UPDATED INFORMED CONSENT
2/2/24

Birth to Three – Cavity Free: Effectiveness of a Psychoeducational Intervention for ECC Prevention

Unique Protocol Identification Number: UH3DE029443
National Clinical Trial (NCT) Identified Number: 05756413
Principal Investigator: Karin Weber-Gasparoni
Sponsor: University of Iowa

Grant Title: Birth to Three – Cavity Free: Effectiveness of a Psychoeducational Intervention for ECC Prevention
Grant Number: 22-031-E

FOR IRB USE ONLY
APPROVED BY: IRB-01
IRB ID #: 202002391
APPROVAL DATE: 02/02/24

INFORMED CONSENT DOCUMENT

Project Title: "Birth to Three – Cavity Free: Effectiveness of a Psychoeducational Intervention for ECC Prevention"

Principal Investigator: Karin Weber-Gasparoni

Research Team Contact: Karin Weber-Gasparoni: 319-335-7486; karin-weber@uiowa.edu
Jennifer Bowman-Reif: 319-467-4121; jennifer-bowman-reif@uiowa.edu

This consent form describes the research study to help you decide if you want you and your child to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your and your child's rights as research subjects.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree for you and your child to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you and your child to participate in this research study because you are pregnant and receiving services at your local WIC clinic.

The purpose of this research study is to assess the value of an educational method to prevent early childhood caries, which refers to cavities in infants and toddlers that can badly damage children's teeth.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately634 pregnant women and their future child will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL MY CHILD AND I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 4 years:

- You will have four in-person study visits at your local WIC clinic that will take approximately 1-1.5 hours: during your pregnancy (between -16-36 weeks gestation), and when your future child is 12 months, 24 months, and 36 months of age.
- Between in-person visits at the WIC clinic, we will ask you to complete questionnaires and watch videos. The questionnaires will take approximately 20 minutes and the videos will be approximately 5 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be randomly assigned to one of two groups. This means that whichever study group you are in will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of getting into either group. Some mothers will be assigned to a neutral message video group, which is standard care and gives mothers basic information on both your own and your child's oral health. Other mothers will be assigned to an intervention message video group which will provide the same basic information using motivational strategies. The following procedures are involved in this study:

Visit 1 at WIC clinic: If you agree to participate, you will be asked to fill out some questionnaires and watch a videotaped oral health presentation.

1-month after Visit 1: You will be asked to fill out some questionnaires that will be sent to you electronically (text and/or email).

3-month after Visit 1: You will be asked to watch a brief video that will be sent to you electronically (text and/or email).
9-month after Visit 1: You will be asked to fill out some questionnaires that will be sent to you electronically (text and/or email).

Visits 2 and 3 at WIC clinic: If you agree to continue participation, you will be asked to fill out some questionnaires and watch a videotaped oral health presentation. Your child will receive a dental screening and a sample of your child's dental plaque will be obtained. During the dental screening procedure, a University of Iowa dental provider will examine your child's teeth and check for cavities and plaque. The plaque sample will be obtained using a sterile cotton tip to swab all teeth surfaces. This plaque sample will be used to count the amount of bacteria (germs that cause cavities) present in your child's mouth.

1-month after Visits 2 and 3: You will be asked to fill out some questionnaires that will be sent to you electronically (text and/or email).
3-month after Visits 2 and 3: You will be asked to watch a brief video that will be sent to you electronically (text and/or email).
9-month after Visits 2 and 3: You will be asked to fill out some questionnaires that will be sent to you electronically (text and/or email).

Visit 4 at WIC clinic: If you agree to continue participation, you will be asked to fill out some questionnaires. Your child will receive a dental screening and a sample of your child's dental plaque will be obtained.
A description of the types of information collected on each of the questionnaires that you will be completing during the study visits is summarized below. You are free to skip any questions that you would prefer not to answer.

Demographic Questionnaire: information on participants' ages, address, telephone number, race, household income, mother's marital status and level of education
Knowledge Questionnaire: Mother's knowledge of ECC
Behavior Questionnaires: Mother's behavior about hers and her child's brushing and dietary habits
Intention Questionnaire: Mother's behavioral intentions regarding her child's brushing and dietary habits
Health Care Climate Questionnaire: Mother's impressions about the videotaped oral health presentation
Internalization Questionnaire: Mothers' reactions to the videotaped oral health presentation

- In addition to the procedures described above, you will be asked to sign an authorization for your local WIC clinic to release information about your child's height and weight history.
- As part of this study, we are obtaining plaque samples from your child. We would like to study your child's plaque samples in the future, after this study is over. Your child's sample, information, and/or data may be placed in a central repository at the University of Iowa College of Dentistry & Dental Clinics and/or the National Institutes of Health. If this happens, your child's sample will be stored *without* a name or any other kind of link that would enable us to identify which sample(s) are theirs. Therefore, if you give permission to store your child's plaque sample, it will be available for use in future research studies indefinitely and cannot be removed.

