University of North Carolina at Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study

Consent to Participate in a Research Study - Adult Participants [PARENT]

Consent Form Version Date: 10 December 2021

IRB Study # 20-3273
Title of Study: Phase II, proof-of-concept randomized controlled trial to evaluate dental caries preventive effects of fluoridated bottle water (waterBEST)
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CONCISE SUMMARY

The purpose of this research study is to learn if fluoride in bottled water helps in preventing tooth decay in young children. If you decide to participate, your child will be assigned by chance (like the flip of a coin) to receive either bottled water with fluoride, or bottled water without fluoride. For about 3½ years, this study water will be provided to you and your family in 5-gallon bottles with a dispenser. Sippy cups and other drinking aids will be provided for your child. These will be delivered to your home once every two months and you will be phoned once a month for about five minutes to check your need for new deliveries.

During the 3½ year follow-up period, you will be interviewed every 3 months to update information about your child's health, nutrition, and dental health habits. These interviews will take about 30 minutes and will be done either by phone, videoconference, or in person during a visit to your home. Once a year, a study team member will visit your home to check your child's dental health. At these annual visits, the study team member will collect fingernail and toenail clippings from your child and a tap water sample from your home to measure fluoride levels. When your child turns 4 years, there will be a final, one hour visit to your home. At this visit the study's dentist will examine your child's teeth for possible tooth decay. The total study length is about 3½ years and includes six visits to your home for interviews, 20-26 visits to your home to deliver water bottles, and 45-55 phone interviews, depending on when your child started the study. You can receive up to $120 Visa gift cards every year you are in the study. The total amount you can receive is $480. The possible benefits include provision of bottled water for your entire household at no cost for 3½ years and a dental health exam for your child. Known risks of this study include the chance of too much fluoride intake, accidental injury from nail trims, and breach of confidentiality. If you are interested in learning more about this study, please continue to read below.

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

You are being asked to allow your child to take part in a research study. To join the study is voluntary. You may decide to not allow your child to participate, or you may withdraw your permission for your child 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. Your child 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 or your child's relationship with the researchers, health care providers, or the University of North Carolina-Chapel Hill. If your child is a patient with an illness, your child does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice for your child and yourself about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn if fluoride in bottled water is helpful in preventing tooth decay in young children. This is an important question because one in four U.S. children aged 2-5 years old has tooth decay. Our team is looking at a possible way to help reduce tooth decay. The research team is using bottled water because many communities do not have access to a public water system that contains fluoride.

Your child is being asked to be in the study because they are aged 2-6 months and live in Lenoir County, NC or the surrounding district. If more than one child in your family meets the selection criteria for the study, only one of them will participate in the study.

Are there any reasons your child should not be in this study?

Your child should not be in this study if he/she:

- Weighed less than 3 pounds 5 ounces at birth
- Was born before 34 weeks of gestational age
- A serious illness, for example requiring frequent inpatient hospitalization;
- Is taking fluoride supplements or is likely to take fluoride supplements before his/her 4th birthday;
- Lives in a home with fluoridated tap water or well water that is naturally fluoridated;
- Is living in a home where another child is enrolled in the waterBEST study; or
- Is likely to move more than 30 miles from Kinston before his/her 4th birthday.

How many people will take part in this study?

Approximately 200 children will take part in this study.

How long will your child's part in this study last?

Your child will be in this study until they are 4 years old. During the follow-up period of about 3½ years, there will be six visits to your home for interviews, 20-26 visits to your home to deliver water, and 45-55 phone interviews, depending on when your child starts the study and has the final visit.

What will happen if your child takes part in the study?

If you and your child agree to take part in this research, the following things will happen.

- At the enrollment visit, a study team member will visit your home to interview you about your child and your household, and to ask for contact information of people who could help us contact you in the event you move. The study team member also collect a sample of tap water from your home. This information will be used to determine if you and your child are eligible for the study.
- The randomization visit will occur one month after screening. If your child is eligible to be in the study, a study team member will visit your home to deliver 5-gallon water bottles, a water dispenser with cooler, drinking aids and information about using them. If your child usually sleeps for at least one night per week at another home, the study team will also provide water and drinking supplies at that home. The water will either be fluoridated or non-fluoridated and will be assigned by chance, like flipping a coin. This is called randomization. No-one on the research team will know whether the bottles of water given to you contain fluoride. However, the Principal Investigator can find out this information in the event of an emergency.
- During monthly interviews for about 3½ years, the study team will speak to you by telephone or videoconference to ask how much water has been used and to arrange a drop-off of additional water bottles, if needed.
- Water bottle deliveries will be made to your home once every two months for about 3½ years. A study team member will deliver replacement water bottles and take away empty bottles.
- Every third month for about 3½ years, a study team member will interview you, either by phone, videoconference or in person at your home, to update your child's health status and to record any major illnesses. You will be told if our child is due to visit your primary healthcare provider.
- Once a year for about 3½ years, the study team will visit you at your home to interview you and check your child's teeth. They will also collect nail clippings that you will be asked to clip from your child's fingers and toes twice before the visit. Samples of tap water and study water from your home will also be collected. The nail clippings and water sample will be sent to the study's research laboratory to measure the amount of fluoride in them. At the end of the visit, you will be told whether or not a dental visit is recommended.
- Near the time of your child's fourth birthday, the study dentist will make a final home visit to measure any tooth decay that may have developed in your child's teeth. At the end of the visit, you will be told if decay is present and whether a dental visit is recommended. Also, at this final visit, the study water and dispenser will be removed.

