

STUDY PROTOCOL

“My wellbeing-their wellbeing “– An eHealth intervention for managing obesity in early care and education: Protocol for the Go NAPSACC Cares cluster randomized control trial

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Abstract

Background

To fully leverage the potential of the early care and education (ECE) setting for childhood obesity prevention, initiatives must not intervene solely at the organizational level, but rather they should also address the health needs of the ECE workers. Workers suffer disproportionately high rates of obesity, and have reported low confidence in modeling and promoting healthy eating and activity behaviors. However, information regarding the effectiveness of improving ECE workers’ health behaviors or whether such improvements elicit meaningful change in the ECE environment and/or the children in their care is limited.

Method

The proposed study will integrate a staff wellness intervention into a nationally recognized, ECE obesity prevention initiative (Go NAPSACC). Go NAPSACC+ Staff Wellness program will be assessed using a clustered randomized controlled trial including 84 ECE centers, 168 workers, and 672 2–5-year-old children. Centers will be randomly assigned to 1) standard “Go NAPSACC” or 2) Go NAPSACC+ Staff Wellness. Outcome measures will assess impact on dietary intake and PA behaviors of 2-5-year-old children at 6 months (primary aim) and 12 months. Secondarily, we will compare the impact of the intervention on centers’ implementation of healthy weight practices and the effect on ECE workers’ diet quality and PA at 6- and 12 months.

relevant data from this study will be made available upon study completion.

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Competing interests: The authors have declared that no competing interests exist.

Discussion

This trial expects to increase our understanding of how ECE worker's personal health behaviors impact the health behaviors of the children in their care and the ECE environment.

Trial registration

ClinicalTrials.gov: [NCT05656807](https://clinicaltrials.gov/ct2/show/study/NCT05656807), registered on 19 December 2022. Protocol version 1.0, 22 March 2023.

Introduction

Despite significant efforts to thwart the increasing incidence of obesity, rates have continued to climb over the past two decades [1–3]. Once established, obesity is associated with a myriad of health issues including type 2 diabetes [4–6], cardiovascular disease [6–8], several cancers [9–11], lower quality of life [12] and high burden of medical costs (~\$150 billion annually) [13,14]. Research shows that the ages between 0–5 years are a critical period in the development of obesity [15–17], and that childhood obesity is highly predictive of adult obesity [15,18]. Poor eating and physical activity habits, developed during childhood, are important causes of excessive weight gain [18]. Moreover, the environment to which young children are exposed, especially the adult-child relationships they experience, play a key role in shaping these habits that mediate risk of obesity [16,17,19]. As a result, early care and education (ECE) centers — and their staff — have been identified as critical partners in public health efforts to address today's obesity epidemic.

Developed over 20 years ago, “Go NAPSACC” is one of the most widely implemented evidence-based childhood obesity prevention initiative [20–24]. Go NAPSACC's user-friendly and interactive tools guide ECE directors through a five-step improvement process [20,25]. Go NAPSACC has been implemented in over 25 states and received national recognition as “best evidence for impact” on childhood obesity [26]. While Go NAPSACC is shown to be efficacious in improving organizational-level policies and practices around healthy eating and physical activity in ECE programs, the program is primarily delivered through ECE directors with little direct engagement of other workers (e.g., teachers, assistants, cooks). Research has shown that workers' own eating and physical activity patterns reduce their confidence and ability to model and promote healthy lifestyle behaviors to children [27–30]. ECE workers specifically list their own lack of knowledge about nutrition and physical activity as critical barriers to obesity prevention efforts [31,32], including Go NAPSACC [33]. Untapped opportunities exist to address workers' health that would both improve their own quality of life and create healthier environments for the children in their care.

Using Go NAPSACC, we have the opportunity to assess if a comprehensive early childhood obesity prevention initiative that also addresses the health of ECE workers elicits meaningful change in the ECE environment and health behaviors of children in their care. If successful, findings will provide a highly implementable, scalable, and sustainable strategy that would enhance the standard paradigm of early childhood obesity prevention initiatives. This manuscript presents the background, rationale, and design to be used in this study.

Materials and methods

Funding

The primary sponsor of this study is the National Institute of Diabetes and Digestive and Kidney Diseases as part of the United States National Institutes of Health, (R01DK128174).

