Mobile Integrated Care for Childhood Obesity

Study Proposal

NCT05936385

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RESEARCH STRATEGY

A. SIGNIFICANCE

A.1 BACKGROUND

Obesity is a significant public health problem affecting nearly 1 in 5 children in this country. Children of racial and ethnic minority groups, of low socioeconomic status, and living in rural communities continue to have the highest rates of obesity.[1-3] Obesity increases a child's risk for health conditions, including diabetes, cardiovascular disease, pulmonary disease, and orthopedic problems.[4-5] Children with obesity are at increased risk for mental health problems and experience reduced quality of life[6-7] and obesity in adulthood, all contributing to significant healthcare utilization and costs.[4-5]

Lifestyle behavior interventions are the cornerstone of treatment for childhood obesity, but this approach only addresses one aspect of this complex condition. Family, community, and sociodemographic factors are equally important to address.[17] Families from rural and underserved communities experience barriers to engaging in healthy lifestyle behaviors, including challenges affording and accessing nutritious food, lack of safe opportunities and spaces for physical activity, and stressed home environments and also may have difficulties accessing obesity interventions due to transportation obstacles, time and competing priorities, or reduced access to healthcare generally.[8-22] Failing to adequately target these barriers may help to explain why obesity interventions have not been as successful in these populations, exacerbating existing disparities.[8-10]

Dietz and colleagues have a framework that emphasizes the need to integrate community systems with healthcare delivery to improve obesity care and reduce disparities (Figure 2).[27] Within this framework, community systems provide resources to facilitate healthy behaviors and healthcare systems provide multidisciplinary care, leveraging information technology to support clinical decision-making and facilitate self-management. These systems inform and interact with one another, leading to productive interactions between families and healthcare providers, a supportive community environment, and tools for self-management to engage and empower families.

A.2 RIGOR OF PRIOR RESEARCH

Previous studies evaluating integrated interventions to address obesity have gaps in approach, including inattention to psychosocial determinants, lack of robust community engagement, and failure to target rural populations. Taveras et al. conducted a study enhancing primary care management of children with obesity at six primary care sites in Massachusetts using a neighborhood resource guide to community-based lifestyle programs and text messaging to support lifestyle behavior change.[33] Armstrong et al. combined physical activity opportunities through recreational facilities in North Carolina with multidisciplinary obesity treatment.[34] Families in both studies reported improved health behaviors, but effects on weight were small or non-significant. These studies did not address psychosocial determinants of obesity or engage communities beyond referral to community-based lifestyle programs. Scientific mentorship team member Eneli has established the Primary Care Obesity Network in Ohio, a model for integrating obesity care into the medical home and creating patient-centered neighborhoods.[35] Children who received integrated obesity care through the network demonstrated successful weight outcomes, but there were challenges in sustaining aspects of the network, underscoring the importance of engaging families, practices, and communities in developing and sustaining integrated care systems.

