Title: Group Telehealth Weight Management Visits for Adolescents With Obesity

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Study: Group Telehealth Adolescent Weight Management Pilot Study

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Introduction

Study Abstract

Multi-disciplinary tertiary care programs have been recommended by the AAP and other medical organizations for children and youth with severe obesity or obesity refractory to primary care management; however, such models of care are expensive, difficult to implement, have significant patient retention challenges, and have been shown to be only modestly effective. Health interventions delivered remotely to patients, whether at their local medical home/ primary health care providers' offices, or to patient homes, via electronic means such as online web-based platforms, also known as "Telehealth," have been shown to be feasible and effective methods for delivery of care for various chronic medical conditions such as diabetes mellitus in adults.

This is a pilot study that aims to compare treatment for obesity in adolescents delivered via a group telehealth model with treatment provided via our traditional in-clinic Empower weight management program, in order to assess feasibility, cost-effectiveness, and efficacy of group telehealth. We will assess efficacy by measuring: (1) Changes in BMI, blood pressure, and relevant laboratory values (2) Quality of life scores (3) Self-efficacy scores (4) Patient satisfaction. Subject recruitment and study design: Patients that have been referred to Empower and the KidsNFitness program will be eligible, as well as CHLA patients seen in a multitude of environments, including outpatient clinics, the Emergency Department, the inpatient setting seen by Physical Therapy, Occupational Therapy, and Clinical Nutrition. In order to be recruited to the intervention group, participants must be between 14 and 18 years of age; informed consent will be obtained. After obtaining their consent, intervention group participants will be assigned to the intervention telehealth group (final total n=32). We plan to run two consecutive 6-month cohorts. Each cohort will consist of two telehealth groups of 6-8 participants each (total 12-16). We plan to over-enroll each group to account for expected attrition; we will enroll a minimum of 6 and maximum of 8 participants in each of the two telehealth groups, for a total of approximately 30 participants (final total n=32) between the two 6-month cohorts. Parents will be contacted on a weekly basis to update them about their child’s session attendance, the general content of the sessions, and to remind them to prompt their child to log on to their twice monthly telehealth sessions. We will ask for their preferred mode of contact (text message, email, and/or phone) and use all preferred methods to contact them. Intervention group subjects will be enrolled into a group telehealth program, in which twice monthly sessions will be held using a HIPAA compliant web-based platform, for 6 months.

The intervention group will be asked to come in for in-person research visits at 0, 3 and 6 months for collection of weight, blood pressure, and other anthropometric measures; they will be asked to complete baseline, 3 month, and 6 month questionnaires regarding quality of life, self-efficacy, diet, and physical activity habits; an additional survey regarding satisfaction with treatment will be administered at end of the 6 month study period, and repeat bloodwork will be obtained at that time.

For the control group, we will use retrospective data for all eligible patients from our Empower clinic whose first clinic visit was between January 2015 and June 30, 2019. The end point for data collection will be no later than December 31, 2019. Those who are matched to the intervention group for age, gender, and severity of obesity; we will request a waiver of consent for this group.

Statistics and data analysis plans: The target recruitment of approximately 206 subjects (30 intervention and 176 control) was arrived at based on practicality and feasibility for a pilot study, and modified per recommendations of our current biostatistician, based on the limited data available upon chart review for many of the clinic control subjects. For evaluation of changes in the continuous outcomes, BMI, blood pressure, and hemoglobin A1C, triglyceride level, and ALT, assessed at baseline and immediately following the end of the 6 month intervention, we

will utilize regression analyses, which will allow us to compare the magnitude of change between the telehealth intervention and the comparison group, taking into account both change from baseline to follow-up time points as well as relevant baseline covariates. For these analyses covariates will be participants' age, gender, and presence of existing medical conditions (e.g. diabetes; rheumatologic conditions) that could affect weight loss.

Background

Prior Literature

EMPOWER is a multi-disciplinary, team-based clinic model, involving physicians, psychologists, registered dietitians (RDs), and physical therapists (PTs) providing tertiary care management of obesity. Data from the first two years of EMPOWER show that patients with four or more visits (n=109) experienced a decrease in average BMI z-score (-0.09SD). This, though modest, is promising; however, both cost and patient retention present significant challenges to EMPOWER and other tertiary care pediatric obesity programs and may be barriers to further progress. Much administrative personnel time is consumed in working with insurers in order to authorize visits, and nevertheless, this type of hospital-based care is poorly reimbursed. Getting to CHLA is often a major challenge for our patients, due to the large urban sprawl of Los Angeles, traffic, limited and expensive parking, and poor public transportation. Frequent visits result in missed work and school days, a burden to families. Our adolescent patients face even greater challenges, as they they are in the process of learning to manage their own health and balance the emotional and social changes required in the transition to adulthood, with family and parental expectations and limitations.

