

Tucker Reinders, L., Buckingham-Schutt, L.

A study to determine the effect of the Count the Kicks (CTK) app on the rate of stillbirth

Appendix 5

INFORMED CONSENT DOCUMENT

Please download and print a copy of this form for your records.

Title of Study: **A study to determine the effect of the Count the Kicks (CTK) app on the rate of stillbirth.**

Who is conducting this study?:

Ms. Lina Tucker Reinders, MPH – Healthy Birth Day, Inc., Co-Principal Investigator, Associate Director of Programs

Dr. Lyndi Buckingham-Schutt – Drake University, Co-Principal Investigator, Associate Director of Wellness & Nutrition Policy, The Harkin Institute for Public Policy & Citizen Engagement

Dr. Pamela A. Duffy – Des Moines University, Associate Professor, Department of Public Health

Ms. Kerry Biondi-Morlan – Healthy Birth Day, Inc., Founder and Board Vice-President

Mr. Benjamin Williamson – Des Moines University, Master of Public Health Research Assistant

Introduction

This is a research study about monitoring fetal movement. You have been asked to participate in this study because our records indicate you downloaded and used the *Count the Kicks* mobile application (app) in 2016 or 2017. This form describes the research project. It has information to help you decide whether or not you wish to participate. Research studies include only people who choose to take part—your participation is completely voluntary. You are welcome to discuss any questions you have about the study or about this form with the project staff before deciding to participate. Healthy Birth Day, Inc. (HBD) is the sponsor of this research study. HBD is the nonprofit organization that created the *Count the Kicks* stillbirth prevention campaign.

What is the purpose of this study?

The purpose of this study is to assess the effectiveness of the *Count the Kicks* stillbirth prevention campaign, including: 1) how expectant women use the Count the Kicks app during their pregnancy; 2) if the app was effective in helping mothers track their babies' movements; 3) if the app increased awareness of a change in fetal movement, and; 4) if so, the health outcome of their baby(babies). We will also measure the rate of stillbirth among app users and compare it to the national stillbirth rate during the same time period.

What will I be asked to do?

If you agree to participate, you will also be asked to complete a 15-minute survey that asks you to recall information about using the *Count the Kicks* app, your pregnancy, and delivery of your baby(babies) in 2017. You will also be asked to allow the research team to match your survey

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responses to the kick counting data from your use of the *Count the Kicks* app associated with your email address. This information will allow us to understand if there is a relationship between how often a pregnant mother tracks and records her baby's(babies') movements and the birth outcome.

Why am I invited to participate in this study?

You are being invited to participate in this study because our records show that you downloaded the Count the Kicks app and entered a due date that indicates that you likely delivered your baby(babies) in the calendar year 2017. You should not participate if:

- you are under the age of 18; or
- you did not deliver a baby in the year 2017; or
- feel that answering questions about pregnancy and your baby's(babies') delivery will induce stress or trigger negative emotions due to previous trauma;
- you are unable to effectively read and answer questions in English.

You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. You may skip any survey questions you do not want to answer.

How will the study be carried out?

At the bottom of this page you will be asked three questions, 1) if you are at least 18 years of age, 2) if you agree to participate in the survey, and 3) if you agree to allow the research team to match your survey answers to the kick counting data associated with your email address that was recorded from your use of the Count the Kicks app. When you originally downloaded the app, the user agreement indicated that your information could be used by Healthy Birth Day, Inc. for program improvement purposes. The research study extends beyond the initial app user agreement, therefore your permission to match your kick session data with your survey answers is required for the research team to examine your kick session data. Your data will not be accessed without your permission. With your permission, the researchers will use your kick counting data to help determine if there is a relationship between kick counting and birth outcomes. If you answer yes to the three questions below, you will continue immediately with the survey. If you answer no to any of the three questions, you will be removed from the study and your data will not be included in the research project.

Are there any risks involved?

While participating in this study you may experience the following risks: emotional distress if your pregnancy and/or birth of your child(ren) was a traumatic experience. If you are negatively impacted at any time during or after this study, please contact the project investigator at Reinders.Lina@healthybirthday.org or 515-608-9643 or Drake IRB at irb@drake.edu or 515-271-3472. If you are seeking pregnancy loss resources, please visit www.pregnancylossdirectory.com.

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Are there any benefits to me?

You may not receive any direct benefit from taking part in this study. We hope that the information gained in this study will benefit society by improving awareness of stillbirth prevention strategies.

Will I be paid to participate?

If you participate, you will receive entrance into a drawing for one of ten \$20 gift certificates to Amazon.com. Your chances of being selected as a winner in the drawing are estimated to be 1 in 700. Actual odds of being selected will depend on the total number of people participating in the survey.

What are my rights?

Your participation in this study is completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled. If you agree to participate in the survey, you can skip any questions that you do not wish to answer.

How will you assure confidentiality?

Any information collected for this research study that is connected with you will only be disclosed with your permission; your answers and app data will be kept confidential. In any written reports or publications, no individual participant will be identified or be identifiable and only group data will be presented. However, Healthy Birth Day, Inc., federal government regulatory agencies, auditing departments of Drake University, and the Institutional Review Boards (a committee that reviews and approves human subject research studies) of Drake University and Des Moines University may inspect and/or copy study records for quality assurance and data analysis. These records may contain private information.

To ensure confidentiality to the extent permitted by law, the following measures will be taken: Any information that could identify you as the survey respondent will be coded for anonymity. Only the researchers listed above will have access to the coding system. All the researchers have completed training on the importance of and methods for protecting identifiable information. Survey and kick counting data will be stored separately in password protected computer files maintained by Healthy Birth Day, Inc. and Drake University. Any printed copies of the data will be kept in locked filing cabinet maintained by Healthy Birth Day, Inc. and Drake University; only the researchers will have access to the keys. Data will be stored for a minimum of 3 years after completion of the study and then will be deleted/destroyed. No publication resulting from the study will contain any identifiable information.

Who can I contact if I have questions?

You are encouraged to ask questions at any time during this study.

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- For further information about the study contact Lina Tucker Reinders, Associate Director of Programs, Healthy Birth Day, Inc. at Reinders.Lina@healthybirthday.org or 515-608-9643.
- If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 271-3472, irb@drake.edu.

How do I agree to participate and take the survey?

Answering yes to the following questions is considered consent. Please consider each question carefully. If you are at least 18 years of age and agree to both subsequent questions you will be taken directly to the survey. If you are under than the age of 18 or you choose no for either of the following questions, you will not be offered the survey and you will not be contacted again regarding this research study. Thank you for your consideration.

1. Are you 18 years of age or older?
2. Do you agree to participate in the survey to help determine if there is a relationship between kick counting and birth outcomes? Yes / No
3. Do you allow the researchers to obtain the kick counting data gathered by the *Count the Kicks* app during your use of the app, and pair it to your survey answers? Yes/ No