Title: Location Initiated Individualized Texts for Adolescent Health (LIITAH)

PI: Dr. Susan Woolford, MD, MPH

NCT: NCT03762135

IRB Approval Date: 7/7/2021

SPECIFIC AIMS

Significance – The Problem: Adolescent excess weight is a public health concern due to its high prevalence (Black 40%, Hispanic 38%, White 31%).[1-4] Excess weight puts adolescents at risk for developing illnesses such as liver disease and hypertension in their youth and for premature death as adults from numerous comorbid conditions (e.g., cancer, diabetes, and cardiovascular disease).[5-8] This epidemic is influenced by consumption of calorie dense foods prepared outside of the home.[9,10] Youth consume 35% of their calories outside of the home: with most of these coming from restaurants.[11-14] The majority of Black (65%) and Hispanic (62%) youth live in low-income families, often in communities with a greater density of fast food restaurants.[15-18] The Knowledge Gap: We need effective ways to help adolescents make healthy choices in obesogenic places.

NIMHD STTR Phase 1 – To fill this need, MEI Research, Ltd (a company that builds complex mobile health systems) partnered with the PI to create the Location Initiated Individualized Texts for African American Adolescent Health (*LIITA³H)* program.[19] The program was delivered via an app and prompted adolescents to make healthy food purchases. Phase 1 confirmed that it 1) identified when users entered an eating venue 90% of the time, delivered meal suggestions tailored to users' preferences and the menu at that location, and asked users for a photo of their purchase, annotated with their health rating of the food; 2) delivered tailored messages (adapted from our evidence-based MPOWERed Messages library) at the point of purchase and other times; were validated as culturally relevant by focus groups of Black adolescents; and 3) the program proved feasible in a 1-month pilot and in follow-up interviews that revealed users' enthusiasm for the program. [20,21]

The Product – In Phase 2, 'LIITA³H' will become the Location Initiated Individualized Texts for Adolescent Health *(LIITAH*) program. Technological Innovation: LIITAH is novel, delivering actionable content tailored to individual characteristics and the food options on the menu at the users' location.[22] In Phase 2 at users' requests we will incorporate 1) deeper individual tailoring making the content even more relevant to users from different races/ethnicities; 2) a dyad capability for parents to use the app coordinated with their adolescent; and 3) additional engagement features to remind participants to use the app frequently. Impact: This product will improve weight management efforts by providing personally relevant cues to action when they can immediately impact intake of high calorie foods. Other behavior change interventions will be enhanced by incorporating personally relevant messaging delivered at key times based on the users' location.

Long term Goal – To create a powerful coaching presence that helps form healthy habits through culturally and individually tailored messages delivered to users when they can act immediately on the information.

Hypothesis – Use of the LIITAH program will improve health habits among a diverse population of adolescents, as demonstrated by fewer calories purchased at restaurants. Thus, the Specific Aims are to:

Aim 1: *Expand the program technology* to work on all mobile operating systems, develop a companion application for parents, link locations and menu data for food outlets nationwide, allow remote message personalization, and test integration of the program into the Fruit Street platform.

Approach: Development will proceed with iterative testing/input provided by a participant advisory board.

Aim 2: *Augment the message library* to include messages and meal recommendations tailored to Hispanic adolescents and to parents (building on the current library that is tailored to Black and to White adolescents).

Approach: Focus groups with Hispanic adolescents and with parents will inform revised tailoring of messages.

[Ame00100677 – due to the COVID-19 situation, this amendment is modifying the focus group study activities including recruitment, screening, consent, and the focus group itself to be virtual data collection. Recruitment will be conducted through UMHealthResearch.org and social media (via MICHR).
Due to the need to comply with social distancing guidelines implemented prior to the completion of the focus groups with Hispanic youth, an online survey will be administered addressing similar content to the in-person focus group interview guide. This will replace the need to conduct any additional groups in person.]

Aim 3: *Demonstrate the impact* of using LIITAH on the main outcome of calories purchased from restaurants by adolescents, and the secondary outcomes of their visits to restaurants, and their body mass index (BMI)

Approach: A 3-month trial will assess statistically significant differences between intervention and control groups for calories purchased from restaurants (from photos of purchases cross-referenced with online nutrition data), geo-location data of visits to restaurants, and measured pre-post BMI.

Ame00105576 The focus group part of the study has been completed for both parents and all teens on 9/2020. 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.

Expected Outcomes – We expect that the program will offer a cost-effective means to improve health. It will be easily scalable and will be adapted in the commercialization phase to go beyond food choices to address other health issues (e.g., physical activity, smoking) where disparities exist.

Commercial Application – The target market consists of healthcare systems/providers that engage patients, employees and families in healthy lifestyle programs. The commercialization strategy is to license the program for use in this arena. *The first commercial partner is Fruit Street Telehealth* – a company with $7 million in revenue from licensing software to healthcare providers and systems. As part of Phase 2, Fruit Street will assess mechanisms to incorporate the LIITAH program into their platform for Phase 3 commercialization.

RESEARCH STRATEGY

A. Significance

The Problem**:** *Excess weight puts millions of adolescents in the US at risk for weight-related illnesses and premature death, and disproportionately impacts Black and Hispanic populations*. Excess weight (Body Mass Index (BMI) >85th percentile for age and sex) is the most common chronic illness among adolescents in the US, with 31.5% (over 7.5 million) affected.[1-4] Black and Hispanic adolescents have a disproportionately high prevalence of excess weight (Black 40%, Hispanic 38%, White 31%). and often have poorer treatment outcomes than their White peers.[2,23-25] This has serious health consequences in youth and increases the risk of premature death as an adult from illnesses such as cardiovascular disease and stroke.[5-8] In addition, excess weight in adolescence increases healthcare costs over their life course [26-29] As adolescence is a time when many lifestyle habits are formed, it is important to address obesity early.

Adolescents consume 35% of their daily calories from meals prepared outside of the home – typically from restaurants.[11-14] Research suggests that consuming foods prepared outside of the home is associated with a higher BMI.[9-12] Black and Hispanic youth are more likely to be exposed to communities with high densities of fast food restaurants.[16-18] We need ways to help adolescents make healthy choices in obesogenic settings that are relevant to and have been tested in populations who are at the highest risk for obesity its associated costs.

The Knowledge Gap: *Excess weight is refractory to treatment.*[30] *Clinical treatments for obese adolescents have shown no or only modest success, and are often even less effective for non-White populations*.[23-25,31] The Michigan Pediatric Outpatient Weight Evaluation and Reduction (MPOWER) program (a multidisciplinary program we created for adolescents with obesity) demonstrated promising results that did not vary by race, using an individually tailored, family-focused approach based on the Self-Determination Theory (SDT) and motivational interviewing (MI) to deliver evidence-based content.[32-34] Our clinical experience in MPOWER suggests that adolescents' success with making healthy choices is greatly impacted by food prepared outside the home.[35] Finding ways to help adolescents make healthy food choices when away from home is imperative to improving health. In addition, helping parents support adolescents may improve their likelihood of success especially as recent data show that Americans are spending more on dining out than in previous years.[35-37]

The Product: To address the problem, we will create the *Location Initiated Individualized Texts for Adolescent Health (LIITAH) program*. It will expand the Location Initiated Individualized Texts for African American Adolescent Health (LIITA^{3}H) mobile program this team developed in a Phase I STTR in several ways. LIITAH will still deliver individually and culturally tailored messaging to adolescents encouraging them to make healthy food choices via a smartphone app. These messages will come from individual user communication preferences, individual goals and the improved MPOWERed library created by the PI, based on MI and SDT and tested with adolescents in the MPOWER program.[20,38,39] Messages will be delivered exactly when users are engaged in the behavior we are seeking to influence and combined with immediately actionable recommendations (e.g., in the case of food choices: foods available on the menu, documented past choices, dietary goals). Among the enhancements to be added are:

- use of any mobile operating system (Android, iOS, Windows Mobile),
- true geo-fencing capability
- links to resource data (restaurant / fast food locations, menus with nutritional content of each item),

- greater individual tailoring, allowing it to be relevant to users of different races/ ethnicities,
- a dyad capability allowing parents to use the app with the adolescents, as they indicated that parents often buy fast food for them,
- features to keep users engaged with the app throughout the day.

