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Title: A Health Systems Intervention to Reduce Sugar-Sweetened Beverage Consumption in Young Children and Families

Wake Forest School of Medicine

Division of Public Health Sciences,

Department of Epidemiology and Prevention

# THE SCOPE-IT STUDY: SUGAR-SWEETENED BEVERAGES IN CHILDREN: OBSERVATIONAL AND PRAGMATIC RESEARCH USING THE ELECTRONIC HEALTH RECORD – INTERVENTION TRIAL

Informed Consent Form to Participate in a Pilot Randomized Controlled Trial

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## SUMMARY

You and your child are invited to participate in a research study. You are invited to be in this study because your child attends a Wake Forest Baptist Health pediatric office and you may have indicated that s(he) drinks more than two sugary drinks per day.

The purpose of this research is to improve the health of families by promoting healthier drink choices. We will test a new way of encouraging families to reduce sugary drink intake, promote guideline-appropriate amounts of fruit juice and encourage drinking more water. Sixty families (1parent/1child per family) will participate in the study. This research study will include two groups of volunteers. If you participate, you and your child will be randomized into one of these groups. This means that, similar to a coin flip, after you agree to participate, you will be randomly put into one of two groups. In total, 30 families will be randomly assigned to try out the new tools we have developed and the other 30 families will be randomly assigned a different group that answers survey questions but does not try out the tools. The main goal of our study is to compare the change in families' drink choices over a 6-month period between these groups.

All research studies involve some risks. Risks in this study are minimal and are no more than that which you would experience if you were to participate in a conversation with a healthcare team member. There may or may not be direct benefit to you. We hope the information learned from this research will benefit you and your family by learning to make healthier drink choices.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study

is Dr. Kristina Lewis. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is [redacted] or khlewis@wakehealth.edu.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted]

## INTRODUCTION

You and your child are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because your child attends a pediatric office at Wake Forest Baptist Health and you may have indicated that (s)he drinks more than two sugary drinks per day. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to test some new tools that may assist families with making healthier drink choices. We will test a new way of encouraging families to reduce sugary drink intake, promote healthy amounts of fruit juice and encourage drinking more water.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

60 families whose children receive pediatric care at Wake Forest. From each family, we will gather specific information from one parent or caregiver (you) and one child. This means that 120 people total will contribute specific information from the study. Other members of your household will end up using the tools – we just won't be asking them survey questions.

## WHAT IS INVOLVED IN THE STUDY?

If you agree to participate, and in light of COVID-19 safety guidelines, we'll follow a virtual study format so you and your child won't need to make in-person study related visits besides your child's already-scheduled doctor's appointment. At the beginning of the study, we'll ask you to complete a phone call or web-based visit (like Zoom or Webex), depending on what is easiest for you. This first call will take about an hour. During this call/web visit you will speak with one of our research team members who will be collecting information from you using several different surveys. These surveys will ask questions about:

- Your and your child's usual food and drink intake
- What you think, know or believe about drink choices for kids and adults
- Information about you and your family such as your identified race and ethnicity, age, and education level



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At the end of this first call/web visit, you will be randomized into one of two groups. Randomization means that you will be placed into a group by chance. Similar to a coin flip, after you agree to participate, you will be randomly put into one of two groups. In total, 30 families will be randomly assigned to try out the new tools we have developed and the other 30 families will be randomly assigned a different group that answers survey questions but does not try out the tools. The main goal of our study is to compare the change in families' drink choices over a 6-month period between these groups (those getting not getting the tools).

You will have an equal chance of being placed in either group, **but it is important that you think about whether you would still want to participate in this study even if you don't get assigned to the group that will try out the new tools**.

**INTERVENTION GROUP:** One group of participants (we call this the "intervention" group) will be asked to try out several tools over a 6-month period. If you are randomly selected to be in this group, here are the tools you will receive:

- **VIDEO:** A 5-minute video that you can access through the internet with your phone or other internet-enabled device, like a laptop or tablet. Our team will receive a notification about whether you watch the video or not and may reach out to help you if it looks like you have not been able to watch it on your own. You will also be asked to complete a short survey (about 2 minutes) online after watching the video.

- **WELCOME KIT:** A welcome kit with water bottles and other items for your family will be given to you by your child's pediatric office.

- **PHONE APP:** A mobile phone application. This app would be installed on your smartphone and would help you keep track of what your family is drinking. Information about whether and how your family is using the app will be transmitted securely from your phone, and stored in a file for research purposes only. It will not be sold to a third party or accessed by anyone outside of the Wake Forest Baptist Health App development team or research team. The study will not pay for data fees associated with the use of the app.

  The information on the app will not include identifiable details about you like your full name, address or phone number. You will be given a study ID to use for logging in and that is how your information will be labeled when it is transferred (i.e. not with your full name or phone number).

- **PHONE CALLS:** A series of 14 phone calls will be made to you over 6 months at a

phone number that you provide. Each call will take about 3 to 5 minutes. The first 8 calls will made be once per week, and then after that they will become less frequent.

