Title:	**Behavioral Economics for Activity Motivation in Adolescents and Young Adults with Prediabetes and Type 2 Diabetes**
Short Title	**BEAM Trial**
Drug or Device Name(s):	N/A
FDA IND	N/A
Regulatory Sponsor:	NIH
eIRB Number :	STUDY21040122
Protocol Date:	July 2, 2021

Amendment 1 Date: February 22, 2022 [added option to recruit from Adolescent Medicine in addition to Endocrinology]

Sponsor: National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Disorders

K23DK125719-02 (PI: Mary Ellen Vajravelu, MD MSHP)

Study Principal Investigator: Mary Ellen Vajravelu, MD MSHP

Children's Hospital of Pittsburgh

Division of Pediatric Endocrinology, Diabetes, and Metabolism
University of Pittsburgh School of Medicine
email: MaryEllen.Vajravelu@pitt.edu

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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse event
AYA	Adolescent and Young Adult
BEAM	Behavioral Economics for Activity Motivation trial
BMI	Body mass index
BREQ-3	Behavioral Regulation in Exercise Questionnaire-3
mHealth	Mobile Health
MCQ	Monetary Choice Questionnaire
MVPA	Moderate to vigorous physical activity
PCTRC	Pediatric Clinical and Translational Research Center
PHI	Protected Health Information
RAI	Relative Autonomy Index
SAE	Serious adverse event
T2D	Type 2 Diabetes
W2H	Way to Health

ABSTRACT

Context: There is an urgent need to engineer targeted physical activity interventions that are effective and scalable for obese adolescents and young adults (AYA) with type 2 diabetes (T2D), who often have very low levels of physical activity. The BEAM Trial is a proposed mobile health (mHealth) intervention that uses behavioral economic-informed financial incentives and text messaging to promote physical activity in AYA with T2D and prediabetes.

Objectives: The primary objective is to determine the main and interactive effects of four intervention components ("factors") on time spent in moderate to vigorous physical activity (MVPA). Secondary objectives include to determine the main and interactive effects of the four intervention components on steps per day, body mass index Z-score; hemoglobin A1c; fasting insulin, glucose, triglycerides, LDL, and HDL; and liver enzymes (AST, ALT).

Study Design: 2^4 full factorial trial; participants randomized to one of 16 experimental conditions (combination of 4 factors with 2 levels each: 1) text messages sent (a) once daily, or (b) twice daily; 2) financial incentives that are (a) loss- or (b) gain-framed; 3) step count goals set as (a) weekly or (b) daily; and 4) step count goal set as (a) ramped or (b) fixed)

Setting/Participants: 13-22 year-old AYA who are overweight or obese (BMI≥85th percentile for age/sex, or ≥25 kg/m2 if ≥18 years old), have prediabetes or type 2 diabetes, and attend the Endocrinology or Adolescent Medicine outpatient clinic at the Children's Hospital of Pittsburgh; 75 participants will be recruited.

Study Interventions and Measures: Vitals, body size measurement, pubertal status, medical history, nutrition, physical activity questionnaires, behavioral questionnaires, and laboratory assessments will be assessed at two in-person study visits; labs (insulin, glucose, hemoglobin A1c, lipids, liver enzymes) will be collected after overnight fast. The primary outcome of MVPA and secondary outcome of step count will be measured using Fitbit physical activity trackers worn daily during a 12-week intervention, which will take place after a 2-week run-in.

PROTOCOL SYNOPSIS

Study Title	Behavioral Economics for Activity Motivation in Adolescents and Young Adults with Prediabetes and Type 2 Diabetes Trial
Funder	National Institutes of Health
Study Rationale	Early intervention to reduce risks associated with youth-onset type 2 diabetes (T2D) is critical due to high rates of cardiovascular comorbidities early in the disease and a 15-year reduction in life expectancy. Due to the difficulty of treating T2D in younger people and the more rapid progression of disease, efforts to prevent disease progression in young people with prediabetes, and new and better ways to treat and prevent T2D in youth are needed. The proposed study uses a highly efficient experimental design to investigate multiple potential intervention components, such as text messages and behavioral economic-based financial incentives, aimed at creating an engaging, effective intervention.
Study Objective(s)	**Primary**: to determine the impact of each intervention component on time spent in moderate to vigorous physical activity (MVPA). **Secondary**: to determine the impact of each intervention component on daily step count; body mass index Z-score; hemoglobin A1c; fasting insulin, glucose, triglycerides, LDL, HDL; liver enzymes.
Test Article	Each participant will be randomized to 1 combination of 4 intervention components, each with two levels. The four intervention components are: 1) text messages sent (a) once daily or (b) twice daily; 2) financial incentives framed as (a) losses or (b) gains; 3) step count goals set as (a) weekly or (b) daily goals; and 4) step count goals: (a) ramped up gradually or (b) set at a fixed goal throughout the intervention.
Study Design	Factorial trial
Subject Population key criteria for Inclusion and Exclusion:	**Inclusion Criteria** 1. Males or females age 13 to 22 years 2. Overweight or obese (BMI $\geq 85^{th}$ percentile for age/sex, or ≥ 25 kg/m^2 for participants ≥ 18 years) 3. Diagnosis with a condition associated with insulin resistance, including prediabetes or type 2 diabetes 4. Consent (adult subjects), parental/guardian permission (if applicable), assent (if applicable) 5. Willingness to wear Fitbit during waking hours daily for duration of run-in and intervention 6. Possession of a smartphone with data plan.

	Exclusion Criteria 7. Potential subject unable to speak or read in English 8. Severe cognitive impairment 9. Permanent or temporary physical disability that impairs ambulation or precludes engagement in MVPA 10. Current pregnancy 11. Previously-diagnosed or current restrictive or purging eating disorder 12. MVPA>30 minutes per day or Fitbit wear < 4 days during second week of 2-week run-in period
Number Of Subjects	75 total, all at Children's Hospital of Pittsburgh
Study Duration	Each participant will attend 2 in-person study visits that will last 2-3 hours each. The duration from study entry to completion will be no longer than 17 weeks.
Study Phases	**Screening and recruitment**: Potential subjects will be identified via review of Endocrinology clinic schedules weekly and by using the CAYAH RESEARCH INTEREST FORM distributed by Adolescent medicine. After potential subjects are identified, they will be contacted along with their parents/guardians (as applicable), to screen for eligibility.Subjects will be consented and will be scheduled for a morning study visit at the Pediatric Clinical and Translational Research Center (PCTRC). They will be instructed to complete an overnight 12 hour fast at home prior to the study visit. **Visit 1 (in-person):** Participants will undergo fasting laboratory evaluations, vitals, anthropometry, pubertal status, medical history, and physical activity and behavioral questionnaires. Participants will be given Fitbit physical activity trackers to wear for the duration of the study during waking hours and will be instructed on use. **Run-In:** Participants will wear the Fitbit daily during waking hours for 14 consecutive days. They will receive daily reminder text messages to wear the Fitbit. At the end of 14 days, mean daily MVPA and number of days Fitbit was worn during days 8-14 will be determined. Participants will be excluded if their MVPA was >30 minutes/day or Fitbit wear was <4 days. Eligible participants will be randomized to 1 of 16 experimental conditions (4 factors, 2 levels each = 4^2=16) and step count goals assigned. **Visit 2**: Randomized participants will be called to review step goal; ineligible participants will be called to inform of study completion and will be asked to return the Fitbit via prepaid envelope. **Intervention:** Participants will wear Fitbits daily for 12 weeks. Three nutrition recalls will be conducted via phone (weeks 1-2). A

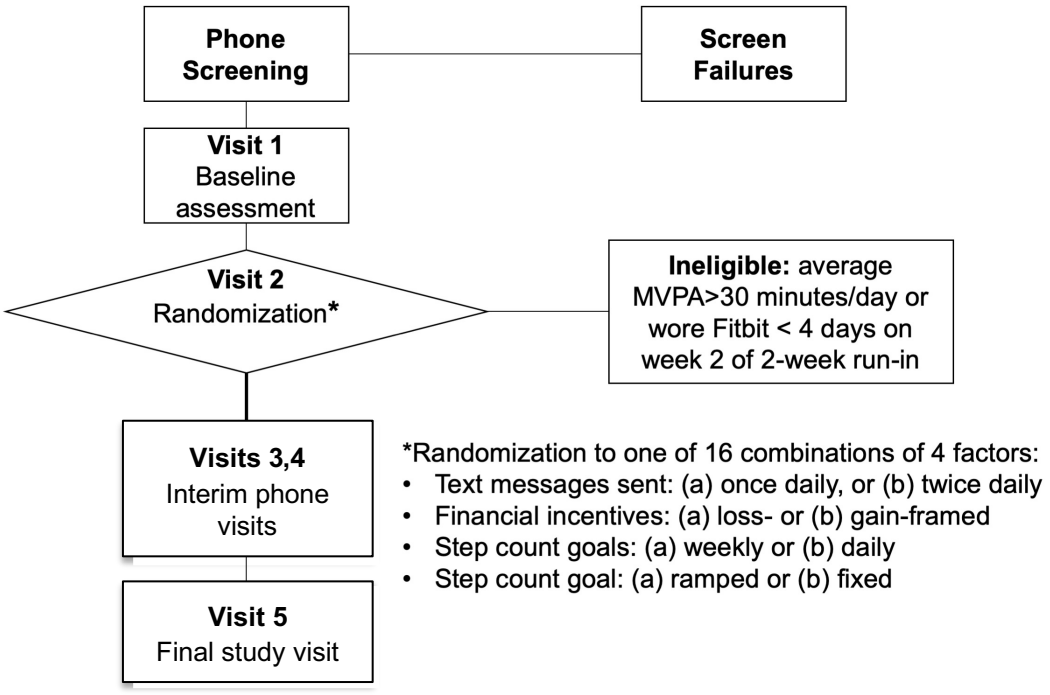
	safety check phone call (**Visit 3**) will take place during week 2 and another safety check and step count goal review phone call will take place during week 6 (**Visit 4**) . **Visit 5 (in-person):** After a 12-hour overnight fast at home, participants will attend the final study visit to undergo fasting laboratory evaluations, vitals, anthropometry, and exit interviews. Participants will return the Fitbit physical activity trackers.
Efficacy Evaluations	Change in minutes spent in MVPA (primary) and daily step count (secondary) from baseline to intervention week 12
Safety Evaluations	Adverse events are not anticipated. Any AEs and SAEs will be reported to IRB within the allotted timeframe.
Statistical And Analytic Plan	Demographic and clinical characteristics of subjects will be described using summary statistics, including means, standard deviations, medians, and ranges for continuous variables, and frequencies and percentages of participants for categorical variables. Data will be assessed for outliers. Scatter plots and box plots will be used to examine the relationship between independent (e.g. individual characteristics or component level, such as gain versus loss-framed incentives) and dependent variables. Longitudinal data will be summarized by factor level (e.g. loss-framed versus gain-framed incentives). Statistical analyses will be conducted using Stata 17 or R: A language and environment for statistical computing. The significance level for two-sided hypothesis testing will be set at 0.05. Effect coding will be used to represent each factor level (e.g. -1 for loss-framed and +1 for gain-framed financial incentives). ANOVA will be used to evaluate main and interactive effects of intervention components and component levels on the primary outcome of change in MVPA from baseline to 12 weeks, as well as secondary outcomes of change in BMI Z-score, fasting insulin, triglycerides, LDL and HDL from Visits 1 to 5. Main and interactive effects that demonstrate an increase in MVPA of $\geq$15 minutes per day from baseline to week 12 will be considered effective. The main and interactive effects of intervention components on change in MVPA from baseline to 6 weeks (mid-point) will also be explored using ANOVA.
DATA AND SAFETY MONITORING PLAN	The study team will be responsible for data management and collection and are responsible for the accuracy and completeness. Only investigators and study team members that have completed appropriate IRB training/approval are eligible to collect and work on information collected from this study. Data will be entered directly into REDCap by the study team or by participants when responding to surveys. In order to guard against disclosure of PHI, each study participant will be assigned a unique identification code.