Impact on weight management – LIITAH will impact weight management efforts by providing personally relevant cues to action at a time when they can most influence high calorie intake. It will allow providers to impact adolescent and parent choices in a manner that was not previously possible, and will expand the capacity of healthy lifestyle interventions to provide content relevant to diverse populations. In this project, the impact on calories purchased, number of restaurant visits, and BMI will be measured during the Aim 3 trial.

Future impact of LIITAH on health – The LIITAH technologies will have an impact beyond obesity. Location-based messaging could be useful for other health issues such as smoking cessation and preventing sexually transmitted infection. Furthermore, the LIITAH culturally and individually tailored messaging may help inform other behavior change efforts using mobile technology to address illnesses where disparities exist.

Value of LIITAH in Lifestyle Interventions for Obesity: The Institute of Medicine highlights the urgent need to effectively intervene on obesity, particularly among diverse populations.[40] By identifying when users are making meal choices in eating venues and automatically sending messages that are tailored to cultural and individual preferences, the LIITAH program is designed to significantly impact dietary choices and lower BMI.

Commercial Potential

Overview of Commercialization Plan: The University of Michigan and MEI Research intend to license the LIITAH program to entities that offer healthy lifestyle programs. These include healthcare organizations (hospitals, wellness centers and insurers) that enroll patients, or employees and their families. First we will pursue businesses that can use the LIITAH offerings to enhance programs they have created for healthcare. The first, Fruit Street, already has committed to seek a license when this project succeeds. By integrated LIITAH technologies and content, the Fruit Street platform would be enhanced with numerous features that would be sold at an additional charge to providers.

Fruit Street, has developed and markets a telemedicine software product to healthcare professionals.[41] The Fruit Street platform allows providers to conduct video consultations with patients and monitor their health, diet, and lifestyle using medical devices, wearable devices, and the Fruit Street iPhone and Android application. As part of Aim 1, Fruit Street will examine the LIITAH program and determine the requirements to integrate it into the Fruit Street platform to be marketed to their customers as part of their premium package.

a) **Market** - Chronic diseases such as obesity and diabetes are often preventable by lifestyle modification[40,42,43] As obesity impacts over one third of the US population, and almost half of those with obesity have prediabetes or diabetes, these diseases result in a tremendous societal cost.[4,26,43,44] This market opportunity is highlighted by the Centers for Medicare and Medicaid Services' proposed reimbursement of the diabetes prevention program, which is a landmark achievement in reimbursement for preventive care.[45] As the reimbursement climate shifts from sick care toward preventive health care, well-designed programs stand to capitalize on a market that affects over half of Americans, yet has traditionally avoided monetization. By delivering tailored and immediately actionable messages the LIITAH program will help users learn to make healthy choices.

b) **Competition** – There are very many stand-alone mobile apps with the goal of helping people eat better and lose weight.[46] However, we are not aware of any that attempt to passively determine the most appropriate time to deliver a recommendation. And certainly none that combine that with highly tailored messages that are immediately and accurately actionable. Even further, none offer feedback mechanisms enabling professionals to make continuous improvements nor involve parents.

The first licensee, Fruit Street, has competitors that focus on video visits alone (e.g. evisit, snap.md, chironhealth, and gethealthie), or urgent care that does not incorporate lifestyle risk factors. Examples of these video platforms include Zoom and Doxy.me, while platforms like Teladoc and MDLive focus on urgent care telemedicine. There are platform competitors that incorporate lifestyle risk factor modification into a given program, such as Omada Health, which has a diabetes prevention program that includes education and coaching, but does not allow organizations to use their own providers, or conduct video visits. A similar program to Omada without a set time frame are Retrofitme and Vida, which allow video visits (again, this uses a Vida coach rather than the actual providers of the medical team).

d) **Other applications of the technology** – This project will demonstrate the capabilities of LIITAH to address lifestyle risk factor modification related to food choices and diet. The advanced features to be

developed, such location-based interaction, present additional opportunities for intervention. Patients passing near a park or gym, could be alerted to the opportunity to increase their daily level of exercise. Fine location tagging in grocery stores could suggest healthy ingredients for home cooked meals. Weight-associated pathologies, such as osteoarthritis, and diet-related autoimmune diseases or congestive heart failure, along with health concerns not related to weight such as smoking and contraception could also benefit from location-based prompts for behavior modification or to encourage treatment compliance. MEI Research already is involved with numerous projects to address smoking, alcohol and drug use, medication adherence, and physical activity.

B. Innovation

B.1. Personal Geo-location Technology

The Problem: Adolescents often are in obesogenic environments with easy access to calorie dense foods. Tailored messages may raise health awareness, but as suggested in our MPOWERed Messages study, and reiterated by our Phase 1 findings, messages are viewed as most effective if received at times when food is present. This complex task of registering eating venues, tailoring messages specific to each venue and adolescent, identifying when users arrive at an eating venue with the intent to eat (not merely passing by, in which case a message could potentiate eating), and linking message delivery to a precise location at a relevant time, was accomplished in our Phase 1 project. This is a first for obesity interventions. However, the need for additional technological enhancements also was confirmed. First, we need to incorporate greater individual tailoring (that allows relevance to a wider range of ethnicities). Second, additional engagement features (goal setting, rewards/point system) are needed. Third, components that allow adolescents to participate as a dyad with their parents (who often buy the restaurant food for the family) also were requested in the Phase 1 project.

The Innovations: In conjunction with the PI, MEI Research developed the prototype LIITA^{3}H mobile program. LIITA^{3}H was delivered via a custom Android mobile app that was supported by MEI's patented PiLR Health™ mobile backend as a service (mBaaS) infrastructure. PiLR Health and other apps from MEI, such as PiLR EMA and LiaD, are combined in flexible systems to deliver customizable ecological momentary assessments (EMA) and tailored interactions with users based on conditions, such as location.[47-50] The systems also facilitate data collection and presentation via a user friendly dashboard for healthcare providers to analyze.[51] This native software (i.e., it lives on the phone and does not need the internet), has features to ensure reliability (e.g., automatic restart).[52] ***Key technological innovations of LIITA^{3}H included***:

- Creating a Personal Location Information System (pLIS) that allowed users to register preferred eating venues as they were encountered. *In Phase 2, we will add an enhanced location identification (ELI) system that also will identify when users are in restaurants from a database of known restaurant coordinates.*
- A system that recorded and refined venue time/ radius parameters to improve prediction accuracy.
- An integrated tailoring engine to deliver tailored messages at the point of sale, prior to users purchasing their food. *In Phase 2, we will create the dyad component that will allow parents (and friends if desired by the adolescent) to participate along with the adolescent.*
- The 'self-report of nutrients by annotated photos' (SNAP) component to document purchases.
- Engagement features including delivery of tailored health-related messages. *For Phase II, rather than messages sent at set times, they will be delivered at times selected by users. In addition, a goal setting component and point system will be added.*

B.2. Culturally and Individually Tailored Content

The Problem: While it is important to deliver messages at the right time and location, it is also necessary to deliver content that is personally relevant to maximize the impact on behavior.[53] This was tested successfully for Black adolescents in Phase 1 and for White adolescents in the MPOWERed Messages study. This has yet to be developed/tested for Hispanic adolescents or parents of adolescents in a weight-related mobile intervention.

The Innovation: Our messages will be innovative in three ways:

1. They will be tailored to participants' individual characteristics (e.g., values, goals) and food preferences.
2. They will reflect the style, tone, vernacular, graphics and content preferred by the target population of Black, Hispanic and White adolescents and parents (determined by prior work in cultural tailoring and from the Phase 2 Aim 2 focus group findings).
3. Recommended choices will be linked to menu options for their location from a database of menus (the healthiest options on the online menus will be identified in advance for use in the project) and from adolescents' favorite local restaurants, which will be added as they identify them.

Relevance to current state of the science – This moves the field forward by allowing the linkage of location-triggered message delivery with individually and culturally tailored messages. Thus, making it possible to impact behavior at times when participants can immediately act on the information provided. Such 'just in time' messaging has the potential to alter the way behavioral interventions are delivered. This technology will allow future advancements in the management of chronic conditions that are impacted by lifestyle choices.

