Protocol Synopsis for Research Project Involving Human Subjects

PROTOCOL INFORMATION

Title of Research Activity: Lifestyle Medicine Health Education and Intervention Program "Family Central E-Health".

Name of Principal Investigator: Christina Robinson, MD

Institution: University of North Texas Health Science Center

Names of each Co-Investigator: Maya Nair, PhD (University of North Texas Health Science Center)

Sponsoring Agency / Company (if applicable): Ardmore Institute of Health, NIH

Sponsor's Protocol Number (if applicable): PA-19-053

A. Specific Aims – State the specific scientific objectives of the research.

1) To examine and quantify the improvement in the knowledge, attitudes, and lifestyle behaviors of caregivers (e.g. parents, grandparents, aunts, uncles) of Pediatric Mobile Clinic patients toward the six "Family Central" topics (including Nutrition, Physical Activity, Tobacco Avoidance, Sleep, Stress Management, and Social Connection). The randomized control study will consist of two research arms either a) text message reminders of health education available to participants through the patient portal of the electronic medical record of their child or b) text message briefs about six Family Central topics.

2) To examine and quantify the improvement in five vital signs [including blood pressure, blood glucose, total cholesterol, waist circumference, and body mass index (BMI) of caregivers (e.g. parents, grandparents, aunts, uncles) of Pediatric Mobile Clinic patients at the onset and throughout the "Family Central" program that includes the total period of 6 months.

B. Background and Significance -*Briefly* sketch the background leading to the present proposal. Describe the contributions that the study may make to the health of human beings and/or to the scientific community, using documentation from the literature, where appropriate. Although it is helpful for the Board to have a decent understanding of the basis for conducting a research project, it is *not* necessary to have a full-blown literature review or extensive background and rationale for the proposed research plan of activity.

Worldwide, two-thirds of deaths are attributed to chronic disease such as cardiovascular disease, diabetes, and cancer (WHO, 2012). The situation is the same in the United States, with Americans being even less healthy in terms of chronic disease, when compared to countries of similar income. In fact, chronic conditions related to lifestyle are increasing (Johnston & Moreno, 2014). According to the Centers for Disease Control and Prevention, half of all adults in the United States have one or more

chronic disease, with one quarter of adults having two or more (CDC, 2012). Heart disease and cancer are two lifestyle related chronic diseases that contribute to 46% of all deaths in the United States (CDC, 2012). Additionally, evidence indicates that the root causes of chronic diseases are associated with adverse lifestyle factors that include smoking, physical inactivity, poor diet, stress, negative emotion, etc. (CDC, 2012). New research indicates that children of mothers who have a healthy lifestyle have a much lower risk for obesity compared to children whose mothers do not have healthy lifestyles (Dhana et al, 2018). Conversely, Parental obesity more than doubles the risk of adult obesity among both obese and non-obese children under the age of 10 years old. (Whitaker et al. 1997).

The pattern of chronic disease rates in Tarrant County are like those of the United States and the state of Texas in general. The leading causes of death are heart disease, cancer, and cerebrovascular disease—all of which are related to lifestyle behaviors (Brewer et al., 2012). Prevalence of chronic disease is increasing in Tarrant County, with rates of hypertension, heart disease, and diabetes rising between 2004 and 2009 (Brewer et al., 2012). All three of these diseases disproportionately affect African Americans, who experience much higher rates than any other racial/ethnic group in Tarrant County (Brewer et al., 2012). Tarrant county also has a higher percentage of smokers (18.5%) compared to the rest of Texas (15.8%), further contributing to chronic disease rates (Brewer et al., 2012). Two-thirds of Tarrant County residents are overweight or obese while only one-fourth regularly meet fruit and vegetable consumption recommendations (Brewer et al., 2012). Additionally, less than half meet CDC recommendations for physical activity (Brewer et al., 2012). Although overweight and obesity rates are high among all residents, they are disproportionately higher among racial/ethnic minorities, specifically Hispanic/Latinos and African Americans (Brewer et al., 2012).

