characteristics determining treatment selection and timing	**1** Step count **2** Season **3** Weather **4** Day of week	**1** Stress and anxiety scores **2** Location
Decision points	Times when a participant may be randomized to receive levels of a treatment	Five pre-selected time points each day	When a participant is within Y distance of a fast food restaurant
Decision rules	Operationalizes the provision of support by establishing levels, ranges, or thresholds for treatment delivery	IF step count <200 in the 30 minutes prior to a decision point THEN randomize provision of activity notification ELSE no notification	IF < Y-feet from a fast food restaurant THEN randomize provision of dietary notification ELSE no notification
Randomization probability	Likelihood of receiving a treatment at each decision point	• 60% activity notifications • 40% no notification	• 50% dietary notification tailored on stress and anxiety • 50% generic notification
Participant availability	Rules governing when a participant will not be randomized at a decision point	Unavailable when: • No internet connection • Driving • Recently active (step count ≥200 in prior 30 minutes)	Unavailable when: • No internet connection
Intervention options	Treatments or actions at a decision point	• Notification recommending activity within current context • No notification	• Notification promoting a heart-healthy diet • No notification

Table 3:

Sample size as a function of standardized effect size ($\bar{d}$) and participant's availability excepted availability $E[I_t]$.

$\bar{d}$, $E[I_t]$	0.3	0.4	0.5	0.6
0.05	293	220	177	148
0.06	204	154	124	103
0.07	151	114	91	77
0.08	116	88	71	59
0.09	92	70	56	47
0.10	75	57	46	39