PRETLOW STUDY PROTOCOL (v4.0: 4/17/17)

PI: Alaina Vidmar
Co-Investigators: Steven Mittelman, Robert Pretlow and Claudia Borzutsky
Coordinator: Emily Millen

Sponsor: Robert Pretlow, E-Health International. Contract is pending and will be added to the IRB at a later date

Study Question: Can the W8 Loss2Go program be used as an effective intervention tool in selected children referred to a tertiary care weight management clinic?

Study Title: W8 Loss2Go: Behavioral Weight Loss Intervention utilizing Mobile Health Technology in Pediatric Patients Referred to a Weight Management Clinic.

Background and Rationale: About one in five 12-18 years olds in the U.S. are obese, despite the implementation of current evidence-based weight management strategies. Obesity is caused by excess caloric intake relative to energy expended. It has been theorized that overeating in some individuals may have addictive qualities, and that specific foods may have addictive potential for these people. But few weight management interventions have tested therapeutic techniques founded in addiction medicine principles to date. Therefore, it remains unknown whether the use of tools gained from treatment of other addiction disorders (such as alcohol addiction and smoking cessation) could be a viable strategy for weight management.

Intervention: We will test a recent mobile technology based (mHealth) behavioral weight loss intervention (W8Loss2Go), which is designed for children and adolescents, and uses an addiction model to promote a staged withdrawal from problem foods, snacking, and excessive amounts at meals.

Primary outcome

Anthropometry:

(1) Height and weight will be measured at baseline and at program completion. These measurements will be converted to BMI (kg/m2) and zBMI scores (using CDC growth charts). A historical control group derived from EMPOWER clinic will provide a comparator.

(2) Interim face-to-face weight measurements at q3-month time points during the study, at a CHLA clinic.

Secondary outcomes

(1) Yale Food Addiction Scale (Gearhardt, 2011)
(2) Food responsiveness and emotional overeating as assessed by the Eating Behaviors Questionnaire (EBQ-Merlo, 2009), and success in identifying and withdrawing from "problem foods", eliminating snacking, and reducing the amounts of foods consumed at home meals. Success in these areas will be determined by participant self-report, as well as data collected from within the App.

Process evaluation

(1) Reach
Proportion of patients referred to EMPOWER meeting the food addiction eligibility criteria. Proportion of patients that declined, dropped out or completed the intervention. The reasons for refusal and drop out. (Data collected by study personnel)

(2) Fidelity
Extent to which intervention was implemented as planned. To be measured by number of patients completing problem food withdrawal, snacking control, and withdrawal from excessive amounts at home meals. (Data derived from app tracking)

(3) Dose of intervention received (exposure)
Opinion on patient's ability to understand and implement intervention. Adherence to commitments made by patient. (Data collected from mentor by questionnaire)

(4) Dose of intervention received (satisfaction)
Overall opinion of patient of intervention (parent and child)
Benefits and burden of intervention (parent and child)
Usefulness experienced by patient (parent and child)
Recommendation to others (parent and child)

(5) Barriers
The extent to which problems were encountered while applying intervention (Data collected from mentor)

Study Population: Twenty obese 12-18 year old adolescents will be recruited from new patients referred to the CHLA EMPOWER Clinic. Recruitment will begin with a pilot of 2 patients followed for 60-90 days before open enrollment begins.

Controls: historical controls using EMPOWER patient
These participants will be selected from new referrals to the EMPOWER clinic which have a negative score on the YFAS-c. Control participants will continue through the standard of care EMPOWER clinic which included monthly multidisciplinary team visits with Physician, Dietitian, Psychologist and Physical Therapies. Anthropometric measures including weight, height and BMI will be obtained at each visit.

Participant Compensation: $300 will be given to the participant, in the form of AMAZON gift cards after returning the iPhone and all accessories in good working condition to the study investigators at the end of study period.

<u>Participant Eligibility</u>

Inclusion:
1. Age 12-18 years
2. Patients referred to EMPOWER
3. Positive screen on the Yale Food Addiction Scale for Children (see below)
4. Participants will not be leaving the country during the study period.