With lifestyle behaviors accounting for the leading causes of disease and mortality, it is a necessity to use lifestyle medicine interventions to shape behavioral choices in order to prevent and treat chronic disease while promoting overall health and wellness. Lifestyle Medicine can prevent up to 80 percent of chronic disease (American College of Lifestyle Medicine, 2015). Additionally, lifestyle changes have the potential to reverse existing chronic disease (ACLM, 2015). A recent Lifestyle Medicine study found that health education and promotion of behaviors such as increased fruit and vegetable intake, tobacco cessation, and participation in physical activity have been successful at reducing obesity and preventing related chronic conditions among Hispanic adults (Tucker et al., 2016). For most individuals, reaching a healthy Body Mass Index (BMI) requires not only behavior change, but also social and educational support (Johnston & Moreno, 2014). This can be accomplished through community health promotion efforts aimed at changing behaviors and supporting the target population. Lifestyle interventions have also successfully improved adherence to healthy behaviors and some biometric health markers (e.g. blood pressure) in varying populations, including African-Americans and Hispanic/Latinos (Dickinson et al., 2006; Kent et al., 2015; Pekmezi, Marquez, & Marcus-Blank, 2010; Tucker et al., 2014; Tucker et al., 2016). It is especially important to assist modifying health behaviors in populations of low socioeconomic status and ethnic and racial minority groups who are disproportionately affected by chronic disease such as overweight and obesity, hypertension, heart disease, and diabetes (Tucker et al., 2014; Brewer et al., 2012). Additionally, community health promotion programs help deinstitutionalize healthcare by having medical providers directly in the community and making health promotion more accessible to those who traditionally do not have good access to medical care (Tucker et al., 2014).

The University of North Texas Health Science Center (UNTHSC) Pediatric Mobile Clinic, run by pediatrician Dr. Christina Robinson, currently provides free medical care and vaccines to uninsured children in underserved areas of Fort Worth. The mobile clinic reaches patients who generally do not have good access to care by driving directly to each neighborhood, helping overcome transportation barriers and financial constraints that a traditional medical appointment can cause for low-income

individuals. The families in the neighborhoods served by the Pediatric Mobile Clinic are primarily African American or Hispanic/Latino. The health concerns among mobile clinic families reflect a need for a Lifestyle Medicine intervention to promote healthy eating, physical activity, and other healthy behaviors to prevent and treat disease and promote health among caregivers, thereby improving the health of the entire family.

In collaboration with the lifestyle medicine specialist, the mobile clinic team has planned to conduct a lifestyle medicine oriented mobile clinic health education and intervention program for participant groups which come from current Pediatric Mobile Clinic sites in the following neighborhoods: Morningside (a community in East Fort Worth), Northside (a community in North Fort Worth), and Stop Six (a community in Southeast Fort Worth bordered by Lancaster Street, East Loop 820, and South 287).

The purpose of the present study is to conduct a Lifestyle Medicine oriented E-health education and intervention program to improve lifestyle behaviors among caregivers leading to health promotion and disease prevention regarding the selected six core Lifestyle Medicine topical areas: Nutrition, Physical Activity, Tobacco Avoidance, Sleep, Stress Management, and Social Connection to caregivers of Pediatric Mobile Clinic patients in the Mobile Clinic setting. This research was originally funded by Ardmore Institute, which will be completed in April 2020. The NIH recently awarded funding to support the research as well which will be the main funding source for this study after April 2020. This research is covered by a Certificate of Confidentiality from the National Institutes of Health, which prevents researchers from releasing information, documents, or samples that may identify participants in any action or suit including federal, state, local, civil, criminal, administrative, legislative, or other proceedings.

C. Preliminary Studies - Summarize preliminary studies conducted by the investigator pertinent to this proposal. State "none" if applicable.

For a sense of feasibility, the team conducted a trial of Lifestyle Medicine health education sessions on the six topics to the caregivers at four summer camps in the Stop Six area. Most participants wanted to know their vitals and how those numbers related to their health. Participants were all provided a health education booklet along with guided discussion of the topics. The program was well received by participants, and they voiced a desire for further information on the six Lifestyle Medicine topics.

D. Investigator Experience -Provide a brief synopsis of the principal investigator's expertise, experience, and capability to perform this research. Submit a copy of the curriculum vitae of the principal investigator in IRBNet.

<u>Dr. Christina Robinson: Principal Investigator (Pediatrics)</u>

Dr. Christina Robinson has taken a leadership role in providing health care directly to children in Fort Worth's most underserved communities. As the medical director of the new UNTHSC Pediatric Mobile Clinic, she is helping provide high-quality health care at no cost to families. The overall goal of her work is to improve the health and wellbeing of underserved patient populations and their communities. As the first college graduate and physician in her immediate and extended family, her familiarity with the difficulties that arise from limited resources inspired me to find feasible solutions for underserved patients. Although her ultimate goal was to become a physician, she realized that health is impacted by our culture and community, so she pursed my bachelor's degree in Sociology to help her understand the theoretical basis of culture. Her current work on the UNTHSC Pediatric Mobile Clinic has reinforced for her the interplay of social determinants on health outcomes. This complexity continues to challenge her to advocate for communities that often are forgotten and under-represented in research and policies. Her hope is to discover the bridge between theoretical

solutions and clinical solutions that will transform patient behavior choices and translate to improved health outcomes.

