Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-49195
Status: Approved
Initial Submit Date: 12/14/2020
Approval Period: 4/1/2021 - 1/5/2026

Section Aa: Title & PI

A1. Main Title

FIT24: USING TECHNOLOGY TO IMPROVE ACTIVITY AND SLEEP IN HISPANIC YOUTH

A2. Principal Investigator

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A3. Administrative Contact

None

A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

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A5. Funding Source:

Organization: NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
HCHD: Harris County Hospital District

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
No

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?
The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,
- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:
NCT04953442

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Hispanic adolescents are disproportionately burdened by obesity (25.8% vs 18.5% general population) and type 2 diabetes (T2D) compared to non-Hispanic white youth. Disparities in T2D emerge early in life and are driven in part by unhealthy lifestyle behaviors including low levels of physical activity (PA), excessive time spent in sedentary behaviors (SB), and short sleep durations. Given that Hispanic youth are the fastest growing pediatric subgroup in the U.S., developing strategies to promote healthy lifestyle behaviors and addressing T2D disparities is a public health imperative. Wearable activity monitoring devices like Fitbits are designed to continuously monitor both wake time and sleep behaviors. Studies using wearable devices in conjunction with text-messaging or smartphone applications have been effective in increasing PA in adults; however, less is known about the use of these technology-based tools among adolescents, particularly among high-risk youth like Hispanic adolescents. Therefore the purpose of this study is to examine the feasibility, acceptability, and preliminary efficacy of a technology-based intervention that uses a Fitbit and text messages grounded in the Self-Determination Theory to promote healthy lifestyle habits and reduce risk for type 2 diabetes among a sample of Hispanic adolescents (14-16 years) with obesity.

Section D: Purpose and Objectives

The purpose of this study is to examine the feasibility of a 12-week goal-setting intervention that utilizes a Fitbit device and text messages grounded in the Self-Determination Theory (SDT) to promote healthy wake time (PA,SB) and sleep behaviors in Hispanic adolescents (14-16 years old) with obesity (BMI%≥95th).

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs)

Ethnicity:
Hispanic Or Latino

Primary Language:
English, Spanish

Groups to be recruited will include:
Healthy, non-patient, normals

Which if any of the following vulnerable populations will be recruited as subjects?
Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Informed consent will be obtained from parents of participating adolescents and child assent will be obtained from participating adolescents. Consent and assent will be obtained electronically by a trained research staff member. In this study, qualitative interviews will be conducted remotely, thus an electronic consent/assent will be sent to the participant via REDCap, we will schedule a time and day to speak to the participant and his/her parent or legal guardian, at which time we will review the forms over the phone and answer any questions, and then the participant and his/her parent or legal guardian will electronically sign the consent form and send it back to the research team. For participation in the intervention, the participant and his/her legal guardian will complete the electronic consent/assent form in person. The research staff member will explain all aspects of the study and answer any questions. Whether the participant is completing the consent/assent forms remotely or in person, we will ask comprehension questions to ensure that parents and adolescents understand all study procedures, risks, benefits, and the voluntary nature of this study. We will also provide all participants and parents or legal guardians with a paper copy of the consent and assent forms for their personal records.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

In collaboration with Hispanic youth (N=30) and an expert panel (N=6), text message content will be adapted and refined from a previously conducted pilot study. A mixed-methods approach (surveys and interviews) will be applied to ensure that text message content adheres to the SDT and is age and culturally appropriate. A different sample of Hispanic youth (N=48) will be recruited and randomized to the intervention or a wait-list control group. In the intervention, the youth will receive guidance from the research team on setting weekly steps/day and hours of sleep/night goals, a Fitbit device to self-monitor progress towards goals, and theory-informed text messages that promote autonomous motivation for behavior change. At the end of the initial 12-week intervention, youth in the wait-list control group will be invited to participate in the intervention. Feasibility will be evaluated using a priori criteria for recruitment, data collection, intervention implementation, and acceptability.

