An integrated closed-loop feedback system for pediatric cardiometabolic disease.

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FINAL PROJECT REPORT

1. STRUCTURED ABSTRACT

Purpose

To improve understanding of the health behaviors associated with cardiometabolic disease in youth and how technology can be used to modify these behaviors.

Scope

The high prevalence and burden of cardiometabolic disease underlie the urgent need to identify novel approaches for management and prevention. Lifestyle/health behaviors including physical activity (PA), sleep, screen time, and sugar sweetened beverage (SSB) consumption, contribute to cardiometabolic risk and are difficult to modify once established. This study is ongoing. In phase 1, now complete, we developed a novel set of mHealth tools capable of collecting health behavior information among children ages 6-12 years at risk for cardiometabolic disease, as well as, a system for providing closed-loop clinical feedback system. In phase 2, which has not yet begun, we plan to test using the newly developed mHealth tools for providing closed-loop clinical feedback on cardiometabolic health behaviors.

Methods

We designed and built a wristband that collects objective health behavior data on PA, sleep, and screen time, along with reported data on SSB, as well as, a mobile application where families can access information and feedback on their child's health behaviors. We plan to test the use of providing feedback on objective health behavior data for improving cardiometabolic risk in children.

Results

The wristband was developed and built, and along with collecting objective data on PA and sleep, is able to determine when a child is watching television, providing an objective assessment of screen time in children as well.

Key Words

mHealth, cardiometabolic, pediatric, health behaviors

2. PURPOSE (Objectives of the study)

The goal of this study is to improve understanding of the health behaviors associated with cardiometabolic disease in youth and test how technology can be used to modify these health behaviors by providing clinical feedback on cardiometabolic-related health behaviors.

Prior research has identified certain health behaviors as important and actionable in modifying cardiometabolic risk, namely weight management, physical activity, screen-time, sleep, and consumption of sugar sweetened beverages. The current traditional system for providing health behavior counseling in the physician's office is well known to have may obstacles. There is a need to develop novel health behavior counseling modalities that leverage the strengths of evidence-based medicine and science, include sound clinical recommendations, improve on the quality of data utilized in decision making, engage the patient directly by providing timely feedback on health behaviors, and can continue to provide feedback longitudinally over time. It is not yet well understood how patient-generated data on longitudinal health behaviors can be seamlessly collected and then used to provide evidence-based feedback to patients to improve health outcomes. We focused on identifying and developing new strategies for using mHealth technology to seamlessly collect and provide feedback on health behaviors associated with cardiometabolic risk in youth. Overall, the two primary aims or this project are to:

1) Develop an integrated closed-loop feedback system that incorporates longitudinal mHealth data and uses clinical decision support systems to manage cardiometabolic disease among at-risk families. (Phase 1)

2) Determine the extent to which an integrated closed-loop system that provides feedback on patient-generated data improves cardiometabolic risk in at-risk families, as measured by changes in weight, physical activity, screen-time, sleep, and sugar-sweetened beverage consumption. (Phase 2)

3. SCOPE (Background, Context, Setting, Participants, Incidence, Prevalence)

Background

Cardiometabolic disease, including obesity, diabetes, liver enzyme dysregulation, and risk in children for adult-onset cardiovascular disease, represent a major population-wide health burden in the United States. Managing cardiometabolic disease also imposes a substantial financial burden on the economy and ties up significant healthcare resources. It is well-known that many of the lifestyle and health behaviors that contribute to cardiometabolic disease are difficult to modify once established, and childhood represents an opportune time for promoting healthy behaviors. Prior research has identified certain health behaviors as important and actionable in modifying cardiometabolic risk, namely weight management, physical activity, screen-time, sleep, and consumption of sugar sweetened beverages. Less well understood is how patient-generated data on these longitudinal health behaviors can be seamlessly collected and then used to provide evidence-based feedback to patients to improve health outcomes. We have focused on identifying and developing new strategies for using mHealth technology to seamlessly collect and provide feedback on health behaviors associated with cardiometabolic risk in youth.

Context

The current traditional system for providing health behavior counseling in the physician's office is well known to have may obstacles. Provider barriers include time constraints, limited reimbursement, physician training and attitudes. In addition, office-based counseling relies on a patient's self-reported health behavior information. As such, there is a need to develop novel health behavior counseling modalities that leverage the strengths of evidence-based medicine and science, include sound clinical recommendations, improve on the quality of data utilized in decision making, engage the patient directly by providing timely feedback on health behaviors, and can continue to provide feedback longitudinally over time. On the patient end, lifestyle and health behaviors are difficult to modify. The field of patient-centered outcomes research (PCOR) has begun to identify specific factor that pose the greatest risk (including weight management, physical activity, screen-time, sleep, and consumption of sugar sweetened beverages), while beginning to study which intervention tools may have the biggest impact. Because efforts to change lifestyle and behavior are fundamentally difficult, some clinical research has focused on the younger generation, namely children, who have been shown to be more receptive to behavior change and establishing new habits. Establishing healthy behaviors at an early age can also provide a good foundation for adult life. In the US, increased awareness of diet and the impact of sugar has recently produced some favorable results in the lowering of obesity rates in young children. However, there continues to be a need to provide clinical and family guidelines as well as information tools that can help support children, parents, and pediatricians during this critical stage of development.

