Online consent template

FAB_DAD_ ICF ONLINE

Title of Research Study: The Mothers and Babies Text Project –*MB Dad Pilot*

IRB Study Number: STU00203918

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Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. The purpose of this study is to develop and determine the feasibility and acceptability of a) conducting the FAB intervention protocol and b) assessing paternal and dyadic outcomes across HV programs.

- You will be asked to participate in the Fathers and Babies (FAB) text-based course/intervention.
- **FAB** supports fathers' mental health and promotes support of their partners as they become parents together. You will receive one phone or in person 15 minute session with your partner's home visitor or a research team member and receive text messages. The messages will be spaced 2-3 days apart and you will receive a total of 51 messages. Some of the text messages will require a brief response.
- You will be asked to complete internet-based surveys that ask about your mood, stress, social supports, and the usefulness of text messages. If you are unable to complete surveys online, we will conduct the surveys by telephone.
- Surveys will take approximately 30 minutes to complete, and will be conducted at the beginning of the study, 3-months after enrollment, and 6-months after enrollment. Members of the research team will be in communication with you throughout the research study using phone, e-mail, and/or Facebook.

We expect that you will be in this research study for 9-12 months.

The primary risk of participation is you may feel emotional or upset when answering some of the survey questions. The Text-messaging system is automated and does not provide direct communication with a provider or therapist.

The main benefit of participation is your participation may help home visiting programs better meet their clients' needs. The possible benefits to you from the Fathers and Babies program include learning how to better manage stress.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you will be a father or are a father. Your partner is pregnant or has a young child or children and is receiving services with a home visiting program or an early childhood program.

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How many people will be studied?

We expect approximately 36 women receiving home visiting services and 36 male partners to participate in this study.

What should I know about a research study?

- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.

If you say that "Yes, you want to be in this research," here is what you will do

- You will be asked to participate in the Fathers and Babies (FAB) text-based course/intervention. FAB supports fathers' mental health and promotes support of their partners as they become parents together. You will receive one phone or in person 15 minute session with your partner's home visitor or a research team member and receive text messages. Your partner will receive the Mothers and Babies 1-on-1 course with supplemental text messages from your home visitor during your regular home visits.

- The text messages will be spaced 2-3 days apart and you will receive a total of 51 messages. Some of the text messages will require a brief response.

- All of our text messages are sent by an automated system. That means that there is not a live person sending, receiving, or monitoring the content of messages. Although we will review the content of the messages received by participants, we cannot respond to individual messages.

- The goal of the text messages is to provide additional strategies and reinforce the skills presented during the FAB curriculum covering Pleasant Activities, Mood, and Contact with Others.

- You will be asked to complete internet-based surveys that ask about your mood, stress, social supports, the usefulness of text messages and the program. If you are unable to complete surveys online, we will conduct the surveys by telephone.

- Surveys will take approximately 30 minutes to complete, and will be conducted at the beginning of the study, 3-months after enrollment, and 6-months after enrollment. Members of the research team will be in communication with you throughout the research study using phone, e-mail, and/or Facebook.

What happens if I do not want to be in this research or if I say "Yes", but I change my mind later?

You can decide not to participate in this research and it will not be held against you. You can refuse to be in the study and it will not be held against you. Refusal to participate in the study will not affect your partner's home visiting or early childhood services.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete

secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

A description of this clinical trial NCT03427528 will be available at 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Minority Health and Health Disparities which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

This survey is being hosted by REDCapand involves a secure connection. Terms of service, addressing confidentiality, may be viewed at https://www.project-redcap.org/

Upon receiving results of your survey, any possible identifiers will be deleted. You will be identified only by a unique subject number. Your email address will be stored separately from your survey data, and is only being collected for payment purposes. All information will be kept on a password protected computer only accessible by the research team. The results of the research study may be published, but your name will not be used.

Mandated Reporters

The only exception to our promise of confidentiality is that we are legally obligated to report evidence of child abuse or neglect. We will not ask you about child abuse or neglect, but if you tell us about child abuse or neglect we are required by law to report your name to state authorities. In addition, should you report thoughts of harming yourself or others, and/or severe depression symptoms, we will share that information with your home visiting program, in order for them to provide you with an appropriate mental health resource referral. Depending on the severity, we may also take additional steps to ensure the safety of you and/or others.

Data Sharing

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De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

Participation in this study will involve no cost to you. We will provide assistance to participate in the text-messaging portion of the study, $10 monthly stipend (PNC Visa card) to you and your partner until you have received all the text messages and completed FAB or after 6 months. You will be given a $20 PNC Visa card after completing each of the 3 surveys (at the beginning of study and 3-months and 6-months after enrollment) for a maximum of $60, to compensate you for your time.

Who can I talk to?

If you have questions, concerns, or complaints, you can talk to the Principal Investigator Darius Tandon at 312-503-3398 or dtandon@northwestern.edu. and Jaime Hamil at 312-503-2645 jaime.hamil@northwestern.edu. This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

Consent to be contacted for future studies:

Check one of the following to indicate your choice:

_____ I agree to be contacted about participating in a focus group or key informant interview after receiving FAB.

_____ I do not agree to be contacted about participating in a focus group or key informant interview after receiving FAB.

_____ I agree to be contacted for another study in the future

_____ I do not agree to be contacted for another study in the future

Consent

If you want a copy of this consent for your records, you can print it from the screen.

If you wish to participate, please click the "I Agree" button and you will be taken to the survey.

If you do not wish to participate in this study, please select "I Disagree" or select X in the corner of your browser.