C. Approach

Report of Phase 1 Progress

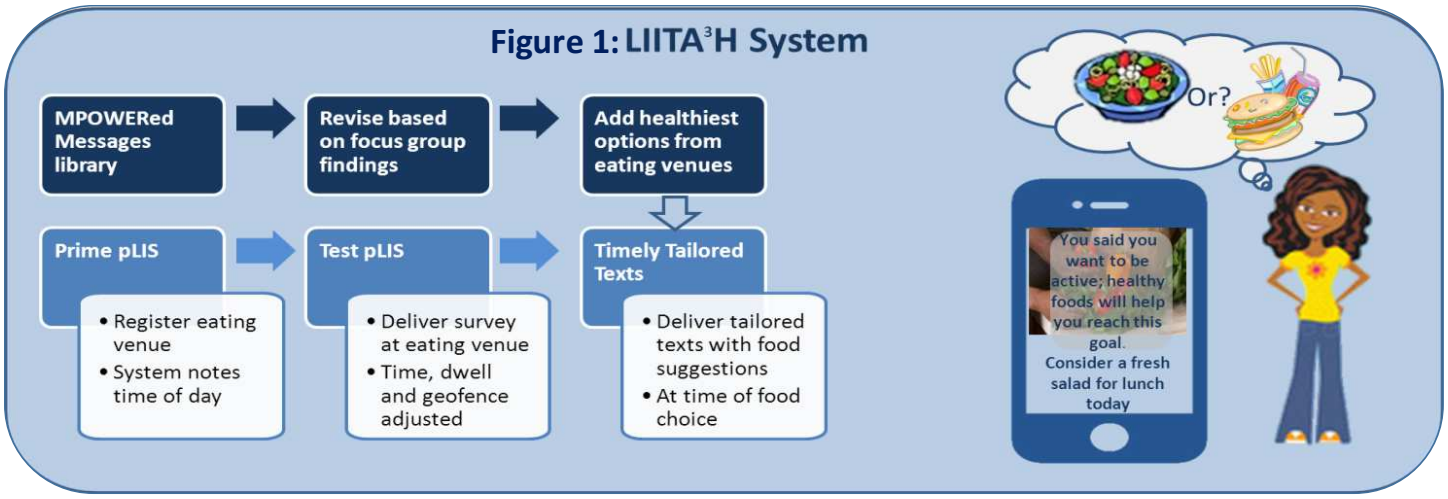
Phase 1 Aim 1: To develop an integrated mobile phone application that would a) accurately identify when students are in their school cafeteria or other eating venue, b) automatically deliver a tailored text message that prompts healthy choices, and c) receive a photo of food choices annotated with users' health rating of the food. Starting in July 2014, we prototyped capabilities to identify when users were in eating venues with the "intent to eat" and deliver messages tailored to prompt venue-specific healthy choices. This was achieved with personal geo-location technology, applied on Android phones and controlled remotely.

Technological Achievements of Phase 1 Project

Registration and Detection of Eating Venues with Intent to Eat. We created pLIS to detect when participants were in an eating venue with the intent to eat. Traditional Geographic Information Systems (GIS) were too burdensome and expensive for an individually targeted app. Behaviors and environments experienced by a single person have interactions with a limited number of locations. The system dynamically integrated objective and context data into "just enough" mapping. In Phase 1 the pLIS a) rapidly determined location indoors and outdoors,[54] b) enabled each participant to mark a unique set of eating locations, and c) recognized presence in an eating venue with an "intent to eat" by creating customizable recognition boundaries around each marked location, assigning a "dwell time" of duration within the boundary that could be modified by the user and a coach/provider prior to delivery of tailored texts.

Message and Intervention Framework to Automatically Deliver Tailored Texts and EMA

Message coordination and content was organized and presented with the PiLR capabilities. The MPOWERed message library was transferred to a database integrated by a Common Record Interface and MIME type that identifies content. The EMA tool was used to assess students' feedback about the app's functioning and on individual questions (e.g. "yesterday you rated your meal as unhealthy, are healthier items available today?").[50]



Receiving Photos of Food Choices Annotated with the User's Health Rating of the Food

The program allowed participants to submit photos of their food, and to annotate them with a Likert scale rating of very healthy to very unhealthy. Annotations were possible either by voice recording or touch screen buttons.

Pretest – A convenience sample of undergraduate students pretested the program and gave feedback.

Location registration – Before pilot testing began, each participant planned up to 7 destination venues that they would visit. These were not required to be eating venues, just recognizable places presenting a variety of boundaries. Upon visiting each venue, the participant added them through the app.

Location detection – In addition to logging arrival at the destination, we tracked proximity to all venues on the

list to assess discrimination. Notifications and a food suggestion were delivered for each 'arrival'. If a participant arrived at a venue on their list and failed to receive a notification, they were asked to open a 'Tracking tab' and report on the 'Log your arrival' form. This tracked false negative triggers from which the detection radius and/or location centroid could be adjusted. To increase data density and assess whether to track snacking in the pilot tests we allowed 6 time windows/day instead of just 3 corresponding to major meals.

Aim 1 Outcome: Beta testing by the project team demonstrated successful functioning of these features allowing them to be ready for integration with the tailored messaging developed in Aim 2.

Phase 1 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.

Message Library Phase 1 Testing and Findings

Participants were recruited from high schools in metro Detroit to participate in focus groups to provide their perceptions regarding message content. Messages were revised based on these findings. Images were replaced using the recommendations made by the groups.

From the Phase 1 focus groups with Black teens, the following themes emerged regarding message content[21]:

1. For messages at the point of sale (incorporating menu options)
    a. Money influenced their choices – Students consistently expressed a concern about the cost of food. Getting the most for their money was valued over consuming healthier options.
    b. Direction preferred over questions – Students preferred direct statements rather than questions asking them to reflect on the relationship between their choices and their values.
2. For the health promotion messages (sent at other times of day selected by the user)
    c. Familiar foods were preferred – Students wanted suggestions to reflect foods they generally eat rather than unfamiliar ones.
    d. Practical tips and recipes were preferred – Students expressed a strong preference for messages with practical tips and recipes they could try at home.

Regarding images that accompany the messages, the following themes emerged[21]:

1. Reality matters – Students emphasized the importance of the images appearing realistic. Things that appeared staged were viewed as "fake" and were not appealing.
2. Relatable images are key – Students preferred images deemed most like them (e.g., a photo of a teen with excess weight making a healthy choice (irrespective of race) was viewed as relatable).
3. Diversity is important – Regarding the race/ethnicity of the subjects in the images, pictures with Black subjects were popular, but many preferred images that showed a diversity of races/ethnicities. Their own diversity was also important, as participants frequently indicated that they do not all share the same preferences, so the ability to tailor to their individual preferences was viewed positively.

Aim 2 Outcome: The focus groups of Black adolescents identified the most important content. Some themes mirrored findings from the MPOWERed with mainly White adolescents. An important finding was greater individual tailoring. From Aim 2 we had messages, approved by consensus, ready for the Aim 3 pilot.

Phase 1 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.

Pilot Testing and Semi-Structured Interviews with Adolescents

The app was tested with Black adolescents (n=20) recruited from high schools in metro Detroit. Upon signing in to the app, they completed a survey that collected information on eating habits and food preferences. The adolescents were asked to use the app for four weeks. During this time, they were encouraged to identify, with the pLIS, whenever they entered an eating venue (i.e. school cafeteria, home kitchen, local convenience stores and restaurants) with the intention to eat. For any subsequent visit to a known eating venue, participants would receive a notification asking if they had arrived at "x" location. Based on the participant's response, the app would then provide food suggestions for the specific venue from a preloaded menu. In addition, they were

prompted to take pictures of their choices and to annotate them with a health rating on a scale of 1 to 4 (from very unhealthy to very healthy). They also were sent daily messages to promote healthy lifestyle habits.

Semi-structured interviews were conducted at the end of the trial to explore participants' perspectives of the app's features, its usefulness, ideas for improvement, and the likelihood that they would continue using it. The transcripts were coded and themes identified.