Design overview

The proposed study is a cluster-randomized trial with a six-month active intervention and a six-month no contact follow-up period. Centers in both arms will receive the standard Go NAPSACC program. The intervention arm will be enhanced with an ECE worker-level healthy lifestyle intervention that encourages healthy eating, increased physical activity, and weight management (Go NAPSACC+ Staff Wellness). The dual primary outcomes are child's diet quality and physical activity between baseline and post-intervention (6 months); secondary outcomes include worker diet quality, physical activity, weight, and centers' use of evidence-based healthy lifestyle practices. The assessment schedule is shown in Table 1. This study has been approved by the Institutional Review Board at the University of North Carolina-Chapel Hill and registered at Clinicaltrials.gov (NCT05656807, Protocol version 1.0, 22 March 2023).

Recruitment

A convenience sample of 84 ECE centers will be recruited in four cohorts across four years from central North Carolina. ECE centers will be identified from the NC Division of Child Development and Early Education website (ncchildcare.ncdhhs.gov/childcaresearch), a publicly available database of licensed ECE facilities. Recruitment efforts will incorporate a multi-phase approach to ensure the engagement of centers and center directors as well as workers and parents. Recruitment efforts within each county will start by identifying community organizations which have established working relationships with local ECE centers. These community partners will be asked to endorse study participation and help distribute study information through their existing communication channels (e.g., newsletters, emails, partner

Table 1. Assessment schedule.

TIMEPOINT	STUDY PERIOD										
	Pre-allocation	Allocation	Post-allocation								
	$-t_1$	0	6-month active intervention							t_1 post intervention	t_2 6-month follow-up
ENROLMENT:											
<i>Eligibility screen</i>	X										
<i>Written informed consent</i>	X										
<i>Allocation</i>		X									
INTERVENTIONS:											
<i>Standard Go NAPSACC</i>			X	X	X	X	X	X			
<i>Go NAPSACC+ Staff Wellness</i>			X	X	X	X	X	X			
ASSESSMENTS:											
<i>Demographics</i>	X										
<i>Anthropometrics (Teacher only)</i>	X								X	X	
<i>Child/Teacher Physical Activity</i>	X								X	X	
<i>Child/Teacher Diet Quality</i>	X								X	X	
<i>Center level Physical Activity/Nutrition Environment</i>	X								X	X	

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website, group meetings). These communications will be followed by personalized email and mailed invitations about the study directly to centers from the study team. Then the team will follow up with direct solicitation to center directors to gauge interest and confirm center eligibility. Eligible ECE centers must 1) be open year-round, 2) be licensed with no plans to close in the next two years, 3) have been in operation for at least one year, 4) have at least two classrooms serving children 2–5 years-old, 5) serve lunch, 6) have no history of Go NAPSACC participation in the past 6 months. Additionally, two ECE classroom teachers serving 2–5-year-old children and eight primary caregivers of children from each classroom must provide written consent to participate. Once initial interest and eligibility are confirmed, an in-person recruitment visit will be scheduled to introduce the study to ECE teachers, answer questions about participation, invite teacher participation, and conduct informed written consent procedures. Eligible ECE workers must 1) be 18 years-old or older, 2) be a teacher of a 2–5-year-old classroom, 3) be able to read English, and 4) not be pregnant, nor planning to become pregnant in the next year. Once a center and teachers agree to participate, we will work with them to recruit children from their center. A follow up visit will be scheduled to collect written consents and answer any questions from primary caregivers. Eligible children must 1) be in a classroom with a participating ECE teacher, 2) be 2–5 years old, and 3) consenting primary caregiver must be able to read English.

Randomization

Centers will serve as the unit of randomization. Following baseline testing of each cohort, the centers will be randomized to either standard Go NAPSACC or Go NAPSACC+ Staff Wellness. Randomization tables will be created by the data manager using a permuted block approach, with block sizes of four. The project manager will use this randomization table to assign centers to each arm (1:1). Results of randomization will be restricted to only essential team members. Only the project manager and study staff helping to deliver the intervention will be aware of arm assignment. Investigators, study statistician, and data collectors will remain blinded.

Intervention overview

Standard Go NAPSACC (0–6 months). All participating ECE centers will implement the Go NAPSACC program. Go NAPSACC provides a well-known platform within the ECE setting that allows intervention materials and support to be available continuously; thus, participants can engage with intervention materials on their own schedule and progress at their own pace. Go NAPSACC offers a suite of interactive, online tools that guide center directors through a 5-step improvement process (described below) to increase use of healthy eating and physical activity evidence-based practices (<https://gonapsacc.org/>) [20–24].