	The code will be kept in a password-protected file on the PI's University-managed secure server.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	**Screening (Phone)**	**Baseline (PCTRC)**	**Run-In (Home)**	**Assign Goal (Phone)**	**Intervention (Home)**	**Interim Visits (Phone)**	**Follow-up (PCTRC)**
Visit Number		**1**		**2**		**3, 4**	**5**
Study Days			2-weeks	Within 1 week of run-in	12-week intervention	Weeks 2 and 6 of Intervention	Up to 2 weeks after Intervention
Verbal Consent/Assent	X						
Review Inclusion/Exclusion Criteria	X	X		X			
Written Documentation of Consent/Assent		X					
Demographics/Medical History		X					
Physical Examination		X					X
Vital Signs: BP, HR, RR		X					X
Anthropometry		X					X
Urine Pregnancy Test		X					
Prior/Concomitant Medications		X					X
Clinical Laboratory Evaluation		X					X
Individual interview, surveys		X					X
Dietary recall					X		
Randomization				X			
Provide/Collect Fitbit		X					X
Fitbit compliance, goal review			X	X		X	
Assess baseline physical activity			X	X			
Adverse Event Assessment				X		X	X
Daily Fitbit use			X		X		

FIGURE 1: STUDY DIAGRAM



1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Obese adolescents and young adults with type 2 diabetes are significantly less active than non-diabetic peers, despite the many cardiovascular and diabetes-related benefits of physical activity. Mobile health (mHealth) strategies offer benefits over in-person physical activity interventions including convenience, but convenience alone is unlikely to significantly alter behavior. The BEAM Trial (Behavioral Economics for Activity Motivation in Adolescents and Young Adults with Prediabetes and Type 2 Diabetes) seeks to be the first to use behavioral economic principals, combined with traditional health behavior change theory, in an mHealth intervention to effectively motivate obese adolescents and young adults with prediabetes and type 2 diabetes to increase moderate to vigorous physical activity (MVPA). This work is supported by a funded NIH K23 Career Development Award. The trial will use Way to Health (W2H), a web-based platform that allows two-way text messaging, delivery of behavioral economic-informed financial incentives, and integration with the physical activity tracker Fitbit.

1.2 Name and Description of Intervention

This trial will evaluate four intervention components ("factors"), each with two levels: once- or twice-daily behavior change theory-informed text messages, loss- versus gain-framed financial incentives, weekly versus daily step count goals, and ramped versus fixed stepcount goals.

1.3 Relevant Literature and Data

Youth-onset T2D is rising in incidence and associated with severe comorbidities, but effective methods of delaying or preventing disease progression are lacking. The incidence of youth-onset T2D is rising, with the greatest rate of increase among racial and ethnic minorities.(Mayer-Davis, Lawrence et al. 2017) Youth-onset, as compared to adult-onset T2D is especially worrisome due to faster decline in pancreatic beta-cell function,(Nadeau, Anderson et al. 2016) as well as high rates of diabetes-related complications soon after diagnosis, including elevated blood pressure (14%), microalbuminuria (13%), low HDL cholesterol levels (80%), and high triglycerides (10%).(Copeland, Zeitler et al. 2011) Individuals with youth-onset T2D also face a striking 15-year reduction in life expectancy.(Rhodes, Prosser et al. 2012) Unfortunately, effective medications to preserve beta-cell function in youth are lacking,(Consortium 2018) leaving only lifestyle interventions to reduce obesity-related risks.

Physical inactivity is an important modifiable risk factor for individuals with T2D and prediabetes. Physical activity in youth is associated with decreased fasting insulin, increased insulin sensitivity(Ho, Garnett et al. 2013, Lee, Deldin et al. 2013, Fedewa, Gist et al. 2014) and improved body composition,(Lee, Deldin et al. 2013) and youth with T2D are recommended to engage in at least 60 minutes of MVPA daily, the same as for healthy youth.(Copeland, Silverstein et al. 2013, Colberg, Sigal et al. 2016) However, youth with T2D are significantly less active than obese youth without T2D, ranging from 8 minutes per day of MVPA in 15-18 year-old girls to 35 minutes per day in 10-14 year-old boys.(Kriska,

Delahanty et al. 2013) Overweight youth in Philadelphia are similarly failing to meet activity recommendations: only 31% reported being physically active for ≥5 hours per week, while 30% reported being active for ≤2 hours per week.(Deatrick, Klusaritz et al. 2019)

Example activities that constitute MVPA in youth include walking > 4.0 miles/hour, team sports, jogging, biking, and housework including sweeping and vacuuming.(Butte, Watson et al. 2018) Longer average time spent in MVPA daily is negatively associated with body mass index Z-score in youth. Increased physical activity can reverse impaired glucose tolerance, impaired fasting glucose, and elevated hemoglobin A1c in youth(Weiss, Taksali et al. 2005, Savoye, Caprio et al. 2014, Love-Osborne, Sheeder et al. 2017) and adults(Knowler, Barrett-Connor et al. 2002) with prediabetes, although evidence for improvement in glycemic control is mixed for youth with T2D,(Group, Zeitler et al. 2012, Herbst, Kapellen et al. 2015) likely reflecting differences in intervention design. In addition to a potential impact on glycemic control, greater PA has been associated with improved perception of physical abilities among youth with T2D,(O'Neill, Liese et al. 2012) as well as improvement in depression,(Brown, Pearson et al. 2013, McGavock, Dart et al. 2015) psychological well-being, executive functioning, and school performance(Pivovarov, Taplin et al. 2015) among children and adolescents without diabetes. Even time spent in low-intensity physical activity has been associated with improved diastolic blood pressure and higher HDL in adolescents(Carson, Ridgers et al. 2013) as well as lower prevalence of hyperglycemia(Manders, Van Dijk et al. 2010) and greater insulin sensitivity(Newsom, Everett et al. 2013) in adults with T2D. Due to the potential benefits of increased physical activity for AYA with prediabetes and T2D, methods to successfully promote engagement in PA interventions are needed.

Mobile health (mHealth) interventions are a promising way to promote health behavior change in youth. In-person lifestyle interventions(Elvsaas, Giske et al. 2017) face challenges with scalability due to the need for dedicated space and multidisciplinary staff, and in-person interventions have high attrition rates, particularly among economically disadvantaged and minority youth.(Zeller, Kirk et al. 2004) mHealth strategies have been used successfully for a wide variety of health behavior change interventions in youth(Fedele, Cushing et al. 2017) and allow interventions to be more scalable, especially given the near-ubiquity of smartphone use among adolescents.(Pew Research Center)

The effectiveness of mHealth-based interventions can be improved through the use of behavior change theories as well as strategies to promote user engagement.(Vandelanotte, Muller et al. 2016) Use of health behavior change theories can allow for systematic identification of targets for behavior change interventions.(Glanz, Rimer et al. 2015) The Theory of Planned Behavior (TPB),(Azjen 1991) a commonly used model for adolescent and adult health behavior change interventions,(Muzaffar, Chapman-Novakofski et al. 2014) suggests that *intention* to engage in a behavior is the proximal determinant of that behavior. Intention, in turn, is predicted by the 3 main constructs of the TPB: attitude (belief about consequences of behavior combined with evaluation of consequence), subjective norm (belief about what others want one to do and motivation to comply), and perceived behavioral control (belief about amount of control one has to successfully perform the behavior).

Although the TPB posits that behavior follows intention, the field of behavioral economics (BE) emphasizes that humans do not always act in their best interest and applies psychological insights to explain behaviors that are in apparent opposition to health behavior goals. BE-informed interventions have been used in numerous studies of adults to promote health behavior change.(Volpp, John et al. 2008, Patel, Asch et al. 2016, Patel, Benjamin et al. 2017, Patel, Volpp et al. 2018, Glanz, Shaw et al. 2019) One BE insight is that framing, or the presentation of the same information in ways that highlight different informational cues, can significantly impact decision-making.(Thaler 1999, Dhami 2016) As losses tend to be felt more acutely than gains (*loss aversion*),(Kahneman and Tversky 1979, Patel, Asch et al. 2016, Wong, Miller et al. 2017) presenting information in a "loss-framed" manner tends to be a convincing strategy. In addition, the concept of *delay discounting* describes the tendency to prefer smaller rewards sooner over larger rewards later.(Laibson 1997) Higher rates of delay discounting have been associated with worse glycemic control and lower physical activity among adults with prediabetes and type 2 diabetes.(Epstein, Paluch et al. 2020) Although use of traditional behavior change theories is common among mHealth-based interventions, application of BE principals to the design of behavior change interventions has been understudied.

