

**A Hybrid Effectiveness-Implementation Trial of Go NAPSACC: A
Childcare-Based Obesity Prevention Program**

NCT number NCT03938103
Document Date 01/24/2024

PROTOCOL TEMPLATE: INTERVENTIONAL STUDY

Complete Title: A hybrid effectiveness-implementation trial of Go NAPSACC: a childcare-based obesity prevention program

Short Title: Evaluation of an Enhanced Delivery Model for Go NAPSACC

Drug or Device Name(s): N/A

FDA IND/IDE (if applicable): N/A

Sponsor: NIH NHLBI

Protocol Date: 01/10/2024

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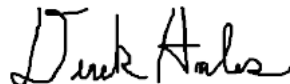
Protocol Version: 1.0

Version Date: January 10, 2024

I confirm that I have read this protocol and understand it.

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Date: 1/24/24

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PROTOCOL SYNOPSIS

Study Title	A hybrid effectiveness-implementation trial of Go NAPSACC: a childcare-based obesity prevention program
Funder	NIH NHLBI
Clinical Phase	<i>Not Applicable</i>
Study Rationale	<ul style="list-style-type: none">• Child care is a crucial setting for obesity prevention initiatives given environmental influences on eating, and physical activity and the number of US children in some form of child care (12 million; 6 million in center based-program).• National authorities (e.g., Institute of Medicine, American Academy of Pediatrics) and Federal programs (e.g., Child and Adult Care Food Program) recommend that child care programs serve healthy foods, provide adequate time for active play, limit screen time, provide healthy role models, and educate children about healthy lifestyle choices.• Implementation studies are a critical next step in identifying effective approaches for child care-based health promotion and obesity prevention. But existing studies offer little insight into scaling up and implementing these evidence-based practices in child care.• The NAPSACC program is a notable exception, offering a structured process that helps child care programs adopt and implement best practices for obesity prevention. “Go NAPSACC” was created to translate core elements into user-friendly and interactive online tools that child care programs can use independently.• While pilot studies suggest that Go NAPSACC retains its effectiveness in improving their practices, further study is needed to confirm its effectiveness and examine strategies to enhance its implementation.
Study Objective(s)	<p>This study will evaluate the impact of Go NAPSACC on child care center practices as well as the adoption, implementation, and maintenance achieved with Go NAPSACC when using basic vs. enhanced implementation models.</p> <ul style="list-style-type: none">• <u>Primary Aim:</u> Aim 1. Compare Basic vs. Enhanced Go NAPSACC’s impact on centers’ implementation of healthy weight practices.• <u>Secondary Aims:</u> Aim 2. Evaluate adoption, implementation, and maintenance of Go NAPSACC; Aim 3. Examine how organizational factors predict implementation; Aim 4. Calculate incremental cost-effectiveness ratio in terms of environmental change; Aim 5. Compare impact on children’s diet quality and physical activity at child care.
Test Article(s) <i>(If Applicable)</i>	<p>TA Coaches are randomized to provide Basic Go NAPSACC or Enhanced Go NAPSACC delivery to their enrolled centers.</p> <p>In Basic Go NAPSACC (general prescription) TA Coaches will:</p> <ul style="list-style-type: none">• invite their centers to register, complete self-assessments, and create action plans• encourage centers to complete 2 cycles of Go NAPSACC’s 5-step improvement process• check in monthly to evaluate progress, provide suggestions, and trouble shoot issues. <p>In Enhanced Go NAPSACC TA Coaches will:</p> <ul style="list-style-type: none">• Help center create an implementation team, conduct a readiness assessment, and guide choice of a priority challenge for each center.• Invite centers to register and complete self-assessments.• Help director create an implementation plan for the improvement process. This plan will be tailored based on the priority challenge identified from readiness assessment.• Check in monthly to evaluate progress, provide suggestions, and trouble shoot issues.• Facilitate quarterly cross-center meetings to create community and discuss issues.• Participate in a group check-in with a Go NAPSACC advisor (UNC research team) monthly and talk with UNC team individually each quarter.

Study Design	This is a type 3 hybrid effectiveness-implementation RCT with a clustered parallel group intervention design. TA coaches were randomized to deliver Basic Go NAPSACC or Enhanced Go NAPSACC to their enrolled centers.
Subject Population <i>Key criteria for Inclusion and Exclusion:</i>	<p>For this study we will recruit Technical Assistants (TA Coaches) and child care centers. From each center, we will recruit and enroll a director and 2 teachers.</p> <p>TA Coaches</p> <ul style="list-style-type: none"> • Must either be Quality coach or a Healthy and Safety coach • Must be able to read and speak English <p>Child Care Centers</p> <ul style="list-style-type: none"> • Must be part of a participating TA coach's current caseload • Have no plans to close in the coming year • Have at least one classroom serving preschool children • Serve at least lunch to the children • Not serve special needs children exclusively <p>Child Care Providers</p> <ul style="list-style-type: none"> • Teacher must be the lead teacher in a preschool classroom • Center directors and teachers must be able to read and speak English
Number Of Subjects	<p>TA Coaches: BL n = 27; FU n = 26</p> <p>Child Care Centers: BL n = 97; FU n = 88</p> <p>Child Care Providers: BL n = 257; FU old n = 139, FU new n = 82</p>
Study Duration	Each subject's participation will last approximately 14 months; 1 month for baseline data collection, 12 months of intervention, and 1 month of follow up data collection. The entire study is expected to last approximately 3 ½ years.
Study Phases	<p>(1) <u>Screening and recruitment</u>: During this phase we will identify and recruit TA coaches and get lists of the centers they serve. Centers will be screened for eligibility and recruited randomly. After a director and teachers consent, baseline data collection will be completed (2) <u>Intervention</u>: After baseline measurement, TAs will be randomly assigned to Basic or Enhanced Go NAPSACC implementation and the 12-month intervention will proceed (3) <u>Follow-Up</u>: After the 12-month intervention, follow up measures and process evaluations will be completed.</p>
Efficacy Evaluations	<ul style="list-style-type: none"> • Primary Objective <ul style="list-style-type: none"> ○ Aim 1. Compare intervention impact on implementation of healthy weight practices. <ul style="list-style-type: none"> ▪ EPAO-SR Nutrition and Physical activity environment scores. • Secondary Objectives <ul style="list-style-type: none"> ○ Aim 2. Evaluate adoption, implementation, and maintenance by group. <ul style="list-style-type: none"> ▪ Percent of centers creating accounts, completing self-assessments, selecting goals, and creation of action plans will be captured by the Go NAPSACC website and extracted using the registration and detailed activity reports. ○ Aim 3. Examine how organizational factors predict implementation. <ul style="list-style-type: none"> ▪ Surveys completed by directors, teachers, and TA coaches. ▪ Fernandez's CFIR Inner Setting: Culture, Culture Stress, Culture Effort, Implementation Climate, Leadership Engagement, and Available Resources. ▪ TCU's Organizational Readiness for Change: Networks and Communications and Access to Knowledge and Information. ○ Aim 4. Calculate incremental cost-effectiveness ratio for environment change. <ul style="list-style-type: none"> ▪ Costs include TA coaches time and any resources required to train and support centers for 12 months. Costs will be tracked in the TA Activity and

