Official Title: Using Real-Time Data Capture to Examine Affective Mechanisms as Mediators of Physical Activity Adherence in Interventions: Formative Study

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Study Procedures

1. Background/Rationale

Cancer is responsible for 600,000 deaths per year in the United States. Of these cases, 15% are potentially avoidable through adequate physical activity and weight maintenance.[1] Despite public health guidelines outlining the frequency, duration, and intensity of exercise needed for these protective benefits, however, large-scale accelerometry research reveals that more than 95% of American adults remain physically inactive.[2] To increase the probability of physical activity engagement, researchers have previously manipulated individual cognitions,[3,4] targeting constructs such as self-efficacy, outcome expectancies, and intentions.[5–10] These interventions have had limited success. Research is desperately needed to elucidate novel mechanisms—beyond cognitive processes—that might change physical activity behaviors.

The type, context, and affective responses surrounding physical activity engagement represent valuable mechanisms that might be contributing to the exercise intention-behavior gap.[11] Recent evidence suggests that affect, independently of cognitive processes, is a powerful predictor of physical activity engagement and enjoyment.[12–16] Exercise itself elicits robust changes to emotional states, triggering affectively-charged motivations that—per incentive salience theory—lead to pursuit or avoidance of future associated behaviors.[17] While many individuals react positively to light intensity exercise and negatively to vigorous intensity exercise,[18] great inter-individual variability exists in the affective response to moderate intensity physical activity.[19–22] For example, individuals with overweight/obesity or who are typically inactive are more likely to experience unpleasant feelings when exercising.[23] This can harm their intentions to maintain healthy levels of activity over time.[24] Research shows that part of the heterogeneity in affective response is due to the activity type (e.g., dance, yoga, brisk walking)[25,26] and context (e.g., being with others or outdoors).[27–34] Interventions that leverage activity types and contexts to strategically increase favorable affective responses might therefore improve physical activity maintenance in groups vulnerable to avoidable cancers.

The exploration of how and why certain treatment components bring about desired changes is a crucial step that has previously been overlooked. While later-stage interventions are well-positioned to address efficacy, they leave many unanswered questions about underlying behavior change mechanisms—resulting in limited generalizability and a field-wide replication crisis.[11] Early-stage intervention development studies are needed to elucidate theoretical components that determine why certain interventions are successful—and why others fail.

2. Purpose/Objectives/Aims/Research Questions

In response to these research gaps, the present study will examine whether affective mechanisms (1) can be experimentally manipulated in real-world settings; and (2) mediate the relationship between interventions and physical activity behavior. As an ORBIT model phase 1 trial, the research will begin with a 3-week Formative study to assess acceptability and feasibility of a novel physical activity intervention in adults with increased risk for cancer. A 19-week Comparison study will then test the intervention to achieve the following aims.

AIM 1: Refine and optimize treatments to experimentally manipulate affective mechanisms in real-world settings.
H1*:* Within-subjects, positive affective responses and affectively charged motivations, and physical activity will be higher in the affect-based (vs. intensity-based) condition.
H2: Between-subjects, positive affective responses and affectively charged motivations, and physical activity will be higher in the affect-based condition with TYPE/CONTEXT (vs. without TYPE/CONTEXT).
H3: Between-subjects, the association between affective responses and affectively charged motivations will be stronger, and physical activity will be higher in the affect-based condition with SAVOR (vs. without SAVOR).

AIM 2: Determine whether affective mechanisms mediate effects of treatments on physical activity.
H4: Within-subjects, affective response and affectively charged motivations will mediate associations between intervention engagement and physical activity at the day-/week-level in all conditions of the Comparison study.

AIM 3: Explore cross-person and cross-situation moderating effects.

H5: The above Comparison study effects will be larger among individuals with lower self-regulatory capacity (e.g., self-control, self-efficacy) and on days with more situational constraints (e.g., incidental stress, pain).

3. Participants (sample)

The sample (N=416) will be comprised of adults who are at an elevated cancer risk due to physical inactivity and overweight or obesity. Inclusion criteria are: (a) adults aged ≥18 years; (b) residing in the United States; (c) self-reported BMI ≥ 25; (d) currently engaging in < 60 minutes per week of structured physical activity; (e) owning a personal smartphone device; (f) residing in an area with Internet or Wi-Fi connectivity during the study period; (g) able to speak and read in English; (h) interested and willing to start a physical activity program; (i) willing to wear a Fitbit Versa smartwatch provided by the study team everyday continuously (including at work and during physical activity), in place of any Fitbits or smartwatches they previously wore, for the duration of the study period; and (j) able to read the small font on a smartwatch screen without glasses, or willing to carry reading glasses during physical activity for the purpose of reading the smartwatch screen. In addition to those who do not meet the inclusion criteria, we will exclude individuals who (a) are unable to provide informed consent due to cognitive disability; (b) are unable to engage in one or more key treatment or assessment components, including those with medical conditions that preclude physical activity engagement or who cannot wear an accelerometer on the wrist for any reason; (c) are currently pregnant, given the extreme change to physical activity levels commonly observed within this population; or (d) are referred to the study by either another participant or through Reddit. Children are excluded given their unique physical activity needs.