Standard Go NAPSACC theoretical model

The Go NAPSACC program is guided by Social Cognitive Theory (SCT) and the Social Ecological Model (SEM). A core concept in SCT is reciprocal determinism, which suggests that behavior is shaped by the dynamic and reciprocal interaction between personal, environmental, and behavioral factors. SCT also recognizes that behavioral capability, observational learning, reinforcement, expectancies, and self-efficacy influence behavior. SEM posits that health behaviors are shaped by individuals' interactions with the physical and social environment, recognizing sources of influence coming from individual, interpersonal, organizational, community, and public policy levels. Go NAPSACC applies this to children in ECE by recognizing that their eating and physical activity behaviors will be shaped by this ECE environment, and

the opportunities it offers to experience, learn about, and build skills needed to adopt healthy lifestyle habits.

Standard Go NAPSACC components

Centers will have 6 months to complete two 3-month mini-cycles of Go NAPSACC's five-step improvement process using the child nutrition and physical activity modules. The order of starting module will be randomized.

Director orientation. The director will lead the Go NAPSACC effort for their ECE center, helping ensure changes are applied center wide and not just to specific classrooms. The directors will take part in a 1-hour video conference orientation. The orientation will be provided by research staff using standardized materials, which will include a slide presentation with talking points and a user guide. The orientation will instruct center directors on how to use the Go NAPSACC online tools and guide them through the creation of a personalized account. Sessions will be recorded and 10% of sessions will be reviewed using a study specific fidelity checklist on a rolling basis to confirm the information was delivered as intended.

Access to Go NAPSACC tools. Directors will use their personalized account to access Go NAPSACC's interactive, online tools that guide them through the 5-step improvement process: 1) **Assess** tools provide self-assessments to help directors reflect on their current practices. 2) **Plan** tools help directors use feedback from their self-assessment to select goals and create customized action plans to reach those goals. 3) **Take action** tools offer a library of tips and materials that help directors as they work through their action plan steps. 4) **Learn more** tools offer trainings to improve knowledge. 5) **Keep it up** tools encourage directors to retake the self-assessment to gauge progress, celebrate, and identify areas for future work.

Support for center implementation. Directors will receive monthly check-ins by video conference, telephone, or email from research staff. Check-ins will be used to encourage directors to complete at least one cycle of Go NAPSACC's 5-step process for both the physical activity and nutrition modules, assist with goal setting and action planning, inquire about progress on goals, provide suggestions for meeting goals as needed, troubleshoot technical issues, and support navigation of the tips and materials library and trainings.

Go NAPSACC+ staff wellness (0–6 months)

Centers randomized to the Go NAPSACC+ Staff Wellness arm will receive the traditional Go NAPSACC program (described above); in addition, consented ECE teachers will simultaneously receive an evidence-based healthy lifestyle intervention adapted from prior evidence-based weight management interventions [34–36]. Each teacher will have their own account (set up at orientation) through which to access materials that will support their adoption of evidence-based strategies for improving healthy eating and physical activity.

Go NAPSACC+ Staff Wellness theoretical model

Healthy lifestyle intervention strategies, also guided by SCT, pull from national nutrition and physical activity recommendations [37–40] and behavior change techniques that increase intervention adherence and improve health behaviors. The intervention integrates techniques known to be most effective for changing diet and physical activity behaviors, including intention formation, goal setting (e.g., weight loss, weight maintenance), self-monitoring (diet, physical activity, weight), and personal feedback [41]. These techniques will be enhanced by employing behavior shaping (gradually modifying physical activity goals), stimulus control (strategies to decrease cues for less desirable and increase cues for more desirable diet and physical activity behaviors), including cognitive strategies to increase self-efficacy and problem

solving, such as identifying and developing plans for high-risk situations, making changes in the home and social environments, responding to stress with non-food techniques, and relapse prevention strategies to teach participants to recognize precursors and consequences of lapses.

Go NAPSACC+ staff wellness components

ECE teacher orientation. ECE teachers will take part in a 1-hour in-person orientation session at their center, where research staff will introduce the healthy lifestyle intervention, including an overview of the Go NAPSACC+ Staff Wellness mobile web application that can be accessed on a desktop, phone, or tablet, a detailed description of the diet and physical activity goals, instructions on setting up and using the digital health devices, and reviewing program timeline and expectations. All participants will be provided a Fitbit Inspire 3™ activity tracker, an Aria Air smart scale (Fitbit, Inc., San Francisco, CA), and welcome items (e.g., microfiber towel, water bottle, exercise bands). Time will be allotted for demos, practice, questions, and troubleshooting (e.g., internet connectivity, web application data entry). Any technical issues will be resolved by contacting research staff by phone or email. A randomly selected 10% of sessions will be screened by a secondary staff member using a study specific fidelity checklist on a rolling basis to confirm the information was delivered as intended.

