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Improving Nutritional Choices in Adolescents (LIITA3H)

NCT03693144

IRB Approval Date: 3/1/2021

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## SPECIFIC AIMS

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**The project will develop and pilot test the Location Initiated Individualized Texts for African American Adolescent Health (LIITA<sup>3</sup>H), a mobile application to aid healthy food choices.**

The obesity epidemic in the US has disproportionately affected African American (AA) adolescents who have a prevalence of obesity that is almost 50% higher than that of their Caucasian peers. This higher prevalence is due in part to greater exposure to, and higher consumption of, fast food and calorie dense foods among minority populations than their majority peers. Finding effective ways to address dietary habits affecting childhood obesity in general and in African American adolescents particularly is vital to averting the magnitude of obesity-related illnesses and the associated costs that are likely to cloud the future of American children.

Youth consume a significant proportion of their calories during school, often from two sources 1) school meals and 2) other eating venues (e.g., fast food restaurants, convenience stores) near schools. For AA adolescents, school-related food choices are uniquely impacted by economic and environmental factors. Specifically, many receive free/reduced meals, thus packing a lunch is often difficult and selecting from the options at school is the most feasible approach. Furthermore, a significant number of AA adolescents live and attend school in low-income communities with a disproportionally high prevalence of surrounding fast food restaurants and convenience stores. **Better ways to help AA adolescents make healthy choices in these obesogenic environments is critical to reduce the disparity between them and their peers.**

Our clinical and research experience suggests that tailored texts linked to location will improve choices. Our clinical work in the Michigan Pediatric Outpatient Weight Evaluation and Reduction (MPOWER) program suggests that an intervention based on Self-Determination Theory that uses motivational interviewing to increase motivation is effective, but adolescents' success with making healthy choices is greatly impacted by their school environment. Our preliminary research in the MPOWERed Messages intervention, incorporating the theories used in MPOWER, indicated that adolescents welcomed individually relevant health-related texts that used social marketing and provided cues to action. Importantly, they believed the texts helped them make healthy choices but suggested it would be better if they were sent at times when they faced dietary choices.

**Proposed Intervention:** The LIITA<sup>3</sup>H intervention will include 3 components: 1) **Personal Geo-location mobile technology** to identify when students are in their school cafeteria or other eating venues with an "intent to eat"; 2) **Culturally and individually tailored text messages** to promote healthy choices in these venues; and 3) **Messages delivered** to students when they are in eating locations and a mechanism for them to respond with information about their eating experience such as an annotated photo of their selection.

**Hypothesis:** We hypothesize that the LIITA<sup>3</sup>H intervention can be developed to automatically and accurately send text messages, tailored to recipients' preferences /characteristics, when they are making selections in their school cafeteria or other eating venues, and that these health-focused messages will encourage healthy choices.

We will accomplish the following 3 specific aims:

**Aim 1:** To develop an integrated mobile phone application that will a) accurately identify when students are in their school cafeteria or other eating venue, b) automatically deliver a tailored text message that prompts healthy choices, and c) receive a photo of food choices annotated with the user's health rating of the food. [For this amendment we aim to optimize the previously developed app to automatically identify a larger number of fast food restaurants (FFR) using GPS monitoring and by incorporating additional user input regarding the app design]

**Aim 2:** To develop a message library adapted from the previously tested MPOWERed Messages library that can be tailored to students' food preferences, the menu options from their school and fast food venues, and incorporate cultural tailoring with input from the target population. [For this amendment we will utilize additional focus groups and an Adolescent Advisory board to provide additional input regarding the tailored messages and app design]

**Aim 3:** To explore, in a 1-month pilot, the acceptability, feasibility and use of the intervention developed in Aims 1 and 2, via usage data collected by the application plus semi-structured interviews with participants and with school personnel who might speak to any disruption to school functioning encountered during the pilot. [For this amendment we will pilot test the enhanced app to assess whether its use, over 6 months, is associated with fewer calories purchased from FFR and fewer visits to FFR.

We have shortened our study period time frame from 6 months to 1 month due to the COVID-19 pandemic.

This study will provide pilot data to inform our planned Ro1 proposal to test the impact of the intervention on behavior. We expect to develop LIITA<sup>3</sup>H as a marketable intervention, attractive to institutions interested in cost-effective means of improving health and impacting point of purchase choices. As a mHealth intervention, it can easily be scaled to include numerous participants. Further, the methodology may be adapted to address other conditions, offering the potential to reduce a wide range of health disparities.