This study is ongoing. During phase 1 of this project, we developed an integrated closed-loop feedback system that incorporates longitudinal mHealth data and uses clinical decision support systems to manage cardiometabolic disease. During phase 2 of the project, we plan to test using the newly developed mHealth tools for providing closed-loop clinical feedback on cardiometabolic health behaviors.

Participants

There were no participants during phase 1 of the study (technology development phase). In phase 2 of the project, we will recruit sixty-eight pediatric patients for participation. A 1-week baseline data collection and enrollment survey shall be used to identify the primary obesity risk factor that each child needs to improve. Each child shall then be subscribed to one of 4 different behavioral intervention groups: *sleep improvement, physical activity, sweet beverage consumption, screen time reduction (TV and phone watching).*

4. METHODS (Study Design, Data Sources, Interventions, Measures, Limitations)

Study Design

Phase 2 will be a pilot randomized controlled family-based intervention lasting 6 months, taking place in the greater Metropolitan Boston area. The pilot RCT will compare the clinical effectiveness of two patient-centered approaches to using an integrated closed-loop feedback system to collect, transmit, and analyze longitudinal patient data and provide feedback to assist with clinical counseling and disease self-management. Control families will receive feedback in the form of data reports on their patient-generated data and may use the information for self-guided disease management. Intervention families will receive feedback on their patient-generated data in the form of personalized evidence-based mobile messages designed to promote positive self-efficacy, cognitive change, and response modulation. The primary outcome will examine the extent to which an integrated closed-loop feedback system results in a decreased BMI in children. We will also examine the extent to which an integrated closed-loop feedback system decreases BMI in the adult family member and decreases health behaviors associated with cardiometabolic risk in children and adults.

Data Sources

Briefly, clinical data will be collected through a combination of wearable sensors and a custom mobile application running on the participant's mobile phone, both of which were developed and tested during phase 1 of the project. Ecological momentary assessment (EMA) data will be collected via the custom mobile application to assess sweetened beverage consumption. These technologies are explained in further detail below. Another mobile software tool, Funf (funf.org) will be used to assess phone screen time.

In order to enable the ability to monitor patient behavior in a more continuous manner, we developed a software platform and study infrastructure that implements a closed-loop feedback system and can be used by children and their families to modify children's health behaviors related to cardiometabolic disease. The goal was to create a system that could provide a feedback to the children and families on a much smaller time scale than what is the current standard of medical care. Rather than providing feedback every 3-6 months, whenever the patient comes into the clinic for an appointment, the system we've designed provides feedback to the children and families on a weekly basis, and does not require any significant workload burden on the physician. We decided to name our project and our technology platform "STRIVE". The mHealth platform includes: a wearable wristband device, a data server, a mobile application, and a project web site. Each of these components is described briefly in sections below.

Wearable Sensor: The wristband is one of the components of the closed-loop feedback system, and functions to collect the child's objective health behavior data. Data is processed in real-time in the wristband, then uploaded via BlueTooth to the mobile application on the parent's mobile phone, which in turn uploads the data to the remote data server. (Figure 1) Because the child does not carry a mobile phone, the data must be stored on the sensor band itself, and then it transfers the data files to the parent's mobile phone once per day at bedtime. Bed time was chosen, since we felt that this was a reliable and regular time when the parent and child are together. This also is a good time of the day to reflect on the previous day's behaviors and a good opportunity for the parent to provide counselling and coaching to the child.

The sensor band was designed to contain several important sensors that enables various physiological measurements as well as measurement and monitoring of behavior. These sensors include:

- **Accelerometer:** this sensor is used to perform actigraphy and provides measures of physical activity and sleep, using the 3-axies acceleration data. Unlike commercial sensor bands, which have a high sampling rate (~100 Hz), we have developed an algorithm that enables measurement of these behaviors using a sampling rate of only 8 Hz. This lower sampling rate enables longer battery life.
- **Color Light Sensor:** includes a color light sensor to enable a basic measurement of screen time. This is based on the principle that electronic screens (e.g. TV) produce dynamic color patterns, which can be distinguished from physical movement of the sensor band.
- **Temperature and Humidity**: includes a temperature and humidity sensor which faces the skin. These data are primarily used to determine when the sensor band is being worn.
- **Heart rate:** A heart rate sensor is also integrated into the sensor band. However, the integration of this sensor was not used for this study.