Go NAPSACC+ Staff Wellness website. The staff wellness mobile web application created for ECE workers will focus on personal healthy behavior change strategies and will include self-assessments, behavioral lessons, tailored feedback, food monitoring, and will link data from various mHealth devices (e.g., Fitbit, digital scales) to display on participants' personal website accounts. Sample screenshots of the online application are shown in Fig 1.

Self-Assessment. Upon first login to the website participants will be prompted to complete a self-assessment, including questions about weight management goals (e.g., weight loss or weight maintenance), recent physical activity and eating behaviors, and recently used strategies and behaviors that an individual may have engaged in when trying to lose or maintain their weight. Responses from the self-assessment are used to create participants' starting eating, physical activity, and their choice of a weight loss or weight maintenance goals will drive the messaging they receive throughout the program.

Dietary modification. Dietary recommendations will use an approach adapted from the Stoplight Diet (SLD). The SLD, originally developed by Epstein [42], is an effective weight loss strategy for both children [42–44] and adults [45–48]. Stoplight approaches categorize foods by energy content: green (low calories/high nutrients: consume freely), yellow (moderate calories/high nutrients: consume in moderation), and red (high calories/low nutrients: consume sparingly). Stoplight approaches may be easier for participants to understand and take less

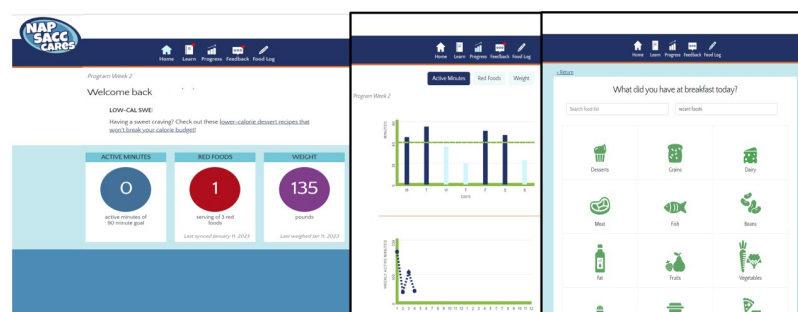


Fig 1. Sample Screenshots of the online web application.

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time than traditional calorie monitoring, particularly when asked to track only red foods. Tracking only red or high-calorie foods is a form of simplified or partial self-monitoring with demonstrated feasibility, acceptable adherence rates, and leads to clinically relevant weight losses [34,47,49]. In this study, lists and/or pictures of foods will be provided and will be color-coded for use in meal planning, shopping, and snacking. Teachers will receive a personalized daily red food goal based on their starting weight and weight change goal (e.g., a participant wanting to lose weight who is 250 lbs. will receive a daily red food goal of 3) and will be asked to reduce and record their servings of red foods in the food log section of the website.

Physical activity. We will prescribe a progressive moderate-intensity physical activity program (i.e., walking, jogging, biking, etc.) as recommended by the "physical activity Guidelines for Americans." [38] Participants will receive a daily activity goal, with starting goals based on self-reported recent activity levels from the self-assessment: 0 minutes/ week = 10 minutes/day goal; 1–59 minutes/week. = 15 minutes /day goal, >60 minutes/week = 20 minutes/day goal. Attainment of weekly goals and progression will be based on data collected using Fitbit. If participants reach the equivalent of 5 times their daily activity goal in a given week, the following week, their daily goal will be increased by 5 minutes, up to a maximum of 60 minutes/day.

Self-monitoring. Participants will be asked to self-monitor red foods on the web application, physical activity using their Fitbit, and self-weigh daily using their smart scale. These data, which are synced to study servers in real-time, will be used for displaying participant progress, tailoring study messages, and for staff to assess fidelity of the program. *Diet.* Participants will log their red foods in the web application food log and view their dietary progress on the "Diet" page of the Go NAPSACC+ Staff Wellness web application. They can view the current day's tally of red foods and beverages, in addition to a graph of totals over time. *Physical activity.* Participants will wear their Fitbit activity tracker and can also track activities manually in the Fitbit app when needed. They can view the current day's activity minutes and graphs of progress over time on the "Activity" page of the web application. *Body weight.* Participants will weigh themselves using their smart scale which will sync their weight with the Fitbit app and study servers. They can view their most recent weight and overall weight progress on the "Weight" section of the web application.