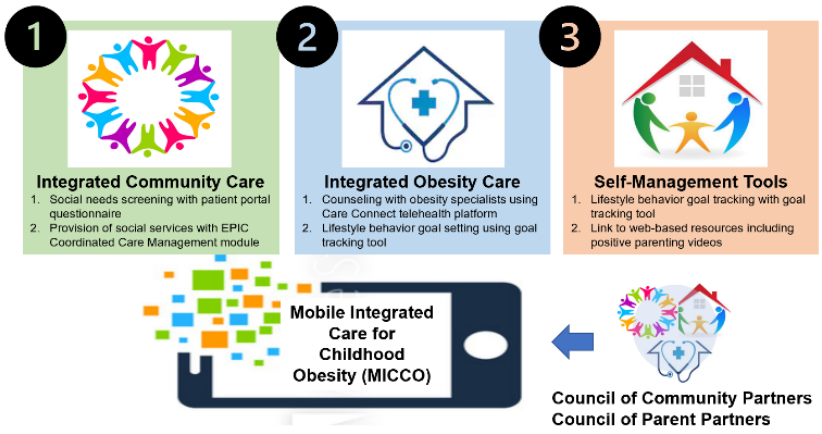
A.3 PRELIMINARY WORK

Our research team has demonstrated the importance of addressing psychosocial determinants of health among families of children with obesity. The research project leader's (RPL) Academic Pediatric Association Research in Academic Pediatrics Initiative on Diversity Award study of children ages 4-12 years seeking treatment in the Nemours Weight Management Clinic found that families with moderate-high psychosocial risk, especially related to financial difficulties and caregiver and child mental health problems, were three times more likely to be lost to follow-up or not have a meaningful decrease in weight. Families who received psychological counseling were twice as likely to remain in obesity treatment.[11] Analyzing data on >7000 children in the National Health and Nutrition Examination Survey database, we found that children with severe obesity were two times more likely to be of a racial or ethnic minority backgrounds, from single-parent households, or from households experiencing poverty.[3] Finally, in a survey of over 200 families of overweight children under age 5 from a Nemours primary care clinic, 85% endorsed one or more psychosocial needs.[21] Our qualitative research,[22] coupled with work by the Nemours Value Based Services Organization with 450 families across Delaware, led to the development of a 13-item literacy-sensitive, family-friendly psychosocial needs screener, incorporating items from validated measures and feedback from families.

Preliminary data from the RPL's K23 show that self-management tools keep families engaged in obesity treatment. Driven by our previous work demonstrating that parents with higher psychosocial risk report lower self-efficacy managing their child's behaviors,[36-37] we developed and tested a video-based parenting intervention for families of children ages 4-12 with obesity.[32] Qualitative interviews with caregivers produced three themes that informed design of the intervention and this proposed project: the value of hearing from other families of children with obesity of diverse backgrounds, the importance of choice and convenience in how the intervention is delivered, and the need to be activated. The intervention has been tested in a pilot RCT with 120 families attending the Nemours Healthy Weight and Wellness Clinic, with preliminary data showing improved short-term visit adherence among families who viewed the videos.

Our team has spearheaded studies demonstrating the value of telehealth in improving the reach of childhood obesity care. A survey of 159 Nemours pediatric primary care providers (PCP) demonstrated their desire to connect families with community resources and have obesity specialists accessible by telehealth.[26] We presented findings from 85 telehealth visits with the Nemours Healthy Weight and Wellness Clinic among families in rural Delaware. Not only did 100% of families surveyed report that telehealth visits were more convenient, but no-show rates were significantly lower than in-person visits.[31] We also conducted a pilot RCT with 45 adolescents, which found that integrating telehealth visits with obesity specialists between primary care visits was linked to better weight outcomes.[28] Finally, Dr. Phan and Dr. Davis have demonstrated the effectiveness of iAmHealthy, a family-based behavioral group treatment delivered via telehealth, in the IDeA States Pediatric Clinical Trials Network (ISPCTN).[38-40]

A.4 PROPOSED PROJECT



Based on our preliminary work and the Clinical-Community Integration Framework, we have developed Mobile Integrated Care for Childhood Obesity (MICCO, Figure 2). MICCO is an evidence-based, multi-component intervention that combines integrated community care to address psychosocial needs, multidisciplinary obesity care, and self-management tools to promote healthy lifestyle behaviors. All components are delivered through a single mobile platform to increase accessibility for underserved populations and are integrated into the patient-centered medical home through the mobile platform's integration with the EHR. **Aim 1:** Community-engaged and qualitative research methods will be used to refine MICCO and ensure it is community-centered and family-friendly. **Aims 2 and 3:** MICCO will then be tested in a RCT with families of children with obesity from rural primary care practices to examine its impact on family engagement in treatment, child weight status and disparities in these outcomes.

B. INNOVATION

Because attrition is one of the most challenging problems in obesity treatment, developing and testing interventions that increase family engagement is critical. MICCO will change practice paradigms by combining and delivering evidence-based interventions in an innovative way, leveraging technology, the patient-centered medical home, and the community to increase engagement and sustainability beyond the clinical trial.

B.1 MICCO will address psychosocial determinants of health to reduce disparities in childhood obesity outcomes. Most childhood obesity interventions focus on changing diet and physical activity.[8] However, we have demonstrated the importance of addressing psychosocial determinants of health in the treatment of childhood obesity, especially to decrease attrition from treatment.[3,11] Each component of MICCO is aligned with this goal. MICCO provides targeted psychosocial services to families in partnership with community organizations; visits with obesity specialists including a psychologist to assist families with behavior change, parenting, mood, and self-esteem; and psychoeducational tools to educate, engage, and empower families.