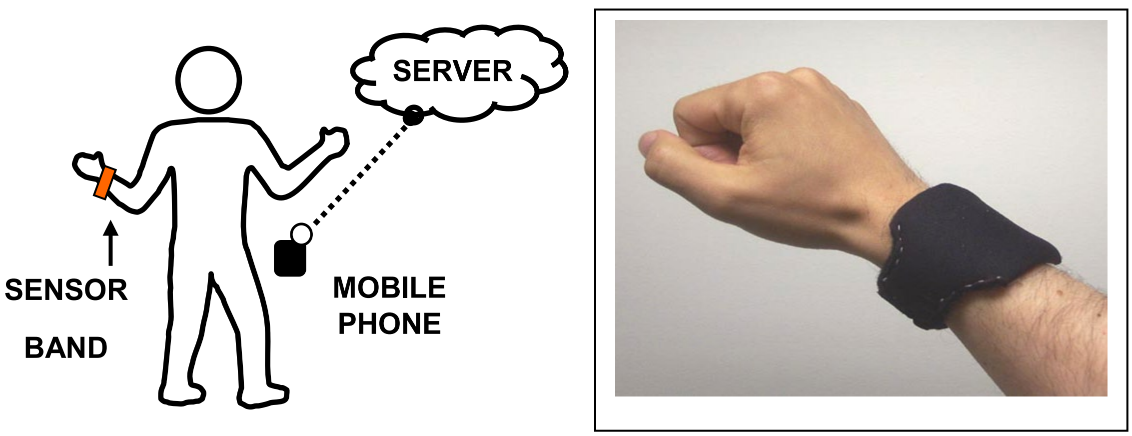


Fig. 1. (left) Basic system architecture; (right) Photo of multi-sensor band device developed.

We developed and produced several iterations of the electronic wristband, with the primary goals being to optimize the trade-off between small size and maximum battery life. Several versions of the sensor band were manufactured and tested until arriving on our final design for a child-worn wristband. The packaging of the sensor band was particularly important and time intensive. We designed and tested two types of bands: 1) rubber molded band; and 2) a fabric band. While the molded rubber strap was waterproof and comfortable, it was not feasible to create a reliable clasping mechanism for the band without a significant amount of funding and custom tooling, For this reason, we designed and utilized a comfortable fabric band, which could be readily manufactured by a local sewing company, and is attached using velcro pads.

Calculation and Identification of Behaviors: Since the sensor band collects a large amount of data, if these data were uploaded to the server, this would consume a large amount of battery power. Instead, in order to maximize battery life, the sensor band internally calculates the current “behavior state”, and then writes this information to its internal memory. By transferring only this “state transition” information to the parent’s mobile phone, a great deal of power is saved.

Both physical activity and sleep behaviors are estimated using the accelerometer data. We created a state machine algorithm that runs in real time and assesses the users current state. The states for physical activity and sleep are computed on the same scale and are organized into the following states:

- **State 0** – sensor band is not worn
- **State 1** – Sleep state
- **State 2** – Sedentary state
- **State 3** – Low physical activity
- **State 4** – Moderate physical activity
- **State 5** – Vigorous physical activity

State 0 is determined by a separate sensor (humidity) in order to determine if the sensor band is on or off the body. The remaining states use a counter based algorithm, with hysteresis, in order to determine the state. The algorithms to determine these states were validated using an Actigraph device with accompanying software.

For screen time assessment, the data from the light sensor is organized into the following data:

- **State 0** – Infrared light (IR) present (child is assumed to be outside)
- **State 1** – No IR, high RGB correlation
- **State 2** – No IR, Low RGB correlation

Algorithm on the server then makes use of the data to infer screen time. Results of the algorithm testing are included in the Results section of this report.

Mobile Application and EMA: Since it was not possible to create an automated method for measuring the consumption of sugar-sweetened beverages, a mobile application was created, which included a daily assessment by the parents of the child’s consumption of sugar-sweetened beverages, otherwise known as Ecological Momentary Assessment (EMA). A daily text reminder is sent to the parent’s phone, which when clicked automatically opens the STRIVE mobile app that enables the parent to select from a list of numbers to report the number of beverages the child consumed.

Table 1: measured behaviors

CLINICAL VARIABLE	HOW IT WILL BE MEASURED
Physical activity	3-axis accelerometer
TV Screen time	Light spectrum, accelerometer
Phone screen time	Mobile app, accelerometer
Sleep	Accelerometer, skin conductance
Sugar beverage consumption	EMA assessment
Weight	Bluetooth weight scale

Web site: We created a website that serves as a portal for children and their families to access information on the study, explains all the mHealth electronic programs and devices used in the study, and provides contact information to reach study staff with questions. The website is also linked to a server, and functions as a back-up reservoir for the collected data.