Behavioral lessons. The Go NAPSACC+ Staff Wellness web application will unlock new lessons weekly for the first 12 weeks and then biweekly the next twelve (6 months total). Lessons will consist of written content focusing on reinforcing weight management strategies, including what strategies look like, why they are important, and practical tips for incorporating them into their everyday lives. Lessons will include topics such as portion sizes, reducing caloric beverages and red foods, emotional eating, behavioral strategies to increase physical activity, importance of sleep and stress management, stimulus control, sustaining changes, problem solving, and relapse prevention. Lessons will also include a Caregiver Corner that is specifically created for teachers working in the ECE setting. The Caregiver Corner will provide suggestions for incorporating lesson topics into their classroom. For example, a lesson about making healthy choices in social situations includes a Caregiver Corner section offering strategies for planning healthy classroom parties with children.

Tailored weekly feedback. Participants will receive weekly summaries of their progress on the web application. Participants self-monitoring data on diet, physical activity, and weight, along with their weight goal (loss or maintenance) will be used to tailor their feedback, which will include positive reinforcement for meeting goals and encouragement, tips, and specific behavior change techniques to promote future tracking and goal adherence.

Text messages. Participants will receive up to 5 text messages per week, which will include prompts to complete the lessons and review resource materials, messages that are tailored to

their self-monitoring data to remind them to track or help them reach their eating, activity, or weight goals, and general tips for healthy behaviors in the childcare classroom.

Secondary users

As per protocol two teachers from each center will be recruited and enrolled for all study components. However, at centers randomized to the Go NAPSACC+ Staff Wellness arm, all other workers will be invited to register as a secondary user. These users will not officially be enrolled in study outcome measures and will not receive Fitbit trackers or scales but will have access to the web application and its resources. They will be encouraged to manually log their activity and weight in the Fitbit app, will be able to view their progress on the study web application, and will receive text messages and tailored weekly feedback. The number of secondary users within each center will be recorded as part of process measures. For centers randomized to the control arm, once all study data has been collected at the 12 month follow up, any worker will be provided information about becoming a secondary user.

No contact follow-up (7–12 mos). After the 6-month intervention period, all centers will continue to have access to the Go NAPSACC online tools and will be encouraged to continue additional cycles of the improvement process; however, the active engagement with research staff and their ongoing support will cease. Similarly, participants in the Go NAPSACC+ Staff Wellness arm will also continue to have access to the healthy lifestyle intervention suite of online tools and self-monitoring devices (i.e., Fitbit and smart scale); however, the active engagement of participants via reminders, tailored feedback, and motivational messages will cease.

Measures

ECE workers (i.e., center directors, classroom teachers) and children will complete a series of assessments at three time points: baseline (month 0), post-intervention (month 6), and post no contact follow-up (month 12). Although the Go NAPSACC program will be implemented center-wide (affecting the environment of all children and ECE workers in each center), measurements will only be collected on children and ECE teachers formally enrolled in the study. These measures will be collected during a two-day on-site visit to the ECE center and supplemented with self-administered web-based surveys. This on-site visit will be conducted by data collectors who have undergone extensive training and certification on all measurement procedures and are blinded to study-arm assignment. Identical data collection protocols will be used at each timepoint. Detailed descriptions of measures and plans for analysis for each aim are provided below.

Dietary quality

Children's dietary intakes will be assessed using the Dietary Observation for ECE (DOCC). DOCC is a direct observation protocol developed by our team [50], used to assess foods consumed by children while at ECE. The DOCC collects detailed dietary data, including types of foods provided to children, amounts served, consumed, traded, spilled, and shared, and has been shown to be a reliable method (inter-rater $r > 0.98$) for collecting observational dietary data in ECE centers [51]. Data collectors trained and certified in the DOCC protocol can assess up to three children at a time. The DOCC data will be entered into Nutrition Data System for Research (NDSR) to calculate children's daily intake of food groups, calories, and nutrients. Using NDSR output, we will calculate Healthy Eating Index-2015 (HEI-2015) scores which assess conformance with dietary guidelines, providing a score ranging from 0 to 100, where scores closer to 100 indicate higher diet quality [52–54].

Teachers' dietary intake will be assessed using food records collected and analyzed by the Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool developed by the National Cancer Institute. This tool has demonstrated acceptable psychometric properties [55–57] and has been validated in adults [58]. ASA24 is an automated web-based tool which allows multiple 24-hour recalls to be completed independently by participants using any internet enabled device. The website prompts participants to report detailed information about all the food and beverages consumed, using a multi-step process in which they record eating occasions, times, and add foods and beverages consumed. Teachers will record all food, beverages, and supplements consumed for 3 days (2 weekdays, 1 weekend day) within a 2-week period. Using ASA24 output, we will calculate HEI-2015 scores [52–54].

