PROTOCOL TITLE:

Digital Wellness Nurse – FIT Families: Virtual Family Intervention for Adolescent Obesity

PRINCIPAL INVESTIGATOR:

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1.0 Objectives / Specific Aims

Machine and Human Interaction is a digital health company focused on improving patient outcomes through a virtual care platform, the Digital Wellness Nurse (DWN). The DWN uses human-in-the-loop automation, web, and mobile technology to deliver evidence-based interventions that increase a patient population's access and adherence to treatment and their engagement in healthy behaviors. The focus of the DWN for this study, in collaboration with the Medical University of South Carolina (MUSC), is to evaluate its feasibility in delivering key components of FIT Families (HL155793), a multicomponent behavioral intervention designed to treat 12-to-17-year-old African American (AA) adolescents with obesity (AAAO).

The study aims to expand the FIT Families intervention through a digital adaptation that utilizes mobile technology and automation to increase access and adherence. Specifically, the DWN platform will assist AAAOs and their primary caregivers (participants) in understanding, tracking, and completing intervention components; delivering educational content when needed; and collecting information from external sources such as wearables. An analysis of their progression will provide the participants' incentives for adhering to intervention components, for example increasing their participation in self-monitoring (SM) and physical activity (PA). The DWN enables social support (SS) by allowing additional family members or friends to offer messages of encouragement to the participants throughout the treatment. Using our web-based dashboard, community health workers (CHWs) will monitor the progress of their families, meeting with them weekly via video conference within the DWN mobile application.

DWN-FIT will evaluate the feasibility of a digital intervention to expand access and facilitate adherence to family-oriented, evidence-based treatment for AAAOs and their caregivers. Additionally, the realization of DWN-FIT will enable future research and development of evidence-based digital interventions targeting AAAOs. Successful outcomes of the proposed work will provide the evidence needed to support a larger, more comprehensive randomized clinical trial and commercialization of DWN (Phase II).

Specific Aims:

Aim 1: Feasibility Testing. Evaluate the DWN-FIT intervention (delivered by 2 CHWs) with 16 families (AAAO and caregiver, overweight or obese) undergoing treatment for adolescent obesity to determine the degree to which the DWN mobile app promotes the client's engagement in healthy behaviors, increased access to treatment for rural AA families, and improved treatment retention compared to the baseline (27% - 55% attrition). Additionally, we will determine the degree to which SS, as an additional element of DWN-FIT, enhances engagement and retention of families in the treatment.

Expected Outcome: We anticipate that healthy behaviors (increased step count, PA, nutrition SM, etc.) will be positively correlated with increased measures of engagement. Continuous engagement, we hypothesize, is highly linked to improved health outcomes, such as weight loss, which should also be reflected in measures of adherence. We also expect that SS will have a positive effect on each healthy measure, serving to increase the average step count, PA participation, and SM when compared to the non-SS condition.

Aim 2: User Centered Evaluations. Conduct a needs analysis before the intervention, a usability evaluation during the intervention and participant focus groups after the intervention to determine if the DWN app met their needs related to accessing (participants), delivering (CHWs), and providing support during the treatment.

Expected Outcome: We expect that the responses from the participants' surveys and the resulting themes will indicate that the DWN app met the participants' goals and needs related to accessing, delivering, and providing support during the treatment and was usable, efficient and effective.

2.0 Background

Obesity in the United States is a public health problem among all racial/ethnic groups, ages, genders, and geographic areas. However, compared to their counterparts, the prevalence of obesity among AA adults is higher (47.8% vs. 34.9%)[1]. Likewise, AA youth between the ages of 10 to 17 are more likely to be obese than their Hispanic, White and Asian counterparts (23.8% vs 21.4% vs 12.0% vs 8.1%)[2]. Further impacting these disparities and their corresponding health risks, adherence to physical activity (PA) guidelines is suboptimal, especially among AA families with adolescents[3,4]. In South Carolina, the site of the proposed study, the obesity rate among youth is 20.1%, ranking third in the nation[2] . The short-term health implications resulting from adolescent obesity include an increased risk for asthma and other cardiometabolic disorders[5–13]. The annual economic impact of direct outpatient and inpatient costs of childhood obesity are estimated to be $14.1 billion[14] and $237.6 million[15], respectively. The long-term effect of obesity for adolescents is their increased chances as an adult for persistent obesity, cardiovascular conditions, Type 2 diabetes, morbidity, and mortality[8,10,13]. Since adolescent obesity is a risk factor for adult obesity, there is need for prevention at an early age to reduce the high medical and productivity costs. In the United States, $173 billion is spent annually on medical costs pertaining to adult obesity[16].