Rationale for this Study

Telehealth technology presents an innovative, cost-effective, and often highly engaging alternative to in-person visits, which bypasses many of the logistical difficulties of getting to CHLA. Moreover, adolescents today are highly attuned to, and aligned with, digital and mobile technologies, and are natural consumers of media in this format. There is strong evidence from numerous published studies that telehealth can be an effective tool for chronic disease management (1,2, 3). Additionally, many youth with obesity are significantly socially isolated, and our current individual patient-provider model does not effectively address this isolation in the way we expect a group session will; various published studies of group treatment have demonstrated inter-participant support and positive effects of social interaction (4, 5, 6).

While our current model leads to successful weight management in many of our patients, success is often modest, as mentioned above; and for some of our patients, it simply does not work. With this proposal, we wish to pilot a group telehealth model targeted at adolescents with obesity.

Citations:
1) Bashshur RL, Shannon GW, Smith BR, et.al. (2014). The empirical foundations of telemedicine interventions for chronic disease management. Telemed J E Health. Sep; 20(9):769-800.
2) Polisena J, Tran K, Cimon K, et.al. (2010). Home telehealth for chronic obstructive pulmonary disease: a systematic review and meta-analysis. J Telemed Telecare. 2010; 16(3):120-7.
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randomized controlled trial examining peer support and behavioral weight loss treatment. Journal of Adolescence. 44:117-123.
6) Tanofsky-Kraff, M., Shomaker, LB., Young, JF., Wilfley, DE. (2016). Interpersonal psychotherapy for the prevention of excess weight gain and eating disorders: A brief case study. Psychotherapy, 53(2).

Study Objective

Primary Aim -

To pilot a new care delivery model for adolescent patients with obesity, using group telehealth visits

Secondary Aim -

To assess the feasibility of using telehealth with adolescent patients

Tertiary Aim -

To test the efficacy of group appointments using telehealth

Rationale for the Selection of Outcome Measures

1. Use of shared medical appointments via telehealth is a feasible, cost-effective care delivery model for adolescents being treated for obesity.
2. The efficacy of this model will be comparable to, or better than, standard multi-disciplinary in-person visits.
3. Attendance to telehealth visits will be better than attendance to standard in-person visits, as measured by no-show rates and same-day reschedules

Study Design

Overview Design Summary

There will be two cohorts for this study, each lasting 6 months. Each cohort will consist of an intervention arm of 12 subjects. We will recruit a minimum of 12 subjects, up to a maximum of 17 subjects in the first cohort and a maximum of 15 in the second cohort, this over-recruitment will attempt to account for possible attrition from the groups.

All study staff are HIPAA and CITI certified and will be trained in the use of the web-based platform. Additionally, all clinical staff conducting telehealth sessions will be oriented to the semi-structured curriculum, and the study coordinator who will also be conducting the inter-session coaching will be trained and mentored by a CHLA researcher who has recently conducted a similar study utilizing a cell-phone based app and brief coaching for treatment of adolescents with obesity.

Subject Selection and Withdrawal

Inclusion Criteria

Prospective Group:

Youth age 14-18 who meet criteria for or are currently enrolled in the Empower weight management clinic will be included. These criteria include body mass index (kg/m2) that is either greater than the 99th percentile, or greater than the 95th percentile accompanied by an obesity-related comorbid condition such as hyperlipidemia, pre-diabetes or diabetes, non-alcoholic fatty liver disease (NAFLD), obstructive sleep apnea, or polycystic ovarian syndrome.
Youth will need to speak English but those whose parents' primary language is Spanish will be included.
Retrospective Control Group:

All eligible youth from our EMPOWER clinic patients whose first clinic visit occurred between January 2015 and June 30, 2019, and were 14-18 years old, were included in our control group.

Exclusion Criteria

Prospective Group: (1) significant intellectual or neurodevelopmental disability, ie previous diagnosis of autism spectrum disorder or developmental delay (2) non-English speaking; (3) age < 14 years and > 18 years (4) weight greater than 255 kg.