B.2 Our study differentiates itself in the design and testing of a mobile application that is state-of-the-art, user-friendly, and integrated with the healthcare system.[41] Nearly all families of children with obesity (95%) in our prior studies reported access to the internet through a mobile device, making it an accessible and convenient platform to augment healthcare delivery. Other studies have utilized mobile apps for childhood obesity,[41] but few have been integrated with the healthcare system. Our project leverages the family-friendly

Nemours App and its integration with the Nemours EHR to deliver MICCO, combining components that families can use on their own with components that allow families to interact with their healthcare team, enhancing family engagement with the intervention.[41] Our study will refine MICCO with best-practice methods used in private (marketing) and healthcare (e-health) settings to improve the usability of new technologies[42-43] and will leverage our collaboration with the Nemours App developers to ensure changes are made quickly and that the newest technological innovations are employed in the intervention.

B.3 We will employ best-practice community-engaged research strategies to ensure that MICCO is feasible, relevant, and poised to create sustainable change.[44-45] While engagement of community stakeholders is increasing in childhood obesity studies, fully engaging stakeholders in a meaningful and rigorous manner is still uncommon.[46] We will engage a diverse group of stakeholders in rural communities in Delaware, including families, community organizations, and primary care practices, as partners in all phases of research design and execution to enhance alignment of MICCO with community resources and stakeholder values, ensure MICCO is family-friendly, and facilitate effective recruitment, retention, and dissemination.

C. APPROACH

C1. OVERVIEW: The proposed study will refine and test an evidence-based, multi-component intervention, Mobile Integrated Care for Childhood Obesity (MICCO), delivered through a mobile application platform linked to the Nemours EHR. We will engage a Council of Community Partners and a Council of Parent Partners and use Think Aloud testing to refine MICCO (Aim 1), which will then be tested in a RCT with families of young children with obesity from three primary care practices in rural Delaware to examine impact on attrition and child weight (Aim 2) and disparities in these outcomes (Aim 3). **Overall project goal:** Improve the relevance and accessibility of obesity interventions for families in underserved rural communities to reduce health disparities.

C.2 RESEARCH TEAM: Our team is exceptionally well-qualified to conduct this study, with expertise spanning all methodological and conceptual aspects of the proposed work (see Biosketches). **Thao-Ly Phan, MD, MPH (RPL)** is the Medical Director of the Nemours Healthy Weight and Wellness Clinic who has been awarded two career development grants to address psychosocial factors that impact weight outcomes, leveraging EHR-based technology. Her senior mentorship team has diverse and complimentary areas of expertise and connections with professional networks that will strengthen Dr. Phan's research: (1) **Anne Kazak, PhD, ABPP,** Director of the Nemours CHDS and Nemours PI of PEDSnet, has expertise in psychosocial interventions and implementation science and has served as Dr. Phan's primary mentor on multiple projects; (2) **Ann Davis, PhD, MPH,** Director of the Center for Children's Healthy Lifestyles & Nutrition at the University of Kansas Medical Center, has expertise in telehealth obesity interventions for rural populations and has collaborated with Dr. Phan through the ISPCTN; (3) **Ihouma Eneli, MD, MS,** Director of the Center for Healthy Weight and Nutrition at Nationwide Children's Hospital and Director of the Primary Care Obesity Network in Central Ohio, has expertise in integrating obesity treatment into primary care and has collaborated with Dr. Phan on PEDSnet and AAP Institute for Healthy Childhood Weight activities; and (4) **Allison Karpyn, PhD** is the Director of the Center for Research Education and Social Policy at the University of Delaware and member of the ACCEL Community Engagement Core, with expertise in community-engaged research and improving access to healthy food for underserved communities. This project leverages robust resources offered by the **IMPACT Core**, including mobile app development expertise, and extends our collaboration with Nemours primary care practices and caregivers of children with obesity in rural Delaware with the assistance of the **PROMISE Core** (see C.4, Aim 1).