4. Recruitment & Screening

Participants will be recruited online through ResearchMatch, a national health volunteer registry created by academic institutions and supported by the NIH as part of the Clinical Translational Science Award (CTSA) program. They can also be recruited through a link to our screener on our study website. All recruitment and screening procedures will be conducted remotely and on a rolling basis, with an expected 8 to 20 participants enrolled per month. Interested individuals will be directed to an online screening survey with medical history-related questions based on the Physical Activity Readiness Questionnaire for Everyone (PAR-Q+).[35] Individuals with contraindications to beginning a physical activity program as identified on the PAR-Q+ and clarified with a follow-up phone call (e.g., recent myocardial infarction or electrocardiography changes, complete heart block, acute congestive heart failure, unstable angina, and uncontrolled hypertension) will be asked to provide physician's clearance before being eligible to join the study. Those determined to be eligible will be contacted by a study team member and scheduled for a private video conference consent session. During this session, participants will be provided with more information about the study's purpose, procedures, and data confidentiality. The voluntary nature of participation will be emphasized. Participants will be informed that there is no guarantee of direct benefits from participation; risks related to participation will also be explained. Research staff will inform participants that they can withdraw from the study at any time without fear of consequences, and any concerns or questions about participation will be addressed at this time. Those who wish to participate will then be asked to sign a HIPAA-compliant informed consent document via REDCap. Study staff will screen, recruit, consent, and collect data in English. Study staff will clearly communicate to participants that they might be proactively removed from participation by investigators at any point in time and for any reason. For the Formative Study, recruitment will be stratified to achieve approximately equal representation of age, sex, and BMI groups in the sample. For the Comparison Study, recruitment will be stratified to ensure no greater that a 70% female/30% male difference in sex distribution. Participants recruited to the Comparison Study starting March 2025 (n=120) will complete two additional types of assessments (i.e., "smartphone word match activity" and exit interview) that participants recruited befor and after those dates will not complete. .

5. Methods

Procedures

Both the Formative and Comparison Studies will follow the general procedures outlined in Table 1.

Consent. Participants provide informed consent during a scheduled private video conference with a trained study team member.

Table 1. Study Procedures

Start-Up	Onboarding	Intervention	Exit
Informed Consent	Orientation	Morning/Evening Goal Sessions	Post-Study Questionnaire
Baseline Questionnaire	Random Assignment [a]	Wear Fitbit	Exit Interview [b]
Morning/Evening Goal Sessions ("Text Messages")	Run-In Period	EMA ("Check-Ins")	
Mail Fitbit & Instructions		Mid-Study Questionnaire [a]	
		Implicit Associations Test (IAT)[a]	

Note. [a] Comparison Study only; [b] Formative Study only.

Baseline Questionnaire. Following informed consent, participants receive an email with a link to a 45-minute HIPAA-compliant REDCap baseline questionnaire. This survey measures self-regulatory capacity (self-control, intentions, self-efficacy) and importance of psychological needs; sociodemographic, anthropometric (self-reported height and weight), personality, mental health, physical activity information, and participants' addresses will also be collected. If participants indicate that they complete more than 800 minutes of MVPA or greater than 60 minutes of vigorous physical activity on the baseline questionnaire, they can be found ineligible and be removed the study.

Morning/Evening Goal Sessions ("text messages"). Following the baseline questionnaire, participants are asked to complete ≤3 days of morning and evening goal sessions ("text messages"). These sessions include seven affect items and include a question at the end asking, "Do you think you could answer a survey like this most morning and evenings for 19 weeks?". The study team will use this as a brief check before sending participants a Fitbit Versa smartwatch.

Mail Fitbit and Instructions. The study staff then mail a Fitbit Versa smartwatch with instructions to each participant.

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Note. [a] Comparison Study only; [b] Formative Study only.

Orientation. Once study materials are received, the participant attends a remote orientation session where they will be introduced to the study and watch a summary presentation with instructions on how to participate. During this session, participants are led through setting up their smartphone and Fitbit Versa smartwatch to our study platform through Fitabase, to allow for tracking of physical activity and delivery of EMA ("check-ins"); study staff then teach them how to complete smartphone based morning and evening goal sessions and how to respond to EMA ("check-ins") on their Fitbit smartwatch.