E. Experimental Design and Methods -

Benchmarks	7-15-19 to 8-31-19	12-16-19 to 12-20-19	1-03-20 to 5-15-20	5-16-20 to 6-30-20
Pre-launch	→			
Text message content written	√			
Community resource list complete	√			
Family Central E-health intervention		→	→	
Recruit participants		√	√	
Health status measurements		√	√	
E-health content delivery		√	√	
Post intervention				
Community Celebration with community leaders and participant families				√
Data analysis completed				√
Results reported and published				√

This randomized control study will examine knowledge, attitudes, and healthy lifestyle practices regarding six “Lifestyle Medicine Health Education” topics including Nutrition, Physical Activity, Tobacco Avoidance, Sleep, Stress Management, and Social Connection, among caregivers (e.g. parents, grandparents, aunts, uncles) of Pediatric Mobile Clinic patients. In addition, clinical outcomes such as blood pressure, blood glucose, total cholesterol, waist circumference, and Body Mass Index (BMI) within this population will be assessed; and the study will assess the change in outcomes from baseline to completion of this “Family Central” program. As a contingency plan in light of the disruption recently caused by COVID-19, we will also offer electronic informed consent and HIPPA authorization via DocuSign. Caregivers may request to complete consent procedures using a combination of phone and mail/fax if they have concerns about electronic completion. All potential participants will be offered the opportunity to ask questions via email, phone, or video conference with a member of the research team prior to or after enrollment. After enrollment, we will deliver a scale and a tape measure to the caregiver at the address of their choice. The measurements will be submitted via our text-messaging platform. The caregiver will complete a virtual training on correct measurement of height, weight, and waist circumference. Participants will be stratified to groups based upon enrolling family member’s BMI and child’s BMI measured at the time of randomization. Participants will be assigned into one of two research arms a) the e-health intervention group or b) a control group of usual care. All participants will engage in the study with non-web- based, two-way SMS text messaging via their personal cell phone. Data will not be used to participate. However, SMS text messages will be used. The e-health intervention group will receive health education briefs that will cover all six lifestyle modifications every 6 weeks. Over the 6-month study period, each lifestyle modification topic will be covered 4 times. The usual care group will receive text messages directing caregivers to consult the electronic medical record patient portal of their child, which has a library of health literature, related to lifestyle behaviors, their child’s lab results, and appointment reminders. There is no information about the caregiver listed in the child’s medical record. When caregivers complete the intervention, they will be permitted to keep the tape measure and scale, and will be compensated for their study participation if they join a live or virtual community celebration within 30 days of receiving the celebration invitation. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will

not include identifiable patient information but will include a summary of the results. The research is based on the following hypotheses:

Primary Hypothesis: The participants will improve knowledge, attitudes, and behaviors towards six healthy lifestyle topics (Nutrition, Physical Activity, Tobacco Avoidance, Sleep, Stress Management, and Social Connection) after participating in the e-health "Family Central" program offered by the Pediatric Mobile Clinic.

Secondary Hypothesis: The participants will improve their health status including five vital signs (blood pressure, blood glucose, total cholesterol, waist circumference, and Body Mass Index) after participating in the "Family Central" sessions offered by the Pediatric Mobile Clinic.

1) *Methods and Procedures* - Describe the procedure (s) in sequential detail. Describe the methods. Clearly identify any experimental elements of the study. Include a thorough description of any investigational drugs, therapeutic procedures, monitoring techniques, test procedures or medical devices.