supplemental resources log. These data will be used to calculate the total cost per center to implement Go NAPSACC. Cost will be used with EPAO-SR outcomes (aim 1) to calculate the incremental cost-effectiveness ratio.

- Aim 5. Compare impact on children’s diet quality and physical activity at child care.
 - EPAO-SR food and meal reporting will be used to summarize center-level dietary intake and to calculate diet quality (Healthy Eating Index 2015)
 - EPAO-SR daily activities reporting will be used to summarize the activity levels of children. Outdoor time, active indoor time, vigorous minutes, and teacher ratings of activity level will be used to calculate an activity level index.

Safety Evaluations *Not Applicable, study is minimal risk*

Statistical And Analytic Plan The primary outcomes are change in nutrition and physical activity best practices in the Enhanced and Basic Go NAPSACC groups computed from the EPAO-SR collected from director and staff.

Power and Sample Size: Power calculations specify the sample size needed to detect significant differences with 80% power, an alpha of 0.05, effect size of 0.6, and an ICC of 0.001. Cluster size is estimated at 10-15 centers per region. Based on these specifications, a sample size of 88 centers is needed. The **final sample size of 97 centers** allows for 10% attrition. Depending on the number and capacity of TA providers, we will need to recruit approximately 8 TA providers, each will need to recruit 12-13 child care centers.

Statistical Analysis: Our primary analyses will test the hypothesis under the intent-to-treat (ITT) principle using Generalized Linear Mixed Models (GLMM) that account for the clustering of child care centers within regions/TAs. The primary GLMM will include a random intercept for region (b_0) and fixed effects for the baseline value of the primary outcome (β_1) and the intervention (β_2) to test if the differences in mean changes in primary outcomes is zero, where β_0 is the fixed intercept, and e is error.

$$\text{Change in Primary Outcome}_{12m} = \beta_0 + \beta_1 \text{Primary Outcome}_{\text{baseline}} + \beta_2 \text{Intervention} + b_0 + e$$

Baseline demographics and EPAO scores will be compared between centers with and without follow-up measures to inspect for potential bias. In addition, we will examine: 1) baseline covariates, determined a priori, relevant to change in EPAO scores; 2) interaction between treatment group and other covariates; and 3) completers only.

Similar analytic models will be used to assess aims 2-5.

DATA AND SAFETY MONITORING PLAN Data quality management and ongoing assessment of safety will be completed by a Data Safety Monitor Officer as needed.

BACKGROUND AND RATIONALE

Introduction

More than 12 million children under the age of six participate in some form of child care, of which 56% are enrolled in center-based programs such as Head Start, preschool, and prekindergarten. Child care is a crucial setting for childhood obesity prevention initiatives given its known influence on children's eating, physical activity, and weight. Drawing on the growing evidence from child care studies, national authorities (e.g., Institute of Medicine, American Academy of Pediatrics, American Public Health Association) recommend that child care programs serve healthy foods and limit unhealthy ones, provide adequate time for active play, limit screen time, provide healthy role models, and educate children about healthy lifestyle choices. Federally-funded programs (e.g., Child and Adult Care Food Program, Child Care Reauthorization Act) have also increased their emphasis on health promotion at child care, which will likely increase demand for effective strategies and tools to implement these evidence-based practices. Hence, implementation studies are a critical next step in identifying effective approaches for child care-based health promotion and obesity prevention. Existing studies offer little insight into scaling up and implementing these evidence-based practices in child care. The Nutrition and Physical Activity Self-Assessment for Child Care (NAPSACC) is a notable exception, offering a structured process that helps child care programs adopt and implement best practices for obesity prevention. NAPSACC has been promoted by the White House Task Force on Childhood Obesity as well as the CDC-funded program DP13-1305 (State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health). Even so, implementation has been modest due to barriers such as a reliance on specially-trained technical assistance (TA) professionals (i.e., NAPSACC Consultants) and child care programs' organizational capacity. "Go NAPSACC" was created to address this first barrier, translating core elements of the original program into user-friendly and interactive online tools that child care programs can use independently. While pilot studies suggest that Go NAPSACC retains its effectiveness in improving their practices, further study is needed to confirm its effectiveness and examine strategies to enhance its implementation.

This study will address these gaps using a type 3 hybrid effectiveness-implementation design with a randomized controlled trial to evaluate the impact of Go NAPSACC on child care centers' practices as well as the reach, adoption, implementation, and maintenance achieved with Go NAPSACC when using basic vs. enhanced implementation strategies (i.e., Basic Go NAPSACC vs. Enhanced Go NAPSACC). Working in Kentucky, the state with the sixth highest rate of child obesity, we will partner with Child Care Aware Kentucky and their existing regional TA providers to recruit 97 centers across the state. Enhanced implementation strategies, which are guided by the Quality Implementation Framework, will allow regional TA coaches to support centers' general and intervention-specific capacity. Outcome measures, guided by RE-AIM and the Consolidated Framework for Implementation Research (CFIR), will assess implementation outcomes (e.g., changes in centers' practices, markers of implementation, costs, impact on children's diet quality and physical activity) and determinants of implementation (e.g., contextual factors).