Random Assignment. Random assignment will be stratified by sex at birth and assigned using the randomization allocation table via REDCap. Participants will be assigned to one of eight groups (n=45 each), based on order and intervention components: Intensity > Affect (No Enhancements), Intensity > Affect (Tailored Recommendations), Intensity > Affect (Savoring), Intensity > Affect (Tailored Recommendations & Savoring), Affect (No Enhancements) > Intensity, Affect (Tailored Recommendations) > Intensity, Affect (Savoring) > Intensity, Affect (Tailored Recommendations & Savoring) > Intensity.

Run-in Period. The Comparison Study will begin with a week-long Fitbit smartwatch assessment-only run-in period to introduce participants to wearing and charging the Fitbit smartwatch and collect baseline physical activity data.

Intervention Period. The 19 weeks of study participation for the Comparison Study and three weeks for the Formative Study officially "start" on the first day of the run-in period. While everyone receives physical activity prescriptions, treatment delivery varies by group assignment (affect- or intensity-based goal setting), which is randomized for the Comparison Study. Morning and evening goal sessions, Fitbit wearing, and EMA ("check-in") procedures are described in the Intervention and Instrumentation sections below. During the morning goal sessions, they also will complete a mobile Implicit Associoations Tests (IAT) (i.e., called a "smartphone word match activity") (for the sub-sample recruited to the Comparison Study n=120). Participants in the Comparison Study will additionally respond to a Mid-Study Questionnaire halfway through the study. Upon study completion, participants are asked to fill out a 30-minute REDCap questionnaire, with Formative Study and participants in the Comparison Study subsample recruited starting March 2025 (n=120) additionally completing an open-ended qualitative exit interview. The consent, orientation, and exit interview remote sessions are all scheduled by the participant using a Calendly integration. Periodic emails and text messages will also be sent to encourage study participants' progress every few weeks.

The three-week Formative study (N=56) will iteratively test and refine the implementation of a novel treatment to manipulate affective mechanisms during physical activity. Acceptability and feasibility of content, delivery, device usage, engagement, and achieving clinically meaningful changes in affective mechanisms will be addressed.[36] Treatment components targeting intensity-based goals and affect-based goals will be tested separately in four groups of n=14 participants: [1] intensity-based goal setting alone; [2] affect-based goals + TYPE/CONTEXT; [3] affect-based goals + SAVOR; [4] affect-based goals + TYPE/CONTEXT + SAVOR. Testing occurs on a rolling basis with 1–2-week gaps to allow for iterative refinements.

The 19-week Comparison study (N=360) will then use a Multiphase Optimization Strategy (MOST) design to determine the effects of each intervention component.[37,38] Specifically, we will compare affect- and intensity-based goals within-persons and affect-based goal condition enhancements between-persons (Figure 1). Participants are randomly assigned to treatment groups. The study protocol begins with a run-in period (described above), followed by either affect- or intensity-based goals for the first 8-weeks, a two week washout period, and a cross-over to receive the alternate condition for the remaining 8-weeks. During the affect-based goal condition, participants also randomly receive one of four possible combinations of TYPE/CONTEXT and SAVOR enhancements: [1] affect-based goal setting alone; [2] affect-based goals + TYPE/CONTEXT; [3] affect-based goals + SAVOR, [4] affect-based goal setting + TYPE/CONTEXT + SAVOR.

Figure 1. Comparison Study Design

Daily Physical Activity Goals (Within-Subjects Cross-over)		
Study Part	Affect-based Goal Condition	Intensity-based Goal Condition
Part 1	n = 180	n = 180
Part 2	n = 180	n = 180

Enhancements to Affect-based Goal Condition (Between-Subjects RCT)		TYPE/CONTEXT [b]	
		with	without
SAVOR [a]	with	n = 90	n = 90
	without	n = 90	n = 90

Note. [a] Brief savoring experiences; [b] Tailored recommendations for activity types and contexts to satisfy important psychological needs.

Intervention

This study will add affect-based physical activity goals to an existing mHealth intervention called MyDayPlan, which delivers morning and evening goal sessions. Every Sunday, participants receive a text message with a link to a brief REDCap questionnaire where they are asked about their tentative sleep and physical activity schedule for that upcoming week. On days participants have planned to do physical activity (according to the Sunday scheduling survey), they will engage in two goal sessions: one in the morning and one in the evening. Participants are alerted to complete a session with a text message that has a link to a REDCap form. Morning goal sessions provide an activity goal for the day ("goal module"); ask the participant to create a concrete plan for achieving this goal ("action plan module"); and prompt the participant to anticipate barriers and brainstorm solutions to accomplish the goal ("coping plan module"). Evening goal sessions have participants reflect on whether they were able to meet this goal ("self-monitoring module"). The focus of the goal module differs according to the participant's assigned condition. For each condition, the Fitbit Versa smartwatch will feature a custom watch face with a clock (current local time), the date, current device battery levels, and a physical activity button. The physical activity button can be pressed whenever a subject wants to engage in physical activity, and provides real-time feedback on activity duration. If the subject's moving average HR is too low following the physical activity button press, the Fitbit smartwatch will ask "Still exercising?" twice (options No; Yes) before auto-concluding the session. [Note: for the Comparison Study, the wording of this question will be "Still being physically active?"]. Participants will also have the option to view short explanatory videos throughout their participation that summarize aspects of what is expected of them in the study.