   [The description of investigational medical devices should include information about each important component, ingredient, principle of operation, and anticipated developmental changes in the device. On a separate page, describe and address issues associated with the device presenting "Significant Risk" or "Non-Significant Risk"]

   i. Recruitment

Upon approval by UNTHSC IRB, participants who are the caregivers of patients will be recruited during Pediatric Mobile Clinic patient visits in the communities: Morningside, Northside, and Stop Six. Participants will be recruited by electronic and printed flyers posted on the website for UNTHSC Pediatric Mobile Clinic and forwarded to community partners of the Pediatric Mobile Clinic for public posting. The study team will recruit participants individually when caregivers accompany pediatric patients to the mobile clinic during regularly scheduled clinic days in these communities or contact the Pediatric Mobile Clinic research team. The caregivers will receive an explanation about the study while they are registering their child for a clinic visit or as a follow-up call to a participant initiated message. If the caregiver is interested, they will be able to complete a pre-screening form for themselves. Inclusion criteria are family member has a child who is a current or former patient of Pediatric Mobile Clinic with a medical diagnosis of overweight/obese, defined as BMI percentile of 85% or above, age of the child is 6 months to 11 years old, family member is a primary caregiver to the child, family member over the age of 18 years, family member is not currently pregnant, and family member has a cell phone with SMS text message capability. Exclusion criteria is family member has a terminal illness. Once the form is completed if the caregiver meets the inclusion criteria, the caregiver will receive an informed consent form. The research team will use a stratified randomization method to enroll eligible participants into the study. Participants will be stratified to research arms based upon enrolling family member's BMI and child's BMI measured at the time of randomization. Only the study team will recruit potential study participants during regular clinical care or follow-up calls from participant initiated inquiries. Recruitment will continue at each of the selected clinic sites until a 71 caregivers per research arm are included in the program, which will take approximately 6 weeks based on the previous experience of the number of caregiver clinic visits per clinic day. The study closure will be marked by a live or virtual community celebration. Community partners have served as a platform currently with the Pediatric Mobile Clinic over 4 years to inform families of the resource available to them through the Pediatric Mobile Clinic. The community partners will continue to refer pediatric patients and their caregivers to the services provided by the Pediatric Mobile Clinic and will not provide any information to caregivers regarding the research study but may post or distribute the research flyer to allow families to contact the Pediatric Mobile Clinic directly. No recruitment will occur at the community celebration event. The recruitment materials used in this study will be the study flyer.

ii. Participant Informed Consent Form

During the recruitment period, each participant who met the inclusion criteria will be provided with the consent letter to read and the Research Assistant will read in English to help the participants achieve full understanding. The consent form and HIPPA form will outline the benefits and any potential risks that may ensue because of taking part in the study. Once the participants have had the opportunity to read and understand the forms and ask questions to the research team, the participants who agree to be in this study by completing the informed consent form and HIPPA form will then be enrolled in the "E-health Family Central" program. Participants will be instructed to follow-up with their primary care providers if their clinical tests are cause for concern.

iii. Instrumentation

Surveys will be the key instrument in this study to assess health knowledge, attitudes, and behaviors toward the selected six topics. The surveys are adopted from the American College of Lifestyle Medicine (ACLM, 2015). Surveys will also contain questions to assess demographic characteristics (e.g. gender, race, zip code). The instruments will be prepared in English. Clinical outcomes that will be measured include blood pressure, height, weight, Body Mass Index (BMI), waist circumference, total cholesterol, and blood glucose tests will be measured. In the event that study procedures will move to virtual settings, participants will provide their self-report of most recent blood pressure, total cholesterol, and blood glucose test if known. Participants will not be excluded if they are unable to provide a historical blood pressure, total cholesterol, or blood glucose test result. BMI will be calculated as (kg/m2).

iv. Data Collection

As to the survey of knowledge, attitudes, and behaviors, at enrollment (baseline), the participants will be asked to complete self-administered questionnaire regarding the six healthy lifestyles. Then, during the six-month intervention, participants will receive text messages at intervals set by their preference but at least 2 times per week to ensure adequate space for education delivery and assessment through Likert scale text message surveys relating to Lifestyle Health Education. As to the clinical outcomes, self-reported blood pressure, blood glucose, total cholesterol, waist circumference, and body mass index (BMI) will be collected from the participants at enrollment and at the live or virtual community celebration at the close of "E-health Family Central". The study will occur from June 2020 to December 2020. There will be no monthly meetings or sessions. All information is relayed electronically.

2) *Data Analysis and Data Monitoring* - Describe plans for statistical analysis of data when appropriate. If a data safety monitoring committee is appropriate to protect the safety and/or welfare of subjects, describe its operation (e.g., membership, stopping rules and frequency of review).