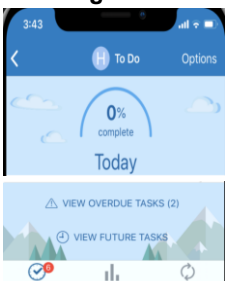
C.3 MICCO INTERVENTION: Based on our preliminary work and the Clinical-Community Integration Framework, we developed a multi-component intervention, Mobile Integrated Care for Childhood Obesity (MICCO, Figure 3), that will be accessible by mobile phone or tablet through a custom dashboard on the Nemours App. The Nemours App is an existing state of the art mobile application platform that provides comprehensive patient services (tools for education, telehealth, appointments, communication with providers, and health management); is accessible by mobile device, tablet, or desktop/laptop computer; and is linked to the Nemours EHR (EPIC, see detailed description of Nemours App in IMPACT Core). All MICCO components will be available in English and Spanish, and families will receive hands-on instruction on using MICCO.

Component 1: Integrated Community Care. Upon beginning the MICCO intervention, the social needs screener , refined and tested by members of the research team (see A.3), will be sent to caregivers through the Nemours App (in English) or a REDCap survey (in Spanish). REDCap survey results will be entered into the EHR by the community health worker. A positive screen will appear on an EHR dashboard for review by trained community health workers who are an integral part of each primary care practice's patient-centered medical home. The decision to incorporate a community health worker as part of the team was based on Community

Partner and Healthcare Partner feedback, given the broader scope of the community health worker's role and their demonstrated effectiveness on the RPL's recent study to increase COVID-19 vaccine uptake among underserved populations. EPIC's care management tool will be used by the community health worker to establish a care plan, refer the family to services (e.g. food banks, transportation services, mental health providers) in their zipcode recommended by the Council of Community Partners, and track community programs that have been accessed. The community health workers will participate in the Council of Community Partners to incorporate resources shared by community and state organizations into the intervention. Based on feedback from the Council of Community Partners, community resources will also include a monthly healthy lifestyle event for participants to encourage peer support and family engagement. Monthly healthy lifestyle events will include a physical activity, healthy dinner, and presentation on a healthy lifestyle topic (e.g., cooking class, mindfulness) provided at no cost to participants.

Component 2: Integrated Obesity Care. Families will receive evidence-based weight management treatment consistent with Stage 3 AAP Expert Committee Recommendations and United States Preventive Services Task Force (USPSTF) guidelines,[8,47] tailored to the needs of each family. Treatment will include biweekly telehealth or in-person (included based on parent and healthcare stakeholder feedback) visits with members of an existing and established transdisciplinary group of obesity specialists (medical provider, psychologist, exercise physiologist, dietitian, and community health worker) from the Nemours Healthy Weight and Wellness Clinic, with an interpreter available for families whose preferred language is Spanish. Telehealth visits will be delivered via the Nemours App and in-person visits will be provided at Nemours Children's Health, Milford. Care provided will include motivational interviewing to establish lifestyle behaviors goals specific to each child's needs but following evidence-based lifestyle recommendations like MyPlate and the Traffic Light Diet, cognitive-behavioral strategies such as self-monitoring and stimulus control, positive parenting strategies, and management of child mood and self-esteem. Based on feedback from parent partners and in recognition of the challenges with attending biweekly visits, providers will reach out to parents by their preferred method of communication (App, phone, or text) if a family misses a visit. This outreach will focus on evaluating progress with lifestyle behavior goals, problem-solving strategies to assist with lifestyle behavior goals, setting new lifestyle behavior goals as appropriate, and ensuring families are connected to community programs as needed.

Figure 3. Goal Tracking



Component 3: Self-Management Tools. Families will be provided with psychoeducational tools in English or Spanish through the Nemours App to promote lifestyle behavior change. These will include a self-monitoring tool (Figure 3) to track daily progress toward lifestyle behavior goals established during visits, a series of culturally-relevant videos developed by the research team to promote positive parenting among families of children with obesity (see A.3, Figure 4), and media-based educational resources (e.g., exercise/ cooking videos) to promote healthy lifestyle behaviors curated by multidisciplinary obesity specialists. Obesity specialists and community health workers will review data on an EHR dashboard about lifestyle behavior goal metrics and anthropometric measurements to inform clinical decisions during visits with families. Participants will also have the option of accessing the YMCA of Delaware's virtual platform through the App at no cost to participants.