Motivation to perform health behaviors such as physical activity can be intrinsic or extrinsic, which may have implications for success and persistence of behavior change.(Ryan and Deci 2000) According to the Self-Determination Theory, intrinsic and extrinsic motivation (divided into external, introjected, identified, and integrated regulation) fall on opposite ends of a continuum.(Ryan and Deci 2000) *Intrinsic regulation* represents a desire to engage in an activity for its own sake, while *extrinsic regulation* represents engagement in activity only to achieve outcomes or to satisfy a requirement (such as meeting a step count goal to obtain a financial incentive). *Introjected regulation* refers to motivation to perform an activity in order to avoid negative feelings; *identified regulation* represents a willingness to perform an activity that is not enjoyable in order to remain consistent with personal values; and *integrated regulation* falls between identified regulation and intrinsic regulation and represents performance of an activity because it is consistent with one's values and needs. *Amotivation* refers to a lack of intention to engage in an activity. Previous studies have found that more autonomous/less extrinsic motivation is associated with greater physical activity in children and adolescents.(Owen, Smith et al. 2014, Navarro, Escobar et al. 2020) Measuring and understanding whether the degree of intrinsic or autonomous motivation changes when extrinsic rewards are offered will add depth to the findings of our proposed intervention.

1.4 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Pittsburgh and University of Pittsburgh Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with institutional Policies and Procedures and all federal requirements.

Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to determine the efficacy of multiple components of an mHealth intervention aimed at promoting increased physical activity in adolescents with prediabetes or T2D.

2.1 Primary Objective

The primary objective is to determine the main and interactive effects of four experimental factors (*once- versus twice-daily behavior change theory-informed text messages, loss- versus gain-framed financial incentives, daily versus weekly step count goals, and ramped versus fixed step count goals*) on time spent in moderate to vigorous physical activity.

2.2 Secondary Objectives

The secondary objectives are to:

- Determine the main and interactive effects of the four intervention components on:
  - Daily step count
  - body mass index Z-score
  - hemoglobin A1c
  - fasting insulin
  - fasting plasma glucose
  - fasting triglycerides, LDL, and HDL
  - AST, ALT
- Explore participant-reported intervention acceptability, including constructs of burden, perceived effectiveness, and impact on self-efficacy
- Assess baseline and intervention-related changes in intrinsic versus extrinsic motivation to pursue physical activity
- Assess the association between baseline delay discounting tendency and baseline and change in MVPA and step count
- Assess the correlation between Fitbit-measured physical activity and smartphone-measured physical activity

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This factorial trial will include screening by phone, completion of two in-person and two phone study visits, completion of dietary recalls by phone at home, and daily wearing of Fitbit physical activity tracker during waking hours for a 14-day run-in period and 12-week intervention.

3.1.1 Screening Phase

Potential subjects will be identified through weekly review of Pediatric Endocrinology and Diabetes clinic schedules. In addition, a list of potentially eligible patients will be generated via review of a list of patients with diagnosis of prediabetes or type 2 diabetes provided by Pitt+ME. Medical records of potential subjects will be screened by the study team using the protocol inclusion and exclusion criteria. The CAYAH RESEARCH INTEREST FORM will also be used for recruitment purposes. This is a REDCap form with a survey link that will contain questions for adolescents to answer self-screen questions which are non-sensitive. Center for Adolescent and Young Adult Health (CAYAH) clinical staff will manage and distribute this survey. CAYAH clinical research staff will advertise the study to the teen. If the teen (age 13 or older) indicates interest in the study by viewing the study advertisement within the CAYAH RESEARCH INTEREST FORM, they will provide their contact information to the CAYAH clinical research staff who will then share it with the study team. Those who appear to meet the criteria will be approached by a member of the study team by phone and asked if they would like to hear about the study. Subjects and/or their parent/guardian will provide demographic, social, and medical information about themselves, their child, or family (as applicable) to confirm eligibility. Subjects will complete an overnight fast at home prior to the baseline study visit.

3.1.2 Baseline Study Visit (Visit 1)

After a 12-hour overnight fast at home, participants will attend Visit 1 at PCTRC to obtain baseline physical and biochemical data, as well as to complete individual interviews and surveys. At that visit, participants will be given a Fitbit to use during the study and instructed on its use. Participants will download the Fitbit app on their smartphone for use during the study. Participants will also work with a study team member to form an individualized implementation intention statement, which will include specific details about what, when, and where the subject will participate in a physical activity of choice, as well as contingency plans to help promote completion of planned activities.

3.1.3 Run-In

To determine baseline physical activity (MVPA), participants will be asked to wear the provided Fitbit for 14 consecutive days during waking hours and to sync the Fitbit daily with the app on their smartphone. They will also receive reminder text messages twice daily. Participants with mean daily MVPA >30 minutes or with < 4 days of Fitbit wear during the second week of run-in will be withdrawn from the study and will not continue on with the intervention. All participants will be called by phone (Visit 2) to review whether they will proceed to the intervention or not. Withdrawn participants will be asked to return the Fitbit using a prepaid envelop.

3.1.4 Intervention

The 12-week intervention will consist of text messages sent to the participant and financial incentives that are dependent on compliance with step count goals. Eligible participants will be randomized and individualized step count goals for the intervention will be reviewed. The participant will be instructed that the intervention will begin on the following Monday and will last for 12 weeks.

During week 2 of the intervention, study staff will call the participant by phone to review adverse events or other safety concerns (Visit 3). During week 6 of the intervention, study staff will call the participant by phone (Visit 4) to obtain feedback from the participant on the intervention and to troubleshoot any issues with the Fitbit.

Dietary recalls (3) will be conducted by phone during the first two weeks of the 12-week intervention.

3.1.5 Follow Up Study Visit (Visit 5)

Within 2 weeks of completing the 12-week intervention, participants will be requested to return to PCTRC for Visit 5 to obtain follow-up physical and biochemical data, as well as exit interview. Participants will be asked to fast for a minimum of 12 hours before the visit, and will be asked to return the Fitbit at study visit 5.

3.2 Allocation to Treatment Groups and Blinding

3.3 Allocation to Treatment Groups

Participants will be randomized via Way to Health to 1 of 16 experimental conditions (4 factors, with 2 levels each; e.g., twice-daily text messages + loss-framed incentive + weekly goals + ramped goals = one experimental condition).

3.4 Study Duration, Enrollment and Number of Sites

3.4.1 Duration of Subject Study Participation

Each in-person study visit is expected to take approximately 1-1.5 hours. Screening, phone study visits, and dietary recalls are expected to take approximately 30 minutes each. The entire study duration per subject is planned to last a maximum of 17-weeks (2-week run-in, up to 1 week between run-in and intervention, 12-week intervention, ending with study visit up to 2 weeks after completion of intervention). However, the time window between completion of the intervention and Visit 5 could be adjusted due to public health recommendations, and/or local, state, federal, and/or institutional guidelines.

3.4.2 Total Number of Study Sites/Total Number of Subjects Projected

This study will be conducted at the Children's Hospital of Pittsburgh. A maximum of 75 subjects will be included.

3.5 Study Population

We will not restrict enrollment based on gender or age within the eligible age group.

We plan to enroll only English-speaking patients.

3.5.1 Inclusion Criteria

1) Males or females age 13 to 22 years.
2) Overweight or obese (BMI ≥85th percentile for age/sex, or ≥25 kg/m^2 for participants ≥18 years)
3) Diagnosis with a condition associated with insulin resistance, including prediabetes or type 2 diabetes.
4) Consent (subjects 18 and older), Parental/guardian permission (subjects 13-17), assent (subjects 13-17)
5) Willingness to wear Fitbit during waking hours daily for duration of run-in and intervention.
6) Possession of a smartphone with data plan.

3.5.2 Exclusion Criteria

1) Potential subject unable to speak or read in English
2) Severe cognitive impairment
3) Permanent or temporary physical disability that impairs ambulation or precludes engagement in MVPA
4) Current pregnancy
5) Previously-diagnosed or current restrictive or purging eating disorder
6) MVPA>30 minutes per day or Fitbit wear < 4 days during second week of 2-week run-in period

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Phone screening

- Medical Record Review
- Brief study overview: 5 minutes
    - Consent/HIPAA Authorization: 5-10 minutes/as long as needed for full comprehension of study involvement
    - Screening questionnaire: 15 minutes

- Overview of 12-hour overnight fast and upcoming screening visit: 5 minutes

4.2 Visit 1

- Vital signs (heart rate, blood pressure): 5 minutes
- Urine pregnancy test (all females): 3 minutes
- Height, weight, waist and hip circumference: 5 minutes
- Focused physical exam, including pubertal status: 5 minutes
- Fasting blood draw: 10 minutes
- Baseline questionnaires: 30 minutes
- Coach participant to form implementation intention statement about physical activity: 10 minutes
- Provide Fitbit, help participant download app, and instruct on use: 5 minutes

4.3 Run-In and Randomization

4.3.1 2-Week Run-In

- Participant wears Fitbit daily during waking hours and syncs daily with smartphone
- Daily text message reminder sent to participant
- On day 15, study team will evaluate MVPA during days 8-14
    - Exclude from intervention if mean > 30 minutes/day or if < 4 days with evaluable Fitbit data
- Calculate mean daily step count during days 8-14, to provide to participant for reference

4.3.2 Visit 2 (Phone)

- Randomize to 1 of 16 experimental conditions

Experimental Condition	*Text*	*Ramped goal*	*Incentive Framing*	*Goal time period*
1	+	+	+	+
2	+	+	+	-
3	+	+	-	+
4	+	+	-	-
5	-	+	+	+
6	-	+	+	-
7	-	+	-	+
8	-	+	-	-
9	+	-	+	+
10	+	-	+	-
11	+	-	-	+
12	+	-	-	-
13	-	-	+	+
14	-	-	+	-
15	-	-	-	+
16	-	-	-	-

Figure 2. $2^4 = 16$ experimental conditions

- Call participant to:
    - Review assigned step count goal
    - Explain financial incentive structure
    - Troubleshoot concerns related to Fitbit or text messages
    - If not eligible based on run-in: inform participant of study completion and request return of Fitbit via prepaid envelope

4.4 12-Week Intervention

4.4.1 Dietary recalls (phone)

- 2 weekday, 1 weekend recall during weeks 1-2 of intervention: 3 x 30 minutes each

4.4.2 Visit 3 (phone), Intervention Week 2

- Assess possible adverse events

4.4.3 Visit 4 (phone), Intervention Week 6

- Assess possible adverse events

- Medical Record Review
- Troubleshoot any concerns related to Fitbit or text messages

4.5 Study Completion

4.5.1 Visit 5, within 2 weeks of Intervention completion

- Medical Record Review
- Assess possible adverse events: 5 minutes
- Current medications: 3 minutes
- Vital signs (heart rate, blood pressure): 5 minutes
- Height, weight, waist and hip circumference: 10 minutes
- Fasting blood draw: 10 minutes
- Individual exit interview: 30 minutes
- Collect Fitbit

.