Data will be analyzed using SAS 9.4 for Windows. To examine the equality of the two groups, baseline sociodemographic and clinical variables will be compared using chi-square or t-tests depending on the level of measurement. Randomization should ensure equal distribution between the two groups of potentially confounding characteristics. However, baseline variables will be used as factors or covariates as appropriate in subsequent analyses. Descriptive statistics (mean ± SD, median with interquartile range or percentage) will be reported to characterize changes in the variables. The statistical analysis will be based on the outcomes, percent change in attitude/knowledge, over the study period. The general method entails an initial analysis that will employ the t-test (or Wilcoxon rank

sum test if non-normality is observed) to compare the outcomes between the two groups. Next, univariate linear regression models will be constructed for each outcome examining the effects of any variable observed to be different between the two groups at baseline. Subsequent analyses of the outcomes on the differences between time points (baseline to 6 months, baseline to 12 months), will involve multiple linear regression, in which the primary predictor variable is group, and any of the factors found to be significant in the univariate regressions, and potential interactions. Finally, longitudinal data analysis will be performed on each outcome using generalized linear equations. This analysis will measure changes over time (baseline, 6 months and 12 months) between the two groups. Comparisons will be made, using this model, between different time points within each group as well as between the two groups. This analysis will be able to identify at which point, if any, the break in improvement between the two groups occurs. This approach will apply to all hypotheses since in each the outcome is a continuous variable.

a. Power Analysis

Due to the complexity involved in power calculations for mixed models, sample size calculations are based on a linear model assumption. Using G-Power Sample Size Calculator, with an assumption of a conservative effect size (f) of 0.15, a power of 0.8 for testing the hypothesis of whether there is an effect of the intervention at α=0.05, we will need a sample size of at least 55 participants in the study. If we increase our power to 0.9, we would need a minimum of 73 participants.

3) *Data Storage and Confidentiality* – Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism, which will prevent unauthorized access to data. State who will have access to the data. If data with subject identifiers will be released, specify the person (s) or agency to whom the information will be released and the purpose of the release.

All study-related materials and documentation will only be accessible to the study personnel. Completed questionnaires will be placed into locked file cabinets in the office of the PI. Clinical outcomes recorded through a shared Microsoft excel drive will only be accessible to key study personnel. Although there is a potential risk for breach of confidentiality, all study personnel will be trained in accordance to Health Insurance Portability and Accountability Act of 1996 (HIPAA) to maintain privacy and confidentiality as completely as possible to prevent this occurrence. Data from the Pre-Screening form will be kept securely and data for those potential participants that were not eligible will be securely destroyed per all federal and institutional policies/guidelines. Research data, in hard copy or electronic form (CDs, DVDs, digital or magnetic tape, hard-drives, flash-memory drives, etc.) will be stored and managed in a secure manner following federal guidelines and according to state and institutional policies and practices. Further, research documents including electronic documents containing subject data, identifiers and linked data will be securely stored in locked containers (file cabinets, lockers, drawers, etc.) in accordance with standard document management practices. At all times, only listed key personnel specifically designated and authorized by the Principal Investigator shall have access to any research related documents. All such personnel will be properly trained and supervised regarding the management and handling of confidential materials. The Principal Investigator assumes full responsibility for such training, supervision, and conduct.

4) *Setting* - Describe briefly where the study will be conducted, e.g., private outpatient clinics, physicians' offices.

The study will be conducted through the Pediatric Mobile Clinic during visits to community sites in

Fort Worth: Morningside, North Side, and Stop Six or virtually through contact with the Pediatric Mobile Clinic research team.

NOTE: If other institutional review committees (IRBs) or approvals are required, note them by name, affiliation and contact person. Also, be aware that the approval of other institutions' IRBs must be obtained before initiation of the project (but are not essential for North Texas Regional IRB *review* to begin).