Phase 1 Results of Pilot Testing

Technological Performance: Of the 20 students enrolled, 18 used the app and registered locations. Proximity verification by polling confirmed that utility increased when the participant was proximate to a venue. Only one participant triggered exclusively distant ('cold') polls (27) – probably by disabling app functions. Closer ('Warm') and arriving ('hot') polls respectively averaged 597 (range 0 to 2460) and 185 (0 to 682). Participants with the fewest cold polls had more 'warm' and 'hot' polls. The app successfully identified whenever students returned to a registered venue, and it triggered delivery of messages. Overall, 143 notifications were delivered and students responded to 129 of these (90.2% compliance). 84 out of 129 arrivals came from a "hot zone" (65%).[22]

Participant Perceptions: Four-week trial participants reported enjoying using the application. However, they wished to be reminded to use the application by prompts at times other than when at an eating venue. Furthermore, they wanted additional health related features included in the application. Their ideas included: points for making healthy choices, ways to connect with other people (their parents) using a companion application, and having the option to set and monitor goals. They embraced the opportunity to get tailored recommendations for healthy options sent to their phone. It was important to them that the meal suggestions were items they could get at the location they were at, and it was a positive factor if the suggestion reflected their food preferences. They also appreciated personally relevant suggestions and the diverse images. They pointed out that it would be helpful for their parents to use the application as they purchase fast food for them, often without the teen present. The opportunity to document their foods via photos was also a positive feature; particularly because the photos were not retained on their device (storage space on phones was a concern).

Participants' Overall Rating – The majority of participants described the app positively using words ranging from interesting and good, to awesome and amazing. The mean rating of their likelihood of continuing to use the app was 7 (median and mode = 8) out of 10.

Summary of Phase 1 Progress – The Phase 1 project led to the successful accomplishment of our aims to development and feasibility/acceptability test of the LIITA3H app. From this project we identified additional features that would increase the impact of the app including greater personalization which also makes it possible to tailor the app to a diverse population rather than only African American adolescents.

Dissemination – The following presentations have been made at international conferences.

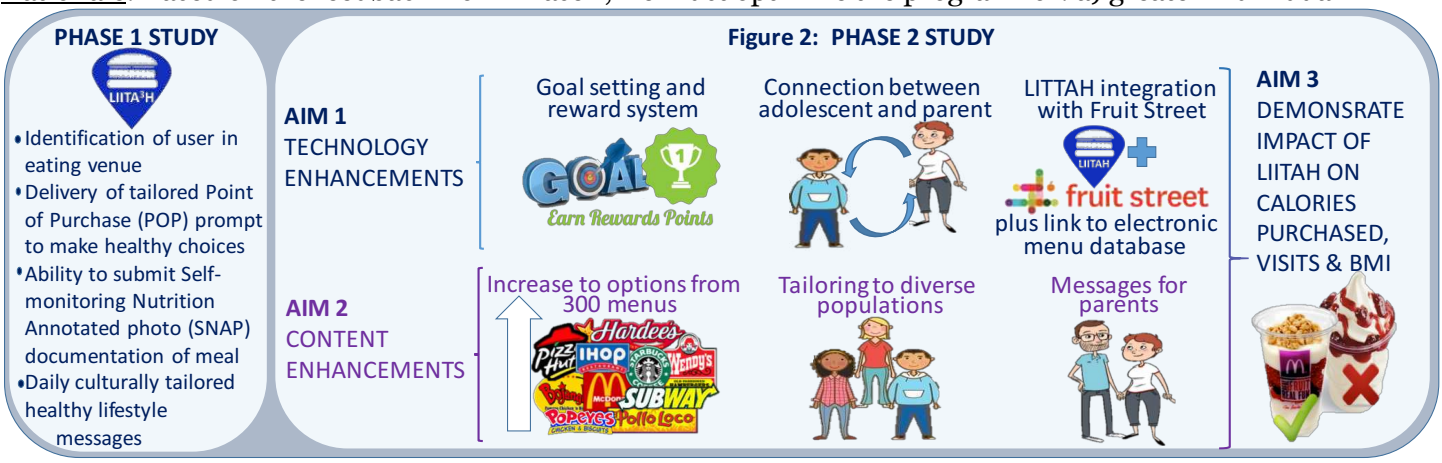
1. "Location Initiated Individualized Texts for African American Adolescent Health". Poster Presentation. The Obesity Society. New Orleans, LA. November 2016
2. "Development of the Location Initiated Individualized Texts for African American Adolescent Health Mobile Application". Oral Presentation. Society for Adolescent Medicine. Washington, DC. March 2016
3. Moon, J; Sieling, J; Francelino-Tomita, K; Schenk, T; Woolford, S. "Delivering Individualized Food Messages by Location", IEEE/EMBC Annual Conference, 2015

Overview of Proposed Phase 2 Project

Work on this project will be performed by the applicant entity, MEI Research, the PI, and Fruit Street. MEI, while partnering with Plot Projects, will develop all the technologies and collaborate with Fruit Street to test deployment and platform integration (Aim 1). The PI with the University of Michigan team will prepare the message databases for commercial use and conduct the outcomes trial (Aims 2 and 3). Throughout, the participant advisory board will test iterations of the technology. Key tasks for all the contributors are: 1) extend the location initiated tailored messaging developed in Phase 1 to increase engagement; and 2) to 'scale up' by incorporate a larger number and a more diverse target audience; then to 3) show that the LIITAH program measurably impacts healthy behaviors.

C.1. Aim 1: Expand the program technology

Rationale: Based on the feedback from Phase 1, we must optimize the program for: a) greater individual



tailoring (design, message timing and learning features that incorporate previous choices) that will be relevant to a diverse population including Hispanic and White families, b) additional engagement features (goal setting, rewards/ point system) and c) dyad features for parents and adolescents to use the app together. Plus, we will integrate the program with the Fruit Street Telehealth Platform in preparation for commercialization.

Update and expand venue registration and location detection

In Phase 1 we limited the app to the Android operating system (OS). Apple (iOS) imposes significantly more restrictions on apps running background processes and access to sensors than Android. These made iOS impractical for proving the user interaction concepts in Phase 1. Further, since the Phase 1, newer versions of the Android OS have added restrictions on background processes similar to iOS. In Phase 2 we will enable venue registration and location detection on both Android and Apple OS. In addition, we will add the ability to pre-load eating venues for specific cities or regions from business databases.

Since completing Phase 1, we have developed location detection for both OS (adding iOS) that are deployed in current studies by City University of New York and the University of California, San Francisco. Briefly, these incorporate elements of a data system originally developed by PlotProjects, Inc that we have made compatible with the Titanium cross-platform environment that we use to compile native applications for both OS. PlotProjects provides a web interface for centroid geofences and geotriggers (exit or entry to a geofence). Because not all locations can be detected with GPS, such as identifying one of several vendors located in proximity in a shopping mall food court. We will add the ability to detect on short range beacons (a specific MAC address broadcast from a WiFi router or Bluetooth device). The same beacon technology may later be used to deliver recommendations at vending machines or particular locations within a grocery stores.

It is possible that some venues of interest for this project will be oddly shaped, so that a centroid will not work to define the space. We will allow entry of overlapping centroids with a naming convention to connect centroids that define a single location of interest. We also need to add heuristics to keep track of venues that might be entered into the system more than once (e.g., if a user creates an entry using the pLIS that already exists).

Automate Use of Restaurant Menus

In a project for Drexel University we added the ability for PiLR EMA to scan bar codes on food labels and search USDA and the private Nutritionix databases to return calorie and nutrient content to a personalized algorithm. Nutritionix[55] is a commercially available food data base. On 12/13/2016, their web site contained 112,441 items from 664 restaurant brands. Our application program interface (API) to the Nutritionix database is a live connection that allows us to query in real time or batch download identifiers and nutritional information about menu items. For this project we will build an easily accessed means for dieticians to associate food preferences and recommendations with menus at registered venues.