## RESEARCH STRATEGY

### A. SIGNIFICANCE

**African American (AA) adolescents have a disproportionately high prevalence of obesity, putting them at risk for a myriad of illnesses in their youth and for incurring a greater burden of morbidity and premature mortality than their Caucasian peers.**

While the prevalence of obesity (BMI >95<sup>th</sup> percentile for age and sex) for Caucasian adolescents is 16.1%, for AA adolescents the prevalence is markedly higher at 23.7%.<sup>1,2</sup> Not only are more AA adolescents obese, but more are severely obese (BMI >97<sup>th</sup> percentile) than their Caucasian peers (18% vs. 11% respectively).<sup>1</sup> The impact of obesity has short and long term health consequences increasing the likelihood of numerous illnesses during their youth, and putting them at risk for developing early cardiovascular disease, Type 2 diabetes, and many cancers as adults.<sup>3-6</sup> Moreover, the effect of obesity goes beyond the individual to impact the society by augmenting healthcare costs, a problem that starts in childhood, as obese children have higher healthcare costs than their normal weight peers.<sup>7-10</sup> **It is vital to find ways to decrease the prevalence of obesity and reduce the burden of disease and related healthcare costs, particularly among AA adolescents.**

Obesity has proven to be remarkably refractory to treatment. Clinical treatments for obese adolescents (both in primary care and multidisciplinary interventions) have shown no or only modest success.<sup>11-13</sup> Furthermore, treatment outcomes are typically worse for AA adolescents, compared to Caucasian participants.<sup>12-14</sup> Based on the Self-Determination Theory and utilizing motivational interviewing to deliver evidence-based content, the Michigan Pediatric Outpatient Weight Evaluation and Reduction (MPOWER) program, is a family-focused, multidisciplinary program for obese adolescents that has shown promising results, that did not differ by race.<sup>15</sup> This likely was due to the level of individual tailoring incorporated into the program. However, our clinical experience in the MPOWER program suggests that despite intensive treatment adolescents' success with making healthy choices is greatly impacted by their school environment. Indeed, youth consume nearly 35 percent of their total daily calories during school hours while food eateries, such as corner stores, located near schools play a major role in their daily food consumption.<sup>16-18</sup> Finding ways to help adolescents make healthy choices during the school day is imperative to improving obesity treatment efforts.

The rapidly increasing capabilities of information and communications technologies along with the ubiquitous use of mobile phones by all ages and races, presents an opportunity to reach out to patients during the course of their daily activities to conveniently deliver individually tailored interventions at low cost.<sup>19,20</sup> As such, the possibility exists to revolutionize health care delivery and to minimize disparities. However, previous research indicates that using these technologies without rigorous testing and attention to *message content and timing* may have unintended effects.<sup>21</sup> In our MPOWERed Messages intervention, we created and tested a library of computer tailored texts addressing weight-related topics that were sent automatically at set times to promote healthy choices. *This study revealed that adolescents were enthusiastic about receiving the messages but they indicated that it would be more effective if they were delivered at times when they faced specific choices, such as at meals.*<sup>22</sup> Augmented location technology has the potential to identify when adolescents are in venues such as a school cafeteria or a restaurant and allow delivery of messages when they might have the greatest impact.

The Institute of Medicine (IOM) report on obesity highlights the urgent need for effective obesity interventions, particularly for minority patients.<sup>23</sup> By identifying when AA adolescents are making meal choices during the school day and automatically sending text messages that are culturally tailored and tailored to individual preferences, **we believe the Location Initiated Individualized Texts for African American Adolescent Health (LIITA<sup>3</sup>H) mobile app has the potential to significantly impact dietary choices and aid the reduction of obesity in this high risk population.**

In this project we will develop the capability to identify when students are in food related venues (e.g., their school cafeteria or in fast food restaurants or convenience stores in the vicinity of their school) and to link this with evidence-based tailored text messages to encourage healthy choices. In addition, we will pilot test the intervention with at-risk AA adolescents who attend schools in low-income neighborhoods where a high proportion of students receive free or reduced school meals and where there is a disproportionately high number of fast food restaurants and convenience stores. This will provide the initial data needed to inform a larger trial in Phase 2 of the intervention to demonstrate impact on food choices and BMI. Furthermore, this technology will have the potential to be extrapolated for use in other interventions requiring sophisticated location data to enhance message delivery. As such, the opportunities for commercialization are vast.