1.1 Name and Description of Investigational Product or Intervention

Go NAPSACC is a suite of online tools designed to help child care programs improve their nutrition and physical activity practices. TA coaches from Child Care Aware in Kentucky will facilitate implementation of the Go NAPSACC program by introducing child care programs to the online tools and providing ongoing support using either a basic or enhanced implementation model.

Basic Go NAPSACC. TA coaches assigned to Basic Go NAPSACC will invite the enrolled center director to register and create a Go NAPSACC account. The director will then participate in a 1-hour orientation provided by their TA coach to learn how to use Go NAPSACC's online tools and resources. Once the director is trained, they will be encouraged to complete 2 cycles of Go NAPSACC's 5-step improvement process focusing on child nutrition and physical activity. In each cycle of Go NAPSACC, the director will: Evaluate their current nutrition and physical activity practices using the self-assessments in these two modules, choose at least 3 goals per module and create an action plan for each goal using the online tools that offer flexible step-by-step guidance, work to implement the action plan utilizing the tip & materials resource library, and log progress and completion of goals. Each cycle

will take about 6 months. At the end of the 12 months, the director will retake the self-assessments on child nutrition and physical activity. Throughout this process, the director will receive brief check-ins from their TA coach via phone, email, or in-person. TA coaches will be asked to log their implementation activities using the TA Activity Log in their Consultant Tools.

Enhanced Go NAPSACC. For centers receiving Enhanced Go NAPSACC, the director will work with their TA coach to identify an implementation team that will support the use of the program and improvements in nutrition and physical activity practices. The team will include a center administrator as well as two staff (at a minimum). Before starting Go NAPSACC, the team will work with their TA coach to conduct a readiness assessment of their center's needs, capacity, and resources. At a minimum this readiness check will be completed by all members of the team, but the team can also extend participation out to all center staff. The readiness check will be completed by center staff anonymously. Summarized results will be presented back to the team by the TA coach and used to identify priority issues for which the team would like extra support from the TA coach as they are working through Go NAPSACC. Once this readiness check is complete, the team will begin their use of Go NAPSACC. All members of the team will be invited to register for a Go NAPSACC account, linked back to their child care center. The team will then participate in a 1-hour orientation provided by their TA coach to learn how to use Go NAPSACC's online tools and resources. Once the team is trained, they will be encouraged to complete 2 cycles of Go NAPSACC's 5-step improvement process focusing on child nutrition and physical activity. The team will be asked to develop a 12-month plan to guide their Go NAPSACC efforts. In each cycle of Go NAPSACC, the team will: Evaluate their current nutrition and physical activity practices using the self-assessments in these two modules, Choose at least 3 goals per module and create an action plan for each goal using online tools that offer flexible step-by-step guidance, Work to implement the action plan and meet their chosen goals drawing from the tip & materials resource library, and Log progress and completion of goals. Each cycle will take 5-6 months. At the end of the 12 months, the team will retake the self-assessments on child nutrition and physical activity. Throughout this process, the team will receive brief check-ins from their TA coaches via phone, email, or in-person. These check-ins will include tailored prompts to offer extra guidance and support on prioritized issues identified from the needs assessment. In addition, teams from different centers within the same region will participate in 2-3 one-hour meetings hosted by the TA coach. These meetings will provide opportunities to reflect on their efforts and share lessons learned. TA coaches will be asked to log all of their implementation activities using the TA Activity Log in their Consultant Tools. TA coaches will participate in monthly conference calls hosted by a Go NAPSACC specialist to discuss progress, reflect on experiences, and promote peer learning. Further, TA coaches will be provided with 2-3 one-on-one coaching sessions to address any specific questions or challenges encountered.

1.4 Relevant Literature and Data

Center-level Nutrition and Physical Activity Environments (Primary Outcome Measure). We will use the Environment and Policy Evaluation and Observation as a Self-Report (EPAO-SR) (1) to measure best practices of nutrition and physical activity environments in child care centers. The EPAO-SR consists of over 800 items, takes about 45–60 min to complete, and includes a Director Survey and two teacher surveys (the Daily Survey and the General Survey). As recommended by the EPAO-SR protocol, when possible surveys are completed by the director and 2 separate classroom teachers; their responses were averaged to provide center-level estimates.

The EPAO-SR Director Survey assesses the general child-care center environment and the presence/absence of written policies around nutrition and physical activity. In terms of nutrition, the Director Survey asks about menus, types of meals and snacks provided to children, food purchase and food preparation practices, and the presence of guidelines for foods brought from home. The survey also asks about the provision of nutrition education to parents, presence of written nutrition policies, and whether written policies addressed 19 practices related to food and feeding, nutrition education, and other nutrition topics (e.g., foods allowed for celebrations, food safety). In terms of physical activity, the Director Survey asks about the availability of specific types of outdoor play toys and equipment, variations in the outdoor play area landscape (e.g., presence of shade, fruit/vegetable gardens), and

the provision of physical activity education to parents. Additional questions captured the presence of written physical activity policies and whether written policies addressed 15 specific practices related to physical activity, screen time, and physical activity education and training. The director will also fill out the food and beverages served section of the Daily Survey on two different days, which assesses food and beverages served to 3-5 year old children at the center.

The EPAO-SR Teacher Surveys include sections on the physical activity part of the Daily Survey and a General Survey. The physical activity part of the Daily Survey assesses provisions physical activity in a preschool classroom. Questions ask about the opportunities for and minutes of physical activity (e.g., total active playtime, structured physical activity) and screen activities (e.g., television) provided to children in the classroom across the entire day. As recommended by the EPAO-SR protocol, the two teachers completing the physical activity section of the Daily Survey will be provided with days of the week they could report out on to ensure that they were reporting on physical activities provided to children on two separate weekdays.