The important thing to understand about these calls is that they will not come from a live human. Instead, the calls will use interactive voice response (IVR) technology to provide you with information about family drink choices. IVR is like a computerized voice, not a real person, that can speak to you and understand your responses. This is kind of like Siri or Alexa if you are familiar with those technologies.

In order for the research team to send you these calls, we will need to put your name, your child's name, the name of your child's doctor, and your phone number into a secure, password-protected system that will distribute the calls.

We will not share your name, your child's name, or your phone number with people outside the research team, and the programs we use to deliver the IVR calls are secure and cannot be accessed by third party vendors or other individuals outside our health system.

Although the phone calls will not be recorded, the research team will be notified about whether or not you complete each call, and a summary of the responses you give on the phone calls will be provided to the research team, also using a secure data transfer process. We may send you a text, email or call you if you miss a scheduled call, to assist with rescheduling.

Also, if you are in the "intervention" group, study team members will contact your child's doctor's office to let them know you are part of the study. So the next time you come in for your child's doctor's appointment, clinic staff should provide you with the welcome toolkit and they may:

- Talk to you briefly about what is in the toolkit.
- Discuss how to access the video for online viewing, and show you the instructions for downloading the mobile phone app.
- Remind you that you will be getting a series of IVR phone calls and ask you to pre-program the phone number from which these calls will originate into your phone.

Finally, the study team will check in by texting you a link once per month to complete a short online survey (about 2 minutes) about how things are going and any technical problems you're having, as well as to verify the best contact information for you. If we aren't able to reach you by text, we will also try phone and email for these monthly check-ins.

**CONTROL GROUP:** The other group of participants – we call this the "control" group - will not be provided with the tools described above, but we will still follow-up with the control group to collect research measures. The study team will check in by texting control group participants once per month with a link to complete a short online survey (about 2 minutes) in order to verify the best current contact information for you. If we aren't able to reach you by text, we will also try to reach you using phone and email for these monthly check-ins. Each family in the control group will receive a "Welcome Kit" (water bottles, book and infusers) after completion of the study, as a token of appreciation.

**RESEARCH VISITS:**
For participants in both groups (intervention and control) we will also schedule several follow-up visits with you by phone/web to do more survey questions. One of these visits will happen after 3 months, and another will happen after 6 months. The visit at 3 months will take about 30 minutes and the one at 6 months will take about 30 minutes for participants in the control group and closer to an hour for participants in the intervention group.

Also, if you agree to be in the study, we will access your child's electronic health record for information about his/her height and weight and how they may or may not change over this same time period.

## How Long Will I Be in the Study?

Your participation in the study will take about 6 months.

## What Are the Risks of the Study?

There are minimal risks to participation this study; however, it is possible that there could be other unforeseeable risks that may also be associated with participating in this study. If any of those come to light as the study progresses, we will notify study participants and the board overseeing this study in a timely fashion.

If the researchers determine that your participation in this study poses increased risk to you or others, or if they feel that you will not be able to attend the sessions due to difficulties in scheduling, recording equipment failures, or any other issues that arise, the researchers may decide to terminate your participation as well.

## Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this research will benefit you and your family as well as other people in the future. The benefits of participating in this study may include improving your family's health by learning to make healthier drink choices reducing your sugary drinks' intake and increasing your water consumption, learning more about water safety and appropriate guidelines for fruit juice intake.



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## WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

## WHAT ARE THE COSTS?

There will be no charge to you for taking part in the study.

## WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The information that you provide will be kept confidential to the full extent permitted by law. Only authorized research staff will have access to the information we collect. This information will be kept in a locked filing cabinet in the Public Health Sciences research department. Your identity will never be reported. We will not disclose any information that can be identified with you, nor associate your name with any information in a report.

The Wake Forest Institutional Review Board, a group of people who oversee research studies at Wake, and the Robert Wood Johnson Foundation, the sponsors of the study, may be permitted to review research records for purposes of insuring that the study is done properly. Names and identifying information will be removed before they are given access to study records.

## WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $25 gift card upon completion of your initial phone/web visit, another $25 gift card upon completion of a 3 month follow up visit and a $50 gift card in 6 months. So you would get up to $100 total if you complete participation in the study, regardless of which group you are randomized to be in.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by The Robert Wood Johnson Foundation, as part of their Healthy Eating Research Program. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study.

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes weight and information about your medical history, health behaviors, and health-related quality of life.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center.

You can tell Dr. Kristina Lewis that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Kristina Lewis, MD
[redacted]



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However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. The investigators also have the right to stop your participation in the study at any time. This could be because you failed to follow instructions or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the study investigator, Dr. Kristina Lewis at [redacted] or [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

## SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature:_____Date:_____Time:_____am/pm



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Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____Date:_____Time:_____am/pm

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature:_____Date:_____Time: _____am/pm



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