Development of Engagement Features – The following new features will be developed into the program:

Goal setting Adolescents will indicate the goals they would like to set such as number of times per week to eat in a fast food venue, health rating of the foods they will consume (i.e. 50% of their choices each week will have a healthy or very healthy rating), number of meal photos they want to submit each week, etc. They will be able to share their goals with their parents (and friends if they have agreed to include a friend in the program). They

will also negotiate with their parents to establish a fitting reward for meeting their goals (i.e., they will enter their desired reward and parents will indicate agreement or propose revisions until they get to consensus).

Point system Adolescents will get points when they interact with the app (e.g., if they submit a photo of their meal, rate their meal (with extra points if it is rated as healthy or very healthy), and if they reach their goal); with bonus points if their parents make healthy choices. The system will pop up on their phone periodically to remind them of their score and how to earn more points. Design iterations will be informed by participants.

Greater Individual Tailoring – The design of the app will allow users to tailor the background pictures, colors, graphic display of their points (e.g., boat at different points along a river, balloon at higher points in the sky). They will also be able to select cultural tailoring of the content (Afrocentric, Hispanic), the timing of daily messages, and the number of daily messages received, along with the topics most relevant to them. We will adapt one of our existing mechanisms for a particular location name to be "piped" into a survey to be linked to the participant and menu. This will allow recommendations to be further tailored to a personal experience.

Iterative feedback (tailoring to previous choices) – The app will provide feedback based on the individual's previous selections. While it will be possible for a provider/dietitian to provide this feedback manually, an automated approach will also be possible. For example, upon returning to a restaurant where the participant recently ate, the app will draw reference to their previous choice and encourage a healthier option this time (if they did not rate their previous purchase as "healthy" or 'very healthy") or encourage them to do as well as they did before if they rated their previous selection as "healthy" or "very healthy").

The LIITA^{3}H app allowed participants 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 were possible either by voice recording or touch screen buttons. These features will be improved to be faster, more seamless and allow the users to select among several forms of response.

Dyad Component – Parents will download a parent version of the app that will allow them to see their child's goals and negotiate rewards (as noted above). They well be able to send "high fives" to their adolescent for making good choices. They will also receive a message when they enter an eating venue that asks if they plan to purchase food for their adolescent. If yes, then they will receive a suggested healthy item that that their adolescent might like (based on the adolescent's data). The child will be notified that their parent has responded in the app and they can send a message (e.g., they do not need fast food, asking for a specific option, or suggesting another venue). If both parents have enrolled, then the other parent would also get these messages. Depending on user interest, a version of the dyad component may be created for friends.

Scaling – The phase 1 project was a proof of concept that included only 30 restaurants and the program was tested with a small number of adolescents. During phase 2 we will increase this to include the 300 largest franchises in the US and testing with Fruit Street will determine what is required for scale up to include venues number greater than 1000. Our PiLR mBaaS is a multi-tenant system that runs on the Amazon Web and MongoDB cloud services. This configuration minimizes cost and IT management. During Phase 1, the PiLR architecture supported 100 participants per project and up to 2,000 in aggregate. Since then, PiLR has been reconfigured for 10 times greater capacity. It currently supports projects of 3,000 participants and is capable of up to 10,000 per project. This is sufficient for the proposed project. However, commercialization by Fruit Street will require up to another 10 fold increase in capacity. As part of this project, MEI and Fruit Street developers will review the architectures of both systems to evaluate the most appropriate means of integration.

Integration into the Fruit Street Platform

There are two primary approaches to integrating the LIITAH capabilities into customer platforms, such as Fruit Street. One is to adapt the LIITAH programmatic architecture to be directly incorporated in the target platform. This would likely require a process of similar magnitude for every subsequent licensee. MEI Research already has installed and maintains PiLR on customer equipment at one hospital, one Federal facility and two research institutions. The other option would be to operate LIITAH services separately and coordinate requests through an application programming interface (API) connection. This configuration would allow the PiLR mBaaS to host the LIITAH system and potentially allow for faster set up with licensees. MEI already published a public API for it base services. This would have to be extended to provide the full capabilities of LIITAH. Fruit Street will assist MEI to determine the scope and validation processes to perform both types of integration.

Participant Advisory Board (PAB)

In keeping with research indicating that advisory boards reflecting the perspectives of the target group often enhance research studies, one will be convened for this project.[56,57]

Recruitment and Population: Adolescents and parents (5 each) will be recruited from the target population. Key informants from the community (e.g., identified with the aid of the Michigan Institute for Clinical and Health Research Community Engagement (MICHR CE) program) will be asked to provide recommendations for possible PAB members. The program manager will contact the parents/ adolescents to describe the PAB. If they give verbal consent for their adolescent to participate, they will be contacted to discuss the study and to assess their interest. Signed consent/assent will be obtained at the first LAAB meeting. LAAB members will receive a $50 monthly incentive. PAB Meetings: The LAB will be convened in month 2 of the project and will meet monthly for 23 months. For convenience, these 90 minute meetings will allow attendance via Skype or VSee teleconferencing if needed. Meetings will be facilitated by the PI who works extensively with adolescents in clinical and research settings and with community advisory boards as part of community-engaged initiatives. PAB input will inform app design and interpretation of findings.

C.2. Aim 2 Enhance Message Library Content

Rationale: The MPOWERed Messages Library was developed based on Self-Determination theory and Motivational Interviewing techniques and allows *individual tailoring* to baseline characteristics, preferences and values. It was tested and refined with adolescents in the MPOWER weight management program which was a mainly White patient population. This library was adapted in Phase 1 to include suggestions from eating venues' menus, and to incorporate *cultural tailoring* to Black adolescents. *In Phase 2 we will incorporate tailoring to i) Hispanic populations, ii) parents, and iii) the menu options for additional restaurants.*

C.2.a Adaptation to Include Tailoring to Hispanic Adolescents

The MPOWERed Messages Library and the LIITAH project library will be translated and adapted for tailoring to Hispanic adolescents. To ensure cultural relevance, we will conduct focus groups with this target population (inclusion criteria: Hispanic, 13-17 years old). This process will be facilitated by a native Spanish speaking RA, who has experience in tailoring for Hispanic populations (both English speaking and Spanish speaking); with guidance from Drs. Cordova and Resnicow, experts in cultural tailoring for Hispanic adolescents.

Population and Recruitment – A convenience sample of adolescents (6 to 8 for each of 3 groups) will be recruited via flyers distributed in health care settings, community agencies, and places of worship with a number to text/call if interested. The project manager will contact parents to describe the project and schedule participants for a focus group. Two groups will be conducted in English and 1 in Spanish. Participants will be asked which one they wish to attend as it is anticipated that some will prefer to receive the messages in Spanish and some in English. This ratio of groups in English and Spanish will be adjusted to meet the requests of the participants. Assent/consent will be obtained at the focus group. A $25 incentive will be given.

Focus Group Discussion – The groups will meet for 2 hours at a community location, will be facilitated by the PI and the Spanish speaking research associate, and will be audio recorded. Basic data will be obtained on age, sex, height and weight. In the first 45 min, the types of messages used in the MPOWERed messages study (Table 1) will be presented and input elicited on ways to make the messages relevant. After a break, the last 45 minutes will explore how language (including topics such as preferences for the term Hispanic vs. Latino), graphics and content might be culturally tailored.

Table 1: MPOWERed Messages Library Message Types

Message Type	Description	Example
Testimonials	Strategies others found helpful	A teen says "hanging out at the pizza place with my friends was one of my favorite things, and I didn't want to cut back. But, now we go to the mall and walk instead; it's fun and active!"
Reflective Questions	Prompts to consider self-generated ideas	"What does being healthy mean to you? How does eating out fit with your goals?"
Point of Purchase Tailored Messages	Tailored to participants' preferences and the options at their location	Someone who likes sweets and who is in a McDonald's might receive the message: "Remember McDonald's has cuties, they're a sweet treat and they're good for you!"

Analysis and Revision of Text Messages – Transcripts will be reviewed, coded, and themes identified independently by 2 team members using the constant comparative method.[58] The language, graphics and content desired by the target population will be incorporated into the messages.