Table 3. Comparison Study Minimum Heart Rate Goals

Week	% HRmax
1	55.0%
2	57.5%
3	60.0%
4	62.5%
5	65.0%
6	67.5%
7	70.0%
8	70.0%

The intensity-based goal condition asks participants to maintain a certain target heart rate range during physical activity (for example, "Today, your goal is to maintain a minimum heart rate of 130 bpm during physical activity."). Starting heart rate reflects the approximate age-adjusted heart rate max, with goals progressively increasing from 55% to 70% heart rate max across 8 weeks (i.e., the moderate intensity activity range) for the Comparison Study (see Table 3), and from 55% to 60% across 2 weeks for the Formative Study. Research staff will show participants how to monitor their heart rate using their Fitbit smartwatch. Specifically, when they press the physical activity button on the Fitbit smartwatch (described above), the watchface will display real-time heart rate in addition to activity duration.

The affect-based goal condition asks participants to engage in either (1) a type (50% of daily goals) or (2) a context (50% of daily goals) of physical activity that allows them to experience positive affect. Goals focused on context are randomly generated to suggest that the participant performs activity (1) in a place; (2) in a social situation; or (3) while listening to something that makes them feel good.

Two enhancements (TYPE/CONTEXT and SAVOR) will augment the treatment effects. TYPE/CONTEXT provides tailored recommendations for activity types and contexts that satisfy personally important psychological needs (i.e., relatedness, social esteem, individual esteem, creativity, mindfulness/reflection, learning, challenge, entertainment/escapism, aesthetic appreciation, morality) as rated by each participant at baseline. Ratings from a crowdsourced panel of adults on Amazon Mechanical Turk will be used to determine the potential for specific activity types[39] and contexts to satisfy psychological needs; our tailoring algorithm will then recommend the corresponding activity type or context while accounting for reported constraints (e.g., ability, access). These details will be incorporated into a tailored recommendation provided to participants during the Sunday Scheduling survey. Specifically, the program will randomly select either type or context (i.e., location, audio, social) recommendations and will rotate every two weeks. For TYPE, participants' top 3 activity types are displayed in the following message: "THIS WEEK, we recommend trying [top 3 activity types] because it will satisfy your unique needs and make the experience more enjoyable." For CONTEXT, participants' top 3 activity contexts are displayed in the following message: "THIS WEEK, we recommend trying a physical activity [top 3 activity contexts] because it will satisfy your unique needs and make the experience more enjoyable." SAVOR implements a brief savoring exercise on the smartphone that takes place either after the planned physical activity session or during the evening goal session (after the self-monitoring module). Participants will respond to questions that are intended to enhance and prolong positive experiences during physical activity. To trigger attentional deployment, a common savoring strategy that involves intensifying experiences by focusing on them,[40,41] participants will answer two open-ended prompts. These prompts are drawn from a prompt pool with

slightly varied wording to promote a sense of novelty. Examples of the three prompts are: "(1) Think about the most positive part of your physical activity session today. What about this part made it positive to you? (2) Next, think about the positive feelings you experienced during this session. Please describe them. (3) Take a moment to appreciate your physical activity session today. What about it are you grateful for?". Savoring prompts will rotate daily and have a day lag built in every week (i.e., Week 1 Monday Savoring Prompts are Week 2 Tuesday Savoring Prompts).