This study will receive assistance from a non-BCM personnel, Marbelly Partida, will assist with the development of project materials, assist with data collection and the implementation of the intervention. Ms. Partida will also assist in conducting literature reviews and assisting in the lab in basic scholarly work such as creating data tables. Ms. Partida will rely on the BCM IRB for her involvement in this research.

Inclusion Criteria:

Participants will be screened using the following inclusion criteria: 1) Self-report as Hispanic 2) obese, defined as body mass index percentile (BMI%) ≥ 95th percentile 3)between the ages of 14-16 years, and 4) own his or her own cellphone.

Exclusion Criteria:

Youth will be excluded based on the following criteria: 1) Taking a medication (i.e. steroids) or diagnosed with a condition (i.e. sleep apnea) that influences activity, sleep, and/or cognition, 2)recent hospitalization or injury that prevents normal physical activity, 3) pregnant, and 4) currently enrolled in an exercise program or currently using a personal activity monitoring device like Fitbit.

F2. Procedure

Hispanic adolescents (N=30) will participate in in-depth interviews. Trained interviewers will use an interview script to elicit information on:1) personal values, 2) given that social frameworks have demonstrated that multiple levels of influence affect health behaviors in high-risk, minority youth we will ask questions as to how to promote wake-time and sleep behaviors in a manner that is feasible and realistic in the environmental and sociocultural context of Hispanic youth, 3) the type of goal-setting guidance and feedback desired, and 4) desired frequency and timing of text messages. To protect staff and participants, we will conduct interviews via zoom until it is safe to host interviews in person. In-depth interviews will be audio-recorded, transcribed, coded by two trained, independent coders, and qualitatively analyzed using NVivo version 9. Thematic content analysis will be used to identify emergent themes to adapt existing text messages. As youth are screened and participate in interviews, parents will complete a text-based survey, to assess their perceptions of the intervention.

An expert panel (N=6) of co-investigators (Soltero, Thompson, Musaad, O'Connor) and consultants (Jason Mendoza, Deborah Parra-Medina) will convene to ensure text messages are age and culturally-appropriate, adhere to the self-determination theory, and use evidence-based strategies to promote healthy behaviors. Consultants will not participate in any data collection or seek IRB Approval from their home institutions. Youth that participated in the interviews will review a revised draft of the text messages and provide feedback via a survey. If extensive modifications are needed an additional review by youth and the expert panel will be conducted.

To test the feasibility and acceptability of the intervention, we will recruit a new sample of Hispanic adolescents (14-16 years) with obesity. Youth will be randomized (1:1) to the intervention or wait-list control .

Intervention In the intervention, youth will be given a Fitbit which has shown high validity and reliability (ICC 0.71 - 1.00) for assessing steps/day and sleep in youth. Participants will download the Fitbit app and staff will input individual user height and weight to improve measurement accuracy. The theory-informed text messages that were previously developed with youth and the expert panel will be sent 3-5 times/week using a text-message platform called Mosio, which is HIPAA compliant and secure. We have exacted a Business Associate Agreement with Mosio. At the start of the week, texts will guide participants to set one activity and one sleep goal. Texts will promote autonomy by encouraging youth to develop their own solutions for achieving their goals. Mid-week texts will emphasize competence, acknowledge progression towards goals, and provide tips and evidence-based strategies for increasing health behaviors (competence). Tips and strategies for increasing physical activity will include suggestions on resources within each participant's neighborhood, which will require the use of their home address. End-of-week texts will provide feedback on goal achievement and encourage participants to connect goal achievement to personal values to build relatedness.