4.6 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules, AEs, or due to adherence to study treatment or visit schedules. The Investigator may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the clinical study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the case report form (CRF) on REDCap.

Fitbit, questionnaire, interview, and clinical data obtained prior to subject withdrawal will be retained.

4.6.1 Early Termination Study Visit

Subjects who withdraw from the study will have all procedures enumerated for Visit 5 as the early termination visit if at least 4 weeks have elapsed since the start of the 12-week intervention.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Medical Record Review

Participants will be interviewed regarding their medical history. To ensure that no major items are missed and to clarify interview answers, the study team will review participant electronic medical records prior to and after the participant interview to confirm the following:

- Date of birth
- Birth history (gestational age, birth weight, complications during pregnancy)
- Anthropometrics (weight, height, BMI)
- Medications
- List of medical problems, especially as they relate to inclusion and exclusion criteria
- Demographic data including race, ethnicity, gender, and insurance type
- Endocrine-related diagnoses, including: insulin resistance, prediabetes, impaired glucose tolerance, impaired fasting glucose, elevated hemoglobin A1c, diabetes mellitus, and polycystic ovary syndrome
- History of attendance at an obesity clinic
- History of bariatric surgery
- Diabetes-related labs, including: plasma and point-of-care glucose, hemoglobin A1c, and insulin
- History of non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, elevated ALT or AST, or other known liver disease

5.1.2 Physical Examination

A study physician (pediatric endocrinologist) will review with the parent and child the child's current and past medical history, a review of systems, and family history (with particular attention to cardiovascular disease and diabetes). A focused physical examination will be conducted, including measurement of height, weight, waist circumference, hip circumference, pubertal staging, and pertinent physical findings associated with insulin resistance, including the presence of acanthosis nigricans, which will be recorded on a standardized form. Investigators will verify that the patient has been fasting for a minimum of 12 hours.

5.1.3 Vital Signs

- Blood pressure (BP) will be recorded while the subject is sitting down by the nursing staff. BP will be measured by auscultation three times, after a five minute rest in a quiet area with the subject in a seated position; the average of the 2nd and 3rd measurements will be used.
- Pulse and respiratory rate will be measured by nursing staff

5.1.4 Laboratory Evaluations

5.1.4.1 Table: Clinical Laboratory Tests

Category	Tests
Biomarkers of glucose metabolism	Hemoglobin A1c, plasma glucose, insulin
Liver function tests	SGOT/AST, SGPT/ALT
Lipids	Triglycerides, LDL, HDL

5.1.4.2 Pregnancy Testing

A urine pregnancy test will be performed for all female subjects at baseline. A positive pregnancy result will be disclosed to the participant only. Pregnancy results will be disclosed to the parent/guardian if the subject gives the investigators permission. Subjects found to be pregnant during the visit will not be able to enroll in this study. The investigators will counsel the subject and guide them to seek the appropriate care.

5.1.5 Medical History and Family History Questionnaire

Will include past medical history, 1st and 2nd degree family history of diabetes, dyslipidemia, cardiovascular disease, and socioeconomic status questions.

5.1.6 Dietary Recalls

During weeks 1-2 of the intervention, three 24-hour (2 weekday, 1 weekend) dietary recall interviews of participants will be conducted by a Children's Hospital of Pittsburgh registered dietitian via phone or in-person. Reported intake will be entered into a nutrition application (e.g. CalorieKing), without any patient-identifying information, in order to determine nutrition information including calories, protein, saturated fat, fatty acids, added sugar, and sodium. These data will be used to calculate the Healthy Eating Index score, (Krebs-Smith, Pannucci et al. 2018) using the scoring standards listed in **Figure 3**.

HEI-2015[1] Components and Scoring Standards

Component	Maximum points	Standard for maximum score	Standard for minimum score of zero
Adequacy:			
Total Fruits[2]	5	≥0.8 cup equivalent per 1,000 kcal	No Fruit
Whole Fruits[3]	5	≥0.4 cup equivalent per 1,000 kcal	No Whole Fruit
Total Vegetables[4]	5	≥1.1 cup equivalent per 1,000 kcal	No Vegetables
Greens and Beans[4]	5	≥0.2 cup equivalent per 1,000 kcal	No Dark-Green Vegetables or Legumes
Whole Grains	10	≥1.5 ounce equivalent per 1,000 kcal	No Whole Grains
Dairy[5]	10	≥1.3 cup equivalent per 1,000 kcal	No Dairy
Total Protein Foods[4]	5	≥2.5 ounce equivalent per 1,000 kcal	No Protein Foods
Seafood and Plant Proteins[4,6]	5	≥0.8 ounce equivalent per 1,000 kcal	No Seafood or Plant Proteins
Fatty Acids[7]	10	(PUFAs + MUFAs) / SFAs ≥2.5	(PUFAs + MUFAs)/SFAs ≤1.2
Moderation:			
Refined Grains	10	≤1.8 ounce equivalent per 1,000 kcal	≥4.3 ounce equivalent per 1,000 kcal
Sodium	10	≤1.1 grams per 1,000 kcal	≥2.0 grams per 1,000 kcal
Added Sugars	10	≤6.5% of energy	≥26% of energy
Saturated Fats	10	≤8% of energy	≥16% of energy

[1] Intakes between the minimum and maximum standards are scored proportionately.

[2] Includes 100% fruit juice.

[3] Includes all forms except juice.

[4] Includes legumes (beans and peas).

[5] Includes all milk products, such as fluid milk, yogurt, and cheese, and fortified soy beverages.

[6] Includes seafood; nuts, seeds, soy products (other than beverages), and legumes (beans and peas).

[7] Ratio of poly- and mono-unsaturated fatty acids (PUFAs and MUFAs) to saturated fatty acids (SFAs).

Figure 3. Healthy Eating Index-2015 Components and Score Standards; https://www.fns.usda.gov/how-hei-scored.

5.1.7 Questionnaire Assessment

PACE+ adolescent physical activity questionnaire will be administered by the study coordinator or appropriate member of the investigative team. PACE+ is a validated, two question measure of physical activity.(Prochaska 2000)

Monetary Choice Questionnaire (MCQ) is a set of 27 questions developed by Kirby et al(Kirby, Petry et al. 1999) that is used to measure temporal discounting, or the tendency to prerfer smaller, sooner rewards over larger, delayed rewards. It is a self-administered questionnaire that has been used in numerous studies of adults and adolescents. Ten ranges of discount rates are used, with delays ranging from 7-186 days. To evaluate the degree of delay discounting, a hyperbolic function is fit to bivariate data on indifference points between delayed rewards (small, medium, and large rewards) and delay. A parameter (k) resulting from the model may be used to compare discount tendencies across individuals or over time.

Behavioral Regulation in Exercise Questionnaire-3 (BREQ-3) is a 24-item questionnaire drawing from Self-Determination Theory(Ryan and Deci 2000) that asks respondants to rate statements about physical activity behaviors as “Not true for me,” “Sometimes true for me,” or “Very true for me.”(Mullan, Markland et al. 1997, Wilson, Rodgers et al. 2006) It is used to assess motivation on the spectrum of intrinsic to extrinsic to amotivation and has been

used to assess motivation to perform physical activity in adolescents.(Navarro, Escobar et al. 2020)

5.1.8 Exit Interview

Semi-structured individual interviews will be conducted by study staff in a private setting at visit 5 to evaluate intervention acceptability, including constructs of burden, perceived effectiveness, and impact on physical activity-related self-efficacy. Interviews will be audiorecorded and then transcribed by a University of Pittsburgh-approved vendor.

5.1.9 Personal smartphone activity tracker data

Once weekly during the 12-week intervention, participants will be asked (via text message) to send in a screenshot of their smartphone's activity tracker's step count measurement for the week. Step counts will be abstracted via study staff and entered into a secure REDCap.

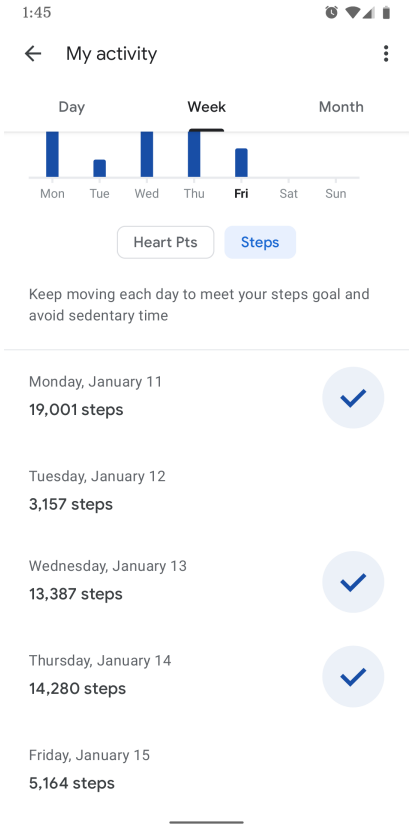


Figure 4. Example of smartphone activity tracker data summary

5.2 Efficacy Evaluations

MVPA (>100 steps per minute) is the primary endpoint to evaluate efficacy and will be obtained via Fitbit and W2H. Fitbit data collected through W2H will include step count, heart rate, manually logged activities, and sleep data, if available due to participant choosing to wear the Fitbit at night. MVPA will be calculated by W2H.

5.3 Safety Evaluations

Participants will be fasting for a minimum of 12 hours prior to on site study visits. This may cause hunger pangs, upset stomach, headache, or light-headedness. If the participant shows any signs of clinical instability or definitively decides to discontinue participation, the study visit will be ended.

The patient will be notified of any clinically relevant abnormal test result(s) performed, by mail and or by phone. It will be recommended that results, especially abnormal results, be discussed by the guardian with the participant's primary care physician.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

We will determine the main and interactive effects of intervention components on mean daily MVPA during week 12 of the intervention.