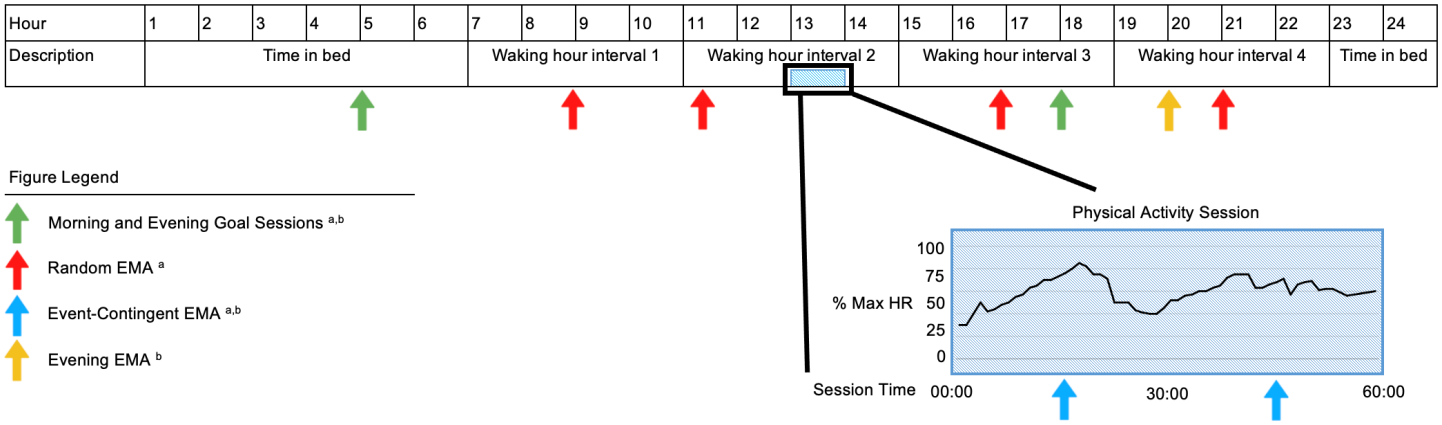
Instrumentation

Study variables will be collected with online questionnaires via REDCap surveys, smartwatch-based EMA ("check-ins"), smartwatch-based accelerometry, and an exit interview (Formative Study only).

Fitbit Versa smartwatch accelerometer: Participants will be loaned a Fitbit Versa smartwatch to be worn on the wrist for the duration of the study period, except while bathing. An internal accelerometer continuously measures physical activity intensity (sedentary, light, moderate, vigorous) and step count at the minute-level. **Heart rate (covariate)** is also recorded continuously and is used to determine smartwatch wear, as well as to calculate average heart rate during activity sessions >10 min. Only days with sufficient wear time (defined as ≥ 10 hours of valid data, where no more than 20 minutes per hour has a consecutive step count of zero) are used for analysis. **Daily steps** and **minutes of light, moderate, and vigorous physical activity (outcome)** are then calculated from minute-level data. Fitbit does not provide access to the raw acceleration data. However, activity intensities, steps, and heart rate measured by Fitbit devices have been shown to be reliable and valid as compared to other activity monitors including Actigraph.[42–45]

EMA via Fitabase Engage: Real-time prompted EMA ("check-ins") will be administered on the smartwatch using Fitabase Engage. If no interaction with the watch face is made, one reminder signal may be emitted before the prompt becomes inaccessible. EMA ("check-ins") take approximately 30 seconds to complete. If a prompt occurs during an incompatible activity (e.g., driving), participants will be instructed to ignore it. To minimize participant burden, all questions are answered by tapping the smartwatch interface.[46,47] Three types of EMA ("check-ins")—random, event-contingent, and evening—will be sent to participants. Random and event-contingent are used for the Formative Study, while the Comparison Study will use event-contingent and evening. Random EMA ("check-ins") will be randomly scheduled to be sent during normal waking hours, with a single prompt sent during each of four evenly spaced time windows: 0-4, 4-8, 8-12-, and 12-16-hours post-waking. Participants are asked to report their incidental affect via seven bipolar Likert Scale items. Five items (Energetic-Fatigued, Happy-Discouraged, Relaxed-Tense, Excited-Bored, Satisfied-Frustrated) are drawn from Russell's Circumplex Model of Affect;[48] one (Good-Bad) represents core affective valence;[49] and one (Proud-Embarrassed) represents self-conscious emotion.[50] One of these seven items is repeated as a validity check (i.e., for a total of eight items). Event-contingent EMA ("check-ins") are triggered when Fitbit sensors detect physical activity via moving average heart rate max. At least a 10-minute buffer (Formative Study) or 30-minute buffer (Comparison Study) separates the first and second event-contingent EMA during a single exercise bout, such that the moving average heart rate is "reset" following completion of the first prompt and the earliest possible second prompt is sent at least 10-minutes later (Formative Study) or 30-minutes later (Comparison Study) assuming the aforementioned threshold is met. A maximum of two event-contingent EMA will be sent within any given 60 min period. Participants are asked to safely pause their activity to answer questions about their **affective response (mediator)**[49,51,52] with the same eight (i.e., 7 unique + 1 repeated) items as the random EMA above. Event-contingent EMA also include end a Rating of Perceived Exertion (RPE) item and end by asking whether the current physical activity is the participant's planned session.[53] Finally, evening EMA ("check-ins") are sent to participants at 8 pm local time every day and ask participants to report their feelings from that day using the same eight affective response items as the random and event-contingent EMA (only modified to ask about their overall affect from that day, rather than their current affect). A depiction of the daily intervention strategies and measures is shown in Figure 2.

Figure 2. Daily eMOTION Intervention and Prompting Schedule



Note. [a] Used in the Formative Study; [b] Used in the Comparison Study.