Youth in the intervention will also receive assistance in goal-setting as well as need supportive feedback on goal attainment. At the start of week 2, research staff will contact participants via text message to guide them in setting goals for steps/day and hours of sleep/night based on their weekly averages from the previous week. In successive weeks, participants will be guided to gradually increase their step count and sleep goals to meet or maintain current recommendations of ~12,000 steps/day and 8-10 hours of sleep/night. Participants with less than 5,000 steps/day will be guided to increase their average by 600 steps/day each week, participants with 5,000-11,999 steps/day will be guided to increase their steps/day goal by 10% of their week 1 average in successive weeks, and participants with greater or equal to12,000 steps/day or greater will be instructed to maintain that level of step counts in successive weeks. Achieving greater or equal to 12,000 steps/day is equivalent to meeting PA recommendations of 60 minutes of PA/day. For sleep, participants that average less than 8 hours of sleep/night will be encouraged to increase their average sleep time by 30 minutes each week and participants with more than 8 hours of sleep/night will be encouraged to maintain that sleep duration. Data collected using the Fitbit Flex is continuously collected and wirelessly transmitted to a web-based platform called Fitabase. This secure, platform aggregates and analyzes step and sleep data at the daily, weekly, and monthly level, and provides customized data reports for each participant. These reports will be downloaded and saved for data checks and goal monitoring. These reports will inform help us develop texts that guide goal-setting and provide feedback on goal achievement.

At the completion of the intervention, youth will return the Fitbit Flex to the study team.

Wait-list Control Group Youth in the wait-list control group will also receive a Fitbit and a one-page handout with standard health information on the importance of PA and sleep to their health. After the 12-week intervention period, youth in the wait-list control group will be invited to participate in the intervention.

Assessments Primary Outcomes: Feasibility will be evaluated using a priori criteria: recruitment, data collection, the integrity of the study protocol, technical issues, internal consistency of measures, and satisfaction. Given this study's high potential for dissemination in clinical settings, 'Recruitment' and 'Data Collection' criteria will assess the feasibility of recruiting and retaining participants from community clinics. 'Integrity of Study Protocol' criteria will be used to identify the feasible and acceptable `dose' of the intervention. `Technical Issues' criteria will assess the feasibility of using the Fitbit device and text messaging as behavior change tools. `Internal Consistency of Measures' criteria will assess the appropriateness of our instruments for Hispanic youth. `Satisfaction' will assess acceptability, which is especially important for interventions in minority populations. This will provide information on the availability of high-risk youth in community clinics and the ability of our recruitment strategies to engage youth from these settings.

Secondary outcomes: Physical activity, sedentary behaviors, and sleep will be assessed using a hip-worn wGT3X-BT accelerometer (Actigraph, Pensacola, Florida). Participants will wear the accelerometer 24 hours a day for 7 days at both timepoints. A research team member will review instructions for device wear and will send daily text messages to remind participants to wear the device to promote compliance. Accelerometer data will be processed using ActiLife v6.13 software. A valid day of wear will be defined as ≥ 18 hours of wear on 4 days or more, one of which has to be a weekend day. Evenson cut points will be used to analyze and categorize SB (defined as <100 counts per minute) and moderate-to-vigorous PA. The Sadeh algorithm will be used to assess sleep duration. While wrist-worn devices are superior for assessing all sleep characteristics (i.e.sleep efficiency, wake after sleep onset, etc), hip-worn devices provide accurate measures of sleep duration and timing. Participants will be asked to complete a wear log to indicate wake and sleep times, which will be used to verify accelerometer data. Data will be reported as average minutes per day spent in PA, SB, and sleep.

Tertiary Outcomes: Height and weight will be measured to the nearest 0.1cm and 0.1 kg, using a portable stadiometer and research scale to calculate BMI percentile. We will assess waist circumference to measure central adiposity. Psychological Needs will be assessed using the Psychological Need Satisfaction in Exercise Scale (18-items), which has shown acceptable validity and reliability among youth. Autonomous motivation for PA will be assessed using a scale from the Behavioral Regulation in Exercise Questionnaire-2 (23-items), which has acceptable psychometric properties among youth. Each participant's social network will be assessed using the interview-administered social network survey to analyze the social connections or ties of each participant in preparation for the next version of this study, which will allow participants to participate and receive support from family members or friends. Information collected via the social network survey will be used to calculate descriptive information on the number of ties the participant reports and the strength of those ties, which will give us an overall measure of how weak or strong their social network is. This data will be unidentified and aggregated. We will only collect first names and will never collect the address, phone number, or any other personal

health information on any of the network ties reported by participants. There will be no attempts to identify or collect data from any of the ties mentioned by participants.