6.2 Secondary Endpoints

Secondary endpoints include main and interactive effects of intervention components on mean steps per day during week 12 of the intervention, and change from visit 1 to visit 5 in:

- body mass index Z-score,
- hemoglobin A1c,
- fasting insulin,
- fasting glucose,
- fasting triglycerides, LDL, HDL, and
- liver enzymes (AST, ALT)

6.3 Exploratory Measures

Self-reported behavioral and motivational measures will be collected to use as covariates in multivariable analysis, as well as for exploratory correlational analyses. These include:

- Delay discounting tendency (k)
- Relative autonomy index
- Healthy eating inventory
- Smartphone-collected step count

6.4 Control of Bias and Confounding

Potentially eligible subjects will be stratified by sex and age (13-18, 19-22), and an equal number of participants will be contacted per group until recruitment goals are reached or all potentially eligible subjects in a category are enrolled or decline to participate.

Multivariable models will adjust for covariates including age, sex, race, ethnicity, disease type (prediabetes versus diabetes), baseline laboratory values, anthropometrics (e.g. BMI-Z), and baseline activity level. The distribution of measured motivation characteristics and delay discounting tendencies will be assessed across intervention components (e.g., proportion with high measures of intrinsic motivation among those randomized to loss-framed versus those randomized gain-framed incentives) will be assessed. If imbalanced across components, these measures will be included in multivariable models.

6.5 Statistical Methods

6.5.1 Analysis of Primary and Secondary Outcomes of Interest

Descriptive and visual statistics: Demographic and clinical characteristics of subjects will be described using summary statistics, including means, standard deviations, medians, and ranges for continuous variables, and frequencies and percentages of participants for categorical variables. Data will be assessed for outliers. Scatter plots and box plots will be used to examine the relationship between independent (e.g. individual characteristics such as age, prediabetes versus T2D, race/ethnicity; as well as component level, such as gain versus loss-framed incentives) and dependent variables. Line plots will be generated for the primary outcome of daily MVPA, with one line per subject and an overall trend line. Longitudinal data will be summarized by factor level (e.g. loss-framed versus gain-framed incentives). Statistical analyses will be conducted using Stata 17 (StataCorp, College Station, TX) or R: A language and environment for statistical computing (R Corp Team, Vienna, Austria). The significance level for two-sided hypothesis testing will be set at 0.05.

Main Effects and Interactions: The trial is a 2^4 full factorial design (4 factors with 2 levels each), resulting in 16 experimental conditions. ***Importantly, this is not a 16-arm randomized control trial***: in factorial designs, subjects are "recycled," allowing for the N per level (e.g. subjects randomized to loss-framing) to be the relevant value rather than the n per experimental condition.(Collins 2018) Effect coding will be used to represent each factor level (e.g. -1 for loss-framed and +1 for gain-framed).(Collins, Dziak et al. 2014) Effect coding allows effect estimates to be uncorrelated when the factorial study is balanced, which allows hypothesis tests to be independent.(Collins 2018) With effect coding, beta coefficient standard errors are equal, so in a balanced design, the power to detect each coefficient is the same.

ANOVA will be used to evaluate main and interactive effects(Collins, Dziak et al. 2014) of intervention components and component levels on the primary outcome of change in weekly mean minutes in MVPA per day from baseline to 12 weeks, as well as secondary outcomes of change in BMI Z-score,(Centers for Disease Control and Prevention 2009) fasting insulin, triglycerides, LDL, and HDL from Visit 1 to Visit 5. For example, the main effect (ME) of ramped (versus no ramping) of step count goal on MVPA would be the mean change in daily MVPA of conditions 1-8 minus that of conditions 8-16: $\boldsymbol{ME_{Ramped}} = (\bar{\boldsymbol{\mu}}_{.+..} - \bar{\boldsymbol{\mu}}_{.-..})$, where **"+/-"** represent levels of each factor (i.e. ramped (+) versus no ramp (-)) and **"."** represents all levels combined. Two-way and three-way interactions will also be assessed. A two-way interaction is calculated by halving the difference in the effect of a factor across the level of a second factor, averaging over all other factors.(Montgomery 2009) For example, the interaction between twice-daily text messages and ramped goals would be half the difference in main effect of twice-daily messages for ramped conditions (mean of conditions 1-4 minus mean of conditions 5-8) and main effect of twice-daily messages for un-ramped conditions (mean of conditions 8-12 minus mean of conditions 9-12): $\boldsymbol{INT_{Ramped\times TwiceText}} = \frac{(\bar{\boldsymbol{\mu}}_{++..} - \bar{\boldsymbol{\mu}}_{-+..}) - (\bar{\boldsymbol{\mu}}_{+-..} - \bar{\boldsymbol{\mu}}_{--..})}{\mathbf{2}}$**.** A 3-way interaction between ramped goals, tailored text messages, and incentive framing (loss versus gain) would be calculated as: $\boldsymbol{INT_{Ramped\times TwiceText\times Incentive}} = \frac{(\bar{\boldsymbol{\mu}}_{+++.} - \bar{\boldsymbol{\mu}}_{-++.}) - (\bar{\boldsymbol{\mu}}_{+-+.} - \bar{\boldsymbol{\mu}}_{--+.}) - (\bar{\boldsymbol{\mu}}_{++-.} - \bar{\boldsymbol{\mu}}_{-+-.}) - (\bar{\boldsymbol{\mu}}_{+--.} - \bar{\boldsymbol{\mu}}_{---.})}{\mathbf{4}}$**.**

This will allow us to investigate the impact of intervention component settings individually and in combination, in order to determine which component settings are most effective at increasing MVPA and should be included in an optimized intervention. Main and interactive

effects that demonstrate an increase in MVPA of ≥15 minutes per day from baseline to week 12 will be considered effective. The main and interactive effects of intervention components on change in MVPA from baseline to 6 weeks (mid-point) will also be explored using ANOVA.

In addition to ANOVA to evaluate effects of the intervention on MVPA at fixed time points (0 versus 12 weeks, 0 versus 6 weeks, Visit 1 versus Visit 5), mixed effects linear regression models will be created, including interactions found to be significant in ANOVA. These models are implemented via maximum likelihood and account for within- and between-subject variability.(Hedeker and Gibbons 2006) Random intercepts will be used to allow for variation between subjects. Sensitivity of the primary analysis to choice of variance model will be examined.

Table 1 summarizes the analyses planned by outcome measure.

6.5.2 Qualitative analysis

After the completion of exit interviews, recordings will be transcribed. Transcripts will be analyzed in NVivo software, using directed content analysis techniques(Merriam and Tisdell 2016) to identify and organize relevant themes. Codes and coding rules for a codebook will be established by the PI and study staff based on the interview guide and transcripts. When the codebook is established, at least two study staff will independently code transcripts to identify themes and sub-themes, resolving disagreements in coding through discussion. Themes will be summarized and compared across demographic groups (e.g. sex, age, race/ethnicity), component-level (e.g., loss- versus gain-framed financial incentives), and diagnosis of prediabetes versus T2D, as well as by intervention effect on MVPA (e.g., more-successful versus less-successful goal achievement by study completion).

6.5.3 Exploratory analyses

Demographic characteristics of participants who were excluded after the run-in period (due to MVPA>30 minutes/day or Fitbit wear < 4 days in week 2) will be compared (mean/t-test or median/ranksum for continuous variables, or Fisher's exact test for categorical variables) to participants who were randomized and began the intervention. Adherence to Fitbit wear and syncing will be assessed as number of days with Fitbit data available during the intervention; adherence will be compared across baseline participant characteristics, including demographics, body size measurements, disease (prediabetes or T2D), relative autonomy index, and delay discounting measure.

Table 1. Analysis plan	
Outcome	**Analysis/statistical test**
MVPA min/day: *baseline* vs 6 and *12 weeks* (**primary outcome**)	Mean/SD or median/IQR, ANOVA/ANCOVA
MVPA min/day: *baseline* vs 6 and *12 weeks*	% of days with ≥60 min/day, Fisher's exact test
MVPA min/day: average per week of intervention	% of days with ≥60 min/day, Fisher's exact test
Steps/day: *baseline* (2nd-week of run-in) versus 6 weeks and *12 weeks*	Mean/SD or median/IQR, ANOVA/ANCOVA
Steps/day: *baseline* (2nd-week of run-in) versus 6 weeks and *12 weeks*	% of days with ≥10,000 steps/day, Fisher's exact test
Steps/day: average per week of intervention	% of days with ≥10,000 steps/day, Fisher's exact test
Body mass index Z-score	Mean/SD or median/IQR, ANOVA/ANCOVA
Hemoglobin A1c, insulin, glucose, triglycerides, LDL, HDL, AST, ALT	Mean/SD or median/IQR, ANOVA/ANCOVA
Hemoglobin A1c	% <5.7%, 5.7-6.4%, ≥6.5%, Fisher's exact test
Healthy Eating Index	Mean/SD or median/IQR, ANCOVA covariate, Pearson/Spearman correlation with demographic variables
Measure of delay discounting, *k,* derived from MCQ	Mean/SD or median/IQR, ANCOVA covariate (visit 1 measure), Pearson/Spearman correlation with demographic variables, paired t-test or Wilcoxon signed rank test to assess whether baseline and follow-up measures differ
Relative Autonomy Index (RAI) from BREQ-3	Mean/SD or median/IQR, ANCOVA covariate (visit 1 measure), Pearson/Spearman correlation with demographic variables, ANOVA/ANCOVA to assess change from visit 1 to 5 by experimental factor
PACE+: number of days with at least 60 minutes of activity per day in (a) past 7 days and (b) typical week	Mean/SD or median/IQR, Pearson/Spearman correlation with demographic variables and with number of days with MVPA ≥60 minutes at baseline and week 12
Steps/week on smartphone activity tracker	Pearson/Spearman correlation with Fitbit-measured steps/week

6.5.4 Missing Data

Step count and MVPA data may be missing for any day if the Fitbit is not used or not synced. To prevent potential downward bias from very low minutes per day, we will ignore days in which fewer than 1000 steps are recorded, as this likely represents a failure to capture actual activity.(Rowe, Mahar et al. 2004, Patel, Benjamin et al. 2017) We will use multiple imputation for missing data or days with fewer than 1000 steps recorded, and results will be combined using standard rules.(Rubin 1987, Allison 2002) Predictors will include baseline daily minutes in MVPA, experimental condition, week in study after baseline (1-12), calendar month, and an indicator variable for weekday or weekend.(Patel, Benjamin et al. 2017) We will perform sensitivity analyses using all collected data without multiple imputation, including or excluding days with fewer than 1000 steps. Of note, mixed effects models allow for handling of incomplete and unbalanced data, making possible an intention-to-treat approach using the missing at random assumption. To minimize confounding for secondary outcomes, in a sensitivity analysis, subjects who start a new medication that may alter weight (including metformin, insulin, or glucagon-like peptide-1 receptor agonists) after visit 1 will have visit 5 weight, waist circumference, and laboratory measurements censored.