REDCap surveys during morning and evening goal sessions are scheduled to be sent at the same time every day: 5:00 AM with approximately 5 reminders sent once every hour (morning goal session), and 6:00 PM with approximately 5 reminders sent once every hour (evening goal session). Sessions are sent via text message and completed via REDCap. These sessions will deliver the intervention components, as discussed above. Morning goal sessions also assess **affectively-charged motivations (mediator)**[54] with one item from the Attraction-Antipathy subscale of the AFFEXX,[55] and **anticipated affect (mediator)** with another item.[56] The morning goal session also measures incidental affective states using the same 7 items as the random and event-contingent EMA, stress,[57] pain,[58] fatigue,[59] illness, and sleepiness[60] as key **situational factors (moderator)**. Finally, the participant is asked whether they want to set a physical activity plan for that day, and whether their plan from the day before is the same or different from the plan they want to set for that day. Evening goal sessions measure **physical activity type** and **context (covariates)** by asking participants to report characteristics about the physical activity they performed that day (e.g., running, dance, hiking, home, park, alone, with spouse, perceived exertion[58]). They are also asked if they enjoyed the activity they did (if receiving affect-based goals) and whether they focused on their goal during physical activity. Three questions ask about the extent to which that day's physical activity satisfied various psychological needs.

Implicit Associations Test (IAT): For a sub-sample of particpants recruited starting March 2025 (n=120), they will receive a personalized ID code and an Internet link at the end of their morning goal session, prompting them click on the link, enter in the ID code, and complete a mobileIIAT on their personal smartphone device (i.e., smartphone word match activity). The mobile IAT asks participants to match to a conceptual target such as sedentary behavior (e.g., sitting, lying) or physical activity (e.g., walking, running) to affective attributes (e.g., good/bad).[61–64] If the participant has a strong automatic association between the attribute and conceptual target, then the reaction time will be shorter.[65] A D-score will be calculated by dividing the difference in the average reaction times between the positive and negative attributes by the pooled standard deviation of all the reaction times.[65] A higher D-score indicated more favorable implicit attitudes toward the target. The mobile IAT will take 2 min to complete.

Baseline Questionnaire: Participants receive an email or text message to complete a 45-minute online questionnaire with the HIPAA-compliant REDCap system at baseline (Baseline Questionnaire).[65] **Self-regulatory capacity (moderator)** is measured with questions related to self-control,[66] intentions,[67] and self-efficacy[16] for physical activity. Participants answer a series of questions about various **physical activity constraints** (e.g., ability, access to equipment) and rate the **importance of psychological needs (intervention enhancement tailoring variables)** across 10 domains (e.g., relatedness, esteem, creativity, challenge, learning) using a 33-item instrument developed in our prior work as an adaptation of the Basic Psychological Need Satisfaction and Frustration Scale.[68,69] The Baseline Questionnaire will also collect **demographics and other traits/behaviors (covariates),** including depression,[70] anxiety,[71] life satisfaction,[72] perceived stress,[73] grit,[74] personality,[75] sensation seeking,[76] stage of change for physical activity,[77,78] self-reported physical activity (International Physical Activity Questionnaire [IPAQ]),[79] physical activity enjoyment,[80] exercise preference/tolerance,[81] affective motivation for physical activity,[82] intrinsic motivation for physical activity,[83,84] physical activity attitudes[85] and identity,[86] sleep,[87] diet,[88] health status,[89] tobacco/alcohol/drug use, and demographics (e.g., race/ethnicity, income). **Anthropometrics (covariates)** in the form of height and weight,

self-reported physical activity habit[90] and lifetime history of activity, implicit attitudes about activity,[91] and mobility are also collected in the baseline questionnaire. **Mailing address** will also be collected during this time, to be able to send participants their Fitbit Versa smartwatch.

Mid-Study Questionnaire: Comparison Study participants will be asked to respond to a 30-minute REDCap questionnaire halfway through their participation in the study. This questionnaire will contain many of the same measures in the Baseline Questionnaire: demographics, general health, sleep schedule, depression, anxiety, life satisfaction, perceived stress, satisfaction of psychological needs through physical activity, physical activity enjoyment, exercise preference/tolerance, affective motivation and intrinsic motivation for physical activity, self-efficacy for physical activity, and physical activity intentions, attitudes, and identity. Participants also complete questions about their physical activity habits, as well as items about their sleep and mobility.

Post-Study Questionnaire: Participants will be asked to respond to a 30-minute REDCap questionnaire upon Formative Study completion. This questionnaire will contain the same questions as the Mid-Study Questionnaire, with additional items to assess the accessibility/usability and sustainability/feasibility of the interactive technology.[92] A similar questionnaire will also be administered after the Comparison Study.

Exit Interview: Participants in the Formative Study, as well as a sub-sample recruited to the Comparison Study starting March 2025 (n=120), will engage in a 45-minute video conference exit interview to assess user experiences, accessibility/usability, burden, thoughts toward specific study components, and issues related to sustainability/feasibility.