Exclusion:

1. Obesity co-morbidities including impaired glucose tolerance, impaired fasting glucose, diabetes, fatty liver with ALT>40, BP > 99th percentile for age, gender, and height
2. Psychiatric illness including depression and anxiety disorder
3. Known developmental delay
4. Does not speak/read English

Study Design/Procedures

Initial Visit:

1. YFAS-c:

All new EMPOWER patients will be verbally consented in order to complete the Yale Food Addiction Scale for Children, a validated 25 item instrument. The YFAS will be administered by a trained interviewer to each patient. Patients are instructed to refer to the past 12 months. Food addiction can be diagnosed when at least three of the seven criteria are met and the criterion of a clinically significant impairment or distress is met. We will use a cutoff of two of the seven criteria. Patients with more than two positive criteria on the YFAS-C will be offered participation in the W8L2Go App study.

2. Consent:

Upon obtaining verbal and written consent to participate in the study participants parents/legal guardian will complete the Eating Behaviors Questionnaire (EBQ- Merlo, 2009), which will be completed at initiation and completion of the program. The EBQ comprises 20 items designed to measure the hypothesized symptoms of food addiction based on adaptations of DSM-IV criteria for substance abuse and dependence.

3. Complete EMPOWER Visit:

Subjects will complete their first EMPOWER clinic visit will include the regular EMPOWER team approach (including healthy diet and exercise instruction, psychological screening, and motivational interviewing).

4. Meeting with Study Coordinator and Distribution of Supplies:

They will meet with the study coordinator for distribution of the iPhones, app, body scale and weigh in scale. Each participant will register with a password on his/her iPhone and fill in user information. Participants will weigh-in on a scale in a private area and enter weight data on their iPhones. Investigators will go through each section of iPhone app and have participants enter data.

Participants will be loaned an iPhone 5S and accessories (including protective case), with an AT&T service plan for the duration of the study that includes: unlimited texting, 3 GB of data, unlimited voice calls to and from other cell telephones, 700 voice call minutes for calls to and from landlines, unlimited night and weekend calls to and from landlines, International calls or texts including Canada are NOT allowed and not covered. Participants will return these phones at the completion of the study. Participants may already own a smart mobile phone and in this case they will have the app downloaded onto their phone.

Study Period (~6 months):

1. Enter app data DAILY, as requested by investigators. (Usually 510 minutes of time per day).
2. Enter weight DAILY using the wireless scale provided to the participant.

3. Weigh all foods at home meals with the wireless food scale provided as directed by investigators.
4. Test all the app features as requested by mentors/investigators.
5. Respond to mentor/investigator messages via app eRoom and voice messaging within 24 hours.
6. Participate in weekly phone conversations with the iPhone. These phone conversations will be audio recorded for analysis purposes and to ensure internal validity. The phone conversations will be transcribed. The mentor will utilize a participant specific script to ensure participant specific barriers are being addressed. These conversations will last approximately 15 minutes.
7. For 10-12 weeks, participants will identify and list all their problem foods and then proceed through withdrawal from each food for a minimum of 10 days, one or two foods at a time. A variety of techniques (gross pictures, motivational tools, coping skills to avoid comfort eating and white noise) are available in the W8Loss2Go app to facilitate this withdrawal and the use of these will be tailored to the needs of participants.
8. For 4-5 weeks, participants will work on eliminating snacking by picking one or more time periods of day when they will avoid snacking morning, afternoon, evening, or nighttime. Once they are able to avoid snacking during a time period for at least 10 days in a row, that period is designated "Incontrol," and they can can then work on a second time period. Snacking elimination is the goal before starting amounts reduction at meals.
9. For 4-5 weeks, the amount of food consumed will be addressed with the goal of reducing the amount of nonproblem foods. This will be achieved by participants cutting serving sizes, no second helpings, smaller plates, someone else serves plate, depleasurizing foods, weighing/measuring foods, stress reduction, relaxation techniques. Weight is closely monitored in this Phase and if weight is not dropping additional reductions in the amounts of food consumed is implemented.