Process Evaluation data will be collected to further evaluate the feasibility, assess the impact of implementation on study outcomes, and identify mechanisms by which the intervention impacts health behaviors and BMI. We will use research team logs and field notes entered into a REDCap online database to assess the recruitment of participants, resources needed for intervention implementation, maintenance of the participants, implementation fidelity, the dose of intervention delivered and received, and potential contamination.

All assessments will be conducted in a private room at a community center partners like Baker Ripley or at the home of the participant. For safety, trained research assistants will travel in pairs for home-based data collection. They will notify their supervisor Dr. Soltero of their time of arrival and departure at the participant's home. Additionally, we will provide reimbursement for use of uber or other ride-share services.

Exit-Interviews. A subsample of participants (N=15) randomized to the intervention will participate in a 1-hour, post-intervention exit interview

Data collection for this study has been concluded. The current database includes N-43 participants. To conduct further analysis and maximize the potential knowledge to be gained from this study we will collaborate with students and faculty at Rice Unviersity through the Data 2 Knowledge capstone program to conduct high-level analysis to identify patterns of 24-hour physical activity and sleep behaviors and their associations with metabolic health. Data shared through this capstone program will be de-identified and will include demographic information, accelerometer derived physical activity, sleep, and sedentary behaviors, anthropometrics (BMI, heigh, weight, waist circumference), zipcode (not full address) as well as surveys on autonomous motivation. An IRB protocol will be submitted at Rice University and all faculty and students working on this project will be added to the IRB protocol at Rice University.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 98 Worldwide: 98

Please indicate why you chose the sample size proposed:

Qualitative interviews will be conducted among 30 adolescents, 20 parents will be invited to complete a parent survey, and 48 adolescents will be recruited for participation in the intervention component. A formal power calculation was not used as the primary purpose of this study is to examine feasibility, which is adequate for estimating feasibility parameters needed to inform a fully powered intervention.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

All qualitative in-depth interviews and exit interviews will be audio-recorded, transcribed verbatim using a professional transcription service, coded by two trained, independent coders, and qualitatively analyzed using NVivo version 9 (QSR International, Cambridge, MA). Thematic content analysis will be used to identify emergent themes on participant satisfaction and opportunities to improve the intervention.

Feasibility and process evaluation data will be collected to further evaluate feasibility, assess the impact of implementation on study outcomes, and identify mechanisms by which the intervention impacts health behaviors and BMI. We will use research team logs and field notes entered into a REDCap online database to assess the recruitment of participants, resources needed for intervention implementation, maintenance of the participants, implementation fidelity, the dose of intervention delivered and received, and potential contamination. Data recorded on the recruitment of participants will include staff time, resources, strategies, and number of participants screened and enrolled. Data on resources for implementation will include staff time, materials, and equipment used for implementation. Data on maintenance of participants will include the number of text messages and calls sent to non-responsive participants and careful documentation of dropouts and reasons for leaving the study. Implementation fidelity, dose delivered, and dose received, will be defined by device wear, the number of technical issues (device or text message malfunction), and text message engagement (number of text messages delivered, opened, and if participants respond when prompted). Potential contamination will be assessed in the exit in-depth interview with intervention participants. Data on environmental factors that could impact physical activity will be collected and analyzed using geographic information systems.

Analyses of Secondary and Tertiary Outcomes: Comparisons of PA, SB, sleep, BMI, waist circumference, blood pressure, and heart rate between (Mann-Whitney U test) and within treatment groups (pre to post; paired t-tests, signed rank test) will be tested. Cronbach's alpha will be used to assess the reliability of the psychological needs satisfaction and autonomous motivation for PA scales. While clinically significant changes in secondary and tertiary outcomes are not

expected, we will examine clinically meaningful effects and estimate the reliable change index. These analyses will guide power calculations for future trials.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