Compensation

Participants will be compensated for their time and efforts based on measure completion. Participants in the Formative Study will receive up to $75/three weeks: $35 for wearing the Fitbit Versa smartwatch all day and night (≥23 h/day), $35 for answering all Fitbit Versa smartwatch EMA ("check-ins"; with no more than one missed per day), and $5 for completing the exit interview (Formative Study only).

For the Comparison Study, participants will receive four payments of up to $100 each (paid every 4 weeks): $50 for wearing the Fitbit Versa smartwatch all day and night (≥23 h/day) and $50 for answering all smartwatch EMA ("check-ins"; except for those that occur while driving, sleeping, or another activity that precludes responding). A $50 payment will also be given during the 2-week "washout" break for wearing the Fitbit Versa smartwatch all day and night (≥23 h/day), and another $50 payment will be given for completing the Baseline ($20), Mid-Study ($15), and Post-Study Questionnaire ($15) s. The total possible compensation for the 19-week Comparison Study is $500, and participants also keep the Fitbit Versa smartwatch upon completion. For the 120 participants in the Comparison Study sub-sample (recruited starting March 2025), the compensation structure will be the same, except they will instead receive four payments of up to $120 each (paid every 4 weeks): $60 for wearing the Fitbit Versa smartwatch all day and night (≥23 h/day) and $60 for answering all smartwatch EMA ("check-ins"; except for those that occur while driving, sleeping, or another activity that precludes responding), and $20 for completing an exit interview, for a total of $600.

Participant Privacy & Data Management

Participants will be informed that all collected data is confidential. The study team will provide participant's personal study data upon request. The participants' names will be removed and replaced with an ID number on all records to preserve the participant's anonymity. Coded data is then entered into a database that will be stored and backed up on a university secured server. All physical materials pertaining to this study will be stored in a locked cabinet in the Real-Time Eating and Activity Children's Health (REACH) Lab that has key code access. Study staff undergo PI-guided specialized training for handling sensitive data in addition to the standard IRB-required training. All lab computers and laptops are password locked. Data collected by the screener will be destroyed after it is used to determine eligibility. Coded EMA ("check-in") and accelerometer data will be sent from the Fitbit to the linked smartphone; the data will then be securely transferred to Fitabase, a fully hosted, cloud-based software solution that implements robust industry standards to maintain secure databases and keep data private. Fitabase code and databases physically reside on the Microsoft Azure platform. Morning and evening goal session and online questionnaire data will be collected through REDCap. USC will store all data captured in REDCap on University servers. Results of the IAT (word match activity) are saved as individual de-

identified files in a limited-access encrypted Google Developer file system. Files are downloaded to secure USC servers for storage, processing, and analysis before being deleted from the Google system. Data will be downloaded from Fitabase servers and stored in a de-identified format on secure servers at USC that operate behind a firewall. Participants are assigned study-specific Fitbit accounts to use for the duration of the study; these accounts are deactivated (i.e., deleted through Fitbit.com by the study team) upon participant completion of the study. All Fitbit smartwatches returned to the study team (i.e., for the Formative Study or participants not finishing the Comparison Study) will be factory reset prior to being reused. Comparison Study participants who keep their Fitbit smartwatches will be instructed to create a new (private) Fitbit account for further use with the device. Participants will be informed of this during the informed consent process. All researchers with access to the data will undergo data sensitivity training specific to this project, beyond standard training required by our IRBs. Publications and presentations of study data will not contain any personal information about the participants. Breach of confidentiality is highly unlikely, given the de-identification and encryption of all sensitive information and materials. A master key linking participant names and ID numbers will be stored in a separate electronic location accessible only by the PI and Project Manager.

The majority of study staff will be blinded to participant assignment for most of the study period.

Data Analysis

Formative Study

For the Formative Study, DTx RWE Framework benchmarks will be assessed with descriptive statistics (e.g., mean scores, frequencies tallied and expressed as percentages of the sample). Most benchmarks explicitly specify the percentage (e.g., <1% or ≥51% of participants) of the sample or the mean score of the scale/measure (e.g., System Usability Scale score ≥68, Delighted-Terrible Scale score of 2-4) that define "success" for that benchmark. The analytic plan for the few benchmarks that are not explicit about the exact statistics used is outlined below. See also the attached document for more details.

For the equity benchmark (overall physical activity program), accessibility and efficacy of the intervention will be compared between the following groups of participants: sex (male; female), race (white; non-white), ethnicity (Hispanic; non-Hispanic), age (continuous/frequency distribution), BMI (continuous/frequency distribution), income (≤$44,999; $45,000 to $84,999; $85,000 to $124,999; ≥$125,000), able-bodied (continuous/frequency distribution of total constraints and total difficulties with mobility). It should be noted that the Formative Study is not statistically powered to compare groups of subjects, so these between-group comparisons will be a subjective examination of System Usability Scale scores (for accessibility) and reported change/lack of change in physical activity enjoyment (for efficacy) across all levels of each of the sub-groups. If these values are approximately equal between the groups, then the benchmark will be achieved. Even though statistical testing will not be performed for this benchmark due to a lack of power, we will report raw tallied data to promote transparency.