Data Server: We developed a server using the open-source OpenMRS platform, which implements the following important functions:

- **Collecting** all of the data generated by the sensor bands and phones.
- Automatically **analyzing** the data using custom algorithms that our team has developed.
- **Storing and delivering** a library of personalized clinical messages as a form of behavioral intervention that we developed. These messages provide personalized feedback and are received by the parents on their mobile phones.

Below are several diagrams explaining how the server is structured and how the data processing is implemented.

Figure 2: Key Steps of Data Work Flow on Server

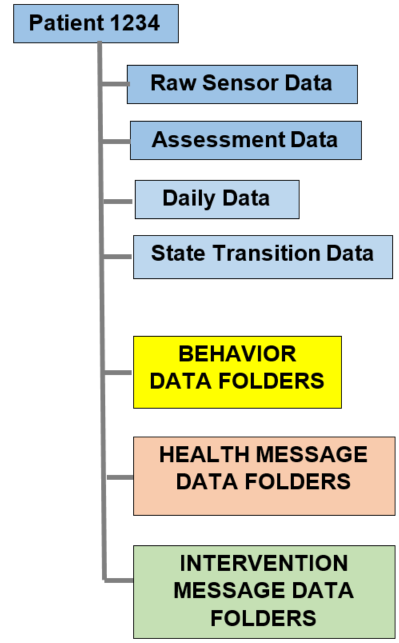


Fig 4. Illustration of server architecture, showing how the data and algorithms are organized on the server for each patient.

How the data is processed: There are three main types of algorithms that will run on the server. Figure 5 outlines the inputs and outputs of each algorithm. The first data form is the raw data that is uploaded from the sensor band. There is one data file per hour. The merging algorithm concatenates the files into 24 hour days starting at 8PM and ending at 7:59PM the following day. The activity algorithm processes this data to return the transition data. Lastly, the transition parser determines the data points for each of the activities, including sleep, screen time, physical activity, and SSB.

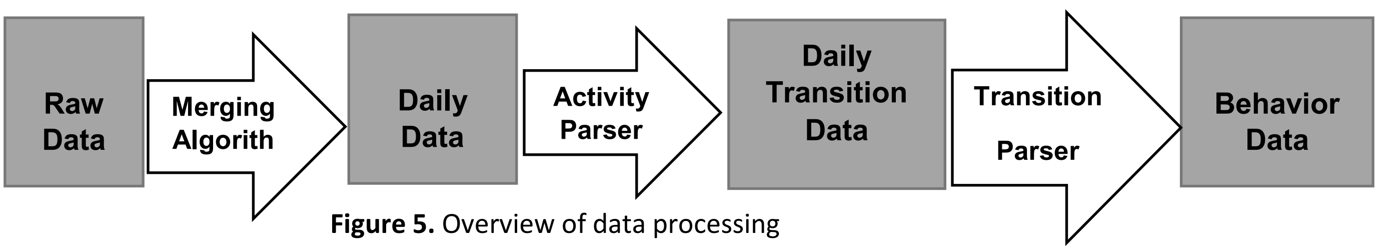
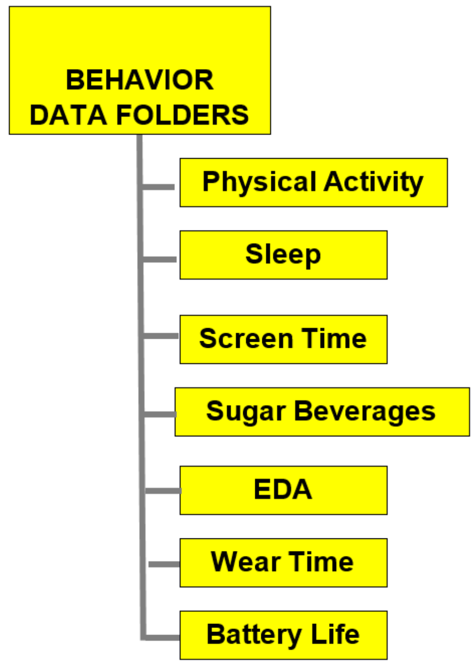


Figure 5. Overview of data processing

As shown in Figure 4, the raw sensor data (accelerometer, light sensor, humidity, battery) are each stored in separate folders. In addition, EMA assessment of sugar-sweetened beverage consumption is also stored separately. Data from the child sensor band are collected only once per day at bedtime. As sleep data cannot be split by the actual date, which changes at midnight, we defined each “day” to start at 8pm and end at 7:59pm the following day, enabling us to aggregate data into meaningful segments.

As we cannot control the exact time that the data are uploaded, and since some families will not always remember to upload the data every day, or the battery of the sensor band may not be charged, we needed to account for data to be uploaded at irregular times and with irregular lengths. Accordingly, a special algorithm on the server processes the incoming raw data files and automatically cuts each file and splices together the segments of files to create a single 24-hour data file for each behavior type. (Physical activity, Sleep, and Screen time), called "Daily Data" files. Figure 5 shows the server architecture for storing the 24-hour data for each behavior as well as the wear time and battery voltage.