Physical activity

Physical activity will be assessed via GT3X+ accelerometers (ActiGraph, Pensacola, FL) worn on participants' non-dominant wrist for 24h/day for 7 days. For the proposed study, accelerometers will be programmed to sample acceleration at 40 Hz. On the morning of the first day of the center site visit, a data collector will fit each participant (teachers and children) with the accelerometer upon arrival at the center. ECE teachers and parents will be instructed on how to reattach and remove the accelerometer. Cut-points developed for preschool-aged children [59] and adults [60]. will be applied to accelerometer data, as appropriate, to calculate minutes spent in different levels of physical activity (total non-sedentary, sedentary, light, moderate, and vigorous).

Anthropometrics

Anthropometrics will be collected in the morning of the onsite visit while participants are in light clothing with shoes removed. *Weight* will be measured to the nearest 0.1 kg using a Seca digital scale (calibrated quarterly; seca, Chino, CA). For children, weight will be an average of 2 measures within 0.3 pounds and for teachers within 1 pound. *Height* will be measured to the nearest 1/8 inch using a stadiometer (Shorr Productions, Olney, MD). For all participants height will be calculated as an average of 2 measures within 0.25-inch BMI (kg/m^2) will be calculated from height and weight.

ECE center environment. Centers' implementation of nutrition and physical activity best practices will be assessed with the Environment and Policy Assessment and Observation (EPAO) instrument [61]. The EPAO uses direct observation and review of written documents to capture environmental components of ECE: foods and beverages provided, feeding practices, feeding environment, menus, time provided for active play and outdoor play, indoor and outdoor play environment, teacher active play practices, screen availability, teacher screen practices, education and professional development, and policy. This measure has good inter-rater reliability [61] and sensitivity to change following interventions [62–64]. For EPAO data collection, each classroom will be observed for a full day. Data will be scored according to the EPAO scoring rubric, which first assesses compliance with nutrition and physical activity best practices, scoring each best practice using a 4-point scale (where higher scores indicate better compliance). Best practice compliance variables are then used to calculate environmental component scores that capture the various aspects of the nutrition and physical activity environment. Each environmental component score is calculated by averaging the relevant best practice compliance scores. Finally, the environmental component scores are summed to determine an overall nutrition and physical activity environment score.

Process measures

As in our previous trial [65], the process evaluation will be guided by Steckler and Linnan [66] and the RE-AIM model framework [67]. As suggested by RE-AIM, we will measure *reach* (% who participate in each intervention component, engagement with website, self-monitoring of PA, diet and weight, and worker representativeness); *effectiveness* (assessed via aims); *adoption* (center level measure of uptake & representativeness); *implementation* (dose delivered; adherence to quality and fidelity of established protocols); and *maintenance* (teacher and center level durability of effects 6-months post-intervention) [67]. The most current guidelines for operationalizing these measures will be utilized [68]. Our previous process evaluation work also includes measuring *recruitment* (# approached, # eligible, # enrolled and costs per center & workers enrolled), and *responsiveness* (teacher satisfaction and use/engagement with intervention components). Process measures will allow us to understand study results more fully—why the intervention did/did not work, for whom and under what conditions the intervention was most/least effective, opportunities for program improvement, and the potential for dissemination/sustainability.

Structured interviews will be conducted by virtual conference call (e.g., zoom) in a 20% random sample of ECE directors and teachers from the Go NAPSACC+ Staff Wellness arm at 6 and 12 months to gather information that might be useful in improving the content or implementation of the intervention in ECE settings. Topics will include preference for intervention format, length, barriers to intervention components, suggestions to improve the intervention, overall satisfaction, including the diet and physical activity recommendations, online trainings, and engagement with research staff.

Data management

Participants will be assigned an ID number as part of the screening process. All data collection forms and tables thereafter will use only this participant ID. Participant information (ID, eligibility/ineligibility, enrollment) will be stored in a database on UNC Center for Health Promotion and Disease Prevention's secure server. This server is only accessible to approved project staff. The Project Manager will oversee quality checking of all data, creation of derived variables, development of a data dictionary and data user manual, and the creation of the final master de-identified dataset. This de-identified dataset will be saved on a shared drive on UNC's secure server. Those wanting access to the analysis dataset will request permission from the principal investigator and project manager, who in turn will work with the data manager to extract the specific data requested.

