

STUDY INFORMED CONSENT

**A hybrid effectiveness-implementation trial of Go NAPSACC: A
childcare-based obesity prevention program
Child Care Center Director Informed Consent**

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**University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants- Director**

Consent Form Version Date: July 20, 2020

IRB Study # 19-0406

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

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CONCISE SUMMARY

Go NAPSACC is a web-based program designed to help child care centers improve their nutrition and physical activity practices, and thereby, the health of young children. This research study will evaluate two technical assistance (TA) support approaches and how they impact center's use of Go NAPSACC and the improvements they achieve. The study will also compare the cost-effectiveness of these approaches.

As a participant, you will be asked to share information about the study with two preschool classroom teachers. The study team will be responsible for getting in touch with the teachers and confirming their participation. As part of the study you will fill out several online surveys before you start using Go NAPSACC and again after using Go NAPSACC for 12 months. These surveys will ask about your demographics, your center's demographics, your center's organization and capacity, foods and beverages provided at your center to preschool children, your center's policies and procedures related to nutrition and physical activity, and how COVID-19 has impacted you and your center. You will also be asked to provide the study team with a month of menus and staff and parent handbooks. Soon after you complete these surveys and provide the menus and handbooks, the study team will randomize (like flipping a coin) your TA coach from Child Care Aware of Kentucky to provide Basic Go NAPSACC or Enhanced Go NAPSACC. Your coach will work with you to provide training and guidance on using Go NAPSACC and its suite of tools. You will work with your coach as you use Go NAPSACC for 12 months.

Following your 12 month use of Go NAPSACC, completion of surveys will be repeated as described above. You may be asked to take part in a 30-45 minute phone interview about your experience with Go NAPSACC and your TA coach. Additionally, you will continue to have access to Go NAPSACC for at least 1 additional year.

Your participation in the study will last about 16-18 months. Research is designed to benefit society by gaining new knowledge. Potential benefits of being in the study are that your center will receive free access to Go NAPSACC's online tools and you may potentially improve the nutrition and physical activity environment in your child care center. Additionally, you will receive \$100 for participating in the initial set of surveys and \$100 for filling out a similar set of surveys, and if asked, participating in an interview, following 12 months of Go NAPSACC participation. Risks associated with this study will be minimal. For example, you may encounter questions in the surveys or follow-up interview that may be embarrassing to

answer. We expect this to be rare; and you will always have the option to not answer a question.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researchers, administration at Child Care Aware of Kentucky, the University of Kentucky, or the University of North Carolina-Chapel Hill.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or any project staff, any questions you have about this study at any time.

What is the purpose of this study?

Go NAPSACC is a web-based program designed to help child care centers improve their nutrition and physical activity practices, and thereby, the health of young children. The purpose of this research study is to evaluate how two different technical assistance support approaches impact center's use of Go NAPSACC and the improvements in their nutrition and physical activity practices they are able to make. Additionally, the study will examine the cost-effectiveness of these support approaches.

How many people will take part in this study?

If you decide to be in this study, you will be 1 of approximately 97 center directors taking part. Approximately 11 TA coaches from Child Care Aware of Kentucky and 194 preschool classroom teachers will also take part, for a total of 302 participants. Additionally, you will join the previous 463 participants who enrolled in the study prior to the relaunch (i.e., 20 TA coaches, 69 center directors, 69 teachers, and 305 3-5 year old children). The total amount of potential participants will be 765.

What will happen if you take part in the study?

A project staff member will email you a study flyer and ask you to share information about this study with two randomly selected teachers of a preschool classroom. Additionally, in your email will be a Qualtrics link to a consent form and a few surveys asking about your demographics, your center's demographics, your center's capacity and organization, and how you feel you and your center have been impacted by COVID-19. You will also be asked to upload a month of menus and policy handbooks.