Figure 4. Positive Parenting Videos

"If you come outside with your kid, they're going to feel loved, they're going to feel important, like you have an interest in their life."

"Constant motivation and complimenting the child will encourage them to keep playing and having more fun when they play."

"The parent is what gets your child to come outside. Your child listens to you and your child looks up to you."

C.4 STUDY DESIGN: See PHS Human Subjects & Clinical Trials form for detailed eligibility criteria, sample size justification, recruitment/retention plan, time-line, human subjects protection, and data/safety monitoring. All participating families will receive compensation for study visits, as detailed on the form.

AIM 1. REFINE MICCO WITH COMMUNITY ENGAGEMENT AND THINK ALOUD TESTING

COMMUNITY ENGAGEMENT

Three communities in Southern Delaware (Milford, Millsboro, and Seaford), each 2+ hours from the NCH-D. will be engaged in the study in collaboration with our PROMISE Core. The Nemours primary care clinics in these three towns have a diverse patient population (Figure 5). Based on EHR data, of the 532 children with obesity ages 4-12 years living in a rural area who had visited one of the primary care clinics in the past year, less than 20% were referred to and less than 10% attended the hospital-based obesity clinic, with children of Hispanic ethnicity being even less likely to be referred, underscoring disparities in accessing care. **A Council of Community Partners and Parent Partners will serve as active members of the research team.** Partners will participate in monthly calls and frequent e-mail correspondence, receiving a stipend for their time. The Councils will provide insight into implementing the study in and disseminating findings to the community, with each partner informing aspects unique to their perspective. There will be three members from each of 3 groups:

Figure 5. Primary care clinics in Southern DE

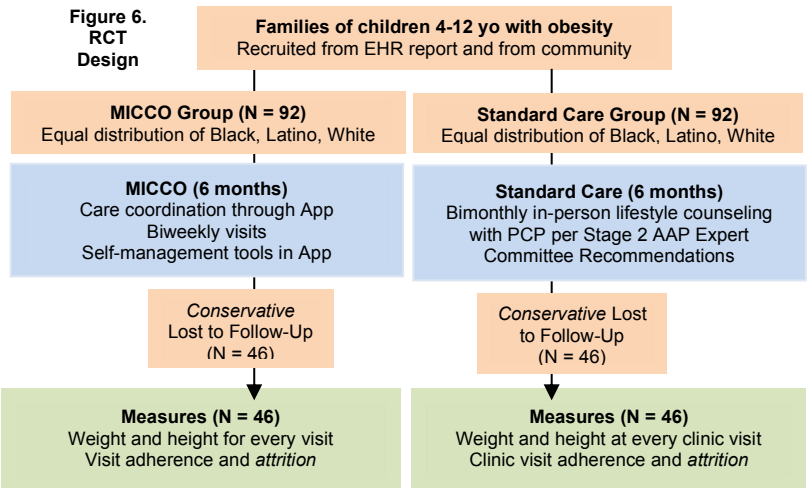
1) **PCPs** will inform integration of MICCO and standard of care into the patient-centered medical home;
2) **Primary care coordinators** will determine best approach for care coordination of psychosocial services;
3) **Community organizations providing social services or community centers** will identify and facilitate access to relevant community-based psychosocial services and lifestyle resources to address family psychosocial needs, will help recruit families from their organizations through advertisement and inform best ways to recruit and engage families during the course of the study .

Six families of children with obesity of diverse backgrounds will serve on a Council of Parent Partners and inform ways to increase the relevance of MICCO content and decrease the burden of participating for families.