Treatment options for adolescent obesity include lifestyle modification, behavioral interventions, pharmacological treatment, and bariatric surgery (BS). However, compared to eight pharmacological options for adults, only three have been approved by the FDA for adolescent obesity, primarily because of a lack of evidence. BS is an option for adolescents with severe obesity and/or serious comorbid conditions[13,17,18] , but there is a lack of data on its long-term safety and effectiveness [13,17]. Further, obese children and adolescents living in rural areas are less likely to undergo an evaluation for BS[19]. Even with recent advances in BS and pharmacologic treatments, the first line of treatment for adolescent obesity continues to be lifestyle modifications in conjunction[20] with BS[19,21,22], medications[23], and multicomponent behavioral interventions[24,25]. Moreover, parental involvement is also associated with the effectiveness of weight loss interventions for obese children[26-29, 19–22]. For African American Adolescents with Obesity (AAAOs) and their family, access to intensive behavioral interventions is a challenge, especially for those living in rural areas who face limited options for healthcare providers[30] specializing in these interventions [31] or inadequate transportation[31,32]. In addition, the types of interventions for AAAO do not address the motivational factors that interfere with adherence to evidence-based recommendations. Treatment studies involving AAs have reported attrition rates ranging from 27% to 55%[33–36]. FIT Families (HL155793), the basis for the DWN-FIT, addresses access issues through an at-home evidence-based intervention and the problems with adherence and motivational factors through Motivational Interviewing (MI) delivered by Community Healthcare Workers (CHWs) and Contingency Management (CM), increasing caregiver participation by monitoring the adolescent's implementation of evidence-based cognitive behavioral skills and physical activity (PA), and modeling these skills by self-monitoring (SM) of their own diet and exercise and increasing their own PA. We propose to expand the intervention components of FIT Families by including social support (SS), which has been cited as a key element in treatment adherence[37–41] when disease management requires significant lifestyle modifications. While several studies have demonstrated a lack of moderator effects of gender on SS, we hypothesize that age (particularly children and adolescents) and race may be important moderators, a hypothesis supported by a recent review by Duh-Leong et al.[42] who framed social support outcomes in the context of a three-component social capital construct.

Through the translation and evaluation of the FIT Families components, we will add to the limited research investigating digital interventions targeting AAAO and their caregivers. Additionally, the realization of DWN will enable future research and development of evidence-based digital interventions targeting AAAO. Successful outcomes of the proposed work will provide the evidence needed to support a larger, more comprehensive randomized clinical trial and commercialization of DWN (Phase II).

This study aims to expand the FIT Families intervention through a digital adaptation using mobile technology and automation to increase AAAO and caregiver (participants) engagement and adherence. Specifically, the DWN platform will assist participants in understanding, tracking and completing intervention components, delivering educational content, and collecting information from external sources such as wearables (i.e. Fitbit smart watch). Through the mobile app, participants will receive weekly Cognitive Behavioral Skills Training (CBST) modules providing educational content in a video format on cognitive behavioral skills that addresses factors that commonly contribute to poor adherence to healthy behavior recommendations. These modules will also include demonstrations of the weekly PA workouts to be performed by the participants.

Accompanying the video modules are the mobile app's self-monitoring (SM) and the PA features. The SM feature consists of a conversational interface that conducts periodic assessments with the participants to assist them in tracking their daily implementation of the cognitive behavioral skills learned. The PA feature retrieves and tracks the step counts and workout sessions of the participants by collecting data from their wearable devices (Fitbits). Data from the SM and PA are collected by DWN, and an automated analysis is conducted comparing them to the goals set by the participants and the CHW. Based on this analysis, the CM feature provides a monetary incentive (disbursed weekly) to the AAAO and the caregiver for adhering to intervention components. Through the mobile app interface, DWN also provides textual and visual feedback to the AAAO and the caregiver as they progress through the intervention. From the mobile app interface, the caregiver can review and comment through the messaging feature on the adolescent's progress. In one of the treatment conditions detailed below, DWN will deliver semi-automated encouraging messages to the participants during the intervention through the Social Support (SS) feature, which provides feedback on the participants' progress to their supporter (family member or friend). From the mobile app interface, the supporter reviews and provides encouraging messages on the participants' progress.

The CHWs will meet weekly with their participants via video conference (telehealth) to deliver the Motivational Interviewing needed. Between the weekly sessions the CHWs monitor the participants' adherence to the intervention using the web-based dashboard. If they are not doing so, the DWN notifies the CHW, who has the option to reach out directly to the participants through our messaging feature.