Fig 5. Illustration of server architecture used for storing individual behavior data as well as essential information for each patient (wear time and battery life).



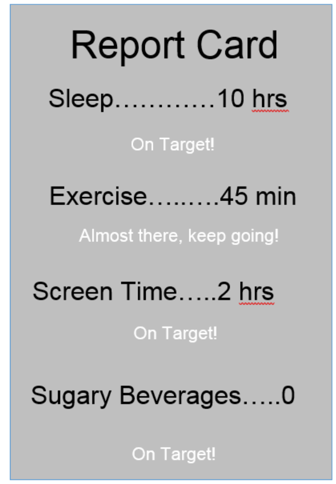
The compiled daily behavior data are then presented to the parent(s) in the form of daily report as well as in the form of a longitudinal time series data plot, showing the trends over time. Data for each patient/participant can also be viewed directly on a secure web site portal operated by the research study team. Each parent only has access to their own child's data through the STRIVE mobile app.

Feedback Loop for Parents and Children:
Collecting data from the wearable sensor band and estimating behaviors are features that are similar to various commercial products. However, the critical element of our study and mHealth platform is the ability to also provide automatic clinical feedback to the families that are participating in the study..

Mobile Application. We developed a mobile application ('app') to be downloaded on the parent's mobile phone. The app is one of the components in the closed-loop feedback system, and functions as the venue through which parents receive information about their child's health behaviors via the child's wristband along with personalized clinical recommendations via the server. Parents also enter sugar sweetened beverage consumption data in the app. The app contains a 'Kidz Zone' page that allows children to monitor their progress and collect e-badges, providing a developmentally appropriate source of motivation and reward for children to modify their health behaviors.

Once a week, on Sundays, instead of a daily message, the parent will receive a report which will display a summary of their child’s weekly data. A screen shot of the report is shown in Figure 6.

Figure 6. Daily report card



For each behavior listed on the phone screen, the report will display the median value for each of the behaviors, and the app will also allow the parent to click on one of the behaviors and view a data plot of the child’s data for the entire study, since day 1 until the present day. The data to generate these reports will be contained in csv files described in the sections above. This plot is generated on the phone. A sample plot is shown in Figure 7.

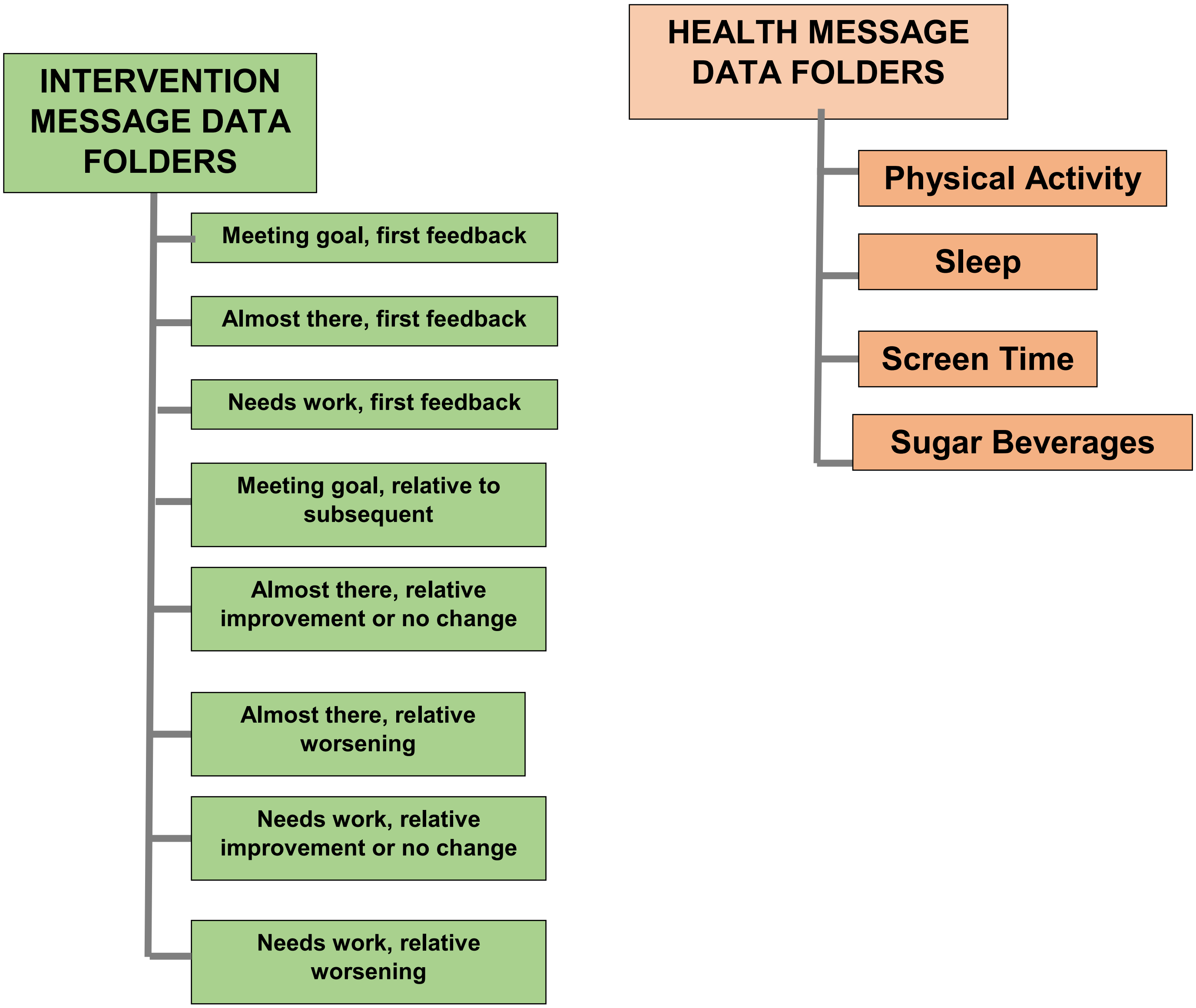
An algorithm is used to calculate which message should be chosen, based on the child’s behavior history. First, algorithms will be run to determine the minutes or hour values for the health behavior being reported on that day. Using the definition given above in Figure 8, the algorithm will first choose an intervention folder according to the child’s status. The **row** is chosen sequentially, so that we cycle through all the messages, to keep the messages fresh without repeating. Then, the algorithm will choose the folder from the health message folders corresponding to the health behavior being reported on that day. Similar to above, the row is chosen sequentially.