Teachers will also complete the EPAO-SR General Survey that assesses general practices and environments around nutrition and physical activity in preschool classrooms. Questions on the General Survey ask teachers to report on how often they engaged in practices such as: encouraging and modeling healthy eating and physical activity, using food, physical activity, and screen time for reward or punishment, or having informal discussions with children about nutrition and physical activity. Questions on the General Survey also capture the availability and accessibility of active play toys and equipment outdoors, and the types of screen equipment available for use with children in the classroom. Questions on professional development capture the frequency with which the teacher received nutrition and physical activity training annually and the specific topics addressed in the trainings.

Items on the EPAO-SR will be used to assess compliance with nutrition and physical activity best practices, and ultimately, to calculate a combined nutrition and physical activity score. Nutrition best practices will be categorized into six domains: foods provided, beverages provided, feeding practices, the feeding environment, nutrition training and education, and nutrition policy. Physical activity best practices were categorized into six domains: active play and screen time provided, the indoor play environment, the outdoor play environment, physical activity and screen practices, physical activity training and education, and physical activity and screen policy. For each best practice, the EPAO-SR will be used to score compliance, ranging from 0 to 3; a score of “0” indicated non-compliance with the best practice, “1”, and “2”, represented partial compliance, while “3” indicated full compliance with the best practice. Best practice compliance scores within each domain will be averaged and then summed to create an overall nutrition (range = 0–18) and an overall physical activity score (range = 0–18). Finally, these overall nutrition and physical activity scores will be summed to create a single, combined nutrition and physical activity score (range = 0–36). Higher scores indicate compliance with a greater number of best practices, which translates to higher-quality environments.

Contextual factors influencing implementation. As recommended by the CFIR framework (2), the most salient constructs were identified based on barriers identified in previous NAPSACC studies (3–7) and our extensive and ongoing work implementing Go NAPSACC. Prioritized constructs were operationalized for the child care setting and a nutrition and physical activity intervention. Self-administered surveys completed by directors, teachers, and coaches at baseline and postintervention will be used to assess these constructs. Survey items draw from existing scales, including Fernandez’s Inner Setting Survey (ISS) (8), the Organizational Readiness for Change (ORC) survey (9,10), and Seward’s Theoretical Domains Framework Questionnaire (TDFQ) for child care (11–13). The ISS and ORC use a 5-point Likert scale, while the TDFQ uses a 7-point Likert scale (where 1 = strongly disagree and 5 or 7 = strongly agree).

Cost-effectiveness. Cost of implementing Go NAPSACC using the basic and enhanced approaches will be tracked from the perspective of Child Care Aware of Kentucky, the organization that employs the

coaches. Coaches will keep records of time spent implementing Go NAPSACC, including both planning time and all direct contacts using the Go NAPSACC website's Add TA Activity, making sure to also note any supplemental expenses.

COVID Impact. As part of the relaunch of this project, we will have TA coaches and child care center directors fill out a survey about the impact COVID-19. TA coaches will be asked questions about the impact COVID has had on their ability to provide technical assistance to the child care centers and on their well-being. Child care center directors will be asked questions on the impact COVID has had on their center, the families at their center, and their well-being.

Participant characteristics. Participants will complete brief demographic surveys to assess age, sex, race, ethnicity, education, and income. For center directors, supplemental questions will be asked about center characteristics (e.g., years of operation, quality rating, participation in subsidy programs).

1 STUDY OBJECTIVES

This study will use a type 3 hybrid effectiveness-implementation design with a randomized controlled trial to evaluate the impact of Go NAPSACC on child care centers' practices as well as the adoption, implementation, and maintenance achieved with Go NAPSACC when using basic vs. enhanced implementation models (i.e., Basic Go NAPSACC vs. Enhanced Go NAPSACC).

1.1 Primary Objective

- Aim 1. Compare Basic vs. Enhanced Go NAPSACC's impact on centers' implementation of healthy weight practices.
 - *Hypothesis 1.* Centers receiving Enhanced Go NAPSACC will make greater improvements in their food and activity provisions, staff practices, and center policies around children's healthy eating and physical activity compared to centers receiving Basic Go NAPSACC.

1.2 Secondary Objective

- Aim 2. Evaluate adoption, implementation, and maintenance of Basic vs. Enhanced Go NAPSACC.
 - *Hypothesis 2.* Reach, adoption, implementation, and maintenance (as defined by RE-AIM) will be higher among centers receiving Enhanced Go NAPSACC compared to centers receiving Basic Go NAPSACC.
- Aim 3. Examine how organizational factors predict implementation under Basic vs. Enhanced conditions.
 - *Hypothesis 3.* Positive organizational factors (as defined by CFIR), such as communication, culture, implementation climate, and readiness, will enhance implementation of Go NAPSACC.
- Aim 4. Calculate incremental cost-effectiveness ratio of Basic vs. Enhanced Go NAPSACC in terms of changing centers' environments.
 - *Hypothesis 4.* Both Enhanced and Basic Go NAPSACC will be cost-effective in terms of costs per outcome achieved, but Enhanced Go NAPSACC will be more efficient than Basic Go NAPSACC.
- Aim 5. Compare Basic vs. Enhanced Go NAPSACC's impact on children's diet quality and physical activity at child care.
 - *Hypothesis 5.* Children enrolled at centers receiving Enhanced Go NAPSACC will have higher diet quality and spend more time in physical activity while at child care compared to children at centers receiving Basic Go NAPSACC.

2 INVESTIGATIONAL PLAN (brief overview)

2.1 Study Design

This study will use a two-arm cluster randomized controlled design. The unit of randomization is the TA coach, and child care centers will be subject to the same randomization assignment as their TA coach.

In order to be randomized, TA coaches must complete baseline measures and their associated centers must have all participants recruited and baseline data collection must be complete. Once randomized to either Basic Go NAPSACC or Enhanced Go NAPSACC, TAs and centers will be involved in intervention for 12 months. Then follow-up data will be collected from TAs and centers.

2.2 Allocation to Treatment Groups and Blinding (if applicable)

The Project Manager from UNC will notify TA coaches of their assignment from the Co-Investigator, Dr. Derek Hales. The onsite manager from UKY will also be aware of the arm assignment. All other study personnel remained blinded to arm assignment.