Preliminary Studies:
FIT Families The NHLBI/NICHD Center Grant (U01HL097889; Naar, consultant in this work) proposed to translate basic behavioral science into novel obesity interventions, targeting the basic science of motivation and communication, and skills training for AAAO using phased intervention development (ORBIT) and a novel design (SMART) to test multiple components that were optimized and are now being tested in a NHLBI-funded clinical trial (R33 HL155793).

Digital Wellness Nurse (DWN): The DWN virtual care platform is based on a research project begun at Clemson University by investigators McClendon, Gilmore and Shumin. We have developed and evaluated the self-monitoring feature of the DWN as part of COVID-19 Pilot Study using 25 participants. During the 3 months of the study, 149 assessments were successfully submitted without error or loss of data. Besides demonstrating self-monitoring, the study also highlighted the implementation of a secure and privacy-based cloud platform including the following mechanisms: data are encrypted on transit and at rest; personal identifiable information (PII) and personal health information (PHI) are stored in two separate cloud storage spaces; the PHI is only linked to users by a unique id that is randomly generated; and tokens are used to authenticate the participants. Through a series of system tests, we have also formally evaluated the scalability of our cloud resource, finding that the DWN platform can handle 500 simultaneous service requests from users, more than the amount of cloud resource needed to conduct Phase 1 studies.

3.0 Intervention to be studied

The two interventions to be studied are: 1) DWN-FIT and 2) DWN-FIT_Social Support.

Components of Digital Intervention for DWN-FIT and DWN-FIT_Social Support:

Cognitive Behavioral Skills Training (CBST) Video Modules: Every week a group of 3 - 5 videos will be made available to the AAAO and their caregiver, no longer than 5-minutes in length. Videos are based on the mandatory modules used within FIT Families. These instructional modules will be translated to scripts and scenes with the guidance of Dr. Naar (Consultant and FIT Families Co-I).

The proposed schedule is as follows:

- Week 0 – DWN-FIT Orientation and Getting Started on the Mobile App
- Weeks 1-2 – physical activity (PA) education
- W3-4 – nutrition education
- W5-6 - parenting strategies (only available to caregiver) and self-monitoring (SM)
- W7-8 - environmental control of nutrition and PA
- W9-10 - managing hunger
- W11-12 - managing cravings

Self-Monitoring (SM) Assessments: Throughout the study, participants will complete assessments via the conversational interface of the mobile app. At the beginning of the intervention (T0), participants will complete a baseline assessment focused on their current engagement in- and perception of-healthy behaviors (eating habits and physical activity level). This assessment will be adapted from the Patient Health Engagement (PHE) Scale[48]. The same questions regarding patient engagement will also be asked at each assessment time point (T1 – T3). The DWN will prompt the participants daily to use the SM feature of the mobile app to complete an assessment that will determine their daily implementation of the physical activity tasks and cognitive behavioral skills learned. For example, participants will be asked to complete a food log that documents the amounts of fruits and vegetables, junk food, water, protein, and whole grains consumed each day. These food types and their suggested quantities are detailed in the nutrition education learning modules. The DWN will also conduct weekly assessments, initially only asking participants to weigh themselves and record their body fat. As the intervention progresses, in collaboration with the CHW they will also be asked to set their weekly treatment goals and reflect on their goals from the past week (barriers that prevent them from reaching their goals and if they need to modify their goals). As a part of SM component, the caregiver and CHW are notified when the AAAO submits or misses submitting an assessment. Once an assessment is submitted, the caregiver reviews the adolescent's progress. If the AAAO does not submit the required assessment or if the caregiver does not review one, the CHW is alerted, and they have the option to reach out directly to the participants through the messaging feature.

Physical Activity (PA): In W1, participants begin wearing the Fitbit wearable provided and set their step count goals during the weekly assessment. In addition, four CBST video categories will demonstrate the independent PA workouts the participants will perform weekly: 1) Warm-up (5 minutes); 2) High intensity interval training for cardiovascular fitness (20 minutes); 3) Resistance band and body weight resistance training (20 min); and 4) Cool down with yoga stretches (5 minutes). Participants will perform these PA workouts while wearing their Fitbit. The number of client workouts during the week depends on their PA goals set during the weekly assessment. The DWN provides textual and visual feedback on the client's step count and workout sessions. As a part of the PA component of the intervention, the caregiver and CHW are notified when the AAAO receives this feedback, at which time the former reviews the adolescent's progress. If the AAAO does not meet their PA goals or if the caregiver does not review the feedback, the CHW is alerted, and they have the option to reach out directly to the participants through the messaging feature. The AAAO and caregiver will receive Fitbit Inspire 3s, resistance bands, a yoga mat, and a Body Composition Scale as a part of the study. The equipment will be returned to the investigator at the end of the intervention phase.