As an exploratory analysis, for days with missing Fitbit data, we will use participant-reported step count data recorded by their smartphones (sent via screenshot once weekly via text message to Way to Health).

6.6 Sample Size and Power

To determine sample size, the MOST R package (FactorialPowerPlan) was used.(Collins, Huang et al. 2017) Using a sample size of 64, 4 factors (n=16/factor, n=4/experimental condition), and two-sided alpha = 0.05, we will have at least 80% power to detect a 15-minute change in MVPA assuming a standard deviation of 20 minutes(Kriska, Delahanty et al. 2013) (**Table 2**). To allow for 64 evaluable subjects, we will recruit 75 AYA (anticipated dropout rate of 15%). In 2020, the Children's Hospital of Pittsburgh Division of Pediatric Endocrinology, Metabolism, and Diabetes followed approximately 2200 patients, approximately 10% (~220) of whom have type 2 diabetes. The vast majority of youth with type 2 diabetes are in the adolescent age range that will be targeted in this intervention. In addition, a variable number of youth with prediabetes are seen by the Division. Based on this, a total sample size of 75 is feasible to enroll over the planned study period. For secondary outcomes including BMI Z-score, labs, and Healthy Eating Index, using a sample size of 64, 4 factors, and two-sided alpha = 0.05, we will have at least 80% power to detect a standardized regression coefficient of 0.36.

Table 2. Effect size and power estimates (N=64)

Δ	SD	Effect size	α	Power
15	20	0.38	0.05	0.84
15	20	0.38	0.1	0.91

-	-	0.36	0.05	0.80
-	-	0.32	0.1	0.80

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, serious adverse events (SAEs) are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with institutional guidelines. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

The relationship of each SAE to the study intervention will be characterized using one of the following terms in accordance with IRB Guidelines: definitely, probably, possibly, unlikely or unrelated.

7.3 IRB/IEC Notification of SAEs and Other Unanticipated Problems

The Investigator will promptly notify the IRB of all on-site unanticipated, serious Adverse Events that are related to the research activity. Other unanticipated problems related to the research involving risk to subjects or others will also be reported promptly. Written reports will be filed using the electronic IRB system and in accordance with the timeline below. External SAEs that are both unexpected and related to the study intervention will be reported promptly after the investigator receives the report.

Type of Unanticipated Problem	Initial Notification (Phone, Email, Fax)	Written Report
Internal (on-site) SAEs Death or Life Threatening	24 hours	Within 2 calendar days
Internal (on-site) SAEs All other SAEs	7 days	Within 7 business days
Unanticipated Problems Related to Research	7 days	Within 7 business days
All other AEs	N/A	Brief Summary of important AEs may be reported at time of continuing review

7.3.1 Follow-up report

If an SAE has not resolved at the time of the initial report and new information arises that changes the investigator's assessment of the event, a follow-up report including all relevant new or reassessed information (e.g., concomitant medication, medical history) will be submitted to the IRB. The investigator will be responsible for ensuring that all SAE are followed until either resolved or stable.

7.4 Investigator Reporting of a Serious Adverse Event to Sponsor

Reporting will be consistent with National Institutes of Health requirements.

7.5 Medical Emergencies

Medical emergencies that might develop during the course of the study at PCTRC will be referred to the CHP emergency room. Medical emergencies that might develop during the course of the study during the at-home intervention will be referred to local emergency medical services.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

The Way to Health platform will be used to generate random sequences to assign eligible participants to one of sixteen experimental conditions. We will use a block randomization approach so that we will have 3-5 participants randomized to each study condition. Demographic and clinical characteristics will be assessed at baseline. If there are differences with respect to key covariates (e.g., age, sex, baseline activity level) across component levels at baseline we will consider including those variables as covariates in our statistical models.

8.1.2 Blinding

It will not be feasible to blind participants to the intervention components, and in fact would be undesirable to do so, as the intent of the behavior change intervention is to leverage behavioral economic insights to promote behavior change. Study staff will not be blinded, in order to ensure financial incentives are provided as intended and that assigned step count goals are communicated correctly to participants. During data analysis, each intervention component (factor) will be assigned a de-identified categorical value (A, B, C, D) with two de-identified levels (1, 2). Thus, the main and interactive effects of each intervention component can be evaluated in a blinded fashion.

8.2 Data Collection and Management

Case report forms (CRF) in a REDCap database will be created by the study team for data capture. REDCap is a secure web-based data management software designed by Vanderbilt University investigators. Study data will be entered through intelligent REDCap forms that adapt to data content, and include built-in eror checks to trap out-of-range or inconsistent entries into the central database.

The PI is responsible for the accuracy and completeness of data collection and management. The PI may designate qualified individual(s) to collect data and manage data. Only investigators and research staff that have completed appropriate IRB training and approval and are listed on the IRB approved protocol are eligible to collect and work on information from the study. Future studies that may use patients or data collected from this study must have separate approved IRB protocols and consent forms, if applicable. Data will be recorded onto the screening questionnaire after consent is documented. Original data will be recorded directly into CRFs by the study coordinator or a study investigator. Copies of laboratory, physical exam, anthropometric, and questionnaire responses will be received through the electronic medical record or through secured email. This information also will be recorded into CRFs in REDCap. The password to log into REDCap will be unique to each member of the study team.

Fitbit Data: Following enrollment and completion of the participant's Way to Health profile, study staff will help connect the participant's mobile device to the participant's Fitbit account and authorize W2H to access their data using OAuth. Participants will be asked to

download the free Fitbit app onto their smartphone to allow the Fitbit to sync at least once daily. Once the participant's account is authenticated to W2H, an hourly background job will query the vendor API for activity since the last data point that was downloaded. The daily Fitbit data will then be available to the study team on the secure, password-protected W2H platform and will be downloaded as a CSV file directly to the PI's institutional shared drive.

Survey Data: Participants will either complete surveys by hand or directly into REDCap. Study IDs will be used to link responses to participants. If used, responses on paper forms will be transferred via study staff to REDCap. Original paper forms will be stored in a secure file cabinet in the PI's office.

Exit Interview Data: Written data collected during the interview will be stored in a secure file cabinet in the PI's office. Only the research team will have access to interview notes, which will be destroyed after a minimum of 7 years after completion of the study. Interviews will also be audio-recorded. Audio recordings will be kept as digital files and kept on the PI's password-protected institutional shared drive. Recordings will be destroyed after the recordings are transcribed and qualitative analysis is complete.

Way to Health Platform:
Way to Health (W2H) is the vendor that will be used to collect Fitbit data and text message responses (screenshot of step count on smartphone). It is a software platform developed by the Penn Center for Health Incentives and Behavioral Economics (CHIBE) at the University of Pennsylvania (UPENN) and is currently operated through a partnership between CHIBE and the Penn Medicine Center for Health Care Innovation. W2H is an integrated, cloud-based platform that blends behavioral science with scalable digital technology to improve clinical outcomes. W2H automates many research functions necessary for conducting randomized controlled trials of healthy behavior interventions. UPENN is not considered to be engaged in the research, as the W2H platform does not directly administer research interventions but instead facilitates research-related activities such as online and mobile participant enrollment; survey administration; integrated biomedical device data transmissions; automated randomization in a variety of schemes; automated communication with participants/patients via voice, text and email; delivery of financial and social incentives; utilization of gamification strategies and more. Furthermore, the W2H services do not merit professional recognition, and services are used at Upenn for both research and non-research purposes. More details are available at https://waytohealth.org.
W2H is a HIPAA compliant platform and collects subjects' names, dates of birth, and phone numbers. To assure that participant confidentiality is preserved, individual identifiers are stored in a single password protected folder on a shared drive that is accessible only to study research, analysis and IT staff. An investigator or statistician who logs in will be able to access only coded data. The W2H administrative group is able to view participant names and contact information, but will not participate in any research activities.

The W2H web development team and Project Director currently have administrative access to PHI. All of these personnel will have completed Human Subjects Protection and HIPAA privacy training. The system automatically generates logs of all data queries which can be

reviewed by research staff to ensure that no unauthorized persons have gained access to identifiable information. This system is hosted on site at The University of Pennsylvania (UPenn) and is protected by a secure firewall and several layers of operational security. Once a participant has been entered into this system, they are given a unique study identification number (ID). Any datasets and computer files that leave the firewall are stripped of all identifiers and individuals are referred to by their study ID. The study ID is also used on all analytical files.

The Penn Medicine Academic Computing Services (PMACS) is the hub for the hardware and database infrastructure that supports the project and the W2H web portal is built on this infrastructure. The data collected for W2H based studies is stored in My Structured Query Language databases on a PMACS-operated blade server environment devoted specifically to W2H. The data center is housed in Information Systems and Computing at 3401 Walnut Street. All data are stored in a single relational database, allowing researchers to correct mistakes. Every Structured Query Language (SQL) transaction, including accessing and changing data, is logged for auditing purposes. Data are entered into the database through several different mechanisms. Participants enter their own personal information and respond to surveys through a PHP-based web interface. Researchers have a separate interface that allows them to manually enter data if needed. Data from biometric/monitoring devices are uploaded automatically, this includes data from mobile phones such as picture or text messaging. Datasets are blinded of all personally identifiable information when exported for analysis. The web application automatically removes all identifiers when a researcher requests an analytic dataset. Personal information and research data will be stored in separate SQL tables and will be linked by a computer-generated ID number. Additionally, any information that leaves this system to communicate with third party data sources (biometrics devices, survey software, etc.) is stripped of any identifiers and transmitted in encrypted format. The same unique study ID is used to link these outside data to the participants.