Given the shared nature of group appointments, participants should be at approximately the same developmental stage as their peers. Discussion topics may include stigma, body image, family dynamics, and school issues, and therefore a wide variance in age range or cognitive status could potentially diminish the effectiveness of the group sessions. Non-English-speaking youth will be excluded due to limitations in translation services for such a small pilot project. Lastly, with respect to the weight limit, we are excluding patients whose baseline weight is greater than 255 kg, because the scale we use for study visits has an upper weight limit of 272 kg. Because we anticipate that some patients will experience weight gain rather than weight loss, we are allowing for the possibility of a 17 kg weight gain over the 6-month course of the study and therefore choosing an upper weight limit which is 17 kg less than the upper limit of the scale.

Subject Recruitment Plan and Consent Process

If potential subjects are interested in hearing more about the study but unwilling to do so at their in-person Adolescent EMPOWER or other clinical encounter (i.e. outpatient clinics, Emergency Department, Physical Therapy, Occupational Therapy, and Clinical Nutrition), we will obtain their telephone or electronic contact information as well as mailing address, and permission to contact them at a later date and to mail consent forms to their electronic or physical mailing address.

If CHLA Health Network pediatricians have patients that are eligible for the study and would like to be referred, they can forward their patients' information to our study coordinator as per the attached email, and we will screen them by phone with the same recruitment screener.

Waiver of consent is being requested only for retrospective control group subjects. This is due to impracticality of obtaining consents from patients we are no longer following clinically, whereas for the telehealth intervention group, which is a prospective group, we will be obtaining informed consent from all adult participants, given the very interactive nature of the intervention. Written consent will be obtained from all subjects who turn 18 during the course of study participation. Their re-consent will be obtained via the addendum document once they turn 18 on their next visit.

Risks and Benefits

- Some of the questions may make the participant feel uneasy or embarrassed.

- There is a small risk that people who are not connected with this study will learn a participant's identity or their personal information.
- Venipuncture risks include mild discomfort (or pain), bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).
- Improvement in some or all of participants' symptoms
- The advancement of knowledge
- A new treatment or therapy for the condition under study

Early Withdrawal of Subjects

- They will not be punished or denied something which they would normally receive (e.g., threatening to withdraw health services to which an individual would otherwise be entitled) if they choose not to participate in this research or choose to withdraw early from participation.

Study Procedures

Screening for Eligibility

Script to be used by study staff and email to be sent to CHLA Health Network pediatrician offices.

Schedule of Measurements

The intervention telehealth group participants will have their anthropometric measurements and vital signs recorded onto their Case Report Forms (CRFs) during their in-person baseline, 3-month, and 6-month visits. Baseline lab reports that have been obtained by primary care providers included in Empower referral packets, if applicable, will also be recorded onto the CRF, as will follow-up lab work obtained at the 6 month in-person visit. If no baseline labs have been collected in the last 6 months by referring PMD, we will collect baseline bloodwork here at the CHLA CTU.

Intervention Visits

(1) Group telehealth sessions twice per month for 6 months. The group sessions will be 60 minutes and involve delivery of a semi-structured curriculum including topics such as nutrition education, reducing barriers to physical activity, and how to celebrate with family and friends in a healthful manner, and will use interactive activities such as photovoice (see attached curriculum). Sessions will be facilitated by EMPOWER providers (physicians, psychologists, RDs, and PTs) who will use a combination of: (1) motivational interviewing techniques, modified for the group setting, (2) supportive exploration of barriers to behavior change and (3) setting SMART goals. Beginning with cohort 2, sessions will be recorded for internal use.

(2) Brief individualized coaching by the research team between sessions, via telephone or email. It will be comparable to the personalized feedback and motivation provided in standard EMPOWER.

(3) Parents will be contacted on a weekly basis to update them about their child's session attendance, the general content of the sessions, and to remind them to prompt their child to log on to their twice monthly telehealth sessions. We will ask for their preferred mode of contact (text message, email, and/or phone) and use all preferred methods to contact them.

4) All Telehealth sessions will be recorded. The recordings may include audio and video (only if the participants have their camera turned on during the session), and video of the research staff running the session. Participants will be reminded verbally before every session that they will be recorded.