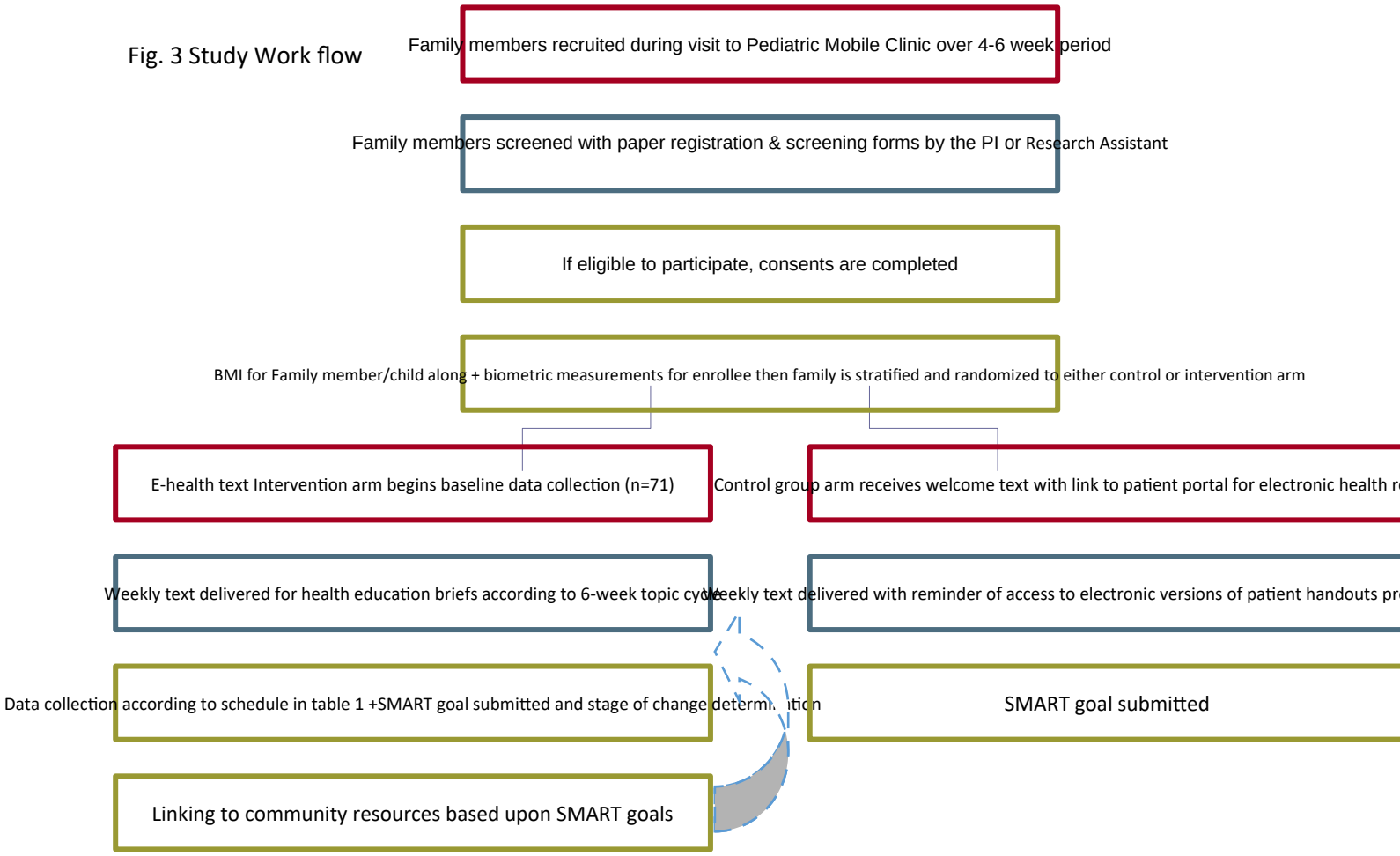
5) *Laboratory methods and facilities* - Indicate where specific laboratory tests will be performed; e.g., hospital chemistry laboratory, investigators' laboratory, radiology clinic, etc. If None, state N/A

Participants will self-report historical blood sugar and total cholesterol testing.

6) *Estimated Period of Time to Complete the Study* – Describe the stages and total time of subject participation as well as overall time for the entire study (start to completion). Also, if study involves more than one visit, describe time range estimates for each visit (e.g., 20-30 minutes; 2 – 3 hrs, etc.). Where possible, use a table or "bullet-point" format to clearly illustrate the flow of activities and procedures.

The study will consist of one recruitment/enrollment 20-30-minute visit, one group meeting lasting 60 minutes to close the study, and 6 months of text message briefs on either 1) health education available to through the patient portal of the electronic medical record for their child or 2) six topics: nutrition, physical activity, sleep, tobacco avoidance, stress management, and social connection. Each week participants will receive text messages at intervals set by participants' preference but at least 2 times per week to include survey assessment and delivery of health lifestyle education briefs. The 6-month study will start upon receiving the IRB approval, followed by a few months of data analysis and management as well as organizing and publishing the results.

Fig. 3 Study Work flow



F. Human Subjects - Describe the characteristics of the research population:

1) *Sample Size*: Number of subjects to be enrolled in this study at this site. Approximately _142_ subjects at _3 community___ sites in Fort Worth will be enrolled in the study overall.

2) Describe both *Inclusion AND Exclusion Criteria*. BE SPECIFIC! Also, if children (persons under age 18) are excluded from this study provide scientific justification for such exclusion. Include physical, mental, cognitive, medical, and other relevant Inclusion and Exclusion criteria.