2.3 Study Duration, Enrollment and Number of Subjects

Study duration varies by participant type. TA coaches will be involved for approximately 18 months, center directors for approximately 16 months, and teachers for approximately 4 weeks.

The goal is to enroll 97 centers, a director and at least 1 teacher at each center. When possible, we will recruit 2 teachers who work with children 3-5 years old at each center. We will enroll 8 TA coaches across the 8 regions of Kentucky through Child Care Aware of Kentucky (Northern Bluegrass, Southern Bluegrass, Salt River Trail, Eastern Mountain, Cumberland, Two Rivers, Jefferson, and The Lakes). This will be done across 4 waves.

2.4 Study Population

For this study we recruited TA coaches and child care centers. From each center, we will recruit and enroll a director and 2 teachers.

TA Coaches

- Must either be Quality coach or a Healthy and Safety coach
- Must be able to read and speak English

Child Care Centers

- Must be part of a participating TA coach's current caseload
- Have no plans to close in the coming year
- Have at least one classroom serving preschool children
- Serve at least lunch to the children
- Not serve special needs children exclusively

Child Care Providers

- Teacher must be the lead teacher in a preschool classroom
- Center directors and teachers must be able to read and speak English

3 STUDY PROCEDURES

3.1 Screening/Baseline Visit procedures

First, all TA coaches will attend a refresher orientation session where they will be refreshed and updated on the relaunch of the project and their roles as both participants and community partners. They will have the opportunity to ask questions and, if willing, sign an addendum consent form explaining the additions. Consented TA coaches will be asked to fill out demographics, TA CFIR context, and COVID-19 impact surveys online through a confidential Qualtrics link. For TA coaches (wave 1 and wave 2) with already enrolled centers, they will be emailed materials and trained on how to reach out to those centers to let them know that our team is relaunching the study and that the study team will be in touch soon to re-engage and consent them. For wave 3 and 4 TA coaches, at their online orientation they will be trained on how to introduce the research study to child care centers in their community using project-provided center recruitment materials. They will also be instructed to target these efforts toward a randomly selected list of centers (drawn from their current caseload) provided by the project team. They will be responsible for gauging initial interest, and then relaying that information to the research team. All TA coaches were previously trained on human subjects protection using the *CIRTI* curriculum (Anderson EE, *CIRTI: Community Involvement in Research Training*, Center for Clinical and Translational Science. University of Illinois at Chicago, 2011; available

at: <http://www.ccts.uic.edu/content/cirtification>). The CIRTification curriculum is geared towards community partners and designed to increase their knowledge of research principles and methods.

For wave 1 and wave 2 previously enrolled centers will be contacted by research staff to explain updated study details, answer questions, and confirm continued interest. For waves 3 and 4, research staff will follow up directly with all centers who expressed initial interest to their TA coach to confirm eligibility, review study details, answer questions, and confirm interest. Once a center director's eligibility and interest is confirmed, 2 lead preschool teachers will be randomly selected to take part in measures. The director will be emailed a flyer about the project to share with the preschool classroom teachers. Additionally, they will be emailed a confidential Qualtrics link to sign an online consent form and fill out an initial set of surveys. These surveys will include questions on their demographics, center demographics, their center's organization and capacity, and the impact of COVID-19. Additionally, directors will be asked to upload a month of menus and their parent and staff handbooks. Once the director has been given a couple days to share this information with the teachers, a research staff member will call back to talk to those classroom teachers (individually). Once two teachers eligibility and interest are confirmed, the research staff member will email the teacher confidential Qualtrics links, which will include an online consent form and several surveys. These surveys will include questions on demographics, their center's organization and capacity, their child nutrition and physical activity behaviors and practices, and nutrition and physical activity environment of their classroom and center. Additionally, directors will be emailed confirmation of teachers' enrollment and be sent a confidential Qualtrics link to fill out the final two surveys asking them about the foods and beverages served to preschool children on two days and their center's policies and procedures related to nutrition and physical activity.

TA coaches will be randomly assigned into either Basic or Enhanced Go NAPSACC, and they will use their assigned implementation model to deliver Go NAPSACC to all of their enrolled centers (cluster randomization).

3.2 Intervention/Treatment procedures (by visits)

Go NAPSACC is a suite of online tools designed to help child care programs improve their nutrition and physical activity practices. TA coaches from Child Care Aware in Kentucky will facilitate implementation of the Go NAPSACC program by introducing child care programs to the online tools and providing ongoing support using either a basic or enhanced implementation model. To prepare TA coaches for this role, they will be trained and supported by Go NAPSACC specialists (program experts from the research team).

- TA coaches randomized to Basic Go NAPSACC will participate in 2 hour-and-a-half-long training webinars, complete homework over a 3-week period, and have a 30 minute video conference call check-in meeting with the outreach specialist one month after training is complete. Their training will cover the importance of child care programs in encouraging children's healthy eating and physical activity behaviors, the purpose of Go NAPSACC, Go NAPSACC's 5-step improvement process and the tools available for child care providers ("Provider Tools"), their role in implementation, the tools available for coaches to support implementation ("Consultant Tools"), how to provide support remotely, and how COVID-19 may impact Go NAPSACC best practices. Wave 1 and 2 TA coaches will be refreshed on similar topics over two trainings (1-hour each) administered over a 2-week period. The 1-month check-in meeting is to go over any questions or concerns coaches have with implementing the project.
- TA coaches randomized to Enhanced Go NAPSACC will participate in 4 hour-long training webinar sessions and complete homework over a 3-5-week period. Their training will cover all topics in the Basic training plus their role in enhanced implementation, the purpose of the readiness check and how to administer it, and resources available to provide tailored support throughout implementation based on findings from the readiness check. Wave 1 and 2 TA coaches will be refreshed on these same topics through 2 one-and-a-half hour trainings. During implementation, TA coaches will participate in monthly conference calls hosted by a Go NAPSACC specialist to discuss progress, reflect on experiences, and promote peer learning.

During the first few monthly calls, TA coaches will be further refreshed on training relevant to where they are in the process through a part 3 training. After training, coaches will be asked to evaluate the effectiveness of the training during those calls through online surveys. Further, TA coaches will be provided with 2-3 one-on-one coaching sessions to address any specific questions or challenges encountered.