Statistical analysis

Our primary analyses will involve testing change in enrolled children's minutes of non-sedentary activity and HEI scores between standard Go NAPSACC and Go NAPSACC+ Staff Wellness groups at 6 (primary outcome) and 12 months (secondary outcome). Using maximum likelihood methods, we will use multi-level linear mixed models (PROC MIXED) with repeated measures to estimate change at 6 and 12 months and to test for statistical differences across groups in changes over time. Models will include random effects for cluster to account for covariance between participants within the same center as well as fixed effects for time, trial arm, and time*arm interaction. A proper error covariance structure will be chosen based on model fit indicated by model likelihood, Akaike Information Criterion and Bayesian Information Criterion. To further explore the effect of the intervention, these analyses will be followed by sensitivity analyses that adjust for baseline variables distributed differently between

intervention groups and examine completers only. Similar analyses will be completed for each secondary outcome including teacher physical activity, HEI scores, weight, as well as center physical activity and nutrition environments. While every effort will be made to avoid missing data, we expect some missing data due to attrition and nonresponse. Missing data patterns will be explored under various assumptions (e.g., missing completely at random, missing at random, or missing not at random) and presented in the outcomes paper.

Power calculation

This trial is powered to detect between group difference (Standard Go NAPSACC vs. Go NAPSACC+ Staff Wellness) of 5 units in child HEI score and 1 minute per hour in non-sedentary physical activity. Based on intraclass correlation (ICC) from our preliminary work and those of others [69,70], we estimate ICC of 0.04 and 0.07 for HEI score and 0.07 and 0.10 for non-sedentary physical activity at the teacher- and center-levels, respectively and standard deviation of change in HEI score of 11 units [71,72] and non-sedentary physical activity of 3 minutes per hour. Furthermore, we calculated power for each of the two primary comparisons using a type I error rate of 2.5%, thus keeping overall Type I error rate at 0.05. Sample size was initially calculated using assumptions associated with non-sedentary physical activity knowing that the higher ICC would require a larger sample size. This sample size was then used to conduct a power analysis for HEI score. Given this, a sample size of 84 centers, with two 2-5-year-old classroom per center, and an average of 4 children per classroom, for a total of 672 children, would allow us to detect a clinically meaningful difference in non-sedentary physical activity with 88% power and HEI score with 99% power at $\alpha = 0.025$ level of significance between the two study arms. Even with up to 20% attrition for centers and children, a completer's only analysis will still provide 81% and 98% power for change in non-sedentary physical activity and HEI score, respectively, which is higher attrition than we expect based on our previous trials [62,69,73]

Participant retention

Every effort will be made to avoid missing data; however, we expect some missing data due to attrition and nonresponse. If participants choose to withdraw from this study, all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless they provide additional written permission for further data collection at the time of their withdrawal. To minimize attrition, a variety of incentives will be provided to encourage participation in the data collection process. Specifically, center directors will receive \$100 per for participating in the 2-day onsite data collection visit at each timepoint. ECE teachers will receive a \$75 incentive for completing outcome assessments at each timepoint and those participating in structured interviews will receive an additional \$25. In addition to monetary incentives, small gifts valued at \$50 per time point will be given to each participating classroom (e.g., magna-tiles, mindfulness map, wooden fruits/veggies) and child (e.g., books, bubbles, chalk). Teachers randomized into Go NAPSACC+ Staff Wellness will be allowed to keep the Fitbit, smart scale, and welcome items. Teachers in the control arm will receive \$225 each as compensation for not receiving healthy lifestyle intervention and devices.

Data safety monitoring

The intervention and measurement protocols pose minimal risk to participants. Given the low potential for risk of participant harm, this data safety monitoring (DSM) plan emphasizes close monitoring of the trial by the principal investigator, project manager, study statistician, and two DSM officers. Data reviews for accrual, adherence, and withdrawals will be reported

to DSM officers quarterly and adverse events will be completed as they occur. DSM officers will review the stopping rules report regarding statistical power implications of drop outs/missing data on a yearly basis. Suboptimal recruitment will be classified as falling into one of three zones—yellow, amber, and red. Red zone classification is the most severe of these categories and is defined as less than 25% of the benchmark at the 25% time point or the 50% time point, or less than 50% of the benchmark at the 75% time point.

Trial status and study timeline

As of April 2023, the study team has completed development of the Staff Wellness website, finalized protocols and project materials, and has started recruiting. Intervention and data collection are expected to be completed by May 2026. Data analysis and paper writing will be completed by the end of January 2027. Any protocol modifications will be reported to the Institutional Review Board at the University of North Carolina-Chapel Hill and updated on Clinicaltrials.gov.

Discussion

Initiation and evaluation of the Go NAPSACC Cares program is based on the premise that ECE workers are critical for the success of ECE-based early childhood obesity prevention initiatives, with the goal of improving ECE workers' eating and activity behaviors such that these positive changes have a ripple effect onto child behaviors. The study is expected to include 84 ECE programs, 168 teachers, and 672 children followed over 12 months. All participating ECE programs will be exposed to the Go NAPSACC program and an implementation specialist for 6 months. In the staff wellness arm teachers will also receive a tailored diet and physical activity intervention during this 6-month period. During the maintenance period (months 7–12) all participants will maintain access to their respective program materials but engagement with research staff and interventionists will cease.