What if your child has to stop taking part in the study?

Your child's participation in the study might be stopped if any of circumstances occur:

- If your child begins taking fluoride supplements;
- If your child moves 30 miles outside of Lenoir County;
- If you move to a home that has fluoride in the tap water or well water; or
- If the principal investigator determines that participation in the study would not be in the best interest of your child (for example, because he/she develops an unanticipated medical condition).

If any of these conditions occur, the study team will advise you and may offer you the choice of either discontinuing use of bottled water or stopping your participation in the study altogether. You can also choose to withdraw from the study at any time.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to **your child** from being in this study include being provided with bottled drinking water for 3½ years and having their dental health checked. You and other household members will also benefit from being provided with bottled drinking water if you chose to drink it.

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

A possible risk to your child in taking part in this research is too much fluoride intake. This risk can occur if your child takes a prescription fluoride supplement. This risk will be minimized by asking that you call the study team if your child starts taking prescription fluoride supplements. You will also be asked about fluoride supplements at three-monthly interviews. If your child takes fluoride supplements, you will have the choice of either discontinuing use of bottled water or stopping your participation in the study.

It is also possible that your child might consume too much fluoride if he/she uses infant formula powder or concentrate that is mixed with study water which contains fluoride. This risk will be minimized by asking that you use household tap water or other non-study water when you mix water with infant formula. You will also be asked if your child uses infant formula at three-monthly interviews and if so, you will be reminded to mix it using non-study water.

It is possible that your child's skin may be scratched or nicked during nail trimming at annual visits. To minimize this risk, the study coordinator will give you a new stainless steel nail clipper designed for young children and demonstrate its use during your study visit. This risk is no greater than the risk of trimming nails in everyday life.

A possible risk to you or your child in taking part in this study is breach of confidentiality, for example if your personal information was obtained by someone outside the study. This risk will be minimized by the research team's use of numbers, not names or addresses, to record information on most study forms and when shipping samples. The numbers will not reveal anything about your identity, which means that if study forms or samples are lost or stolen, there will be no loss of your personal information. An exception occurs during water delivery when the study form will list the address, your name and your child's name.

There may be uncommon or previously unknown risks. You should report any problems to the research team.

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

Findings from your child's annual dental check and the fourth birthday dental examination will be given to you. The examiner will also tell you of any clinical recommendations for dental care. You will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation in the study.

How will information about your child be protected?

You and your child will not be identified in any report or publication about this study. We may use de-identified data or samples with anonymous codes in future research without additional consent. No participants' nail clippings may be used for commercial profit.

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 child's 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.

Study data will be securely stored. There will be a password protected database only accessible to the researchers. All paper data will be stored in a secure area accessible only to study staff. Your residential address will be used in route-planning software owned by Badger Maps Incorporated. The researchers have created an agreement with the company stating how your address information will be used and protected.

You and your child's information may be used in publications or presentations. However, the information will not include any personal information that would allow you or your child to be identified.

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 or your child is injured by this research?

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

If you think you or your child has 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 and your child should do.

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

What if you or your child wants to stop before your part in the study is complete?

You can withdraw yourself and your child from this study at any time, without penalty. The investigators also have the right to stop yours and your child's participation at any time. This could be because your child has had an unexpected reaction, or because the entire study has been stopped.

If you stop participating in the study for any reason, the study team will ask your permission to contact you at the time of your child's fourth birthday. If you are contacted when your child turns four, the study team will, with your permission, interview you about your child's dental health and if it is feasible, the study dentist will examine your child's teeth.

If you do not want to be contacted at the time of your child's fourth birthday, the study team will not contact you again, and no further data will be collected.

If you withdraw or are withdrawn from this study all data collected 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 or your child receive anything for being in this study?

Your child will not receive anything for participating due to their age. However, you will receive payment with Visa gift cards. You can receive up to $120 after completing each annual follow-up visit. When your child turns 4 years old, you will receive $60 and then will receive $60 if your child finishes all study procedures. The total amount you could receive is $480. If you withdraw yourself or your child or if you or your child are withdrawn from the study before completion of all study procedures, you will receive payment for each study procedure completed while in the study.

Will it cost anything for you or your child to be in this study?

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

Who is sponsoring this study?

This research is funded by the National Institute of Dental and Craniofacial Research. This means that the research team's university 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 or your child has questions about this study?

You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, 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 there are questions about your rights or child's rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your child's rights and welfare. If there are questions or concerns about your child's 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.

Parent's Agreement

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child and myself to participate in this research study.

_____

Printed Name of Research Participant (child)

_____ _____

Signature of Parent Date

_____

Printed Name of Parent

_____ _____

(Optional) Signature of Secondary Parent/Guardian or Caregiver Date
[Secondary parental/caregiver involvement is optional and is not required for participation in the study]

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(Optional) Printed Name of Secondary Parent/Guardian or Caregiver

_____ _____

Signature of Research Team Member Obtaining Permission Date

_____

Printed Name of Research Team Member Obtaining Permission

_____ _____

Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form) Date

_____

Printed Name of Witness