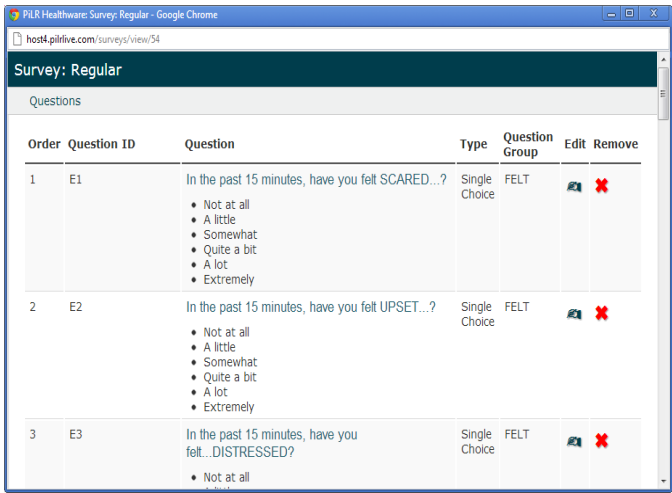
B. INNOVATION

B.1. Personal Geo-location Technology

*The Problem:* AA adolescents are often faced with calorie dense foods and obesogenic environments. Tailored texts may prompt healthy choices, but as suggested by teens in our MPOWEREd messages study, they may be most effective if delivered at the time food is presented. This complex task, that requires linking message delivery to presence in an eating venue at a relevant time, has not been incorporated into interventions for adolescents. Personal geo-location might accomplish this goal, but we believe this requires precision, as our prior work suggests that texts could trigger eating. Specifically, a student near an eating venue, but not aware of it or not planning to eat, may be triggered to eat if they receive a text about food at that venue. Hence, it is important to use the advanced technology we have available to ensure messages are delivered when students are in an eating venue with the intent to eat.

*The Innovations:* MEI Research developed the modular, easily customized “ActiPal™” mobile smart device application.<sup>24,25</sup> ActiPal integrates into a single application data from built-in and external sensors, presents a rich user interface of surveys (e.g., ecological momentary assessments (EMA)) and actionable data, and maintains remote communication.<sup>26,27</sup> ActiPal rapidly configures software that minimizes user burden while performing the functions needed for prospective data collection and behavioral interventions.<sup>28</sup> This native software (i.e., it lives on the phone and does not need an internet connection), has automatic restart and other features that ensure reliable performance.<sup>29</sup>

ActiPal works with “PiLR Healthware” to collect objective and subject-reported data.<sup>30</sup> This very powerful combination of technologies allows investigators to create surveys, assign them to subjects subject groups, and initiate interactions with participants when pre-determined (trigger) conditions (Figure 1). The triggers can be based on any objective source (time, location, speed, etc) or initiated by investigators and participants (e.g., tapping a widget). Responses from the subjects are uploaded to the server real-time for analysis and action by the investigator. is built on a Java application stack (Linux, Tomcat, MySQL, Java Server Pages). The Java application uses Model-View-Controller (MVC) pattern integrated with MongoDB to store data. PiLR delivers software updates and new content to ActiPal on a schedule. ActiPal and PiLR are in nearly constant communication when the mobile device has an internet connection.



The screenshot shows a web browser window titled "PiLR Healthware Survey: Regular - Google Chrome" with the URL "host4.pilr.com/surveys/view/54". The page header says "Survey: Regular". Below is a table of questions:

Order	Question ID	Question	Type	Question Group	Edit	Remove
1	E1	In the past 15 minutes, have you felt SCARED...? • Not at all • A little • Somewhat • Quite a bit • A lot • Extremely	Single Choice	FELT		
2	E2	In the past 15 minutes, have you felt UPSET...? • Not at all • A little • Somewhat • Quite a bit • A lot • Extremely	Single Choice	FELT		
3	E3	In the past 15 minutes, have you felt... DISTRESSED? • Not at all	Single Choice	FELT		

**Figure 1.** Investigator EMA Configuration of Survey. This screen shows questions related to psychological status. or occur in PiLR the

The LIITA<sup>3</sup>H project will use this powerful integrated application and user interface as a novel geo-linked tailored messaging intervention. **Key technological innovations to be created include:**

- 1) *The personal location information system (pLIS) that allows students to register preferred and likely eating venues (cafeteria, fast food restaurant, convenience store) as they are encountered.*
- 2) *System that records and refines venue time/ radius parameters to improve prediction accuracy.*
- 3) *After training the pLIS, it will be activated to deliver tailored texts prior to users choosing a food.*

B.2. Culturally and Individually Tailored Text Messages

*The Problem:* While it is important to deliver texts at the right time and location, it is also necessary to deliver content that is individually and culturally relevant to optimize the impact on behavior. This has yet to be achieved in a weight-related mobile intervention for adolescents. Further, prior studies suggest efforts are needed to aid engagement as teens may ignore the texts over time if they are not viewed as varied or relevant.<sup>31</sup>

*The Innovation:* Our messages will be innovative in 3 ways: 1) they will be tailored to students’ individual characteristics and food preferences, 2) they will reflect the style, tone, vernacular, graphics and content preferred by the target population of AA students (determined by prior work in cultural tailoring and by focus group findings) and 3) recommended choices will be linked to menu options for their location (the healthiest options on the eating venues’ online menus will be identified in advance for use in the study).