Follow-up Testing Groups. A sample of the adapted messages will be tested with the target population (2 groups with 6 to 8 /group – one in English and one in Spanish). Population, recruitment, consent/assent are and incentive as above. Based on methods used successfully in our prior studies, audience response handsets will be used[59] to indicate for each message 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 PI has extensive experience with testing messages for use in behavioral interventions.

[Ame00100677 – due to the COVID-19 situation, this amendment is modifying the focus group study activities including recruitment, screening, consent, and the focus group itself to be virtual data collection. Recruitment will be conducted through UMHealthResearch.org and social media (via MICHR).
Due to the need to comply with social distancing guidelines implemented prior to the completion of the focus groups with Hispanic youth, an online survey will be administered addressing similar content to the in-person focus group interview guide. This will replace the need to conduct any additional groups in person.]

C.2.b Adaptation to Include Tailoring to Parents (White, Black, and Hispanic)

Similarly to C.2.a, focus groups will be conducted to garner parent input to ensure the messages are relevant.

Population and Recruitment – A convenience sample of parents (6 to 8 for each of 6 groups) will be recruited via flyers distributed in health care settings, community agencies, and places of worship with a number to text/call if interested. The project manager will contact parents to describe the project and schedule them for a focus group. Two focus groups will be conducted for each race/ethnic group in the project. For Hispanic parents one will be conducted in English and 1 in Spanish. Additional groups will be conducted if needed to achieve thematic saturation. Consent will be obtained at the focus group. A $25 incentive will be given.

Focus Groups – The same format will be followed as described above to assess, revise and test the messages.

C.2.c Expansion of Tailored Menu Recommendations

Menus will be obtained from restaurants suggested by participants that are not included in the current data base. The healthiest options will be identified from each venue for a variety of categories (e.g., salty foods, dairy foods, etc). The current lists will be augmented with these options and used to offer suggestions based on users' location and preferences (e.g., in McDonald's a participant who said they like dairy foods on the baseline survey, might be asked to try a parfait). In addition, menus from the top 300 restaurant franchises in the US will be added. Thus, tailored suggestions will be available for the vast majority of places where participants eat.

Outcomes: At the completion of Aim 1 and 2 activities, the enhanced LITTAH system will be relevant to a wider range of users, it will allow parents (and friends if desired) to participate and will have additional engagement features. This enhanced system will be integrated into the Fruit Street platform and will be ready to be tested to demonstrate its impact.

C.3. Trial (Aim 3)

Rationale: We will demonstrate the impact of using LIITAH on decreasing calories purchased from restaurants by adolescents, along with the number of visits to restaurants and the impact on their BMI.

Overview: The trial will consist of 2 arms (an intervention and a control arm) over the course of 3 months.

Intervention Group – Will receive the full version of the LIITAH app which consists of 5 components that allow 1) Enhanced Location Identification (ELI), 2) Self-report of Nutrients by Annotated Photos (SNAP), 3) delivery of individually and culturally tailored point of purchase (POP) prompts along with tailored messages sent at other times of day (determined by the participant), 4) use of the app in connection with parents, 5) goal setting capacity, and 6) a point system.

Control Group – Will receive a version of the app with only the ELI and SNAP components. Thus, it will detect their presence in a restaurant and allow users to document their purchases by submitting annotated photos, but it will not deliver any POP prompts encouraging them to make healthy choices, or messages at other times of day. It will not allow goal setting or assign points. The control parents will receive a version of the app with only the ELI system to detect when they are in an eating venue and the SNAP component so they can submit and annotated photo of any food they purchase from a restaurant for their adolescent.

Primary Outcome – Data regarding the number of calories purchased will be calculated based on the photos submitted and the calorie content as listed in the nutrition information from the restaurant. Comparisons will be made between groups to determine the impact of the program on calories purchased. In addition, 24-hour food recalls will be conducted in the baseline week and final week (3 per week) to provide a comparison assessment of caloric intake from restaurants and to explore changes in caloric intake overall.

While photo documentation decreases cost, compared to 24-hour food recalls, it may have an intervention effect. The possibility exists for the Hawthorne effect (i.e., recording may alter behavior) to cause a decrease in the calories purchased by the control group. However, we anticipate that this will be negligible as adolescents take pictures (e.g., Instagram, snapchat) of things like their food frequently, making it unlikely that the control group will be significantly impacted by submitting pictures of their food purchases.

Secondary Outcome A – The number of times the app identifies that users are in a restaurant will be recorded automatically and compared between groups to reveal the program's impact on restaurant visits.

Secondary Outcome B – Height and Weight will be obtained at enrollment and post-intervention sessions to determine potential changes in BMI. Though it is likely that use over a longer time will be needed to achieve a statistically significant decrease in BMI, these measures will be obtained to determine if a trend towards a decreased BMI will be demonstrated by the intervention group.

C.3.a. Population and Recruitment. We will recruit a total of 150 adolescent/parent dyads from schools, hospitals and places of worship using the methods described above, to participate in the trial, with the goal of recruiting approximately one third of the participants from each of the 3 ethnic groups targeted for this trial. In addition, within each ethnic group we will recruit adolescents in the normal weight, overweight and obese categories (a third each). Recruiting 150 dyads will allow for an expected attrition rate of 20% and still provide the 120 dyads needed to have the power to detect the anticipated changes. Inclusion Criteria: Adolescents 13 – 17 years of age, who eat restaurant food at least 3 times per week, and have a parent who agrees to participate. The RA will contact those who text/call indicating an interest in participation. During the call a baseline enrollment session will be scheduled. Dyads will receive a $50 gift card at baseline as an incentive for participation and an additional $50 for each of the two follow-up assessments. A cell phone and payment for data plans will be provided for those who need these in order to participate.

C.3.b. Enrollment Session. Consent/assent will be obtained and height and weight will be measured for adolescents and their participating parents. They will individually complete an online enrollment survey addressing demographics, baseline characteristics, preferences, their level of interest in making dietary changes and any specific changes they wish to make. Adolescent/Parent dyads will download the LIITAH app and receive instruction in its use and ways to tailor features to their preferences (e.g., graphics, language).

Ame00105576 The focus group part of the study has been completed for both parents and all teens on 9/2020. 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.

Randomization: The technology team will randomly assign dyads as they enroll to either the intervention the control group. 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.

C.3.c. Six-Week Intervention

Baseline Data: For the first 2 weeks the app will only record presence in a restaurant and ask users to submit photos of their food. In week 3 the program features will be activated for the intervention group.

Intervention Group: *Point of Purchase (POP) messages will encourage healthy choices when participants are noted to be in a restaurant*. 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 POP prompt, tailored to their preferences and the options available at that location. If they are in a venue without a menu (though this is unlikely as most participants in the developmental project frequented popular franchises with published menus), 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).

Tailored healthy lifestyle messages will be delivered at times selected by participants. In addition to messages prompting healthy choices at the point of sale, participants will receive tailored messages promoting healthy lifestyle choices. Participants will select the timeframe during which they would like to receive these daily messages. The messages will be tailored to their values, characteristics and preferences, and will address topics such as increased physical activity, obtaining sufficient sleep, and healthy nutrition. As described above, these messages will be based on Self Determination Theory and use motivational interviewing approaches.

Participants in the intervention group will also be encouraged to use the other features of the app described above (e.g., goal setting, point system, and dyad component). Participants who want a friend use the dyad component will notify the RA at the enrollment session. The RA will obtain assent/consent and provide them with a version of the dyad component that allows them to send encouragement "high fives" to the participant. The friend's app will only be activated by the tech team it the adolescent is assigned to the intervention group.

Control Group: Participants will receive instructions for identification of restaurant locations and submitting annotated photos of their purchases, but they will not receive the other features.

Participants will be contacted as often as once a week by a member of the research team to ensure that the app is working and to answer any questions. We will ask participants if they would like to be recontacted in the future for any additional studies or study-related matters, and if they would like to keep the app on their phones. Participants who had the control version of the app would be able to experience the intervention version of the app.

C.3.d. Data Collection

Quantitative Data Collection – The app will automatically collect number of visits to restaurants. It will also collect usage data such as how often participants submit pictures and whether they include annotations. In addition, as a gold standard, pre-post 24-hour food recalls will be performed to assess caloric intake. Post intervention sessions will be conducted to measure final heights and weights.