Self-selection approach will be used to recruit the participants in the study based on the following criteria 1) Adults aged 18 years and over; and 2) Primary caregiver of previous or current Pediatric Mobile Clinic patient with a medical diagnosis of overweight/obese, defined as BMI percentile of 85% or above 3) Age of child is 6 months to 11 years old.

The exclusion criteria will be 1) individuals who are younger than 18 years of age; 2) Individuals who are not caregivers of a previous or current Pediatric Mobile Clinic patient; 3) Individuals with severe or terminal illness; 4) non-English speaking individuals 5) Women who are pregnant

3) Describe intended *gender, age range, intended racial and ethnic distribution*. If any vulnerable subjects are involved in this study (e.g., those with limited autonomy or decision-making capabilities), justification must be provided.

No vulnerable subjects will be recruited. Adults aged 18 years and over. Participants will most likely

be racial/ethnic minorities, but that is not a requirement.

4) Identify the *source(s) from which you will obtain your study population*.

The source population comes from caregivers (parents, grandparents, etc.) of previous or current Pediatric Mobile Clinic patients.

5) Describe plans for *recruitment of subjects*. All materials (e.g., flyers, ads, emails, letters, postings, handouts, etc.) to be used for recruiting subjects must be submitted to the IRB for review.

Participants will be recruited individually among the caregivers of pediatric patients from the mobile clinic during regularly scheduled clinic days or through virtual participant initiated contact with the Pediatric Mobile Clinic research team from distributed research flyers, which will lead to verbal introduction of the research project and provision of the pre-screening form.

G. Risk/Benefit Assessment

1) Describe the *level of risk*, and if more than minimal, describe how this research holds the prospect of a *direct benefit for the subjects*. If there is NO direct benefit to subjects, state such in protocol and in the consent documents.

Risk is minimal and may include finger prick lab testing while enrolling in “Family Central” and the survey administration. Subjects may decline the testing or forfeit their survey responses at any time. All participants will engage in the study with non-web- based, two-way SMS text messaging via their personal cell phone. Data will not be used to participate. However, SMS text messages will be used and participants will be responsible for any SMS text message charges with their phone carrier. Participants are encouraged to contact the researchers if they feel any discomfort during the health education and survey process. Furthermore, all staff will be adequately trained to ensure the participants’ privacy and confidentiality and has undergone CITI training.

2) Describe how the anticipated benefit justifies the risk.

The possible benefits of the study are participants may learn more about healthy eating, improved physical activity, limiting or avoiding tobacco intake, improved sleep patterns, adequate stress management, and better social connection, which can improve the overall health of the study participant. Receipt of lab values is also a potential benefit for study participants.

3) Describe how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects.

The possible benefits of the study are that participants will learn their cardiovascular and diabetic health risks. Lastly, participants will learn of community resources that can support healthful living.

4) Describe any potential RISKS OR DISCOMFORTS in detail. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Indicate the methods for detecting adverse reactions. Describe the procedures for protecting against or minimizing potential risks (e.g., confidentiality, reputational injury, direct injury or harm to subject, etc.) and assess their effectiveness. Discuss why the risks to the subjects are reasonable in relation to proposed benefits to humanity. Be sure to describe any anticipated adverse events that might occur during the course of the study.

All study-related materials and documentation will only be accessible to the study personnel.

Completed questionnaires will be placed into locked file cabinets in the office of the PI. Clinical outcomes recorded through a shared Microsoft excel drive will only be accessible to key study personnel. Although there is a potential risk for breach of confidentiality, all study personnel will be trained in accordance to Health Insurance Portability and Accountability Act of 1996 (HIPAA) to maintain privacy and confidentiality as completely as possible to prevent this occurrence.

Risks may include finger prick lab testing while attending "Family Central" and the survey administration. Subjects may decline the testing or forfeit their survey responses at any time. Participants are encouraged to contact the researchers if they feel any discomfort during the health education and survey process. Furthermore, all staff will be adequately trained to ensure the participants' privacy and confidentiality.

H. Payment/Compensation - Describe any financial payments for subject participation (e.g. compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Recall that payments cannot be perceived as coercive (overpayment for time and effort). Remember: payments are NOT benefits.

Grocery tote bags will be provided to participants enrolling in person. Weight scales and tape measures will be provided to all participants. Each participant will be compensated $25 for participation in all study components: enrollment, study intervention, and closing live or virtual community celebration.