## C. APPROACH

This project will test an infrastructure to deliver culturally and individually tailored, evidence-based texts to adolescents at the time and location when they make food choices. During Phase 1 we will determine separately how well each of the functions can be achieved. A Phase 2 proposal will test effects on behavior, ensure long-term engagement, and determine how to achieve ‘scale-up’ that reaches any participant and accommodates an extended geography. As required in an STTR, “commercial development” will occur in Phase 3.

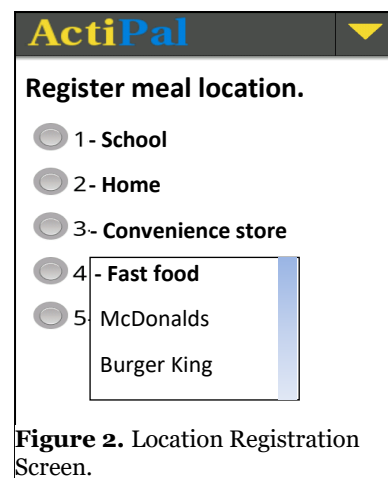
### C.1. Integrated Mobile Phone Application (Aim 1)

*To a) accurately identify when students are in their an eating venue, b) automatically deliver a tailored text message that prompts healthy choices, and c) receive annotated photos of students’ food choices.*

**C.1.a. Registration and Detection of Eating Venues with Intent to Eat.** Detecting when students are in an eating venue with the intent to eat will use our personalized location information system (pLIS). A traditional Geographic Information System (GIS) assigns geographically referenced parameters to data types. For many cities a description of every street, business, bus stop, school and even smaller details are available. However, ‘full up’ GIS is too burdensome and expensive for individually targeted interventions and aren’t needed. Behaviors and environments experienced by a single person have interactions with a limited number of locations. This provides the opportunity to develop a GIS behavioral dataset for each individual, such as our pLIS. The system will dynamically integrate objective and context data into “just enough” mapping.

The personalized location information system (pLIS) will run on a student’s mobile phone to determine when they are in an eating location with the intent to eat. We will enhance and test functions to perform the following:

1. Rapidly determine location indoors and outdoors, using a "fused provider" service that combines cellular tower signal triangulation (E911) with satellite augmented GPS and local RF (e.g., WiFi) signals. will use the Google Location Application Programming Interface (<http://developer.android.com/google/play-services/location.html>).
2. Enable each student to mark a unique set of eating locations by the ActiPal and PiLR Healthware EMA tools (Figure 2).
3. Recognize presence in an eating venue with an “intent to eat” by:
  - a. Creating customizable recognition boundaries around each marked location, called “Geofencing”.
  - b. Assigning a “dwell time” of duration within the eating location boundary that can be modified by the participant and dietitian.
  - c. Assigning “meal times” for each participant that can be modified by students.
  - d. Using the EMA tools to ask students whether they intend to eat in a training period prior to delivery of tailored texts.



**Figure 2.** Location Registration Screen.

[For this amendment newly available databases and technology that make it feasible to automatically identify when users are in FFR, will be used to create an enhance location identification (ELI) system.

**C.1.b. Message and Intervention Content Framework to Automatically Deliver Tailored Texts and EMA questions.** For this Phase 1 proposal, message coordination and content will be organized and presented with the existing PiLR capabilities, described above. These are sufficient to manage up to 100 participants simultaneously. The MPOWERed message library will be transferred to a database logically integrated by a Common Record Interface and MIME type that identifies content. Data formats and standards for objective and subject-report data will be linked to the system through an internal Collector component that implements a Configure interface telling other components details of how the data are collected.

The EMA tool will be used to assess whether the messages are delivered appropriately and will address questions such as: whether the text was received appropriately prior to making a food choice, whether the text was relevant to them, and whether the text influenced their choice. In addition to these general survey questions, individualized questions can be asked such as “yesterday you indicated that your food choice had a health rating of very unhealthy, are healthier options available today?”. [For this amendment newly available technology will be incorporated to enhance the ability to survey participants and to manage hundreds of participants simultaneously].

**C.1.c. Receipt of a Photo of Food Choices Annotated with the User’s Health Rating of the Food.**

Students will use ActiPal’s capability to annotate images to allow students to submit photos of their food choices and to annotate them, based on their perceptions of the food, with a Likert scale rating of very healthy to very unhealthy. Annotations may be made either by voice recording or touching marked buttons on the screen.

**C.2. Culturally and Individually Tailored Text Message Library (Aim 2)**

The MPOWERed Messages Library, designed to be tailored to individual characteristics and food preferences, will be adapted to include recommendations from eating venues’ menus, and to incorporate cultural tailoring.

**C.2.b. Message Library Adaptation.** The MPOWERed Message Library was originally created for obese teens, and texts were tailored to baseline characteristics, preferences, and values. For the proposed project, texts will be revised to ensure relevance for AA adolescents, and those in all weight categories. Further, because the app is not limited to 160 characters, we will be able to expand the messages to include menu-based recommendations tailored to students’ preferences.

