Text4Father Pilot Feasibility, Acceptability Study

NCT04101565

March 25, 2020

Date: March 25, 2020
Principal Investigator: Arik V. Marcell, MD, MPH
Application No.: IRB00226367

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Feasibility, acceptability, & preliminary efficacy of Text4Father for improving infant & family health / **FATHER Consent Form**

Application No.: **IRB00226367**

Sponsor: **National Institutes of Health**

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

- Fathers play a key role in their child's health and development beginning even before their children are born. This study's purpose is to examine if a text-messaging program that we designed to share with fathers during their partner's pregnancy through 2 months after their baby is born (for a total of 7 months) is useful and shows any change in fathers' knowledge, attitudes, or behaviors.
- Sixty fathers will be enrolled during pregnancy through 25 weeks gestation in one of two groups: Text4Father, or usual care control. Which group you are assigned to is determined by chance, like flipping a coin. Fathers' partners will also be recruited to compare outcome data and fathers' interactions with mothers and other caregivers. A total of 120 couples will be recruited (120 fathers and 120 mothers).
- Participation includes completing surveys at the beginning and at the end of the study. Fathers assigned to the Text4Father group, will receive text messages over the course of the study related to Text4Father's educational content. All fathers and mothers will also have 3 text check-ins during the course of the study.

- There are no medical risks however, you may feel uncomfortable or bored when answering questions, and there's a risk that information about you may become known to people outside of this study.
- There may or may not be a benefit to you from being in this study.
- You will be compensated for sending/receiving text messages and phone data use for viewing internet-related resources. You will be paid $110 for participating.

2. Why is this research being done?

The research is being done to help learn about whether a text-messaging program designed for fathers to support their partner and baby during pregnancy and first 2 months of life will be useful to and accepted by fathers. The focus of this study will be on delivery of the "Text4Father" intervention, and satisfaction with the experience. We hope to show that this text program focused on fathers can help involve fathers in the lives of their infants for the benefit of all family members.

Who can join this study?

- Adult expectant fathers who have a pregnant partner through 25 weeks gestation may join the study.
- Adult pregnant mothers who are pregnant through 25 weeks gestation and their partner who has consented to join the study, may join the study.

How many people will be in this study?

120 couples (120 fathers and 120 mothers), a total of 240 participants, are expected to take part in this study.

3. What will happen if you join this study?

If you and your partner agree to be in this study, we will ask you to do the following things:

- At the beginning, you will be asked to fill out a short survey with general questions about yourself, your partner, and your parenting knowledge, attitudes, and skills. The survey should take about 30-40 minutes.
- You will then be assigned by chance to one of 2 study groups, like flipping a coin – to receive the Text4Father texts about twice a week or not.
- All fathers over the course of the study will receive 1 check-in text every 2 months (a total of 3 check-ins) that will require you to respond to the study team by text.
- At the end of the study, you will take part in a follow-up survey during which you will share information about your partner and your parenting knowledge, attitudes, and skills, and satisfaction with Text4Father experience if you were assigned to this study group. The survey should take about 30-40 minutes.
- Your partner will complete a similar baseline and follow-up survey and the 3 check-in texts over the course of the study.

Please note that the researchers are required by law to report any reasonable suspicion of ongoing child abuse and neglect to the proper authorities.

How long will you be in the study?

You will be in the study for 7 months. You will also spend 30-40 minutes completing the baseline survey and 30-40 minutes completing the follow-up survey. After the follow-up survey meeting appointment is finished, your participation in the study will be done.

4. What happens to data that are collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data we collect about you are important to this effort.

If you join this study, you should understand that you will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

How will your data be shared now and in the future?

Sharing data is part of research and may increase what we can learn from each study.

Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) no further review and approval by an Institutional Review Board (IRB) is needed. If data are shared with identifiers, further IRB review and approval may be needed. The IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

5. What are the risks or discomforts of the study?

There are no medical risks to participation in this study.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You may also find some of the questions in the survey or during the conversation may be too personal. You do not have to answer any question you do not want to. If you become upset by any of the questions or if an issue comes up that you want to discuss during or after the sessions, research staff can help connect you with the study doctor who can help connect you to appropriate help.

Content of the text messages are educational in nature. There may be a risk that sensitive information is transmitted by text message, and that other people outside this study may see that information. It is important that you use the features on your phone, such as password protection, to prevent unauthorized viewing of your personal messages.

There is the risk that information about you may become known to people outside this study.

6. Are there benefits to being in the study?

You may or may not benefit from being in this study. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No. You will be required as part of participation to use your personal cell phone to receive/send text messages and to use your data plan for viewing online educational materials that may be sent in a link by text.

9. Will you be paid if you join this study?

You will receive $35 for completing the baseline survey. You will receive $75 after completing the follow-up survey. The total of $110 will compensate you for your time, any costs of receiving/sending text-messages, and travel for participating this study.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Your data will be kept confidential and secure. Our database will not contain any of your identifiers, and you will be assigned unique study number. No identifying data will be included in any of the presentations or publications that may be generated as a consequence of this study. Your contact information will be securely stored for internal use during the study by only members of the research team. At the end of the study, any identifiable information will be destroyed.

Your research data, which is used for research purposes, will be transmitted to and stored using Hopkins' secure, password-protected, and institutionally managed REDCap survey and research database platform. This will not include your contact or identifying information. Rather, your research data will be identified by only a unique study identification number.

13. What if there is a Certificate of Confidentiality for this study?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

14. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator, Dr. Arik V. Marcell at 443-287-8946. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

15. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

Future Contact
We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES □ _____ _____
Signature of Participant Date

NO □ _____ _____
Signature of Participant Date

16. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.