- Data collected on Experimental procedures for the telehealth group include:

  1. Data collection from Empower referral packets and/or the electronic medical record regarding their weight/body mass index (BMI), blood pressure, medications, and lab results, onto the CRFs. Date of study visit, and current zip code will be included, as well as preferred contact method for coaching (ie text, mobile phone, or electronic mail). If contact info itself (ie the actual mobile number or electronic mail address) must be updated, it will be documented onto the subject code list and contact info log. Unstructured notes about the telehealth sessions will be documented onto the CRFs by the session facilitator(s) and may include individual participants' level of engagement and involvement during the session, as well as noted significant changes in patient's home circumstances, life events, travel, or major illnesses.

  2.Twice monthly weights will be entered into the scale’s app will be recorded as well.

  3. Missed telehealth sessions will be tallied at the final study visit for each telehealth group participant.

  4. Questionnaires assessing quality of life, self-efficacy, diet, and physical activity habits will be administered and collected at baseline, 3-month, and 6-month visits; at the 6-month end point they will also complete a survey about satisfaction with care. It is anticipated that it will take participants 30 to 60 minutes to complete these questionnaires, in addition to a brief visit with research staff to obtain their measurements.

  5.A1C, fasting glucose, fasting lipids, AST and ALT will be drawn at 6-month visit, and results will be documented as well. They will also be drawn at baseline, if participants did not have them performed as part of their clinical care during the previous 6 months. Baseline lab results will also be documented.

6.General session information for bi-weekly (every 2 weeks) telehealth sessions will be collected onto the Telehealth Session Report forms by the session facilitators, including which participants attended and how the facilitator felt the session went.

- Experimental procedures for Control Group subjects will be limited to data abstraction from the CHLA KIDS electronic medical record (EMR

Statistical Plan

As noted previously, the target recruitment of 32 intervention and 176 control was arrived at based on practicality and feasibility for a pilot study. For evaluation of changes in the continuous outcomes, BMI, blood pressure, and hemoglobin A1C, triglyceride level, and ALT, assessed at baseline and immediately following the end of the 6 month intervention, we will utilize regression methods, which will allow us to compare the magnitude of change between the telehealth intervention and the comparison group, taking into account both change from baseline to follow-up time points as well as relevant baseline covariates. For these analyses covariates will be participants' age, gender, and presence of existing medical conditions (e.g. diabetes; rheumatologic conditions) that could affect weight loss.

Update June 2021: Matched control group subjects will be identified by calculating a propensity score, by collecting data for all potential control patients seen in EMPOWER clinic in the approved date ranges. There is no change to the nature of the data points, and their data will be extracted from KIDS and entered into REDCap database as already outlined.

Update Dec 2022: Given the limited data available for each of the matched clinic control patients (many had missing lab and other values), it was determined that we should remove the "matched" inclusion criteria and collect data on all 176 eligible control patients, in order to have a statistically meaningful cohort.

Data Handling and Record Keeping

Physical data will be stored in a locked office, locked storage unit, restricted access to authorized study personnel. Electronic data will be accessed through a secure computer/laptop, individual ID plus password protection, network restrictions, security software, and access terminated when authorized personnel leaves the study.
Any audio/video recordings will not be anonymized or de-identified because they will only be used by the study staff. The recordings will be deleted at the end of the study.

Study Monitoring, Auditing, and Inspecting

Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased).

Study Administration

Funding source

All costs of the research will be paid for by the sponsor/funder. The study does not include standard of care procedures; however, costs of parent or participant time off from work, transportation, parking, babysitter fees, food purchased while at the hospital, etc. will not be paid for by the study.
For participants who have not had Hemoglobin A1C, fasting glucose, AST, ALT, and fasting

lipid panel within 6 months of the start of participation, cost of phlebotomy and lab processing will be covered by CTSI voucher awarded in support of this study.

Subject Stipends or Payments
Subjects from the telehealth intervention arm will be compensated with gift cards in the amount of $10 for completion of questionnaires at the 3-month visit and $20 at the 6-month visit. Gift cards will be given directly to the participants, whether they are minor age teens or adults.

Publication Plan
Dissemination of findings will include sharing information in local conferences. After complete data analysis, manuscription will be submitted for publication in a pediatric weight management, or pediatric nutrition journal.

Attachments
Informed Consent Documents (separate pages)
Questionnaires or Surveys (separate pages)

References
1) Bashshur RL, Shannon GW, Smith BR, et.al. (2014). The empirical foundations of telemedicine interventions for chronic disease management. Telemed J E Health. Sep; 20(9):769-800.
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