THINK ALOUD TESTING: Families of children ages 4-12 years with obesity who receive care from the primary care clinics will be recruited using purposeful sampling. Families who meet eligibility criteria will be identified from a report generated from the electronic health record. Legal guardians will receive an initial recruitment text to the preferred mobile number identified in the electronic health record. Research staff will contact legal guardians who express interest to screen for eligibility and review the consent form, if eligible. Legal guardians will provide feedback on the usability of the MICCO mobile application via Think Aloud testing, an evidence-based method for obtaining in-vivo feedback that has been used by members of the IMPACT Core in the development of e-health interventions.[42-43] Legal guardians will meet with a trained research team member via a secure online meeting platform, which will allow them to experience the app with their own internet connection and mobile or computer device. Participants will be asked to remain off camera and to sign onto the meeting with their study ID number to maintain confidentiality. If potential participants prefer to conduct the session in-person, an in-person session can be arranged with a preference for participants to still use their own device to experience the app. After a brief introduction to MICCO, families will be instructed on how to access the MICCO App prototype on their mobile device, tablet, or computer. They will then be instructed to use MICCO and encouraged to say everything that they are thinking and doing as they navigate independently through the components, sharing their screen so that the research team member can view their screen flow. There will also be a brief series of qualitative interview questions to assess for acceptability of the App (please see attached interview guide). The research team member will record the session (audio and screen share if conducted online, audio if conducted in-person) and take notes on observations, including feedback about content and technology. The recording will be transcribed by a professional transcription company. Personal information will be deleted from the transcript and the recording will be deleted after the study is complete. After each session (30-60minutes in length), family feedback will be summarized utilizing a modified cognitive interview analysis protocol.[48] The process will be iterative, with real-time changes made quickly after each session, expedited by our collaboration with the Nemours App developers, and testing ending when saturation is achieved (i.e., no novel suggestions for improvement identified). It is anticipated that 5-10 families will be needed to achieve saturation of responses.[42]

AIMS 2 and 3: EXAMINE IMPACT OF MICCO ON FAMILY ENGAGEMENT AND CHILD ADIPOSITY AND DISPARITIES IN THESE OUTCOMES

PARTICIPANTS: 184 families of children with obesity (BMI percentile ≥ 95th percentile for age) ages 4-12 years who are patients of the primary care practices in Milford, Seaford, or Millsboro serving primarily rural populations will be identified from the EHR and with advertisement at community centers. Participants identified from the EHR will be contacted by text and/or e-mail message. Interested participants will be advised to contact a research team member, who will then contact interested families to assess eligibility criteria and interest in participation. If a family is eligible and interested after this contact, the research team member will arrange a time to conduct an informed consent process with the participant, who will sign an electronic consent.



STUDY DESIGN: Enrolled families will be randomly allocated to receive MICCO (see C.3) or an active control condition (standard care) using a 1:1 randomization scheme stratified by race/ethnicity (three groups impacted most by obesity in the community: Latino, non-Hispanic Black, non-Hispanic White; Figure 6). The intervention will be delivered over 6 months.

STANDARD CARE: An active control condition was selected to demonstrate the impact of the intervention beyond the typical care that a child would receive in primary care. Standard care will include bimonthly in-person visits for lifestyle counseling with the child's PCP per 2023 AAP Clinical Practice Guidelines.[47] PCPs will receive training on these recommendations at the start of the clinical trial, with refresher training provided every six months and a lifestyle handout provided to facilitate education at each nursing visit. PCPs will not be trained on MICCO. Only participants in the MICCO group will have access to the MICCO dashboard on the Nemours App to prevent contamination.

OUTCOME MEASURES

Family Engagement in Treatment: Study visits will be documented in the EHR as part of routine clinical care for all patients, including the number of visits with primary care providers (where obesity and lifestyle counseling was provided, per ICD-10 codes) or obesity specialists (including type of specialist) and number of cancelled/missed visits. Attrition (non-attendance to 6 month follow-up visit) will be assessed via EHR review. In addition, number of days in study will be assessed as a secondary outcome.

Child Adiposity: Weight will be measured with a wireless smart scale that has been used in prior research and demonstrated excellent agreement with research-grade scales.[49-50] Height will be measured using a reliable method used by RPL Phan and mentor Davis using a measuring tape and ruler, which has demonstrated validity when compared to measurement of height with a medical-grade stadiometer measured by a research team (Forset, et al., 2022).[51] Procedures for ensuring reliability of measurements using these devices will be followed, per guidelines established by Krukowski and Ross during the pandemic.[50] Children will be measured by their caregiver each month in advance of visits, with weight measurements transmitted wirelessly to and height measurements entered into the Nemours App for the MICCO Group and measurements entered into the EHR by research staff for the Standard Care group.