The W2H Research Data Center staff is responsible for preventing unauthorized access to the trial participant tracking system database. The secure servers are located in a specially designed, highly secured facility at UPenn with dedicated uninterrupted power supply and strictly limited access. The study will utilize a client-server deployed Data Management System rather than a 'Store and Forward' database configuration, obviating research site database security concerns. Confidential participant information will be entered into the database. Thereafter, confidential information will be made available to authorized users only as specifically needed. No one can gain access to an individual SQL database table unless explicitly granted a user ID, password, and specific access. Even those with user names and passwords cannot gain access to the tables that contain the identifying participant information.

No results will be reported in a personally identifiable manner. All tracking system data will be password-protected with several levels of protection. The first will allow access to the operating system of the computer. The second will allow access to the basic menus of the integrated system; within certain menu options, such as database browsing, a third password will be required. W2H’s team’s prior research employing similar precautions has demonstrated that these techniques are very successful in assuring the protection of subjects.

The W2H portal applies security and privacy requirements generated by the HIPAA Security Rule and subsequently the HITECH requirements. Currently, the data is encrypted at rest and in motion in accordance with these laws and is certified by FDA.

W2H Data Transfer Description
1) Fitbit to Way to Health platform: every day, Fitbit data will be downloaded from Fitbit to the W2H platform. W2H code automates this transfer of data.
2) Way to Health to Site Server: Coded Fitbit data will be converted to a CSV file and downloaded to a dedicated research folder on the study PI's shared drive. No PHI will be involved in this transfer, only the subject's study ID.
All transferred and created files will be stored in a password-protected folder available only to study staff in the PI's institutional shared drive. All identifiers will be removed in publications.

Participant Recruitment Log:
This password-protected Microsoft Excel file, saved on the PI's institutional shared drive will include patient identifying information necessary for registration, enrollment, and follow-up. Following enrollment, this document will be used to maintain a log of enrolled patients. For patients who are not enrolled, patient-identifying information will be destroyed. A non-identifiable list of patients that were not enrolled will be retained for the purpose of calculating response rate.

Consent Forms:
Electronic copies of the consent forms will be stored in a password-protected folder on the PI's shared drive. Participants will be emailed their signed consent form. If a participant turns 18 during the study, the W2H platform will notify the study team, informing that the participant needs to be re-consented, which will be done electronically via REDCap.

Anonymization:
Data will be extracted from the secure W2H platform for the purpose of data analysis. Any datasets and computer files that leave the W2H firewall will be stripped of all identifiers and individuals will be referred to by their study ID. The study ID will also be used on all analytical files.

8.3 Confidentiality

Access to the systems used for this project, including the W2H database, will be limited to staff who meet all relevant training requirements and are assigned to (or support) this project. Security procedures will be in accordance with the National Institute of Standards and Technology Special Publication guidelines. All staff will have completed the Human Subjects Protection Training.

Electronic adherence monitoring data associated with the mobile application will be maintained by W2H, Inc. W2H has designed their database to comply with HIPAA

regulations. The site is HIPAA compliant. The data are maintained on secure servers that are password-protected. Please see Section 8.2 for measures taken to assure confidentiality.

All data and records generated during this study will be kept confidential in accordance with institutional policies and on HIPPA subject privacy. The investigators/study team members/site personnel will not use such data and records for any purpose other than for conducting the study.

As a way to minimize the chance of PHI (protected health information) from being disclosed, a unique identification code will be used for each participant. Specific keys will be saved in an encrypted format on the PI's secure institutional shared drive.

Participants will not be identified by name/PHI on any publications that result from this research.

The information collected as part of this study will be kept for 7 years after study completion. At that time, the information collected will be destroyed or all identifiable information will be removed. All keys will be destroyed at this time, as well. No identifiable data will be used for future studies without first obtaining IRB approval.

8.4 Regulatory and Ethical Considerations

8.4.1 Data and Safety Monitoring Plan

Due to the minimal risk involved in the investigation, a Data and Safety Monitoring Board (DSMB) is not applicable. Study data will be carefully monitored by the PI. The PI will provide weekly supervision to a trained clinical research coordinator who will be involved in data collection. The study team will monitor and track collection of all study data. The team will additionally track all protocol deviations and adverse events and will report these to the IRB, in accordance with reporting guidelines.

8.4.2 Risk Assessment

Study participation poses no more than minimal risk. Expected risks by procedure are as follows:

Phlebotomy: The blood volume collected will be less than 5 ml per study visit (less than 10 ml total). The blood volume removal is much less than the maximum blood volume removal per 8-week period recommended by OHRP (Adults < 10.5 ml/kg or 550 ml). In children, the maximal blood volume removal per 6 week period is 7 ml/kg. Assuming a 13 year old with BMI at the 85%ile would be our smallest participant, and would weigh approximately 60 kg, this would be a maximum of 420 ml over 6 weeks.

There is a risk of bruising and discomfort at the venipuncture site. Blood draw may result in temporary discomfort from needle stick, bruising, fainting, weakness, and rarely an infection at the site.

Overnight Fast: Fasting may cause hunger pangs, upset stomach, headache, or light-headedness. For individuals on basal insulin, prolonged fasting may increase the risk of hypoglycemia. However, the requested fasting period is no longer than usual for most individuals. To reduce the risk of unrecognized hypoglycemia, participants on basal insulin

will be asked to check glucose on their home glucometer upon waking, prior to the fasting study visit. For fasting glucose < 70 mg/dL at home, participants will be asked to eat or drink juice, and to reschedule the study visit.

Anthropometric measurements and pubertal status: Exam poses minimal risks.The anthropometric assessment involves measurements of height, weight, and circumferences. The exam will be performed by staff experienced in obtaining measurements in children at all levels of cognitive ability. The measurements are obtained in a private room. The parent is permitted to stay with the child if it increases their comfort with the exam.

The puberty assessment will be performed by a pediatric endocrinologist in a private setting. The procedure will be explained to the child in advance, and the parent is permitted to be present if preferred by the child. The exam is performed by highly experienced personnel who are familiar with minimizing distress associated with the exam.

Blood pressure measurement by auscultation: Procedure may cause temporary numbness/tingling in the arm

Engagement in moderate to vigorous physical activity (MVPA): Risks for the study population could include physical discomfort or injury. Participants will not be asked to be more active than would be advised for general good health, in line with Physical Activity for Americans guidelines from the US Department of Health and Human Services. Participants will choose their own activity, including the intensity.

There is a very small risk of participants who use insulin becoming hypoglycemic during physical activity. Participants will be reminded of signs and symptoms of hypoglycemia and asked to check glucose using home glucometer if they are concerned for hypoglycemia. They will be reminded how to treat hypoglycemia with fast-acting carbohydrates, or glucagon if necessary. However, the physical activity encouraged by this intervention is no greater than that recommended in usual clinical care. In addition, patients with type 2 diabetes have a very high degree of insulin resistance and low incidence of hypoglycemia. It is anticipated that only a small subset of participants will be on bolus insulin (which carriers a higher risk of hypoglycemia), with the remainder on no insulin or basal insulin only.

Wearing a Fitbit physical activity tracker on wrist: Participants may experience discomfort related to wearing the Fitbit. Participants will be provided with alternative Fitbit wrist bands upon request if needed due to discomfort.

Interview and questionnaires: Potential risks include momentary embarrassment or discomfort as well as breach of privacy and confidentiality. Participants may decline to answer any question on the questionnaires or during the interviews for any reason. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

Sharing of private health information (PHI): There is the potential risk for a breach of confidentiality. Private health information will be collected, accessed and stored according to HIPAA guidelines, including the use of multilevel password protection and enforcement of system user privileges on the database. To limit the risk of disclosure to the minimum necessary to conduct the study, all direct identifiers will be removed as soon as possible and

codes will be substituted for personal identifiers. Records of individuals are stored with ID numbers and a code with no discernible personal identifiers. Code lists and data files will be stored in separate, secure locations. Data will be stored on institutional secure servers hosted and accessed on password-protected computers. To maintain confidentiality, codes will be used in the database, presentations and publications.

8.4.3 Potential Benefits of Trial Participation

Participants may benefit directly by becoming more physically active, which is recommended for all individuals with prediabetes or type 2 diabetes. However, there is no guarantee of direct benefit.

Participants may indirectly benefit from identification of abnormalities such as diabetes from the hemoglobin A1c or fasting glucose. Participants may indirectly benefit from identification of abnormalities such as dyslipidemia from the laboratory evaluations. If clinically relevant abnormalities are found, the family will be notified. With the consent from the family, clinically relevant tests results will be shared with the subject's primary care physician. Only studies performed by CLIA certified labs will be disclosed. Participants found to have an impaired fasting glucose or impaired glucose tolerance who are not aleady under care for the condition will be referred appropriately for further management and treatment.

The physical activity questionnaires and dietary recall may potentially lead the participants/parents/guardians into awareness about making healthy lifestyle options in diet and exercise.

There is also a potential indirect benefit in helping scientists and health providers further develop mHealth interventions using behavioral modification strategies for adolescents with obesity and prediabetes or type 2 diabetes.

8.4.4 Risk-Benefit Assessment

As the risk is no more than minimal and there is significant potential direct and indirect benefits, the risk-benefit balance is favorable.

8.5 Recruitment Strategy

The study will be publicized via flyers placed in the CHP Pediatric Endocrinology clinics. Potential participants will also be identified via review of pediatric endocrinology clinic schedules by the PI (a pediatric endocrinologist in the clinic from which participants will be recruited) or study staff. Potential participants will be approached in-person at scheduled endocrinology clinic visits. In addition, Pitt+ME will be used to obtain a list of potentially eligible participants based on age and diagnosis. Potential participants may be mailed a letter or emailed by Dr. Vajravelu to introduce the study. This email or letter will request that the participant or guardian respond by email or phone with their agreement to be contacted; if no response is made within 1 week of emailing or 2 weeks of mailing, the potential participant will be contacted by the investigator or a member of the research team by phone or by email, using an approved recruitment script. The CAYAH RESEARCH INTEREST FORM will also be used for recruitment purposes. This is a REDCap form with a survey link which will contain questions for the adolescent to answer to self-screen which are non-

sensitive. Center for Adolescent and Young Adult Health (CAYAH) clinical staff will manage and distribute this survey. CAYAH clinical research staff will advertise the study to the teen. If the teen (age 13 or older) indicates interest in the study by viewing our study advertisement within the CAYAH RESEARCH INTEREST FORM, they will provide their contact information to the CAYAH clinical research staff who will then share it with a member of the study team.