Project staff will call the teachers at an agreed upon time to discuss the project. When interest is confirmed by the teachers, the research team will email you and the participating teachers necessary materials. This second email for you will contain a Qualtrics link to two online surveys asking about food and beverages provided by your center to preschool children and your center's policies and procedures on child nutrition and physical activity. The teachers will be emailed a Qualtrics link containing a consent form, a demographics survey, a survey about center organization and capacity, and two surveys to assess the child nutrition and physical activity environment in their classroom and the center.

We will collect this information twice – once before you start Go NAPSACC and again after you have been using Go NAPSACC for about 12 months.

Once this first round of information is collected, your TA coach from Child Care Aware of Kentucky will be randomly assigned (like flipping a coin) to either Basic Go NAPSACC or Enhanced Go NAPSACC. Over the course of 12 months you will be asked to use Go NAPSACC with Basic or Enhanced TA support.

<p><u>If your TA is assigned to Basic Go NAPSACC:</u></p> <ul style="list-style-type: none"> • Your TA coach will invite you to register for a Go NAPSACC account. • Your coach will walk you through using Go NAPSACC's online tools. This training will take about 1 hour. • Once trained, you will be encouraged to complete 2 cycles of Go NAPSACC's 5-step improvement process focusing on nutrition and physical activity. Each cycle is about 6 months long. <ul style="list-style-type: none"> ○ For each cycle you will take self-assessments focused on child nutrition and physical activity to evaluate your centers' current practices, strengths, and areas for improvement. Each self-assessment will take 15-20 minutes to complete. ○ Based on the self-assessment results, you will choose at least 3 goals per topic you want to focus on. Go NAPSACC will provide flexible step-by-step guidance for planning and reaching these goals. ○ You and your staff will commit to working towards meeting your chosen goals. ○ At the end of the first 6 months, you'll log your completed goals and start your second cycle, repeating the steps from above. ○ At the end of the 12 months you will retake the self-assessments on child nutrition and physical activity. • Your coach will check in with you monthly by email, phone, video conference, or in-person. 	<p><u>If your TA is assigned to Enhanced Go NAPSACC:</u></p> <ul style="list-style-type: none"> • Your TA coach will help you identify staff to join you to form a team. The team will work together to use Go NAPSACC and achieve your chosen goals. • Before starting Go NAPSACC, your team will work with your coach to assess your centers' needs, resources, and capacity. This will include having various center staff anonymously complete a readiness check survey. Your coach will summarize the results and present them to the team, where the team will identify priority issues that you would like extra support from coach on as the team uses Go NAPSACC. • Your coach will invite all team members to register for a Go NAPSACC account, linked back to your center. • Your coach will walk your team through using Go NAPSACC's online tools. This training will take about 1 hour. Additionally, your coach will help the team create a 12-month plan for completing 2 cycles of Go NAPSACC's 5-step improvement process focusing on nutrition and physical activity. Each cycle is 5 months long. <ul style="list-style-type: none"> ○ For each cycle you team will take 2 self-assessments focused on child nutrition and physical activity to evaluate your center's current practices, strengths, and areas for improvement. Each self-assessment should take 15-20 minutes to complete. ○ Based on the self-assessment results, the team will choose at least 3 goals per topic to focus on. Go NAPSACC will provide flexible step-by-step guidance for planning and reaching these goals. ○ Your team will commit to working towards meeting your chosen goals. ○ At the end of the first 5 months, your team will log your completed goals and start your second cycle, repeating the steps from above. ○ At the end of the 12 months your team will retake the self-assessments on child nutrition and physical activity.
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	<ul style="list-style-type: none"> • Your coach will check in with your team monthly by email, phone, video conference, or in-person. • Additionally, your coach will host quarterly one-hour conference calls between teams from different centers to provide opportunities for your team to reflect on your efforts and share lessons learned.
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Following the 12 months of using Go NAPSACC, you will be asked to repeat the previously described surveys. You also may be asked to take part in a 30-45-minute phone interview about your experience with Go NAPSACC and the support from your TA coach. The interview will be audio recorded and notes will be taken. Additionally, your center will continue to have access to Go NAPSACC for at least 1 additional year.