Risks associated with this study are classified as no greater than minimal risk. The primary risks of this study will be loss of confidentiality. There is a small risk of causing adolescents or their family anxiety if the adolescent is identified as obese and at high-risk for T2D. There is also a small risk of feeling discomfort when answering questions in qualitative interviews or demographic surveys. This study has a small risk for injury or medical problems when youth increase or participate in regular physical activity exercise (similar to a PE class) as they will be encouraged to do in this study. There are three different SOP's in place for different adverse events that can occur to the participant throughout the study.The three SOP's are for a participant receiving COVID-19 throughout the study, report an injury or if they show signs of psychological or physical harm. If your child, receives COVID-19 or is injured while participating, we will provide them a sheet that will give them steps of what to do in those incidents.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There may be no direct benefits to the participants. However, lifestyle interventions that promote physical activity and sleep have been shown to improve metabolic health and reduce T2D risk in obese youth. The intervention is designed to increase psychological needs satisfaction and youth may become more autonomously motivated to make healthy behavior changes. These behavior changes may improve their weight status, reduce their body mass index, and could reduce their risk for type 2 diabetes and other obesity-related diseases. Youth who participate in the wait-list control group may benefit after the study ends, by being provided the opportunity to participate in the intervention. However, participants in either arm may gain no direct benefit, as the study has not previously been tested for efficacy.

Describe potential benefit(s) to society of the planned work.

In light of the public health goal to decrease health disparities for Hispanic populations, this study has the potential to lead to a program that can reduce obesity-related chronic conditions among Hispanic youth. Identifying novel ways to intervene with this high-risk group is essential. This study will provide much needed information to society on delivering diabetes prevention interventions to vulnerable Hispanic youth using technology-based strategies. This information is essential for developing and implementing age- and culturally-appropriate diabetes prevention strategies that reach and engage this key population to improve their metabolic health. The long-term trajectory of this work could significantly contribute to the limited body of literature on evidence-based diabetes prevention interventions for high-risk, minority youth.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Potential risks are outweighed by the fact that the information gained will significantly advance the science regarding the effects of sedentariness in an underrepresented population. This information, will inform the development of future lifestyle interventions aimed at reducing sedentary behaviors to improve metabolic health in a high-risk, vulnerable population. These intervention shave the potential for scalability and widespread dissemination which has the potential to reach numerous communities and significantly improve health in the Latino population.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Participants will be recruited from community clinics using the following strategies: 1) Monthly provider meetings at collaborating clinics to encourage physicians to refer patients 2) On-site recruitment at clinical settings 3) Post study information on the Texas Children's Hospital Primary Care Practice and Harris Health Pediatric Clinic social media sites and inpatient newsletters. 4) Health fairs, immunizations fairs, back-to-school events, and any other community event, to recruit participants in person. 5) Facebook advertising using a BCM approved lab page

Mothers or fathers will complete a release of information form at their pediatrician's office or during a health fair where we recruit. We will use this information to contact them to provide more information about the study. If the family is interested in participating, a telephone screening with the mother, father or legal guardian will be scheduled. If we cannot schedule a phone screening then a self-screening survey will be texted or emailed to the participant, which will allow us to make decisions regarding eligibility faster. After the self-screener is complete, a research team member will follow up via phone to complete eligibility screening. During the screening call, we will use a scripted screening questionnaire that reviews the inclusion and exclusion criteria for their child's participation. If inclusion criteria are met, we will then ask to speak directly to the adolescent to explain the study, answer questions, and confirm their interest in participating. If the participant is to participate in the first aim of the study, which includes an in-depth interview and feedback survey to help us develop text-messages, then we will schedule their interview appointment which will take place in a private room at a public library or community center. At the beginning of the interview appointment, prior to any study activities, informed consent will be completed by the parent/legal guardian and informed assent will be obtained from the adolescent in English or in Spanish.

After the feedback survey we will conduct a (15-20mins) follow up phone interview to clarify survey responses . Due to the addition of the follow up phone interview, we will call each participant and notify them of the changes to the procedure. If they are interested in participating, we will send them a zoom link and a REDCap link to an electronic short form consent. During the zoom call we will explain all procedures and answer questions. We will obtain their signature prior to conducting the phone interview.