Disparities: Child race/ethnicity and insurance (proxy measure of socioeconomic status) will be collected from the EHR. Age, sex, caregiver preferred language, and social needs (from screener) will also be collected.

C5. DATA ANALYTIC PLAN. **Think Aloud Testing (Aim 1):** Themes from qualitative interviews will be identified using an inductive thematic approach (see PHS Human Subjects Form for more detail).[53] **RCT (Aim 2)**: Based on prior research describing the impact of behavioral interventions on BMI z-scores, we expect a mean difference in adjusted BMI z-score of 0.25 with the intervention, an effect size that has also been associated with a change in cardiometabolic risk.[8] A sample size of 92 participants (46 in each group) can detect an effect size of this magnitude with a power of 80% and a level of significance of 0.05, assuming a 50% attrition rate based

on prior studies,[11-12] we would need to enroll 184 participants (92 in each group). A mixed effects model with random coefficients will be used to assess the longitudinal effects of MICCO on changes in adjusted BMI z-score to minimize the effect of missing data. Logistic regression analysis will be used to assess the effect of the intervention on attrition. **Disparities (Aim 3):** The same models will be used to preliminarily assess the interaction between the intervention and race/ethnicity and insurance on adjusted BMI z-score and attrition to inform a larger multi-site trial that will be fully powered to evaluate disparities. Due to pilot nature of study and variability in engagement, the decision was made by the COBRE External Advisory Committee to end enrollment after 1 year.

C.6 POTENTIAL PROBLEMS, ALTERNATIVES. Analysis of EHR data suggests that it will be feasible to recruit the sample size intended and advertisement of the study through our community partners will also facilitate recruitment. However, if recruitment is slow we may expand eligibility to include children with BMI ≥ 85% or from other Nemours clinics in rural areas. Every effort will be taken to refine MICCO based on input from stakeholders; if MICCO is found to be ineffective in the RCT, we will obtain qualitative feedback from our Councils, analyze app analytics, and assess whether behavior change improved. We understand that technology evolves quickly and modifications may be needed to ensure that the intervention remains current. We will leverage Nemours' investment in innovative technologies and the expertise of our IMPACT Core to continuously improve our intervention to be state of the art.[54] If families are experiencing connectivity issues, we may use primary care space and equipment for telehealth visits. Finally, success depends on effective collaboration with the community and therefore we will incorporate metrics to objectively measure collaborative efforts.[27]

C.7 SCIENTIFIC RIGOR. This study was designed to ensure that it will yield robust, unbiased results. MICCO incorporates evidence-based strategies for the treatment of childhood obesity that align with USPSTF and AAP guidelines and are informed by the team's preliminary work. Best practice community-engaged research methods and usability testing will be used to tailor and refine the intervention for families of children with obesity in rural communities of Delaware. A RCT will be used to evaluate efficacy of the intervention, with planned sample size calculated to detect a reduction in adjusted BMI z-score that would yield positive cardiometabolic outcomes based on prior research and accounting for attrition rates based on prior studies. Stratified randomization will be used to ensure a diverse and representative sample from which disparities can be preliminarily evaluated. Our study will focus on objective outcome measures to assess intervention efficacy, using innovative and automated technology. We will collect additional information about use of MICCO and components of standard care visits to account for potential variability in participant experience of either intervention. Finally, rigorous data analytic approaches and transparent reporting guidelines will be followed.

C.8 FUTURE DIRECTIONS. This study will position Dr. Phan to secure external funding to conduct a large-scale, multi-site implementation trial of MICCO, for example through existing collaborations with the ISPCTN or PEDSnet, leveraging common EPIC interfaces among sites. With a refined intervention and robust data from a single site RCT, Dr. Phan will be highly competitive to apply for funding from the NIH (NICHD/NIDDK R01) or funding from PCORI in year 2 of the COBRE, with a larger goal of transforming healthcare delivery and policy for children with obesity to include integrated preventive care and innovative technologies to expand the reach of this care. Importantly, this study will increase capacity for community-engaged research in rural Delaware to ensure that research with these populations continues to be conducted in a meaningful and impactful manner.