During the 6 months, participants will not return to the EMPOWER clinic for a comprehensive visit unless a specific medical need arises, such as symptoms of comorbid condition, participants will return to CHLA 3 months into the study for a weight check and face to face meeting with the mentors. This visit will take approximately 30 minutes.

After the 6 month period, participants will return to the clinic for a final weigh in. At this visit, the participants will return the iPhones (if one was loaned) and both wireless scales. The participant's parent/legal guardian will also complete the EBQ questionnaire. This visit will last approximately 30 minutes. After completion of the program participants will be offered return to EMPOWER clinic for further follow up if desired.

6 months after completion of the study participants will return to clinic for a follow up weigh in.

Follow-up:

After completion of the program participants will be offered to continue follow up in the EMPWOER clinic if desired.

The iPhone app will be securely integrated with a network server for real-time data access and storage. All participant app data will be periodically backed up to a secure server to preserve data in the event the participant loses or damages his/her iPhone. The investigators will have ongoing access to this data in order to monitor proper use of the app and participant weight loss. The developer of the app will have access to coded data including: weight trends, app usage, problem foods identified, aversion techniques identified and food weights measured by the wireless scale and uploaded to the app. The

app will utilize a code name chosen by the participant for guided prompts and all secure app messages to and from the mentor. No medical advice will be given. Investigators will provide support and prompt participant to enter data as necessary. All phone conversations will be recorded.

Statistics and plans for analysis: All outcome variables will be compared before and after the intervention using paired t-tests. Further analysis will compare the results of the W8Loss2Go program to the contemporary anthropomorphic changes in patients undergoing standard care in our EMPOWER program, using two sample t-tests.

Risk: Less than minimal risk

Study Timeline:
IRB Submission by: 1/5/16
Begin Pilot Recruitment (2 participants): 3/1/16
Pilot: 3/1-5/1
Begin Open Enrollment: 5/1
Study Period: 5/1-1/1
Analysis of Data: 1/1/17-3/1/17
Manuscript Preparation: 3/1/17

Participants Responsibilities:

Participants will be loaned an iPhone 4/5S and accessories, with an AT&T service plan for the duration of the Pilot Study that includes: unlimited texting, 3 GB of data, unlimited voice calls to and from other cell telephones, 700 voice call minutes for calls to and from landlines and unlimited night and weekend calls to and from landlines.

International calls or texts including Canada are NOT allowed and not covered.

Participants will be responsible for the iPhone, any voice call minutes over 700 minutes, and any roaming charges.

Participants must agree to use the iPhone as their primary cell phone and use the W8Loss2Go app as my primary communications mode with the Pilot Study investigators and other members of the study group via the eRoom messaging and group chat system.

Participants must agree to keep the iPhone with them during the day, other than at school where prohibited so that message alerts may be detected.

Participant must agree to keep the iPhone charged and operational at all times and agree to charge the iPhone every evening.

At the completion of the study participants must return the phone in good working condition.

CHLA does not carry damage/replacement insurance on the iPhone. If the participants fail to return the iPhone, the AT&T service will be immediately terminated by AT&T, and the iPhone will be listed as "stolen property" in AT&T's database and will be unusable.

Those using their own iPhone 4S or 5 in the study will continue to be responsible for their own iPhone and iPhone service plans.

They must agree to have the W8Loss2Go app installed on their iPhone for the duration of the study.

Participants must agree to the following iPhone care requirements:

Keep the iPhone charged and operational to the best of my ability every day. Take care of the iPhone to protect against loss or damage; (Take care with charger cable, plug and earphones)

Keep protective skin on iPhone screen at all times.

Will not remove or replace protective case on iPhone at any time. We will replace at meetings if needed.

Will not disable app alerts / notifications.

Will not use iCloud to store anything during the study duration with this iPhone.

Will not take iPhone to ATT or Apple Store for any reason.