Figure 8. Logic to categorize child’s health status.

Health Behavior	**Goal**	**Near Goal**	**Needs Work**
MVPA	60 minutes	40-60 minutes	<40 minutes
Sleep	10 hours	8-10 hours	<8 hours
Screen Time	<= 2 hours	2-2:30 hours	>2:30 hours
SSB	0	1	>1

Server algorithms for selecting intervention messages:

Figure 9. Folder structure for the behavior data folders on the OpenMRS server.



The algorithm which selects the message will analyze the last 3 days of data, and calculate the median value as well as the trend, by using the best fit line. The best fit line can be calculated using a linear regression library in JAVA. However, since we are only fitting a line to 3 data points, this can also be calculated manually.

If x_i is the most recent health score, than xi-1 is the health score from the previous day. $\overline{X}$ is defined as the mean of the health scores from the previous three days. The same process is carried out for the y_i, which represent the days since the start of data collection. The slope and intercept for the line are calculated in Equations 3 and 4 using these results.

For example, if it is 8 PM on February 22nd, then the most recent complete data is from February 21st. Therefore, this algorithm would average over the data points for February 18, 19, and 20 to calculate the equation for the line of best fit.

$$\overline{X}=\frac{x_{i-1}+x_{i-2}+x_{i-3}}{3} \quad (1)$$

$$\overline{Y}=\frac{y_{i-1}+y_{i-2}+y_{i-3}}{3} \quad (2)$$

$$m=\frac{(x_{i-1}-\overline{X})(x_{i-2}-\overline{X})(x_{i-3}-\overline{X})(y_{i-1}-\overline{Y})(y_{i-2}-\overline{Y})(y_{i-3}-\overline{Y})}{[(x_{i-1}-\overline{X})(x_{i-2}-\overline{X})(x_{i-3}-\overline{X})]^2} \quad (3)$$

$$b=\overline{Y}-m\overline{X} \quad (4)$$

Since there are only 4 columns, the algorithm just needs to choose between 1, 2, 3, or 4.

The following section describe how the columns and rows are selected using the data in the behavior score folders:

1. Physical Activity

Take the three most recent PA scores, PA_N, PA_{N-1}, and PA_{N-2}

Column # = INT ($(PA_N + PA_{N-1})/ (PA_N + PA_{N-1})$)

Row # = sequential

2. Sleep

Take the three most recent SL scores, SL_N, SL_{N-1}, and SL_{N-2}

Column # = INT ($(SL_N + SL_{N-1})/ (SL_N + SL_{N-1})$)

Row # = sequential

3. Screen Time

Take the three most recent ST scores, ST_N, ST_{N-1}, and ST_{N-2}

Column # = INT ($(ST_N + ST_{N-1})/ (ST_N + ST_{N-1})$)

Row # = sequential

4. Sugar Beverages

Take the three most recent SB scores, SB_N, SB_{N-1}, and SB_{N-2}

Column # = INT ($(SB_N + SB_{N-1})/ (SB_N + SB_{N-1})$)

Row # = sequential

Intervention
Children in the intervention group will receive daily text messages focused on their chosen health-behavior area of improvement (physical activity, sleep, diet, screen time). Children in the control group will also have data recorded, but will not receive intervention messages. Height and weight will be recorded monthly. As secondary study variable, the child's emotional arousal shall also be measured through the use of the skin conductance data.