Contingency Management (CM): The CM feature provides financial incentives to attend sessions and to encourage families to meet the following weekly goals ($10 per goal): step count, nutrition SM, CBST education, and PA participation. Caregivers have the opportunity to receive bonus incentives ($50 for completion over three consecutive weeks, maximum 3 bonuses over study duration) for reviewing the AAAO's PA participation and nutrition SM entries. AAAOs may also receive bonus incentives using the same pay structure ($50) for every four consecutive weeks of at least a one-pound weight reduction. Session attendance (telehealth visit with CHW) is also incentivized at $50 per session for the AAAO and caregiver, individually. CM

goals will be released along with the accompanying CBST material so that families have adequate knowledge to apply the prescribed strategies. Successful attendance and completion of all goals (including bonuses) over the 12-week period results in a total value of $1230. Incentives will be disbursed as reloadable debit cards (ClinCard).

Video Conferencing (Telehealth): Weekly telehealth sessions lasting approximately 45-minutes to 1 hour are delivered to the participants by the CHW through a video chat interface in the DWN mobile application, including 1) review of SM goals; 2) review of PA steps and calories burned; 3) Goal setting based on assessments and learning modules; and 4) review of CBST learning modules using evidence-based steps for skill acquisition (discussion of rationale, modeling of skill, caregiver and AAAO behavioral rehearsal of skill, feedback), and caregiver and AAAO develop implementation plans for between session skills practice.

DWN-FIT_Social Support (SS) intervention:
Participants randomly selected for the SS condition of the DWN-FIT will receive all of the components of the DWN-FIT intervention as described above. In addition, DWN-FIT_SS families will be asked to invite a family member/friend to serve as the supporter. Once consented and accepted as a research participant, the supporter will be compensated $60 each week of the 12-week study period for providing encouraging messages to both the caregiver and AAAO. The supporter will be instructed by the research assistant to download the application. The supporter is automatically prompted at the following points: one day after release of CBST educational modules; twice per week for PA; and at the beginning, middle, and end of week to encourage SM and follow-up by caregivers.

4.0 Inclusion and Exclusion Criteria/ Study Population

Participants: AA adolescents and their primary caregivers or legal guardians (collectively called “families”) recruited from South Carolina communities with Rural-Urban Commuting Area (RUCA) codes 4 – 10. For the Social Support (SS) treatment condition, supporters (family members or friends) will be invited by the family after agreement on the individual by the AAAO and the caregiver. Supporters must be 18 years of age or older to participate.

Community Healthcare Workers (CHWs): All community health workers (CHWs) hired for the intervention will be invited to participate in the usability assessment and focus groups (Aim 2). These participants must have a bachelor’s degree in Psychology, Public Health, or related field and must complete the study training requirements. CHWs who meet the hiring and training requirements for the existing RCT FIT Families (HL155793) will be eligible for hire as CHWs and as study participants. Existing FIT Families CHWs will be our primary recruitment base. New CHWs joining the study will be required to meet the FIT Families study’s requirements for hiring prior to becoming a part of the study.

Inclusion criteria for families*:*
1) Adolescents (ages 12-17) self-identifying as AA
2) Adolescent BMI ≥ 90th percentile for age and gender
3) Primary caregiver either overweight (BMI 25.0 to 29.9) or obese (BMI ≥ 30) and willing to participate in treatment
4) Adolescent residing primarily with the primary caregiver in a rural community (RUCA Codes 4-10)
5) Both caregiver and adolescent must have (separate) Android or Apple (iOS) smartphone with mobile internet connection
6) Adolescent and caregiver are English proficient
7) Supporters must be 18 years of age or older

Exclusion criteria for youth only:
1) Obesity secondary to medication use for another medical condition (e.g., steroids, antipsychotics)
2) Obesity secondary to a chronic condition (e.g., Down syndrome, Prader-Willi syndrome, Cushing’s syndrome)

Exclusion criteria that apply to both adolescents and caregivers:

1) Pregnancy (e.g., caregivers and youth will be asked each week if they expect if they are pregnant)
2) Mental/emotional disorder (e.g., schizophrenia or other psychosis), suicidal, or homicidal
3) Serious cognitive impairment (e.g., inability to complete questionnaires)
4) Medical condition where weight loss is contraindicated
5) Receiving or planned to receive other obesity treatments (e.g., pharmacologic treatment, bariatric surgery) within the next 6 months

Individuals with mild mental retardation may be included if capable of reading and understanding study measures; however, youth/caregivers with more serious cognitive impairments are excluded.

Inclusion criteria for CHWs:

1) Bachelor's degree in Psychology, Public Health, or related field
2) Completion of the study training requirements
3) Completed the three-month study (for focus group participants only).