For youth who will participate in the Fitbit intervention portion of the study, they will complete the American College of Sports Medicine 2015 exercise screener as part of their screening call to ensure that it is safe for him/her to engage in physical activity. Once both the parent and adolescent agree to participate, they will be scheduled for their initial visit at the clinic in which they were recruited to increase the accessibility of the study. At the initial visit, electronic informed consent will be completed by the parent/legal guardian and electronic assent will be obtained from the adolescent through our tablet. This will be given in their preferred language in English or in Spanish. Next, we will confirm the participant's BMI% by measuring weight and height. If the adolescent qualifies, the remainder of the baseline data collection will be completed and they will be enrolled in the study. In the consent form, youth will be notified that they must return the Fitbit device upon completion of the intervention. For all consents and assents, the research coordinator will explain all study activities and risks to the families and will ask three comprehension questions to check for understanding. Study information, consent/assent, and data collection will be conducted in English and Spanish.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

A full-length informed consent document

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
No

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Will identifiable biospecimens be stored for future research?
NA

If yes, is the storage of biospecimens optional for subjects?
NA

Will identifiable private information be stored for future research?
NA

If yes, is the storage of information optional for subjects?
NA

Questionnaire, Survey, and/or subject diary

NA

Other:

Yes, as described:

We will need participant's home address and phone number. We would also like to take pictures of your child to show others how the study goes. To do this, we will need you and your child to sign an image consent form. This is not needed to participate in this study. Also, in the event that you contract COVID-19 or disclose any evidence of physical or psychological harm, parents and the appropriate medical and non-medical professionals will be notified and your child may be withdrawn from the study. The Principal Investigator reserves the right to withdraw a participant for any reason deemed necessary by the research team.

At what institution will the physical research data be kept?

Physical research data will be kept at Baylor College of Medicine. Physical Data containing demographic information will be kept in a locked cabinet in a locked office. Electronic data will be kept in a secure server and will be password protected.

How will such physical research data be secured?

Physical Data containing demographic information will be kept in a locked cabinet in a locked office. Only the PI will have direct access to the physical data.

At what institution will the electronic research data be kept?

Electronic research data will be kept at Baylor College of Medicine. Electronic data will be kept in a secure server and will be password protected.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

Yes

Such electronic research data will be secured via Other:

No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

Participant's phone numbers will be shared with Mosio, a secure text message platform; however, we will not use the participant's name only their unique participant ID# to identify each participant.

We will collaborate with students and faculty at Rice University through the Data 2 Knowledge capstone program to conduct high-level analysis to identify patterns of 24-hour physical activity and sleep behaviors and their associations with metabolic health. Data shared through this capstone program will be de-identified and will include demographic information, accelerometer derived physical activity, sleep, and sedentary behaviors, anthropometrics (BMI, heigh, weight, waist circumference) as well as surveys on autonomous motivation. Data will be shared via encrypted files and sent through an encrypted email. Only approved individuals will have access to the data. Once the data is at Rice University it will be stored on a password protected computer on a secure server.

Will you obtain a Certificate of Confidentiality (COC) for this study?

No

Please further discuss any potential confidentiality issues related to this study.

There are no other potential confidentiality issue related to this study.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

The participant's insurance will not be responsible for the costs of the tests/analyses related to this study. There will be no direct costs to the participants.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:
200

Distribution Plan:
The participating youth will receive compensation for their time and effort. The funds for compensation will be loaded onto a ClinCard which will be given to participants in person.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance(other than food) that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)
No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?
No

O1. Current Drugs

Is this study placebo-controlled?
No

Will the research involve a radioactive drug?
No

Section P: Device Studies

Does this research study involve the use of ANY device?
No

Section Q: Consent Form(s)

The consent provides information on all research activities, including the risks and benefits, we will use to examine if technology-based intervention can improve physical activity and sleep in Hispanic youth.

The consent provides information on all research activities, including the risks and benefits, which we will use to develop text-messages that will be used to promote healthy activity and sleep behaviors among Hispanic adolescents.

The consent provides information of the brief follow up interviews that we will be conducting regarding the text message feedback survey. The purpose of this brief phone interview is to clarify any of the feedback information that is provided via the survey to aid in the finalization of our text messages, which serve as the primary tool in the Fit24 intervention.

Section R: Advertisements

None