Measures
All study variables are summarized in Table 1. At study completion, data from the intervention group will be compared with data from the control group. The outcomes tracked shall include not only the patient's weight loss or gain, but also how the child's risk factors changed over the course of the study (for example, TV watching decreased, and physical activity increased).

5. RESULTS (Sample Data, Discussion, Conclusions)
As part of phase 1 of this project, we developed several technologies, including a wearable sensor, an feedback-loop mobile application, and a website. This study is ongoing and results from phase 2 of this project are not yet available at this time.

Sample Data
Below are sample data demonstrating transition state data collected using the wearable sensor.

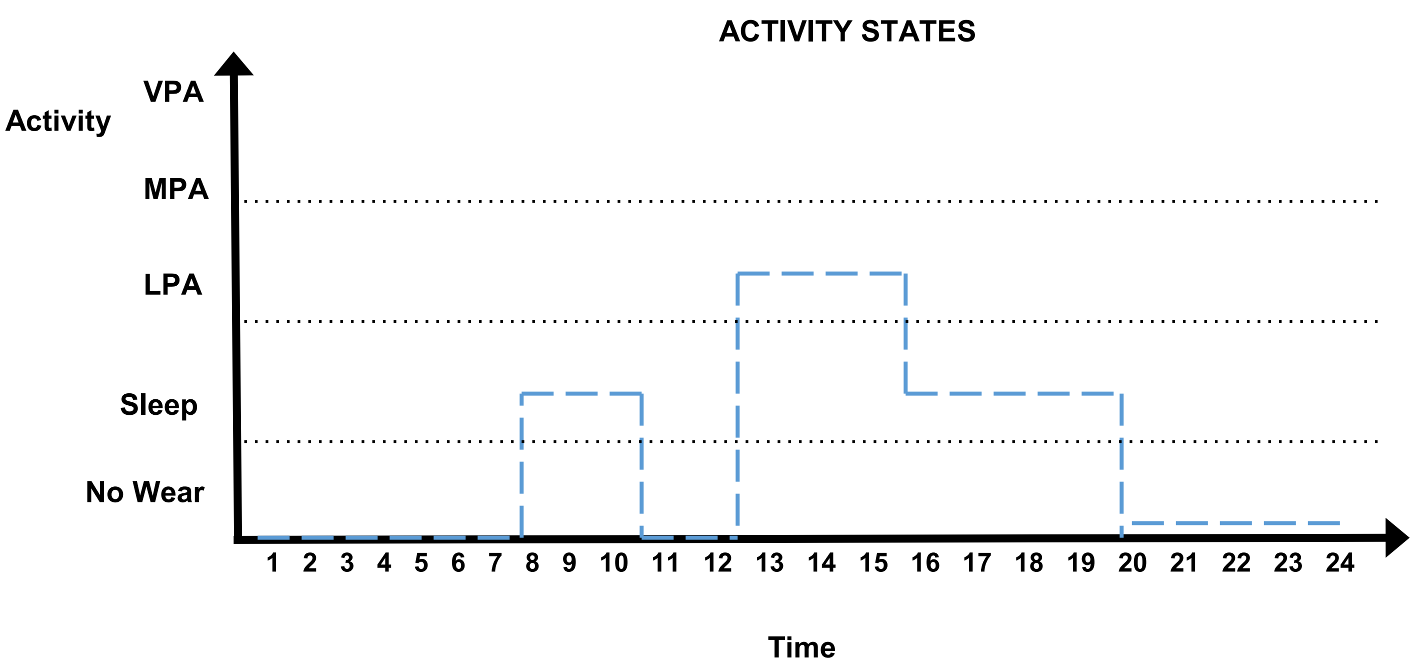
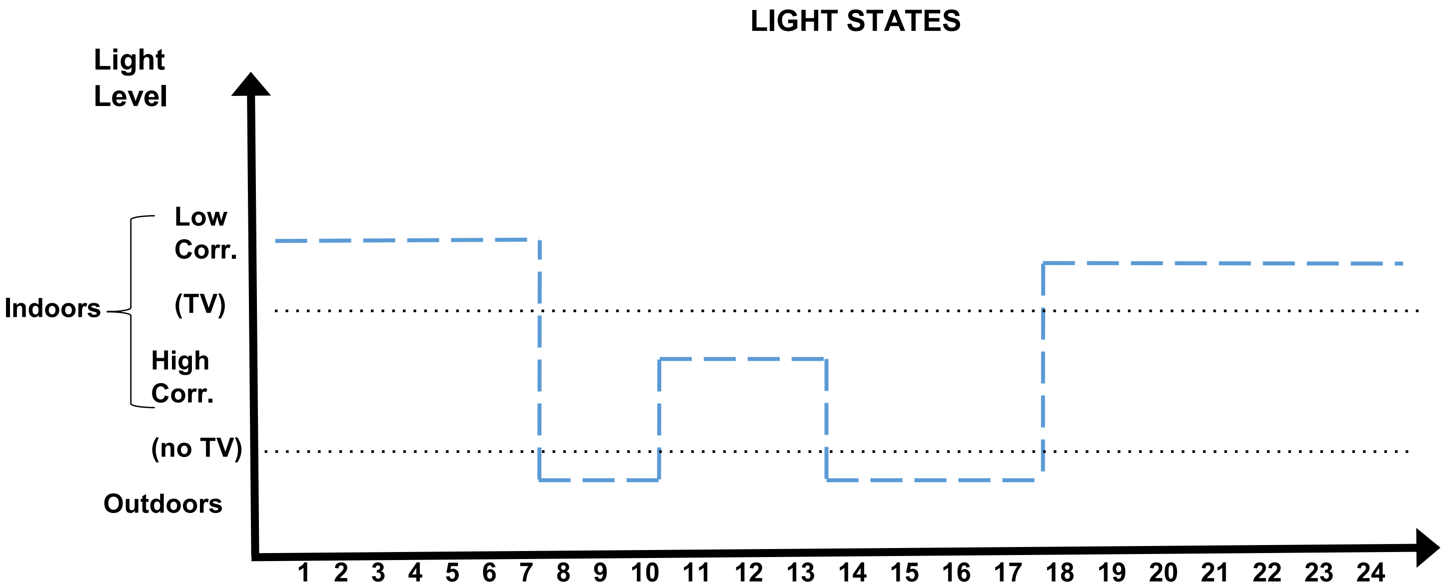