Exclusion criteria for CHWs:

There are no exclusion criteria.

5.0 Number of Subjects

The study will include 16 African American adolescents with obesity and their overweight or obese primary caregiver for a total of 32 participants. There will also be 8 social support persons for the 8 families that are assigned to the SS condition.

The study will also include 2 community health workers.

6.0 Setting

Study participants will be recruited through posting flyers in public places located within rural areas in South Carolina that meet the RUCA codes 4-10. Potential study participants will contact the study PI with any questions about the study.

The entire study will be conducted on the virtual platform, including the focus groups in Aim 2. CHW training will be conducted at the offices of the Division of Global and Community Health at the Medical University of South Carolina in Charleston, SC.

7.0 Recruitment Methods

Caregivers and Adolescents:

The research recruitment team will consist of one research assistant and the project manager (Powell). Caregivers and adolescents will be recruited through flyers advertising the study in community spaces (i.e., churches, schools, workout centers, community centers) in South Carolina communities that meet the RUCA 4 – 10 inclusion criteria. The recruitment flyer will contain a QR code which can be scanned by the potential participant on their mobile phone. The QR code will link the potential participant to a web-based pre-screen tool which contains a self-report of height and weight, gender, and age for the adolescent and for the caregiver. Additionally, there will be a statement that asks the following: "Are you the parent, legal guardian, or primary caregiver of an African American adolescent (age 12 – 17) that you think is overweight and/or obese?" Once this information is entered, a calculation of BMI is automatically conducted and the value is compared to the ≥90 percentile benchmark for the given data. If the adolescent meets the ≥90 percentile for their respective gender and age and the caregiver's BMI is ≥25.0, a message will be shown stating "You may be eligible for this study! Would you like to be contacted to find out more about enrolling in this study?" If the participant agrees then they will be prompted to enter their year of birth (to confirm that the individual indicating a desire to be contacted is the caregiver and not the adolescent), a contact phone number, a best time for contact, and caregiver name. The adolescent will not be permitted to enter contact information or request to be contacted

without the caregiver. If the potential participant responds that they are not the caregiver of a qualifying child or the BMI percentile is outside the included range for the study, then the potential participant will receive a message: “You are not eligible for this study but thank you for your interest.”

The respondents to the flyer and pre-screen tool that meet the study criteria and desire to be contacted will then be contacted by phone by the research assistant using the preferred time given. The research assistant will then confirm the participants’ height, weight, age, and gender entries for the BMI calculation. Additionally, the research assistant will ask the participant for their home address which will be entered into the “Am I Rural” online screening tool to determine the RUCA code at the participant’s zip code of residence. After confirming the address, BMI for adolescent, and overweight/obese status of the caregiver, the research assistant will confirm the availability of compatible mobile devices and a negative pregnancy status. If all criteria are met, the research assistant will ask the participant if they are interested in enrolling in the study, at which point they will be transitioned to the consenting process (below).

Community Health Workers:
All Community Health Workers hired to deliver the study intervention will be asked to participate in the study by a non-supervisor research team member.

8.0 Consent Process

Caregivers and Adolescents
If the adolescent and caregiver meet eligibility requirements and the caregiver and youth are interested, the research assistant (RA) will conduct a consent appointment by phone, either by continuing the eligibility call or scheduling another time to contact the caregiver and youth. The consent appointment may also take place via Microsoft Teams. During the consent session with both the caregiver and youth present, the RA will explain the purpose of the research, the nature of the study, potential benefits and risks, the voluntary nature of participation, and the data collection procedures to caregivers and the youth. Caregivers will provide consent and youth will provide assent by signing the informed consent document if they both agree to participation in the study. The RA conducting the consent session will document the consent process on a study participant contact log.

Youth who turn 18 during the course of the study will be re-consented on the Young Adult consent document.

Families will be sent a link to the consent form by email and will sign the form electronically via REDCap. Upon completion the REDCap platform will retain a signed copy of the consent form. A signed copy will be emailed to the family for their records.

Changes in Primary Caregiver
In the event that the youth experiences a change in his/her primary caregiver during the course of the study, a RA will screen the new caregiver to determine caregiver eligibility. If the caregiver is eligible and interested in participating in the study, a new consent form will be signed by the youth and the new caregiver. If the new caregiver is not eligible and/or not interested in participating in the study but agrees for the youth to continue participation, we will collect signatures from the caregiver and youth on a new consent form.