Basic Go NAPSACC

For centers receiving Basic Go NAPSACC, the director will be invited by their TA coach to register for a Go NAPSACC account. The director will then participate in a 1-hour orientation provided by their TA coach to learn how to use Go NAPSACC's online tools and resources. Once the director is trained, they will be encouraged to complete 2 cycles of Go NAPSACC's 5-step improvement process focusing on child nutrition and physical activity. In each cycle of Go NAPSACC, the director will:

- Evaluate their current nutrition and physical activity practices using the self-assessments in these two modules,
- Choose at least 3 goals per module and create an action plan for each goal using online tools that offer flexible step-by-step guidance,
- Work to implement the action plan and meet their chosen goals drawing from the tip and materials resource library, and
- Log progress and completion of goals.

Each cycle will take about 6 months. At the end of the 12 months, the director will retake the self-assessments on child nutrition and physical activity. Throughout this process, the director will receive brief check-ins from their TA coaches via phone, email, or in-person. TA coaches will be asked to log their implementation activities using the TA Activity Log in their Consultant Tools.

Enhanced Go NAPSACC

For centers receiving Enhanced Go NAPSACC, the director will work with their TA coach to identify an implementation team to support the use of the program and improvements in nutrition and physical activity practices. The team will include a center administrator as well as two staff (at a minimum). Before starting Go NAPSACC, the team will work with their TA coach to conduct an assessment of their center's needs, capacity, and resources. At a minimum this readiness check will be completed by all members of the team, but the team can also extend participation out to all center staff. The readiness check will be completed anonymously and returned to the TA coach for scoring. Summarized results will be presented back to the team by the TA coach and used to identify priority issues for which the team would like extra support from the TA coach as they are working through Go NAPSACC.

Once this readiness check is complete, the team will begin their use of Go NAPSACC. All members of the team will be invited to register for a Go NAPSACC account, linked back to their child care center. The team will then participate in a 1-hour orientation provided by their TA coach to learn how to use Go NAPSACC's online tools and resources. Once the team is trained, they will be encouraged to complete 2 cycles of Go NAPSACC's 5-step improvement process focusing on child nutrition and physical activity. The team will be asked to develop a 12-month plan to guide their Go NAPSACC efforts. In each cycle of Go NAPSACC, the team will:

- Evaluate their current nutrition and physical activity practices using the self-assessments in these two modules.
- Choose at least 3 goals per module and create an action plan for each goal using online tools that offer flexible step-by-step guidance.
- Work to implement the action plan and meet their chosen goals drawing from the tip and materials resource library.
- Log progress and completion of goals.

Each cycle will take about 5-6 months. At the end of the 12 months, the team will retake the self-assessments on child nutrition and physical activity. Throughout this process, the team will receive brief check-ins from their TA coaches via phone, email, or in-person. These check-ins will include tailored

prompts to offer extra guidance and support on prioritized issues identified from the needs assessment. In addition, teams from different centers within the same region will participate in 2-3 one-hour meetings hosted by the TA coach. These meetings will provide opportunities to reflect on their efforts and share lessons learned. TA coaches will be asked to log all of their implementation activities using the TA Activity Log in their Consultant Tools.

3.3 Follow- up procedures (by visits)

Measures from Baseline will be repeated following 12 months of Go NAPSACC participation. Data collection will use the same procedures explained in 3.1. The only addition is that process evaluation questions were added to the Qualtrics link, including questions around the delivery of Basic or Enhanced Go NAPSACC and cost-effectiveness.

In addition, trained research staff will complete interviews over Zoom (via link or call-in phone number) for all TA coaches in a group format based on wave and arm assignment. Trained research staff will also complete Zoom interviews with randomly selected center directors from both arms and teachers from the Enhanced Go NAPSACC arm. Interviews will last approximately 1 hour and will be audio recorded and notes will be taken.

3.4 Unscheduled visits

N/A

3.5 Concomitant Medication documentation

N/A

3.6 Rescue medication administration (if applicable)

N/A

3.7 Subject Completion/Withdrawal procedures

Participants may withdraw at anytime. They are asked to inform the study team by phone or email. If the director withdraws they are asked a few follow-up questions to assess reasons for withdrawal. There are no adverse event criteria for individual withdrawal or full study cessation.

3.8 Screen failure procedures

N/A

4 STUDY EVALUATIONS AND MEASUREMENTS

All baseline measurement will be collected through online Qualtrics surveys. Once TA coaches agree to be a part of the study they are emailed a Qualtrics survey link. Surveys include consent, demographics (general personal demographics; 10 questions), COVID impact (impact on job and work with child care centers; 11 questions), modified Consolidated Framework for Implementation Research (CFIR) questions. The CFIR survey for the TA coaches consists of 48 questions and includes questions from CFIR Constructs: Implementation Climate, Readiness for Implementation- Available Resources, Access to Information and Knowledge, Knowledge and Beliefs About the Intervention, and Self-Efficacy.

Similarly, when directors agree to be enrolled into the study they are emailed a consent form, demographics (general personal and center level demographics; (18 items), COVID impact (impact on center; 24 items), and modified CFIR, Qualtrics survey link (80 items).CFIR constructs for directors include: Networks and Communications, Climate, Implementation Climate, Readiness for Implementation- Available Resources, Access to Information and Knowledge, Knowledge and Beliefs About the Intervention, and Self-Efficacy. At this time, they may also upload a month of menus and policy handbooks (to be coded later by research staff). They are also sent a Qualtrics links to the menu and policy section and two days of the Foods and Beverages provided sections of the Environment and Policy Assessment and Observation- Self Report (EPAO-SR).

Finally, when child care center teachers were enrolled into the study they were emailed a consent form, demographics (personal demographics; 9 items), and CFIR (82 items) Qualtrics survey link. CFIR constructs are the same as the directors noted above. Each teacher is also sent one other Qualtrics link to record normal daily activities for one day (each teacher reports about a different day of the week).