**Cultural Tailoring Focus Groups.** To ensure cultural relevance, we will conduct focus groups with students (inclusion criteria: AA, 13-17 years old; exclusion criteria: Non English speaking).

**Population and Recruitment** – A convenience sample of adolescents (6 to 8 for each of 8 additional groups) will be recruited via flyers distributed at trial schools /community agencies with a number to text/call if interested. The project manager (PM) will contact parents to describe the study and schedule them for a focus group. Assent/consent will be obtained at the focus group. Or for schools that prefer the parents to contact the research team rather than the RA calling the parents, study information packets will be made available for students to take home to their parents. The packets will include a letter of invitation with instructions for the parent to call the research assistant to discuss the study and to provide consent. The package will also include the consent document for parents to sign and return to the study team. Assent will be obtained at the focus groups. A \$25 gift card incentive will be given.

**Focus Group Discussion** – The groups will meet for 2 hours at their school / community location will be facilitated by the PI (along with a note taker) and will be audio recorded. Basic data will be obtained on age, sex, height and weight. In the first 45 min, the app design and messages (Table 1) will be discussed and input elicited on ways tailor it to individual/cultural preferences. After a break, the last 45 minutes participants will complete a survey of preferences for cultural tailoring, along with the Multiethnic Identity Scale.

**Analysis and Revision of Text Messages** – Transcripts will be reviewed, coded, and themes identified independently by 2 team members using the constant comparative method.<sup>32</sup> The language, graphics and content desired by the target population will be incorporated into the texts along with cultural tailoring developed in prior studies.<sup>33</sup>

**Message Testing Groups.** A sample of the adapted texts will be tested with the target population (2 groups with 6 to 8 students/group). Population, recruitment and consent/assent as above. Based on methods used successfully in our prior studies, students will use an OptionFinder audience response handset<sup>34</sup> to indicate for each text if they: (1) Really liked it = No Changes, (2) Thought it was O.K. = Improve, or (3) Did not like it = Reject. Messages with ≥60% “really liked” and those with 60% “did not like” rating will be viewed as a consensus and not discussed further. All others will be discussed to elicit suggestions for improvements. The research team has extensive experience with testing and revising text messages for use in behavioral interventions. Students will receive a \$25 gift card for participating in this 2-hour group. [For this amendment, message testing groups will be replaced with a 5 – 10 member adolescent advisory board recruited. Key informants from the community (e.g., teachers our previous studies) will be asked to provide recommendations for possible members, and adolescents will also be selected from participants in the focus groups. The PM will contact the parents to describe the board. If they give verbal consent for their adolescent to participate, teens will be contacted to discuss the study and to assess their interest. Signed consent/assent will be obtained at the first meeting. Teens will receive a \$50 incentive per month of participation.

For convenience, these 90 minute meetings will be held in Detroit, Flint and Benton Harbor, and attendance via Skype or VSee teleconferencing will be offered. Meetings will be facilitated by the PI who works extensively with adolescents in clinical and research settings.

**Tailored Menu Recommendations.** Additional menus will be obtained from schools and popular fast food venues. The healthiest options will be identified from each venue for a variety of categories (e.g., salty foods, dairy

Table 1: MPOWERed Messages Library Message Types		
Message Type	Description	Example
Testimonials	Strategies others found helpful in weight loss	A teen says “TV was one of my favorite things, and I really didn’t want to cut back. But, I dropped a few shows, and the truth is, I don’t even miss them!”
Reflective Questions	Prompts to consider self-generated ideas	“What does being healthy mean for you? How does screen time fit with your goals?”
Tailored Messages	Created to be tailored to participants’ responses on baseline questionnaire.	Someone who eats breakfast daily might receive the message: “You eat breakfast every day. That’s really smart. It means you’re less likely to overeat later, especially at lunch. Keep up this great habit!”



foods, etc). The lists will be used to offer recommendations based on users' location and preferences (e.g., in McDonald's a student who said they like dairy foods on the baseline survey, might be asked to try a parfait). Following completion of Aims 1 and 2 the LIITA<sup>3</sup>H system (Figure 3) will be ready for pilot testing.