Identified subjects will be screened over the telephone or in-person by study staff. Initial eligibility will be determined, and with subject/parent agreement, verbal consent from the adult subject or parent for the minor subject to fast for the baseline visit will be obtained. See script on WAIVER page.

8.6 Informed Consent/Assent and HIPAA Authorization

8.6.1 Screening

Information obtained via chart review will be preparatory to enrollment and will be limited to the minimum necessary information to determine eligibility for the main study.

8.6.2 Main Study

Consent/assent (as applicable) will be signed electronically via REDCap. A combined consent/assent-authorization document will be used, and subjects will be provided with a copy of the consent form. Subjects will be allowed to read the consent form and ask questions. Written consent/assent will be obtained from the family after all the questions and discussions have been completed and we are reassured that subjects comprehend the nature of the study, the study procedures and the risks-benefits of participation. To maximize subject privacy, the discussion will take place in a private location in or near PCTRC, or via phone. A copy of the fully signed and completed consent form will then be provided via email.

To avoid coercion, we will explain that study participation is voluntary and the subject does not have to partake in the study in order to receive care at CHP. Decision not to participate or decision to withdraw after consent for study participation will not cause penalties or loss of any benefits otherwise entitled to the subject as a patient. In addition, the subject's current and future medical care at CHP will not be affected by final decision for or against study participation.

8.6.3 Re-Consent Plan for Subjects Who Reach Age of Majority

Individuals who turn 18 while enrolled in the study will be contacted by phone and will be asked to provide consent/HIPAA authorization for their continued participation via REDCap.

8.7 Payment to Subjects/Families

All study procedures and expenses will not be billed to the participant but rather to the study's grant.

8.7.1 Reimbursement for travel, parking and meals

Reimbursement will be provided for travel/parking for study visits: $20 per study visit, given via Vincent.

Incentives and compensation will be provided via Vincent as described below.

8.7.2 Payment Schema

Visit 1 Complete: Compensation: $50; Reimbursement for travel/parking: $20

Fitbit wear during Run-In: Incentive: $1/day worn (max $14)

Returning Fitbit for those disqualified based on MVPA or Fitbit wear: Incentive: $25 upon receipt of Fitbit,

Step count goal attainment during intervention: Incentive: $1/day (max $84)

Visit 5 Complete: Compensation: $50; Reimbursement for travel/parking: $20

Fitbit returned: Incentive: $25

Total: Max compensation $223 to participant; max reimbursement for travel: $40

9 PUBLICATION

After completion of the study, the investigator and study team will review and analyze the data for reporting and publication. All published data will be de-identified. No individually identifiable PHI will be published.

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APPENDIX

PACE+ Adolescent Physical Activity Measure

Physical activity is any activity that increases your heart rate and makes you get out of breath some of the time.

Physical activity can be done in sports, playing with friends, or walking to school.

Some examples of **physical activity** are running, brisk walking, rollerblading, biking, dancing, skateboarding, swimming, soccer, basketball, football, and surfing.

Add up all the time you spend in physical activity each day (don't include your physical education or gym class).

P1 Over the past 7 d, on how many days were you physically active for a total of at least 60 min per day?

○	○	○	○	○	○	○	○
0 days	1	2	3	4	5	6	7 days

P2 Over a typical or usual week, on how many days are you physically active for a total of at least 60 min per day?

○	○	○	○	○	○	○	○
0 days	1	2	3	4	5	6	7 days

Scoring: (P1 + P2)/2 < 5 indicates not meeting physical activity guidelines.

EXERCISE REGULATIONS QUESTIONNAIRE (BREQ-3)

Age: _____ years **Sex: male female (please circle)**

WHY DO YOU ENGAGE IN EXERCISE?

We are interested in the reasons underlying peoples' decisions to engage or not engage in physical exercise. Using the scale below, please indicate to what extent each of the following items is true for you. Please note that there are no right or wrong answers and no trick questions. We simply want to know how you personally feel about exercise. Your responses will be held in confidence and only used for our research purposes.

		Not true for me		**Sometimes true for me**		**Very true for me**
1	It's important to me to exercise regularly	0	1	2	3	4
2	I don't see why I should have to exercise	0	1	2	3	4
3	I exercise because it's fun	0	1	2	3	4
4	I feel guilty when I don't exercise	0	1	2	3	4
5	I exercise because it is consistent with my life goals	0	1	2	3	4
6	I exercise because other people say I should	0	1	2	3	4
7	I value the benefits of exercise	0	1	2	3	4
8	I can't see why I should bother exercising	0	1	2	3	4
9	I enjoy my exercise sessions	0	1	2	3	4
10	I feel ashamed when I miss an exercise session	0	1	2	3	4
11	I consider exercise part of my identity	0	1	2	3	4
12	I take part in exercise because my friends/family/partner say I should	0	1	2	3	4
13	I think it is important to make the effort to exercise regularly	0	1	2	3	4

14	I don't see the point in exercising	0	1	2	3	4
15	I find exercise a pleasurable activity	0	1	2	3	4
16	I feel like a failure when I haven't exercised in a while	0	1	2	3	4
17	I consider exercise a fundamental part of who I am	0	1	2	3	4
18	I exercise because others will not be pleased with me if I don't	0	1	2	3	4
19	I get restless if I don't exercise regularly	0	1	2	3	4
20	I think exercising is a waste of time	0	1	2	3	4
21	I get pleasure and satisfaction from participating in exercise	0	1	2	3	4
22	I would feel bad about myself if I was not making time to exercise	0	1	2	3	4
23	I consider exercise consistent with my values	0	1	2	3	4
24	I feel under pressure from my friends/family to exercise	0	1	2	3	4

BREQ-3 Scoring

Amotivation	2	8	14	20	
External regulation	6	12	18	24	
Introjected regulation	4	10	16	22	*
Identified regulation	1	7	13	19	
Integrated regulation	5	11	17	23	
Intrinsic regulation	3	9	15	21	

The relative autonomy index (RAI) is a single score derived from the subscales that gives an index of the *degree* to which respondents feel self-determined. The index is obtained by applying a weighting to each subscale and then summing these weighted scores. In other words, each subscale score is multiplied by its weighting and then these weighted scores are summed. Higher, positive scores indicate greater relative autonomy; lower, negative scores indicate more controlled regulation

For the **BREQ-3** the weightings are as follows:

Amotivation	-3
External regulation	-2
Introjected regulation	-1
Identified regulation	+1
Integrated regulation	+2
Intrinsic regulation	+3

Description: The Monetary-Choice Questionnaire is a 27-item self-administered questionnaire. For each item, the participant chooses between a smaller, immediate monetary reward and a larger, delayed monetary reward. The protocol is scored by calculating where the respondent's answers place him/her amid reference discounting curves, where placement amid steeper curves indicates higher levels of impulsivity.

Protocol: For each of the next 27 choices, please indicate which reward you would prefer: the smaller reward today, or the larger reward in the specified number of days.

1. Would you prefer $54 today, or $55 in 117 days?

    [ ] smaller reward today

    [ ] larger reward in the specified number of days

2. Would you prefer $55 today, or $75 in 61 days?

    [ ] smaller reward today

    [ ] larger reward in the specified number of days

3. Would you prefer $19 today, or $25 in 53 days?

    [ ] smaller reward today

    [ ] larger reward in the specified number of days

4. Would you prefer $31 today, or $85 in 7 days?

    [ ] smaller reward today

    [ ] larger reward in the specified number of days

5. Would you prefer $14 today, or $25 in 19 days?

    [ ] smaller reward today

    [ ] larger reward in the specified number of days

6. Would you prefer $47 today, or $50 in 160 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

7. Would you prefer $15 today, or $35 in 13 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

8. Would you prefer $25 today, or $60 in 14 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

9. Would you prefer $78 today, or $80 in 162 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

10. Would you prefer $40 today, or $55 in 62 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

11. Would you prefer $11 today, or $30 in 7 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

12. Would you prefer $67 today, or $75 in 119 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

13. Would you prefer $34 today, or $35 in 186 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

14. Would you prefer $27 today, or $50 in 21 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

15. Would you prefer $69 today, or $85 in 91 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

16. Would you prefer $49 today, or $60 in 89 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

17. Would you prefer $80 today, or $85 in 157 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

18. Would you prefer $24 today, or $35 in 29 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

19. Would you prefer $33 today, or $80 in 14 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

20. Would you prefer $28 today, or $30 in 179 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

21. Would you prefer $34 today, or $50 in 30 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

22. Would you prefer $25 today, or $30 in 80 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

23. Would you prefer $41 today, or $75 in 20 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

24. Would you prefer $54 today, or $60 in 111 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

25. Would you prefer $54 today, or $80 in 30 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

26. Would you prefer $22 today, or $25 in 136 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

27. Would you prefer $20 today, or $55 in 7 days?

[ ] smaller reward today

[ ] larger reward in the specified number of days

Scoring: A participant's discounting curve may be calculated according to the following function: V = A/(1+kD)

V is the present value of the delayed reward A at delay D, and k is the rate of discounting. k typically falls between 0.0 and 0.5, with smaller values indicating a lack of discounting and preference for delayed rewards and higher values indicating strong discounting and a preference for immediate rewards. Thus higher values of k are indicative of high levels of impulsivity.

There are two ways of scoring the Monetary-Choice Questionnaire. The first involves hand scoring to get an estimate of k following the guidelines given in Kirby (2000). The second involves fitting a logistic regression function to individual responses following procedures described in Wileyto et al. (2004).

Estimating Discounting Rate

The following table lists the calculated k values (the degree of discounting) at indifference for each question (i.e., when the subjective value of the immediate and delayed rewards are equivalent).

Question	*k* at indifference
13	.00016
1	.00016
9	.00016
20	.00040
6	.00040
17	.00040
26	.0010
24	.0010
12	.0010
22	.0025
16	.0025
15	.0025
3	.0060
10	.0060
2	.0060
18	.016
21	.016
25	.016
5	.041
14	.041
23	.041
7	.10
8	.10
19	.10
11	.25
27	.25
4	.25

An estimate of the respondent's discounting rate can be calculated as the geometric mean (to avoid underweighting) of the k at indifference between the two questions that reflect when the respondent changes between choosing the delayed reward versus the immediate reward. In cases where the respondent's change between preferring the delayed versus the immediate reward is not consistent, the two questions that are most proportional to their responses are chosen. If the participant always chooses the immediate reward or the delayed reward, the estimation of k is equal to one of the endpoints (0.25 or 0.00016).