Information regarding the effectiveness of improving worker health behaviors or whether such improvements elicit meaningful change in the ECE environment and the children in their care is limited [73–78]. For example, no study included in a 2020 scoping review of interventions targeting the health status of the ECE workforce reported data on the impact on child outcomes and only 5 of 11 studies reported worker health outcomes. Moreover, the majority of these studies are limited by small samples [74–77], no control groups [76,77], and lack of objective measures of physical activity, environment, and workplace supports [74,76,77]. One study published subsequent to the 2020 scoping review found workers' self-reported increases in their own health status were associated with greater improvements in the classroom environment, however, no objective measures of workers' health or child outcomes were collected [74]. Moreover, the low-intensity of these interventions is an additional methodologic concern as evidence suggests more intensive lifestyle interventions are needed to produce clinically meaningful change in health behaviors [39]. Due to the limited body of evidence available, and the potential health benefits to workers and the children in their care, the 2020 scoping review concluded there is a critical need to develop and evaluate ECE worker health promotion interventions [79]. Considering Go NAPSACC's wide dissemination within ECE setting, it offers a natural platform to deliver a health promotion intervention for ECE workers. This addition will not only address the health needs of workers but could also improve their engagement in Go NAPSACC's program-wide efforts to implement evidence-based childhood obesity prevention practices.

To address gaps in the field, we considered several design features. These included: type of worker intervention, BMI inclusions, dietary strategies, and self-monitoring approaches.

Comprehensive healthy lifestyles approach with a focus on weight management was chosen because it has been identified as a primary health concern of ECE workers [29,80] and our own research has shown a high desire for such interventions. We hypothesize that meeting these demands of the workers, via a Go NAPSACC+ Staff Wellness program, will improve the health status of the worker, boost instruction and modeling of healthy lifestyle behaviors in ECE settings, and may subsequently enhance Go NAPSACC's effect on the ECE environment. We chose to include ECE workers with BMI ≥ 18.5 kg/m². An estimated 88% of the ECE worker population are classified with overweight or obesity [28], therefore, the majority of workers will benefit from a weight management intervention. For individuals who are within the healthy BMI range (18.5–24.9 kg/m²) recommendations will be tailored to improving physical activity and diet quality for general health. Self-monitoring is associated with improved weight loss and maintenance [39,81,82]. Adherence to self-monitoring protocols is improved, and the probability of dropout is reduced in weight management trials using electronic compared with traditional pencil/paper records [83,84]. Thus, to improve the low compliance with self-monitoring seen in our previous trial [85] we chose the Fitbit (PA) and Bluetooth-tooth enabled scales (weight) as these commercially available technologies are easy to use, provide immediate feedback, and interface seamlessly with any Bluetooth-enabled device (e.g. smartphone, tablet computer). The spotlight approach to dietary changes, originally developed by Epstein [42], is an effective weight loss strategy for both children [42–44] and adults [34,45–47] as indicated by a Grade 1 ranking (strong, consistent, supporting evidence) from The Academy of Nutrition and Dietetics Evidence Analysis Library [48].

A unique feature of this study is the inclusion of the secondary users within each center. While per study protocol two 2–5-year-old classroom teachers from each center will be recruited and enrolled for all study components, we will allow access to the staff wellness program to all ECE workers (e.g., other teachers, assistant teachers, and additional staff) in centers randomized to the Go NAPSACC+ Staff Wellness arm. Gauging interest and use of the staff wellness online tool (e.g., logins, lessons completed, health behavior data entered) of staff not officially enrolled in the study will provide insight into pragmatic use of the program in the ECE setting. This information will add additional insight regarding the accessibility and sustainability for future implementation.

Conclusion

In conclusion, Go NAPSACC Cares is a clustered randomized trial to evaluate if improving ECE care workers' health behaviors elicit meaningful change in dietary and physical activity behaviors in 2-5-year-old preschool children in their care and of the ECE environment. The study will improve our understanding of how workers' own health outcomes facilitate the impact of such initiatives. It will also provide a highly implementable, scalable, and sustainable strategy that would optimize obesity prevention in the ECE setting. The Go NAPSACC Cares study represents an important step forward to evaluate the potential impact ECE workers have on the care environment and children's eating and physical activity behaviors.

Supporting information

S1 File. Original institutional review board approved protocol.
(PDF)

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