After randomization and 12-months of intervention, TA coaches and child care center providers will participate in follow-up measures. Similar to baseline, most follow-up measures were done through online Qualtrics links. At follow-up TAs were emailed a link to fill out a set of surveys. Surveys will include the same CFIR from baseline and some process questions around their experience with Basic or Enhanced Go NAPSACC with their centers. For the center director these measures will include modified center demographics, the same CFIR survey and EPAO-SR questions from baseline, and some process evaluation questions around their experiences with Basic or Enhanced Go NAPSACC and costs. Child care center teachers will fill out the same CFIR and EPAO-SR surveys from baseline and additional process evaluation questions around their experiences with Basic or Enhanced Go NAPSACC. All TAs will be interviewed in a group format and interviews will be approximately 1- 1 ½ hours. They will be audio recorded and notes will be taken. Trained research staff will also complete Zoom interviews with randomly selected center directors and when relevant their implementation team regarding their experience using Go NAPSACC and making improvements to nutrition and physical activity practices. These interviews will last approximately 1 hour and will be audio recorded and notes will be taken.

4.1 Efficacy Evaluation (if applicable)

N/A

4.2 Pharmacokinetic Evaluation (if applicable)

N/A

4.3 Safety Evaluations

N/A

STATISTICAL CONSIDERATIONS

4.4 Statistical Methods

Primary Aim:

Our primary analyses will test the hypothesis under the intent-to-treat (ITT) principle using Generalized Linear Mixed Models (GLMM) that account for the clustering of child care centers within regions/TA. The primary GLMM will include a random intercept for region (b_0) and fixed effects for the baseline value of the primary outcome (β_1) and the intervention (β_2) to test if the differences in mean changes in primary outcomes is zero, where β_0 is the fixed intercept, and e is error.

$$\text{Change in Primary Outcome}_{12m} = \beta_0 + \beta_1 \text{ Primary Outcome}_{\text{baseline}} + \beta_2 \text{ Intervention} + b_0 + e$$

To further explore the intervention effect, we will examine: 1) baseline covariates relevant to change in EPAO scores; 2) interaction between treatment group and other covariates; and 3) completers only. Baseline demographics and EPAO scores will be compared between centers with and without follow-up measures to inspect for potential bias.

Secondary Aims:

Analysis for secondary aims will use statistical models like those applied for primary analysis. Generalized Linear Mixed Models (GLMM) that account for the clustering of child care centers within regions/TA under the intent to treat principle will be utilized. The primary GLMM will include a random intercept for region and fixed effects for the baseline value of the outcome and the intervention. Interaction terms will be added to models where needed. Specifics relevant to aims 2-5 include:

Aim 2. Data used to evaluate adoption, implementation, and maintenance of Basic vs. Enhanced Go NAPSACC will be compiled from the Go NAPSACC registration reports and activity reports (Center and TA). Outcomes computed from these reports include: registration, account initiation, first self-assessments, selection of goal, creating action plans, post cycle self-assessment, TA contacts, and TA implementation activities.

Aim 3. Section 1.4 includes a summary of the organizational factors outcomes that will be assessed. In short Fernandez's CFIR Inner Setting: Culture, Culture Stress, Culture Effort, Implementation Climate, Leadership Engagement, and Available Resources along with TCU's Organizational Readiness for Change: Networks and Communications and Access to Knowledge and Information will be collected from surveys completed by directors, teachers, and TA coaches. Organizational outcomes will be examined as moderators of the intervention effects in statistical models. Both continuous and categorical (quartiles) moderation effects will be tested.

Aim 4. Details about computing program cost can be found in section 1.4. The average incremental cost of delivering Enhanced Go NAPSACC will be divided by the incremental change in effectiveness (relative to Basic Go NAPSACC) to quantify the incremental cost-effectiveness ratio. The Incremental Cost-Effectiveness Ratio includes costs over the time period of the study and effectiveness measured by the unit increase in EPAO score. Standard GLMM models will be used to compare cost ratios between intervention groups.

Aim 5. Diet and activity information from the EPAO-sr (see section 1.4) will be used to diet quality of the food served to children and the physical activity time provided. Food and meal reporting will be used to summarize center-level dietary intake and to calculate diet quality (Healthy Eating Index 2015), while daily activities reporting will be used to summarize the activity levels of children. Outdoor time, active indoor time, vigorous minutes, and teacher ratings of activity level will be used to calculate an activity level index. Analysis and statistical models used to evaluate this aim will be nearly identical to those for primary analysis.

4.5 Sample Size and Power

The primary outcome for this study is change in centers' implementation of nutrition and physical activity evidence-based best practices the Enhanced and Basic Go NAPSACC arms based on scores

from the EPAO. Power calculations in Table specify the sample size needed to detect significant differences in changes with 80% power and an alpha of 0.05. An effect size of 0.6 was used, representing a conservative estimate based on published NAPSACC studies (with effects ranging from 0.4 to 1.1). An ICC of 0.001 is included based on our Go NAPSACC pilot (31 centers from 3 regions), which found negligible correlation (> 0.001) in EPAO scores between centers located within the same region. Cluster size is estimated at 10-15 centers per region. While regional TA providers likely have a larger caseload, only a sample of centers will be recruited to take part. Based

on these specifications, a sample size of 88 centers is needed detect an effect size of 0.60 with 80% power and a 0.05 level of significance. The final sample size of 97 centers allows for 10% attrition, which should be more than sufficient based on previous work with child care centers that has demonstrated low center attrition ($<10\%$). Depending on the number and capacity of TA providers, we will need to recruit approximately 8 TA providers, each of which will need to recruit 12-13 child care centers.

Power calculations

alpha	power	effect size	ICC	cluster size	suggested sample size	# of clusters
0.05	0.2	0.5	0.001	10	126.7	12.7
0.05	0.2	0.6	0.001	10	88.0	8.8
0.05	0.2	0.7	0.001	10	64.6	6.5
0.05	0.8	0.5	0.001	15	127.3	8.5
0.05	0.8	0.6	0.001	15	88.4	5.9
0.05	0.8	0.7	0.001	15	65.0	4.3

4.6 Interim Analysis

N/A

5 STUDY INTERVENTION (DEVICE, DRUG, OR OTHER INTERVENTION)

See section 3.2 for further intervention details. No device or drug studied.