Community Health Workers:
Community Health Workers (CHWs) will be asked to participate in the study by participating in the focus group. This data will be used to help improve the DWN-FIT Families intervention and application in the future. We are requesting a waiver of consent for this aspect of the study. Dr. Jordon Gilmore, a non-MUSC project investigator, who is not the CHWs’ supervisor will describe the purpose of the study, focus group, emphasize the voluntary nature of the information requested, and indicate that the CHW can terminate participation in the focus group or decline to answer any of the assessment questions at any time. Confidentiality of the information they provide will also be emphasized.

Social Support Persons:

We are also requesting a Waiver of Consent for individuals requested to be social support persons for families randomly assigned to the DWN-FIT-SS condition. Social support persons will participate in the focus group and provide encouraging messages to the caregiver and adolescent as they progress through the treatment. The research assistant will schedule a time to meet with the social support person by phone or Microsoft Teams. At the appointment, the research assistant will describe the purpose of the study, focus group, emphasize the voluntary nature of the information requested, and indicate that the participant can terminate participation in the focus group or decline to answer any of the assessment questions at any time. Confidentiality of the information they provide will also be emphasized.

Justification of Waivers of Consent
We are requesting waivers of consent for the CHWs and Social Support Persons. The only data collected from these participants will be demographics data and DWN app feedback in the focus group.

9.0 Study Design / Methods

Study participation will last 3 months. Families who consent to participate will be instructed to download the DWN app and compete a demographics survey. The research assistant will schedule the first session with the CHW and mail the weight scale, yoga mat, resistance bands, and Fitbit Inspire 3s to the family. Families will be randomly assigned to one of two intervention groups: the DWN-FIT or the DWN-FIT_Social Support (SS) group. CHWs will meet with families once a week for 3 months via video chat interface on the DWN-FIT app. The sessions will last approximately 45-minutes to 1 hour and will include: 1) review of SM goals; 2) review of PA steps and calories burned; 3) goal setting based on assessments and learning modules; and 4) review of CBST learning modules using evidence-based steps for skill acquisition (discussion of rationale, modeling of skill, caregiver and AAAO behavioral rehearsal of skill, feedback), and caregiver and AAAO develop implementation plans for between session skills practice.

We will also conduct a focus group with the participants after W12 of the study. These 17 focus groups (16 with participants and support person and 1 with all CHWs) will be guided by the responses to the needs analysis and usability evaluation; however, the questions will be open-ended to encourage discussions to obtain a fuller understanding of their personal experiences using the DWN. We will subsequently transcribe the audio recordings and group the data based on the discussion questions. Then, we will use either an inductive thematic analysis or a bottom-up technique to identify themes or recurring patterns in the responses. Caregivers, AAAOs, Supporters, and CHWs will be compensated $195.55 for participating in a focus group.

Aim 1: Feasibility Testing. Evaluate the DWN-FIT intervention (delivered by 2 CHWs) with 16 families (AAAO and caregiver, overweight or obese) undergoing treatment for adolescent obesity to determine the degree to which the components of the digital intervention are correlated with adolescent-caregiver engagement in healthy behaviors and adherence to the prescribed treatment. Additionally, we will determine the degree to which SS, as an additional element of DWN-FIT, enhances engagement and retention of families within treatment.

Methods: This aim follows two conditions (DWN-FIT vs DWN-FIT_Social Support [SS]) x 4 time (T0: baseline, T1: 1-month follow-up, T2: 2-month follow-up, and T3: 3-month end of treatment), with random assignment of 16 families (caregivers/AAAO) to one of the two treatment conditions. The proposed 3-month treatment period is too short to assess the feasibility of this digital treatment with respect to weight loss measurements (secondary outcomes), so instead we will assess feasibility of this approach based on the development of healthy behaviors (primary outcomes) that have been shown to lead to sustainable weight loss over time. Primary outcomes will be measured after each session (weekly) through the data recorded by the DWN app. These primary measures consist of the following measurements via the DWN app: step count, PA and PA video views, frequency and consistency of nutrition SM, messaging read and response rates, frequency and consistency of CBST education participation, telehealth session attendance, and CM rewards. In both treatment conditions, we will determine correlation between these measures and our measures of engagement and adherence. We will also determine the effect of semi-automated SS on each of the measures by comparing outcomes from each treatment group (DWN-FIT vs DWN-FIT_SS). Caregiver and AAAO percent

overweight and body-mass index (BMI) will serve as secondary outcome measures and will be collected each week via a provided digital scale. These secondary outcomes will be used to build preliminary data for a future full time-course (6-month or greater) randomized clinical trial (RCT).

Measures: We will measure ***engagement*** through the delivery of the 9-item Patient Health Engagement (PHE)[48] survey. The PHE is used to determine the degree to which patients are engaged in their own health and describes the patient's ability to manage their own health. PHE has been validated in other work, but a sample size large enough to meet this threshold is outside the scope of this study. The PHE outcomes gathered here will be used as preliminary data for future studies. The PHE survey will be taken via the DWN app at each time point, T0-T3. We will measure ***adherence*** through comparing the prescribed tasks against the task completed, raw counts (video views, SM entries, PA participation), by each set of participants. We will explore how SS is correlated with adherence to the prescribed treatment.