Qualitative Data Collection – At the completion of their 3-month participation (or earlier if drop out seems to have occurred – i.e., they do not use the app for a 3-week period), adolescents will participate in a semi-structured interview. Location data will be used to inform the questions in the interview. For example, participants who, based on the GPS, have not visited restaurants will be asked to share reasons for this change. Those who, based on the GPS, continue to visit restaurants 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.

C.3.e. Analyses

Primary Outcome – Calories purchased (by and for adolescents) will be assessed using annotated photos, and nutrition data from restaurant menus (e.g., if the participant submits a picture of McDonald's fries and indicates that it is a small order, then from the McDonalds menu, we will determine that the calories purchased were 240 kcals). Number of visits will be obtained 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 subjects over time. For calories purchased, we will perform GEE linear regression modeling as a function of time, treatment group (intervention vs. control) and the interaction of time by treatment group ($Y= \beta_0 + \beta_1 Time + \beta_2 Treatment + \beta_3 Time * Treatment + \epsilon$). Residual diagnostics will be performed to examine departures from model assumptions. If needed, we will use transformed outcome variables and refit the models.

Secondary Analyses – Similarly, for the number of visits by the adolescents to restaurants, we will fit a GEE Poisson regression model as a function of time, treatment group (intervention vs. control group) and the interaction of time by treatment group. For change in BMI, we will perform multiple linear regression of change as function of initial BMI and treatment group. We will add participant characteristics to the models discussed above and explore associations between the outcomes and covariates of interest (e.g. extent of app use, initial BMI (adolescent and parent), race/ethnicity). In additional exploratory analyses, using methods described above, changes in calories purchased from restaurants as assessed by the 24-hour recalls will also be examined to compare findings with the photo documentation method of assessing calories. Pre-post changes in total calories reported via the 24-hour food recalls will also be calculated and compared between groups.

Power – The trial will be powered on average calories purchased in restaurants. The average child consumes 765 calories per meal eaten away from the home and the average child eats 2.5 meals per week away from the home.[11,60] While the trial population eat out more often at baseline, this conservative estimate was used in the

power calculation. Programs for youth suggest benefits from a 250 kcal deficit per day.[61] We determined that a clinically significant change would be a minimum decrease of 650 kcal/week. A sample size of 60 in each group (intervention vs. control group) will have 80% power to detect a difference of 650 kcal/week using a two group t-test with a two tailed alpha of 0.05 and a standard deviation of 1200 kcals.[11] Thus by recruiting 75 adolescents per group even with a 20% attrition we will have the power to detect the expected results.

Qualitative Analysis –From the post-trial interviews and the satisfaction survey we will identify participants' perceptions of the intervention overall and of the messages specifically, using the qualitative methods described above. We will explore potential differences for parents' vs adolescents' and by race/ethnicity.

C.4. Project Timeline by Month

	Responsibility			Year 1												Year 2											
Project Activity	**MEI**	**FS**	**UM**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Aim 1 - Technology Update and Enhancement																											
Software Development	Y1,2	Y2		X	X	α	X	X	β	X	R																
Support and maintenance	Y1,2										X	X	X	X	X	X	X	X	X	X	X	X	X				
Integration with Fruit Street	Y1,2	Y2	Y1									X	X	X								X	X	X	X	X	X
Aim 2 - Content Enhancement																											
Expansion of restaurant menus included			Y1	X	X	X	X	X	X																		
Focus Groups			Y1		X	X	X	X	X																		
Adapatation of messages			Y1	X	X	X	X	X	X																		
Aim 3 - Trial																											
Recruitment			Y1		X	X	X	X	X	X	X	X	X	X	X	X	X	X									
Enrollment			Y1							X	X	X	X	X	X	X	X	X									
Intervention	Y1,2	Y2	Y1,2							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Final Assessments & semi-structured Interviews			Y2									X	X	X	X	X	X	X	X	X	X	X	X	X			
Closeout																											
Analysis	Y2	Y2	Y2																X	X	X	X	X	X	X		
Dissemination and next steps	Y2	Y2	Y2																						X	X	X
Key: Y=Year, α =α testing, β =β testing, R=release																											

C.5. Limitations / Potential Problems / Alternative Strategies

While purchases from restaurants might decrease, intake at home may increase. However, as foods consumed outside of the home are generally less healthy than those consumed at home, there may still be benefit in this potential shift in consumption.[11,60] To explore this question we will perform pre-post 24-hour food recalls to assess this possibility and will measure change in BMI. Future work, will focus on prompting healthy choices when users are in other eating venues including eating locations at home (i.e., the kitchen).

There is the possibility of difficulty in recruiting. However, our partnerships with schools and places of worship from prior studies will continue to be a recruitment base. Also, we will work with MICHR which has a strong history of successful recruitment. Plus, in past studies, adolescents have been enthusiastic about participating.

REFERENCES

1. Centers for Disease Control and Prevention. Overweight and Obesity: Childhood Obesity Facts. 2014; http://www.cdc.gov/obesity/data/childhood.html.
2. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity and trends in body mass index among US children and adolescents, 1999-2010. *JAMA*. 2012;307(5):483-490.
3. CDC Body Mass Index: BMI for Children and Teens. http://www.cdc.gov/nccdphp/dnpa/bmi. , 2013.
4. Ogden CL, Carroll MD, Fryar CD, Flegal KM. Prevalence of obesity among adults and youth: United States, 2011-2014. *NCHS Data Brief*. 2015(219):1-8.
5. Dietz WH. Health consequences of obesity in youth: childhood predictors of adult disease. *Pediatrics*. 1998;101(3 Pt 2):518-525.
6. Must A, Strauss RS. Risks and consequences of childhood and adolescent obesity. *Int J Obes Relat Metab Disord*. 1999;23 Suppl 2:S2-11.
7. Srinivasan SR, Bao W, Wattigney WA, Berenson GS. Adolescent overweight is associated with adult overweight and related multiple cardiovascular risk factors: the Bogalusa Heart Study. *Metabolism*. 1996;45(2):235-240.
8. Strauss RS, Pollack HA. Epidemic increase in childhood overweight, 1986-1998. *JAMA*. 2001;286(22):2845-2848.
9. Davis B, Carpenter C. Proximity of fast-food restaurants to schools and adolescent obesity. *Am J Public Health*. 2009;99(3):505-510.
10. Vikraman S, Fryar CD, Ogden CL. Caloric intake from fast food among children and adolescents in the United States, 2011-2012. *NCHS Data Brief*. 2015(213):1-8.
11. Zoumas-Morse C, Rock CL, Sobo EJ, Neuhouser ML. Children's patterns of macronutrient intake and associations with restaurant and home eating. *J Am Diet Assoc*. 2001;101(8):923-925.
12. Larson N, Hannan PJ, Fulkerson JA, Laska MN, Eisenberg ME, Neumark-Sztainer D. Secular trends in fast-food restaurant use among adolescents and maternal caregivers from 1999 to 2010. *Am J Public Health*. 2014;104(5):e62-69.
13. Briefel RR, Wilson, PM G. Consumption of low-nutrient, energy-dense foods and beverages at school, home, and other locations among school lunch participants and nonparticipants. *J Am Diet Assoc*. 2009;109.
14. U.S. Department of Agriculture. Away from Home: Percentages of Selected Nutrients Contributed by Food and Beverages Consumer Away from Home, by Race/Ethnicity and Age. 2013-2014.
15. Jiang Y, Ekono, M., Skinner, C. *Basic Facts About Low-Income Children: Children Under 18 Years, 2014*. National Center for Children in Poverty; February 2016.
16. Kumanyika SK. Environmental influences on childhood obesity: ethnic and cultural influences in context. *Physiol Behav*. 2008;94(1):61-70.
17. Borradaile KE, Sherman S, Vander Veur SS, et al. Snacking in children: the role of urban corner stores. *Pediatrics*. 2009;124(5):1293-1298.
18. Lucan SC, Karpyn A, Sherman S. Storing empty calories and chronic disease risk: snack-food products, nutritive content, and manufacturers in Philadelphia corner stores. *J Urban Health*. 2010;87(3):394-409.
19. Woolford SJ, Sieling J, Blake N, Damus F, Moon J. Development of the Location Initiated Individualized Texts for African American Adolescent Health Mobile Application. Oral Presentation. Society for Adolescent Medicine. Washington, DC. March 2016
20. Woolford SJ, Clark SJ, Strecher VJ, Resnicow K. Tailored mobile phone text messages as an adjunct to obesity treatment for adolescents. *J Telemed Telecare*. 2010;16(8):458-461.
21. Woolford SJ, Moon J, Crawford R, Critchlow, E. Location Initiated Individualized Texts for African American Adolescent Health". Poster Presentation. The Obesity Society. New Orleans, LA. November 2016
22. Moon, J; Sieling, J; Francelino-Tomita, K; Schenk, T; Woolford, S. Delivering Individualized Food Messages by Location, IEEE/EMBC Annual Conference, 2015
23. Kirk S, Zeller M, Claytor R, Santangelo M, Khoury PR, Daniels SR. The relationship of health outcomes to improvement in BMI in children and adolescents. *Obes Res*. 2005;13(5):876-882.
24. Savoye M, Shaw M, Dziura J, et al. Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial. *JAMA*. 2007;297(24):2697-2704.
25. Zeller M, Kirk S, Claytor R, et al. Predictors of attrition from a pediatric weight management program. *J Pediatr*. 2004;144(4):466-470.