Figure 7. Sample plot of activity transition state data. The four activity levels are no wear, sleep, low physical activity (LPA), moderate physical activity (MPA), and vigorous physical activity (VPA).



Discussion

This study is ongoing. We have completed phase 1 of this project (technology development and testing). Developing the technologies during phase 1 of the study took longer than anticipated, thus delaying phase 2. Phase 2 of the project will use the technologies developed during phase 1 to test the using the newly developed mHealth tools to determine to what extent providing closed-loop clinical feedback on health behaviors improves cardiometabolic risk in youth. This is one of the first studies attempting to use patient-generated data to provide just-in-time automated clinical feedback to pediatric patients and their families.

Challenges

This study is delayed due to multiple technology-related challenges we encountered during phase 1 of the project. Designing, creating, and testing the technology has taken considerably more time than we anticipated and budgeted for in the original project plan. Due to budget constraints, the sub-contract site responsible for creating and testing the technology for this project was not able to dedicate a team member to work full-time on this project, and project components had to be parceled out to different people working on limited schedules, making coordination of technology development more challenging, in turn taking more time. Hardware development required multiple iterations to create a wristband design and prototype intended for use with youth that was sufficiently functional, resistant, and aesthetically pleasing. Many students were involved in the technology-related components of the project, and work on the project was often delayed due to student scheduling requirements, including coursework and school vacations.

Significance

Cardiometabolic risk continues to represent a major population-wide health burden in the United States. Management of cardiometabolic disease also imposes a substantial financial burden on the economy and ties up significant healthcare resources. We have developed mobile health technology (mHealth) that can be used to monitor and counsel on common health behaviors associated with cardiometabolic risk. Importantly, many of the data on health habits are objectively collected (physical activity, sleep, screen time), whereas many prior studies have relied of self- or parent-report data. Additionally, by creating a short feedback loop for sending automated messages based on the child's behaviors, we have substantially reduced the feedback loop time through which most children and parents receive personalized clinical recommendations.

Conclusion

The STRIVE wristband collects objective data on multiple health behaviors known to be associated with cardiometabolic risk. The wristband is able to determine when a child is watching television, which provides an objective assessment of screen time in children, an important milestone in behavior science.

6. LIST OF PUBLICATIONS

Oreskovic NM, Fletcher R, Sharifi M, Knutsen JD, Chilingirian A, Taveras EM. (2016). Design and rationale of the STRIVE trial to improve cardiometabolic health among children and families. *Contemporary Clinical Trials*. 49, 149-154. PMID: 27417980. PMCID: PMC4969164.

Fletcher RR, Chamberlain D, Richman DD, Oreskovic NM, Taveras EM. (2016). Wearable sensor and algorithm for automated measurement of screen time. *IEEE Wireless Health Conference*.