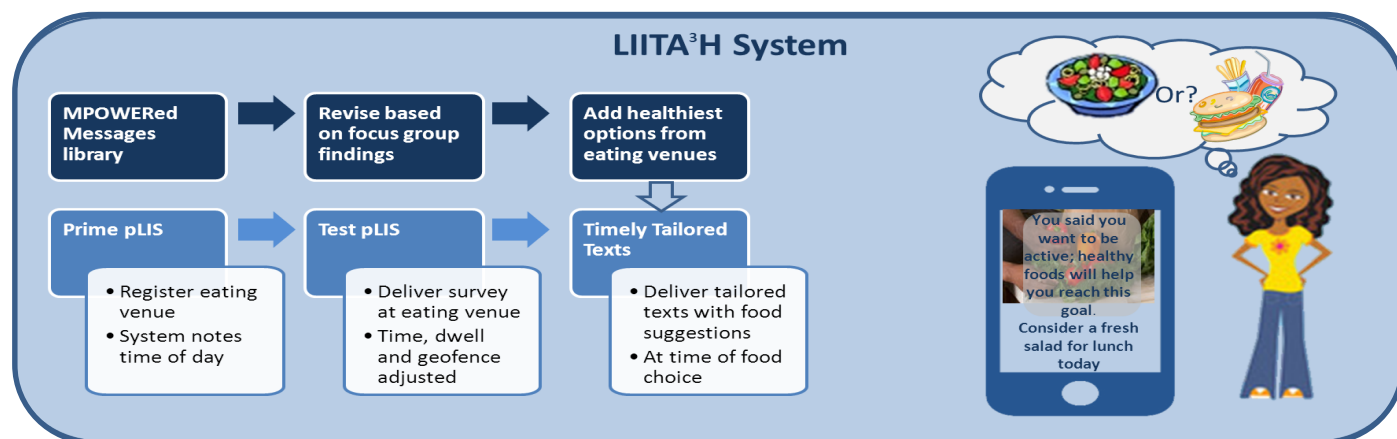
### C.3. Pilot Trial (Aim 3)

We will study the feasibility, acceptability and use of the LIITA<sup>3</sup>H system via a pilot with four 1-week phases. [This amendment will test the app impact on frequency of visits to, and calories purchased from, FFR in a 6-month pilot].

We have shortened our study period time frame from 6 months to 1 month due to the COVID-19 pandemic.

**C.3.a. Population and Recruitment.** We will recruit 150 13-17 year olds, with a BMI > 85<sup>th</sup> percentile who eat at FFR at least 3 times/week) from each of the 3 cities. Recruitment and consent/assent are as above. Students will receive two \$30 gift cards as an incentive for participation. A cell phone will be provided for those who do not own one. Payment will also be provided to cover the costs of internet access for those who need it.

Due to the COVID-19 situation that hampers physical contact, recruitment for the research study trial (to replace the in-person enrollment sessions due to the COVID situation) will be conducted virtually through UMHealthResearch.org and through a Facebook and Instagram advertising campaign managed by MICHR and linked to our UMHealthResearch study page.



**C.3.b. Enrollment Session.** Upon obtaining consent / assent, an enrollment session will be scheduled. At this session students' height and weight will be measured and they will complete an online enrollment survey addressing preferences, baseline characteristics, current habits, values, ethnic identity, their level of interest in making dietary changes and any changes they might wish to make. They will download the app and receive instruction in its use, including photo submission and rating foods on a Likert scale of very healthy to very unhealthy. They will be informed that they will be randomly assigned to use one of three versions of the app by the technology team who will apply to appropriate functionality to their app.

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Due to recruitment and enrollment efforts being conducted virtually because of the COVID-19 pandemic, participants will be guided as they take their own height and weight measurements. Since this will be done remotely, we will send any participants who require a scale, a tape measure, a square, and/or pencils, the necessary materials, which they will be able to keep.

**Randomization** – The technology team will randomly assign participants as they enroll to either the intervention or one of the control groups. They will then adjust the functionality of the app for the participants accordingly, and will send a message to their phone indicating their group assignment, along with instructions for their group. Thus, the research assistant who collects data will be blinded regarding group assignment.

### C.3.c. Four Week Intervention

**Week 1 – Student Registration of Eating Venues.** Students will be asked to identify, using ActiPal, when they are in an eating venue (cafeteria, restaurant, or convenience store). The venue data (time and location) are registered



in PiLR. They will be encouraged to submit a photo of their food choices and annotate it with a rating on the very healthy to very unhealthy scale.<sup>28</sup> By the end of week 1 the system will have collected data about the most frequent eating locations, when they typically eat there, and what food they choose.

**Week 2 – Eating Venue Identification.** We will use the system to identify and contact students when they are in eating venues. We will ask students via an EMA survey whether the system is correct. For erroneous detections the appropriate stored venue criteria (location, geofence, time of day or dwell time) will be adjusted to improve detection.<sup>35</sup> For correct detections they will be asked to report on their food choice.

Throughout the study students will be able to identify newly encountered eating venues. If the app does not recognize it, they will be asked to register that location (as they did in week 1). The first assessment of eating venue recognition accuracy will be calculated. Investigators will make an overall assessment of recognition criteria and potentially correlated factors such as neighborhood or which school the student attends.