Aim 2: Patient Centered Evaluation. Conduct a needs analysis before the intervention, a usability evaluation during the intervention and focus groups with participants after the intervention to determine if DWN met their needs for accessing (participants), delivering (CHWs), and providing support during the treatment.

Needs Analysis: We will develop a pre-survey (at T0 guided by Dr. Naar) consisting of a set of qualitative questions that determine the participants' goals and needs related to accessing, delivering, and providing support during the treatment**.** After completion of the intervention (T3), we will conduct a post-survey to determine if DWN-FIT met their needs and goals. Using responses from these two surveys, we will perform an inductive thematic analysis or a bottom-up technique to identify themes or recurring patterns in participants' responses**.**

Usability Evaluation: We will deliver a usability assessment via the System Usability Scale (SUS)[49] assessment that will be delivered to the participants at the midpoint of the intervention; it will focus on the efficiency and effectiveness of accessing, delivering, and providing support during the treatment including such topics such as readability, technology literacy, and interface design.

Construct	Measure / Items	Informant / Data Source	When Completed*													
			0	1	2	3	4	5	6	7	8	9	10	11	12	13-16
Eligibility/Screening Criteria																
%Overweight	• Body Mass Index (BMI; height and weight measurements)	Youth & CGs	✓													
Primary Outcome Measure																
% Body Fat	• Bioelectrical impedance analysis (BIA)	Youth & CGs		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Secondary Outcome Measure																
Physical Activity (PA)	• Fitbit Inspire 2 accelerometer	Youth & CGs		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• Fitbit data	Youth & CG Fitbit		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Self-Monitoring of Dietary Intake	• Food/Beverage Log	Youth & CGs		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Clinical Note	• Meeting participants	CHW		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• Meeting Duration	CHW		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• Learning module content review	CHW		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• % body fat	CHW		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• Pregnancy screening question	CHW		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• General notes	CHW		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Daily Activity Summary	• Food Log Completion	Youth & CGs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• Number of Steps Taken	Youth & CGs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• Number of calories burned	Youth & CGs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• Time spent on learning modules	Youth & CGs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	• Messaging	Youth & CGs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Patient Engagement	• Patient Health Engagement (PHE) Survey	Youth & CGs		✓				✓				✓				✓
Eligibility	• Pregnancy (asked by CHW)	Youth & CGs		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Demographics	• Family Information Form	Youth, CGs, CHWs	✓													
Qualitative Interview (Focus Groups)	• Gather information on experiences with research and treatment procedures	Youth, CGs, CHWs														✓
Other Measures:																
Mid-Treatment Usability Study	System Usability Scale (SUS) Questionnaire	Youth, CGs, CHWs							✓							
Needs Assessment	Application Needs Pre-Assessment	Youth, CGs, CHWs	✓													
	Application Needs Post-Assessment	Youth, CGs, CHWs													✓	

10.0 Data Management

All data will be safeguarded for confidentiality. Families will be assigned an unique identifier (UID) immediately following enrollment into the study. All sources of data will only have reference to the UID number. A file will also be created that links participants to their UID number. This file, consent and assent documents, screening documents, and de-identified data will all be kept in separate, locked file cabinets in the offices of the RAs at the Medical University of South Carolina in the Division of Global and Community Health (MUSC-GCH). Only study research personnel will have access to data that links research data to participant identifiers during the course of the trial.

Data Analysis Strategy

We will utilize a Pearson correlation coefficient (range -1 to 1) to determine the degree of correlation between components of DWN-FIT and engagement and adherence. Each measure will be quantized into a numerical value that can be used to generate the correlation coefficient. To compare the effect of SS on treatment outcomes we will use an independent two-sample t-test ($\alpha = 0.05$) to determine statistical differences between measures such as step count, PA, SM, etc. with respect to treatment condition.

11.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

The PI will ensure that the trial is conducted according to the approved IRB protocol and will also be responsible for carrying out the data and safety monitoring plan. Basic demographic data about the participants will be collected to ensure they meet the inclusion/exclusion criteria of the study. Data elements collected on paper records will be de-identified to protect study participants' names and identifiers and will be stored in a secure locked cabinet at the RA's MUSC office. The audio recordings from the family sessions and focus groups along with the mobile app chat messages will be downloaded and stored on Box, a HIPAA compliant and MUSC approved protected Cloud Storage System. There is no risk involved in storing the paper records and audio recordings. There is a greater risk storing the data digitally, but we have taken the following steps described in the next paragraph to ensure privacy and security.