How long will your part in this study last?

If you agree to take part, your time in the study will last about 16-18 months and will consist of completing some online surveys, sharing information with two preschool classroom teachers, and participating in a 12-month program. The amount of time that will be needed from you for each of the different pieces are estimated below.

<p>All Participating Centers:</p> <ul style="list-style-type: none"> • Information gathering (pre-and-post Go NAPSACC participation) <ul style="list-style-type: none"> ◦ Sharing study information with two preschool classroom teachers: 10 minutes ◦ Director surveys: ~1.5 hours • 12-month participation in program 	
<p>Basic Go NAPSACC</p> <ul style="list-style-type: none"> • Register for a Go NAPSACC account: 5 minutes • Be oriented on using Go NAPSACC by your TA coach: 1 hour • Monthly check-ins with coach: 10-30 minutes per check-in • Schedule and complete follow-up interview: 35-50 minutes 	<p>Enhanced Go NAPSACC</p> <ul style="list-style-type: none"> • Implementation team identification with TA coach assistance: 1 hour • Plan for and assist coach with distribution and completion of readiness check survey: 1 hour • Review results of the readiness check with your coach: 1-2 hours • Register for a Go NAPSACC account: 5 minutes • Be oriented on using Go NAPSACC and create a 12-month plan with your coach: 1.5 hours • Monthly check-ins with coach- 20-30 minutes per check-in • Quarterly one-hour conference calls between teams of different centers: 1 hour per conference call • Schedule and complete follow-up interview: 35-50 minutes

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. A potential benefit of being in this study is receiving free access to Go NAPSACC’s online tool and support from a coach. You may also improve the nutrition and physical activity environment in your child care center. In addition to these direct benefits, what we learn from this research study will be used to help identify strategies that could be integrated into the existing Go NAPSACC resources for widespread use.

What are the possible risks or discomforts involved from being in this study?

We expect any risks or discomfort from being in the study to be very minimal. For example, you may encounter questions in the surveys that that you are embarrassed to answer. We expect that to be rare, but if that does happen, you can choose not to answer. You are encouraged to be as honest as possible, as all your information is confidential and will not be shared with your other individuals at your center. This program does promote increased physical activity in children and potentially center staff. For adults, increases in physical activity may result in muscle soreness. These types of occurrences are considered rare, as your director will have the flexibility to choose goals, which may not include any that increase children's or staff's physical activity. You should consult with your doctor before increasing your physical activity level. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

We will do our best to protect the privacy of all TA coaches, directors, and teachers taking part in this study. You will be assigned an ID number. All forms used to gather information about you will include only this ID number and not your name or other identifying information. All Qualtrics links will be individualized and only have your ID number embedded into them. Consent forms signed over Qualtrics will be saved in a different file location than data from the surveys. Any hard copies of signed consent form and any forms with identifying information will be stored in a locked file cabinet, in a locked office, to which only approved project staff members have access. Electronic files will be stored on a password-protected server accessible to only approved project staff. Participants will not be identified in any report or publication about this study.

If you are interviewed, you will be audio recorded, which you may request to be turned off at any time. Audio files will be downloaded onto the password protected server and saved using your ID number. Once saved on the server, audio files on the recorder will be deleted within 1 month. Any handwritten notes will be identified with the ID number and stored in a locked filing cabinet in a locked office.

Check the line that best matches your choice for being audio recorded:

_____ OK to record me during the study

_____ Not OK to record me during the study

We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected injury, failed to follow instructions, or because the entire study is stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will receive \$100 for completing the surveys prior to starting Go NAPSACC and \$100 for completing the surveys once more approximately a year after starting Go NAPSACC.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

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Signature of Research Participant	Date
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Printed Name of Research Participant	
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Signature of Project Staff Member Obtaining Consent	Date
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Printed Name of Project Staff Member Obtaining Consent	



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