The tests we or others might want to use to study your child's samples may not even exist at this time. Therefore, we are asking for your permission to store your child's samples so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding the risk factors associated with caries, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your child's samples might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of samples do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your child's samples will be stored *with a code which may be linked to your child's name.* If you agree now to future use of your child's samples but decide in the future that you would like to have it removed from future research, you should contact **[Dr. Karin Weber-Gasparoni at (319) 335-7486**. However, if some research with your child's samples has already been completed, the information from that research may still be used.

WILL I BE NOTIFIED IF MY [DATA\BIOSPECIMENS\IMAGES] RESULT(S) IN AN UNEXPECTED FINDING?

The results from the plaque samples we collect in this research study are not the same quality as what you would receive as part of your routine health care. The plaque samples/results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your plaque samples will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The physical risks for you and your child are minimal and similar to an experience encountered at a routine dental exam. Due to your child's age at their exams, 12-36 months, your child will most likely not want to fully cooperate with the dental procedures. This is to be expected and is normal for young children. Mothers will be present at all times during the dental exam and the dental healthcare provider will use a tell-show-do technique with your child. Your child will be told what will be done before the procedure in simple terms. The dental healthcare provider will also show, by a puppet stuffed animal, how the dental exam is done. While unlikely and rare, there is a risk of infection as a result of these procedures. Standard infection control procedures will be followed to minimize infection risk. There is always a risk of breach of confidentiality. You may feel uncomfortable in answering certain questions and you can choose to decline any aspect of the study at any time. You and your child may discontinue participating at any time without any negative consequences.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you and/or your child will benefit from being in this study. However, if the dental provider who exams your child notices a need for dental care you will receive instructions/recommendations for seeking proper care.

We also hope that, in the future, other people might benefit from this study because of the knowledge gained toward the prevention of early childhood caries.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for you and your child being in this research study.

WILL MY CHILD AND I BE PAID FOR PARTICIPATING?

You will be given gift cards for being in this research study. You will need to provide your address for us to mail the gift cards after you complete the study activities between WIC site visits. You will be paid:

- Visit 1 at WIC: $50 gift card

1-month follow-up questionnaires: $20 check
9-month follow-up questionnaires: $20 check

- Visit 2 at WIC: $75 gift card
  1-month follow-up questionnaires: $20 check
  9-month follow-up questionnaires: $20 check
- Visit 3 at WIC: $100 gift card
  1-month follow-up questionnaires: $20 check
  9-month follow-up questionnaires: $20 check
- Visit 4 at WIC: $125 gift card
  Total compensation: $470.00

- Children will also receive a toothbrush and small toy after each dental exam.

WHO IS FUNDING THIS STUDY?

The National Institute of Dental and Craniofacial Research (NIDCR) is funding this research study. This means that the University of Iowa is receiving payments from NIDCR to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIDCR for conducting this study.

WHAT IF MY CHILD IS INJURED AS A RESULT OF THIS STUDY?

- If your child is injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If your child experiences a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your and your child's participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you and your child.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your and your child's confidentiality, we will keep all your data on a secure site at the University of Iowa. Each individual participant is assigned an individual ID number when starting the study. Your information is entered into a REDCap database using only the individual ID number. This means that when your information and responses to questionnaires are recorded, there is no name directly tied to specific information or data, but to ID numbers only. Only the researcher and research staff have access to a key of the names of participants and ID numbers. We will store your child's plaque sample without direct personal identifiers. All electronic data will be stored in a secure server and any hard-copy data will be securely stored in locked cabinets in a locked office at the UI College of Dentistry. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

WILL MY CHILD'S HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires **WIC** to obtain your permission for the research team to access or create "protected health information" about your child for purposes of this research study. Protected health information is information that personally identifies your child and relates to your child's past, present, or future physical or mental health condition or care. We will access or create health information about your child, as described in this document, for purposes of this research. Once WIC has disclosed your child's protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your child's confidentiality as described under "Confidentiality."

We may share your child's health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, and the NIDCR.

Your decision will not affect yours or your child's right to medical care that is not research-related. Your signature on this Consent Document authorizes the WIC to give us permission to use or create health information about your child.

Although you may not be allowed to see study information until after this study is over, you may be given access to your child's health care records by contacting your health care provider. Your permission for us to access or create protected health information about your child for purposes of this study has no expiration date. You may withdraw your permission for us to use your child's health information for this research study by sending a written notice to Dr. Karin Weber-Gasparoni, Department of Pediatric Dentistry, S202 Dental Science South, Iowa City, IA 52242. However, we may still use your child's health information that was collected before withdrawing your permission. Also, if we have sent your child's health information to a third party, such as the study sponsor, or we have removed your child's identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose for you and your child not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide for you and your child not to be in this study, or if you stop participating at any time, you and child won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide not to be in this study, or if you stop participating at any time, you and child won't be penalized or lose any benefits for which you otherwise qualify.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because funding the for the research has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Jennifer Bowman-Reif, at (319) 467-4121.** If you and/or your child experience a research-related injury, please contact: **Karin Weber-Gasparoni at (319) 335-7486**.

If you have questions, concerns, or complaints about your and your child's rights as a research subject or about

research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form electronically.

Child/Subject's Name (printed if known): _____

Mother/Subject's Name (printed): _____

_____ _____
(Signature of Mother/Subject for own participation) (Date)

_____ _____
(Signature of Mother/Subject for child's participation (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)