After enrolling in the study and finishing the consent process the adolescent, caregiver and support person will be granted access to DWN by a Community Health Worker (CHW). DWN platform is secure and private. Individuals can only use the DWN app through a patient identification (ID) number, a random 9-digit code assigned to them by their CHW. This ID is emailed to the patient along with a link to download the app from the app store. The patient uses the code to register when using the app for the first time. During registration the patient also creates a 6-digit pin, which they use to open the DWN mobile app in order to sign in. This 6-digit pin means the app is password protected. The information transmitted from the app to the cloud is encrypted. The data is also encrypted on the phone and in the cloud database. We have also taken extra precautions in protecting the privacy of the patient by choosing not to store any identifiable information in the same database as health data collected (health and usability assessment responses, wearable data from physical activity, and body fat), meaning the health data in the cloud are associated only with the random patient ID. The patients' names and emails are stored in a file location accessible only by the healthcare provider and senior personnel conducting the study.

Institutional Review Board

Adverse and Serious Adverse Events. Any adverse events (AEs) or serious adverse events (SAEs) that are observed and/or reported will be immediately reported to PI Cunningham. An adverse event is any reaction, side effect or untoward event that occurs during the course of the study. Adverse events are categorized as serious (see below) or non-serious, as related or not related to the study intervention, and as expected or unexpected. For the purpose of the present trial, clinically insignificant events will be excluded from any type of AE documentation. These include colds, flu, cuts, scrapes, coughs, headaches, stomach complaints, general fatigue and mild symptoms. Behavioral AEs that will be tracked in this trial include injury due to physical activity or increases in adolescent behavior problems or family conflict. Serious adverse events (SAEs) are defined as deaths, life-threatening events, permanently or substantially disabling events, congenital anomalies, events

requiring an initial hospitalization or prolonging a current hospitalization, or events that require intervention to prevent permanent impairment or damage. Participants will be screened for AEs and SAEs at each study data collection visit except baseline. AEs and SAEs will be formally elicited at each scheduled data collection point, using an AE Worksheet that will include the expected AEs discussed above and general probes for other physical or behavioral difficulties since the last study contact. AEs that are reported to research staff at times other than those detailed above (e.g. during a phone call to schedule data collection, while working with the computer) will also be recorded and reported as described below. All clinically significant AEs will be categorized as an SAE or non-SAE, as expected or unexpected, and as likely or unlikely to be related to the study treatment by the Co-I or his designate. The Co-I will review all AE reports for concurrence regarding relatedness to the intervention, seriousness, and appropriate resolution. The Co-I or his designate will track all SAEs until resolution has been achieved. All SAEs and AEs will be entered into the study database so that they may be reported to the data and safety monitor. If an SAE is determined to be related to the intervention, then it will be reported to the Data and Safety Monitoring Officer in real time (within 48 hours of occurrence or identification by study personnel).

DSMP Administration

The PI will be responsible for monitoring the safety of this trial, executing the DSMP, and complying with the reporting requirements. Data are randomly inspected weekly and inspected thoroughly on a quarterly basis. All DSMP reports to NIMHD will include a brief description of the trial, baseline sociodemographic characteristics, retention and disposition of study participants, Quality Assurance issues, regulatory issues, AEs and SAEs, and efficacy, as well as any actions or changes with respect to the protocol.

12.0 Risks to Subjects

Risks of participation in the proposed study are considered to be minimal. Two potential risks have been identified as possible outcomes for participants. These risks pertain to (1) embarrassment regarding participation in the study, or (2) distress if personal information obtained during the assessment were released to outside parties. All information obtained from
participants will be confidentially maintained, with only legal obligations to report instances of child abuse and neglect, threat of harm to self or others, as explained in the informed consent, leading to release of participant information to the appropriate authorities.

13.0 Potential Benefits to Subjects or Others

We believe the benefits of our proposed study outweigh the minimal risks associated with participation. This work aims to increase access, adherence and engagement in healthy behaviors for obese African American adolescents. All participants (CHWs, caregivers) will be informed that their data will be used to inform the scientific understanding of within-session therapy processes to improve healthcare outcomes. It is possible that CHWs and caregivers in the proposed study will benefit from providing questionnaire and physiological data, if such activities provide opportunities to reflect upon their treatment experience. Furthermore, this research, if successful, could provide effective, low-cost, automatic, provider fidelity assessment and feedback systems that could be used to transport any evidence-based treatment to real-world underserved racial/ethnic minorities living in under-resourced communities, who seldom receive evidence-based treatments that they so desperately they need.

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