**Week 3 – Delivery of Location Linked Tailored Messages.** In week 3 the system will try to deliver a relevant message when a student enters an eating venue with the intent to eat. EMA surveys will elicit whether messages are appropriate (i.e., received prior to making a choice, the venue is correct, the suggested food is available), relevant (i.e., suggestion matched their preferences), and if/how it influenced their choice. At the end of week 3 the feasibility and acceptability of location linked tailored texts will be demonstrated.

**Week 4 – Inclusion of EMA Questions Including Feedback.** During week 4 we will assess the feasibility and acceptability of including content that provides feedback on earlier choices. The EMA tool will be used to provide information from a recent choice and to request current information (e.g., students may be reminded of the health rating of their choice from the day before and asked whether there are healthier options available today). In addition, the EMA tool will be used to congratulate students for making healthier choices and for submitting the requested photos. Students will be asked to provide their perspectives as in week 3.

For this amendment weeks 1 to 3 will not be repeated. Participants will use the app for 6 months in one of 3 groups.

We have shortened our study period time frame from 6 months to 1 month due to the COVID-19 pandemic.

**Intervention Group 1** – Participants will be asked to keep the app running on their phone. They will receive a ping when the app identifies that they are in a fast food restaurant followed by a point of purchase prompt, tailored to their preferences and the options available at that location. If they are in a venue without a menu, general healthy suggestions will be provided (such as “consider choosing smaller portions” or “does this venue sell fruit?”). If the app does not ping when they enter a restaurant, they will be asked to register that location by tapping the ‘register location’ button on the app and entering the restaurant name. For detection errors, the appropriate stored venue criteria (location, geo-fence, time of day or dwell time) may be adjusted to improve detection. Users will also be asked to take a picture of any items they buy and to annotate it with information that would help to determine the nutrients in the food. Annotations may be audio, text, or made from a selection of descriptive buttons (e.g., to indicate small, medium or large sizes).

**Control Group 2** – Participants in Control Group 2 will receive similar instructions to those given to group 1, but without receiving point of purchase prompts.

**Control Group 3** – The Location Only Control Group 3 will only get information about location detection, and asked to register FFR if the app does not indicate with a ping that they have entered one. Their instructions will not discuss photo documentation of food or prompts as these features will not be active on their app.

During the study period, the participants will be contacted once per month by a research team member. Monthly calls will be added to help gather feedback from participants about the app. Study participants will be contacted by phone on three separate occasions, at times when the participants are not in school (e.g. after 4pm on weekdays or a weekend). If, for any reason, a research team member is unable to reach a study participant after three attempts, we will connect with the parent and/or research liaison (e.g. a staff member at the school or community organization we are working with) for assistance.

### **C.3.d Post Intervention Assessment**

**Semi-Structured Interviews.** At the completion of the 6-month trial (or sooner if they appear to have dropped out), adolescents will be interviewed to obtain detailed feedback about PiLR, the subject interface, methods of prompting, EMA surveys, entering data, submitting photos and rating foods. Location data will be used to inform the questions in the interview. For example, participants who, based on the GPS, have not visited FFR will be asked to share reasons for this change. Those who, based on the GPS, continue to visit FFR, will be asked about the choices made, and what if anything would be most helpful to them when they are making the choice regarding what to

purchase. They will also be asked about the user interface, cultural tailoring, and the SNAP component. Interviews will be transcribed and coded by 2 researchers separately.

For the semi-structured interviews at the end of the study period, study participants will be contacted by phone on three separate occasions, at times when the participants are not in school (e.g. after 4pm on weekdays or a weekend). If, for any reason, a research team member is unable to reach a study participant after three attempts, we will connect with the parent and/or research liaison (e.g. a staff member at the school or community organization we are working with) for assistance.

We have shortened our study period time frame from 6 months to 1 month due to the COVID-19 pandemic.

**Quantitative Survey.** *Acceptability Measure:* A questionnaire will assess acceptability of the format (What was their experience, did they like it?; How would you rate the overall experience?), and feasibility (How easy was it to use the hardware and respond to prompts?). Acceptability and feasibility mean scores of 3.5 or greater, rated on a scale of 1 (poor) to 5 (excellent), are deemed acceptable.

**Assessment of Usage.** *Electronic Usage Measures:* During the pilot, the PiLR will automatically record (1) the time students spent using the system, (2) the frequency of triggering events, (3) compliance with prompts, (4) and whether subjects felt the system was responsive. It will also automatically record number of visits to the FFR. It will also collect usage data in regard to things like frequency of submitting pictures and whether they include annotations.