6 STUDY INTERVENTION ADMINISTRATION (IF APPLICABLE)

Blinding and randomization procedures already explained in sections 2.1, 3.1, and 3.2

7. SAFETY MANAGEMENT

Given the low potential for risk of harm to participants, the data safety monitoring (DSM) plan emphasizes close monitoring of the trial by the principal investigator, project manager, onsite manager, study statistician, and a DSM officer. This DSM team will regularly review subject accrual, adherence to study protocols, dropouts, adverse events, and participant confidentiality. Specifically, the principal investigator and project manager will meet on a biweekly basis throughout all phases of the project to review the study progress and any concerns about quality control and/or participant safety. Additionally, they will review progress with the DSM officer quarterly and within two weeks when adverse events occur. Prior to subject engagement, the full DSM team will meet in person to review study protocols (e.g., recruitment, consent, adverse events monitoring), finalize the DSM plan, and establish a template for quarterly reporting. During active subject engagement, the onsite manager and Kentucky-based co-investigator will participate in biweekly meetings with the principal investigator and project manager. The project manager will also work with the study statistician to prepare reports for the DSM officer on participant accrual, adherence, and withdrawal/dropouts based on the approved reporting template. The DSM officer will be asked to review and approve these reports. In addition to these quarterly reports, any adverse events or concerns regarding confidentiality will be reviewed by the DSM officer within two weeks of the event. We do not anticipate the need for interim analyses for early termination due to intervention effectiveness or futility. We feel that this level of monitoring is commensurate with the risks and complexity of the proposed study.

Measurement and Reporting of Adverse Events

At enrollment, we will inform center staff and TA providers to contact the project manager if they feel an injury or illness may have occurred to them or a child in their care as a result of their participation in this study. If such an event occurs, the project manager will collect a detailed description of the event, the adverse outcome, severity of the adverse event, and whether or not participants viewed it as related to the study. This report will then be reviewed by the DSM officer, who will categorize it as: *definitely*

unrelated, or unlikely, possibly, probably, or definitely related to study participation. Although some injuries may be anticipated as a result of an intervention that promotes regular physical activity for children, in our previous center-based work, no injuries related to participation occurred. We therefore anticipate that injury risk is present, but minimal. Adverse event reports will be submitted to the IRB after they are completed by the DSM officer. A summary of these reports will be submitted to the NIH project officer on an annual basis as needed.

Participant Confidentiality

This study will collect provider and organizational-level measures. Collection of data is for research purposes only and is kept in strict confidence by study personnel. Data collection forms and contact information used to implement the intervention will be kept in locked file cabinets in the UNC-Chapel Hill study offices. Online data collection will occur through Qualtrics and is password protected. Participants will be assigned an ID number which will be used to minimize the use of names on forms. Any forms linking participant ID and name will be stored separately, away from other survey data. Electronic data files will be stored on a secure, password protected server. Except when required by law, participants will not be identified by name, address, telephone number, or any other direct personal identifier in study records disclosed outside of UNC-Chapel Hill. Written informed consent will be obtained using a UNC approved consent form.

8. DATA COLLECTION AND MANAGEMENT

Due to study modifications associated with COVID 19 data collection utilized remote collection methods including phone calls, online surveys, and video conferencing. All methods and modifications were approved by the UNC IRB and funding officers. Data completion and quality was monitored by the project manager and data manager during this transition and throughout baseline and follow-up assessments. All data are housed on secure university servers with direct access limited to relevant research personnel (PI, statistician, project and data managers). De-identified data will be housed for long term access using the UNC data storage system. A more complete description of the important and maintenance of participant confidentiality can be found in section 7 (above).

9. RECRUITMENT STRATEGY

The 97 centers will be recruited over 4 waves from the 11 regions that span the state. We will work with Child Care Aware Kentucky and identify Technical Assistants in each region. We will then identify all licensed child care centers that each TA works with and randomly select a sample of 25 centers for each TA to target for recruitment. TA providers will help distribute recruitment materials (provided by the project) to the child care centers and gauge initial their interest. The names and contact information from interested centers will be supplied to the project team for follow-up. Trained research assistants will follow up with interested centers by telephone to review study details, confirm eligibility, and verify interest of the center. Once participation is confirmed, two 3-5 year old classroom teachers will be chosen to be recruited. A follow up email with information to go over with potential teachers. Then those teachers would be called at the center and recruited by phone to review study materials and confirm interest.

10. CONSENT PROCESS

Once providers have been explained the study over the phone and eligibility and interest is confirmed consent will be collected online via a Qualtrics link that is sent through a study email by a study staff member. A downloadable link will be included in the Qualtrics and a blank copy of the consent form will be attached to the email. Participants can take as much time as they would like to look over the consent form and ask questions before signing online or on paper. If paper is requested a postage provided envelope will be provided to mail back their signed consent form. These paper copies will be kept away from other data in locked cabinets only accessible by study staff.

11. PLANS FOR PUBLICATION

Study results and additional findings with published in 2-3 manuscripts submitted to peer reviewed journals. A protocol paper has been published.

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APPENDIX

Table 2 Measurement of implementation context

CFIR construct	Source	Asked to:	
		Directors and teachers	Coaches
Networks and communications	ORC: Organizational Climate–Communication [41, 42]	Yes	No
Culture	ISS: Culture, Culture Stress, Culture Effort [40]	Yes	No
Implementation climate	ISS: Implementation Climate [40]	Yes	Yes
Readiness for implementation			
Leadership engagement	ISS: Leadership Engagement [40]	Yes	No
Available resources	ISS: Available resources [40]	Yes	Yes
Access to information and knowledge	ORC: Resources–Training [41, 42]	Yes	Yes
Knowledge and beliefs about intervention			
	TDFQ: Knowledge [43–45]	Yes	Yes
	TDFQ: Beliefs and Consequences [43–45]	Yes	Yes
Self-efficacy	TDFQ: Beliefs about Capabilities [43–45]	Yes	Yes