I. Subject Costs - Describe any anticipated costs to research subject. If none, state such.

None

J. List of KEY PERSONNEL. List all individuals directly involved in the conduct, design or reporting of research involving human subjects in this study, including anyone who may be consenting subjects. This list will include the Principal Investigator, Co-Investigators, collaborating investigators, study coordinators, etc.

PI – Dr. Christina Robinson will be backup study team member to perform a finger prick using lancets to draw blood for point of care testing of glucose and cholesterol testing.
Co-I – Dr. Maya Nair provided Lifestyle Medicine Education brief content for text messages.
Collaborator – Debbie Gillespie will advise Lifestyle Medicine content for health education sessions.
Nurse – Connie Smith, LVN will perform a finger prick using lancets to draw blood for point of care testing of glucose and cholesterol testing.
Study Coordinator-Joseph Wascomb, participant recruitment
Data analysis and Data collection- Laura Kade, Rebecca McDonald, Benjamin Trammell, Michael Kranz, Makenzie Bender, Debini Banh, Aimee Lopez, Fatima Abed, Sheena Ghalla, Jenny Thai, Kavita Patel, and Rumaila Hussain will assist

Study coordinator – Joanna Garcia, MPH will coordinate IRB submission and offer administrative support for research study team.
Biostatistician: Andrew Yockey, PhD

K. Literature Cited – If any, the references should be limited to relevant and current literature pertinent to the proposed research.

American College of Lifestyle Medicine (ACLM). 2015. What is Lifestyle Medicine?. Retrieved from https://www.lifestylemedicine.org/about

Brewer, L.K. Moerbe, M.M., Janoski, N., Markham, M.S., Izaguirre, L., Kurian, A.K. (2012). Community health profile Tarrant County, 2005-2010. Retrieved from http://access.tarrantcounty.com/content/dam/main/publichealth/PH%20DOCUMENTS/Epi/Community%20Assessments/TCCH_Profile_2005-2010.pdf

Centers for Disease Control and Prevention. (2012). Preventing chronic disease: Eliminating the leading preventable causes of premature death and disability in the United States. Retrieved from https://www.cdc.gov/chronicdisease/pdf/Preventing-Chronic-Disease-508.pdf

Dhana, K., Haines, J., Liu, G., Zhang, C., Wang, X., Field, A. E., & Sun, Q. (2018). Association between maternal adherence to healthy lifestyle practices and risk of obesity in offspring: results from two prospective cohort studies of mother-child pairs in the United States. BMJ, 362, k2486.

Dickinson, H. O., Mason, J. M., Nicolson, D. J., Campbell, F., Beyer, F. R., Cook, J. V., & Ford, G. A. (2006). Lifestyle interventions to reduce raised blood pressure: a systematic review of randomized controlled trials. Journal of hypertension, 24(2), 215-233.

Johnston, C. A., & Moreno, J. P. (2014). Promotion of Long-Term Adherence to a Healthy Lifestyle. American Journal of Lifestyle Medicine, 8(4), 239-241.
Kent, L. M., Morton, D. P., Rankin, P. M., Gobble, J. E., & Diehl, H. A. (2015). Gender differences in effectiveness of the Complete Health Improvement Program (CHIP). Journal of nutrition education and behavior, 47(1), 44-52.

Pekmezi, D., Marquez, B., & Marcus-Blank, J. (2010). Health promotion in Latinos. American Journal of Lifestyle Medicine, 4(2), 151-165.

Tucker, C. M., Butler, A., Kaye, L. B., Nolan, S. E., Flenar, D. J., Marsiske, M., & Daly, K. (2014). Impact of a culturally sensitive health self-empowerment workshop series on health behaviors/lifestyles, body mass index, and blood pressure of culturally diverse overweight/obese adults. American journal of lifestyle medicine, 8(2), 122-132.

Tucker, C. M., Smith, T. M., Wippold, G. M., Whitehead, N. E., Morrissette, T. A., Williams, J. L., ... & Crosier, B. S. (2016). Impact of a University-Community Partnership Approach to Improving Health Behaviors and Outcomes Among Overweight/Obese Hispanic Adults. American Journal of Lifestyle Medicine, 11(6), 479-488.

Whitaker, R. C., J. A. Wright, M. S. Pepe, K. D. Seidel, and W. H. Dietz. 1997. 'Predicting obesity in young adulthood from childhood and parental obesity', New England Journal of Medicine, 337: 869-73.

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