### C.3.e. Analyses

Primary Outcome – Feasibility of the technological components

Based on students' responses when using the system we will determine 1) the percentage of the time that the system accurately identified presence in an eating venue and correctly identified the registered venue (cafeteria vs. convenience store), and 2) the percentage of time that an appropriate and relevant message was delivered. For this amendment, calories purchased will be assessed using submitted annotated photos, and nutrition data from FFR menus (e.g., if the participant submits a picture of McDonald's fries and indicates it is a small order, then from the McDonalds menu, we will determine that the calories purchased were 240 kcals). Frequency of visits will be obtained directly from the app. We will use population averaged generalized estimating equation regressions (GEE) to compare trajectories of calories purchased and number of visits between groups. The GEE approach allows us to account for the correlation in repeated observations collected from each subject over time. For calories purchased, we will perform GEE linear regression modeling as a function of time, treatment group (intervention vs. control group 2) and the interaction of time by treatment group ( $Y = \beta_0 + \beta_1 Time + \beta_2 Treatment + \beta_3 Time * Treatment + \epsilon$ ). Similarly, for the number of visits, we will fit a GEE Poisson regression model as a function of time, treatment group (intervention vs. control group 2 vs control group 3) and the interaction of time by treatment group. Residual diagnostics will be performed to examine departures from model assumptions. If necessary, we will use transformed outcome variables and refit the models.

Secondary Outcome 1 – Acceptability of the intervention and the messages

From the post-pilot interviews we will identify students' perceptions of the intervention overall and of the messages specifically. We will explore opinions of school personnel on impacts of using the LIITAH at school. Data from post-pilot interviews plus the advisory board input, will inform revisions of the app and planning for a larger trial. For this amendment, we will use the models discussed above to examine associations between calories purchased /number of visits including as covariates participant characteristics such as extent of app use, initial BMI, and ethnic identity (as an ordinal measure assessed via the Multiethnic Identity Scale) as a secondary outcome.

Secondary Outcome 2 – Exploration of food choices

As an exploratory analysis to assess for feasibility in preparation for a phase 2 trial, the U of M research team will apply MPOWER guidelines (regarding fat, fiber, sugar and calorie content) to assess whether students' food choices in week 4 were healthier than those in week 1 using the uploaded photos, accompanying student annotations, and nutrition information from venues' menus. We also will explore any associations between changes in food choice and student characteristics (i.e., sex, level of interest in making changes, BMI).

### C.4. Project Timeline by Month

Project Activity	1	2	3	4	5	6	7	8	9	10	11	12
<b>Aim 1</b>												
Requirement planning and use case design	X	X		X								
Iterative Development (smartphone and server /web-service tools)		X	X	X	X	X						
Prototype mobile application and server						X	X					
<b>Aim 2</b>												
Collect menus and identify healthiest options	X	X	X	X								
Develop questionnaires, interview guides, and focus group prompts	X											
Recruit cultural tailoring focus groups		X	X									
Cultural tailoring focus groups			X	X								
Adapt and culturally tail messages				X	X							
Recruit message testing groups				X	X							
Message testing groups						X						
Revise messages							X	X				
<b>Aim 3 - Pilot Testing and Reports</b>												
Recruit for pilot								X	X	X		
Pilot study									X	X	X	
Data analysis and reporting											X	X

### C.5. Limitations / Potential Problems / Alternative Strategies

For the benefit of cost and time, we will build the Phase 1 system with readily available and free Google services combined with our existing ActiPal objective data / EMA applications. Both require the Android operating system (OS). Android is currently the most popular smart device OS so we expect at least half of the students will have a compatible device. Students who do not own a smart device may be issued one for use in the study. In Phase 2 we will extend the system to Apple (iOS) and other OS popular at that time. iOS is not economical to implement in Phase 1 due to commercial distribution restrictions applied by Apple Corporation.

The Google location API combines all of the most robust services available, including augmented GPS, cellular triangulation (E911) and local RF (e.g., WiFi). An outcome of this Phase 1 will be to assess our ability to detect eating locations. However, for critical locations, such as a school cafeteria, we will be able to augment the current Google location database if failures are detected. The solution is simply to place a \$15 WiFi transmitter anywhere in the eating venue and register its unique “MAC” address with Google. The transmitter would be recovered at the end of the study. The transmitter will not be connected to the internet. More RF sources are being “discovered” and entered in the Google and similar databases constantly, so we expect that by the time Phase 2 work begins supplemental marking devices will not be needed. In any human research there is always the possibility of difficulty in recruiting. However, 3 schools have agreed to be trial schools. Further, in past studies, we have found adolescents are enthusiastic about participating.

### C.6. Commercialization

The ActiPal and PiLR Healthware systems are used in a wide variety of healthy messaging applications, from smoking to weight management and clinical pain control. Once the present methodologies have been developed and proven through an RCT by the University of Michigan and MEI, it will be moved to primary markets, including health and wellness centers, obesity clinics, and corporate wellness programs. This academic and small business collaboration will lead to the development of a sophisticated evidence-based tool likely to aid in reducing health disparities by promoting healthy choices among AA adolescents, and which will be marketable to address this and other situations where timely location-linked messaging may be helpful.

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