For the Psychological Needs Component's accessibility/usability benchmark, the total number of self-reported physical activity type, location, and listening context constraints are tallied for each person. Cross-tabulation tables will then allow for the reported ability to follow activity recommendations (yes/no) to be qualitatively compared across the full range of total constraints (physical activity type, location, and listening context) reported by all participants. To achieve the benchmark, there must not be an observable trend between the number of constraints reported and a person's ability to follow the activity recommendations (e.g., when the cross-tabulation table is studied, participants in the upper half of the distribution for total constraints should be, at the very least, approximately equally as heterogenous as the lower half of the distribution for reported ability to engage [yes/no] in the activity recommendations). As above, the raw tallied data will be reported to promote transparency.

Comparison Study

Exploratory analysis will examine the distributions, identify needed data transformations, investigate multicollinearity, and identify extreme observations. Data will be analyzed with SAS and R. Missing data analyses will involve considerations of imputation methods,[93,94] attrition propensity scores[95] based on the compliance/dropout for each participant,[96] and sensitivity analyses. We will consider age, sex, income,

race/ethnicity, BMI, and fitness as confounders. Other variables associated with outcomes (p<.10) will be included as covariates. Exploratory tests of moderation will also be conducted, as there may be sex and age differences in physical activity[97,98] and affective mechanisms.[99–101] Power estimates were evaluated using Monte Carlo simulations in Mplus.[102–105] The estimated effect size of affect-based physical activity interventions range from a small effect on the primary outcome (affective response) (f^2 =0.04, representing a 0.3 point increase on a 5-point affect scale)[54] to a medium effect on the secondary outcome (physical activity) (f^2 =0.17, representing a 30/min week increase in MVPA).[106] A sample of N=200 participants (100 per condition) (after ~30% attrition) is needed to detect small between-subject effects on change in the outcomes (H2 and H3) with β =.80 and α=.05. To detect within-subject effects (H1 and H4), our level-1 sample sizes will be much larger (e.g., 200x4x4x7 level-1 N for daily data). Thus, we should have sufficient power to detect very small effects for the remaining associations. H5 is exploratory and not statistically powered.

AIM 1: Determine whether affective mechanisms can be experimentally manipulated. In the Formative study, descriptive statistics (means, frequencies) will assess acceptability and feasibility of content, delivery methods, device usage, engagement, and raw values for change in affective mechanisms. The Comparison study will use an "intent to treat" approach to test the (1) within-subject effects of affect- vs. intensity-based goals (H1), (2) between-subject effects of affect-based goals with vs. without TYPE/CONTEXT (H2), and (3) between-subject effects of affect-based goals with vs. without SAVOR (H3) on the primary outcome (affective responses and affectively-charged motivations) and secondary outcome (physical activity). We will use random-effect regression models (level 1-days, level 2-subjects), which adjust for clustering within subjects and incorporate random effects.[107] Each treatment effect and each outcome will be tested in separate models. We will examine cross-level interactions between affect-based goals with vs. without savoring (level 2) and affective responses (level 1) to test H3.

AIM 2: Determine whether affective mechanisms mediate effects of interventions on physical activity (Comparison Study). Multilevel mediation will be tested using a 1-1-1 strategy that fits a set of simultaneous equations using path analysis in R.[108] Analyses will test the effects of intervention engagement on same-day/same-week affectively-charged motivations and affective response; the effects of affectively-charged motivations on same-day/same-week physical activity and the effects of affective responses on next-day/next-week physical activity; the indirect effects of intervention engagement on same- and next-day/same- and next-week physical activity via affective mechanisms (H4); and the total effects (mediated plus unmediated) of intervention engagement on physical activity.

AIM 3: Explore cross-person and cross-situation moderating effects (Comparison study). We will add interaction terms for time-varying and time-invariant effect moderators (H5).[109]

Dissemination of Findings

Team members are actively engaged in professional activities and routinely make presentations to the national and international conferences. We will share data and results generated by this study in several ways, including meetings with weight management clinics, physical and occupational therapists, physical activity practitioners, conference presentations, and publications. The results obtained in this study will be made available to the scientific community through publication in peer-reviewed journals (e.g., Annals of Behavioral Medicine, Health Psychology, Journal of Physical Activity and Health, American Journal of Preventive Medicine), presentations at national and international scientific meetings, and seminar presentations in academic departments. Efforts will be made to share findings with physical activity and public health practitioners by presenting results at conferences of obesity, public health, and physical activity organizations (e.g., Obesity Society, American Public Health Association) and by distributing the information through the Los Angeles County Health Department, which has a long and close collaboration with the University of Southern California.

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