26. Finkelstein EA, Trogdon JG, Cohen JW, Dietz WH. Annual medical spending attributable to obesity: payer-and service-specific estimates. *Health Aff (Millwood)*. 2009;28(5):822-831.
27. Hampl SE, Carroll CA, Simon SD, Sharma V. Resource utilization and expenditures for overweight and obese children. *Arch Pediatr Adolesc Med*. 2007;161(1):11-14.
28. Woolford SJ, Gebremariam A, Clark SJ, Davis MM. Incremental hospital charges associated with obesity as a secondary diagnosis in children. *Obesity (Silver Spring, Md)*. 2007;15(7):1895-1901.
29. Woolford SJ, Gebremariam A, Clark SJ, Davis MM. Persistent gap of incremental charges for obesity as a secondary diagnosis in common pediatric hospitalizations. *J Hosp Med*. 2009;4(3):149-156.
30. Institute of Medicine Committee on Prevention of Obesity in Children and Youth. *Preventing childhood obesity health in the balance National Academies Press*. 2005;Washington, DC.
31. Taveras EM, Gortmaker SL, Hohman K. Randomized Controlled Trial to Improve Primary Care to Prevent and Manage Childhood Obesity: The High Five for Kids Study. *Arch Pediatr Adolesc Med*. 2011;165(8):714-722.
32. Woolford SJ, Sallinen BJ, Clark SJ, Freed GL. Promising results from a clinical multi-disciplinary weight management program. *Clin Pediatr*. 2011;50(3):187-191.
33. Resnicow K, Davis R, Rollnick S. Motivational interviewing for pediatric obesity: Conceptual issues and evidence review. *J Am Diet Assoc*. 2006;106(12):2024-2033.
34. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol*. 2000;55(1):68-78.
35. Woolford SJ, Sallinen BJ, Schaffer S, Clark SJ. Eat, play, love: adolescent and parent perceptions of the components of a multidisciplinary weight management program. *Clin Pediatr (Phila)*. 2012;51(7):678-684.
36. Golan M CS. Targeting parents exclusively in the treatment of childhood obesity: long-term results. *Obesity*. 2004;12(2).
37. Liu M PK, Yen ST Who are consuming food away from home and where? Results from the Consumer Expenditure Surveys. *Eur Rev Agric Econ*. 2013;40(1):191-213.
38. Woolford SJ, Barr KLC, Derry HA, et al. OMG do not say LOL: obese adolescents' perspectives on the content of text messages to enhance weight loss efforts. *Obesity (Silver Spring, Md)*. 2011;19(12):2382-2387.
39. Woolford SJ, Khan S, Barr KL, Clark SJ, Strecher VJ, Resnicow K. A picture may be worth a thousand texts: obese adolescents' perspectives on a modified photovoice activity to aid weight loss. *Child Obes*. 2012;8(3):230-236.
40. Institute of Medicine Committee on Prevention of Obesity in Children and Youth. Preventing childhood obesity: health in the balance. 2005; Washington, DC.
41. Fruit Street. http://www.fruitstreet.com/. Accessed February 1, 2017.
42. Brownell KD. Diet, exercise and behavioural intervention: the nonpharmacological approach. *Eur J Clin Invest*. 1998;28 Suppl 2:19-21; discussion 22.
43. Cali AM, Caprio S. Prediabetes and type 2 diabetes in youth: an emerging epidemic disease? *Curr Opin Endocrinol Diabetes Obes*. 2008;15(2):123-127.
44. Finkelstein EA, Graham WC, Malhotra R. Lifetime direct medical costs of childhood obesity. *Pediatrics*. 2014;133(5):854-862.
45. Services CfMaM. Medicare Diabetes Prevention Program Expansion. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-07.html. Accessed February 21, 2017.
46. Rivera J MA, Hamilton J, Birken C, Coons M, Iyer S, Agarwal A, Lalloo C, Stinson J. Mobile Apps for Weight Management: A Scoping Review. *JMIR Mhealth Uhealth*. 2016;4(3):e87.
47. Moon J, Smith B, Tan Y, Barden C. Developing the Smartphone Sensor Suite for Obesity Research. *Obesity*. 2010;18(2).
48. Wohlers E, Sirard J, Barden C, Moon J. Smart Phones are Usefule for Food Intake and Physical Activity Surveys. Conf Proc IEEE Eng Med Biol Soc.; 2009.
49. Moller A, Pictor A, DeMott A, et al. ActiPal Smartphone Application Development: Monitoring Diet, Activity, and Context". Paper presented at: mHealth Summit2011.
50. Moon J, Tan Y, Barden C, Smith B. Smartphone Tools for Momentary Assessment. *Obesity (Silver Spring)*. 2010;18(2).
51. Moon J, Sieling J, Whigham L, Roemmich J. Multiple input modes for context appropriate diet reporting. International Society for Behavioral Nutrition and Physical Activity (ISBNPA) 2012 Annual Conference; 2012.

52. Moon J, Sieling J, Wang L, Barden C, Moller A. Performance of a Smartphone for Ecological Momentary Assessment and Objective Monitoring. RACMEM; 2011.
53. Brug J, Campbell M, van Assema P. The application and impact of computer-generated personalized nutrition education: a review of the literature. *Patient Educ Couns*. 1999;36(2):145-156.
54. Android. Making Your App Location Aware. http://developer.android.com/google/play-services/location.html. Accessed January 1, 2017.
55. Nutritionix. https://www.nutritionix.com/. Accessed January 1, 2017.
56. Latham TP, Sales JM, Renfro TL, et al. Employing a teen advisory board to adapt an evidence-based HIV/STD intervention for incarcerated African-American adolescent women. *Health Educ Res*. 2012;27(5):895-903.
57. Nollen NL, Hutcheson T, Carlson S, et al. Development and functionality of a handheld computer program to improve fruit and vegetable intake among low-income youth. *Health Educ Res*. 2013;28(2):249-264.
58. Glaser B, Strauss A. *The Discovery of Grounded Theory: Strategies for Qualitative Research*. New York, NY: Aldine Publishing Co; 1967.
59. Qwizdom. http://qwizdom.com/?lang=en. Accessed January 6, 2011.
60. National Center for Chronic Disease Prevention and Heath Promotion Division of Nutrition PA, and Obesity. Incorporating Away-From-Home Food into a Heatlhy Eating Plan. https://www.cdc.gov/nccdphp/dnpa/nutrition/pdf/r2p_away_from_home_food.pdf. Accessed February 7, 2017.
61. Whitlock EP, O'Connor EA, Williams SB, Beil TL, Lutz KW. Effectiveness of weight management interventions in children: a targeted systematic review for the USPSTF. *Pediatrics*. 2010;125(2):e396-418.