Breastfeeding Education Support Tool for Baby (BEST4Baby)

Consent for Participants

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CONSENT FOR PARTICIPANTS

Breastfeeding Education Support Tool for Baby Study

(BEST4Baby)

INVESTIGATORS: Dr. N S Mahantshetti, Principal Investigator

Dr. Shivaprasad S Goudar, Co-Investigator

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Purpose of the research

We (KLE University's J N Medical College Belgaum in collaboration with Thomas Jefferson University, USA) are conducting a "BEST4Baby" Study to promote adequate infant feeding practices in Karnataka, India. It has the potential to reduce as many as 156,000 child deaths each year in India and prevent 3.4 respiratory infections, and 3.9 million episodes of diarrhea in young children. Global rates of optimal BF practices, especially exclusive breastfeeding (EBF), have remained stagnant over the past decade in India. We want to find ways to improve the infant feeding practices. We believe that you can help us by participating in this study where in you will receive support from peer counselors, regarding feeding practices, by providing information either via paper or mobile (Text message and/or video using a mobile phone), and follow-up visits during the 6 months post-delivery.

Type of Study

This research will involve your participation as the study subject for a period during pregnancy and six months post delivery.

Voluntary Participation

Your participation in this study is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, all the services you receive at the local health centre will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier.

Potential Risks or Discomfort

There is no risk for being in this study. There is a possibility that answering the questions posed to you during the study by the study personnel may bring back memories and you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question if you feel the question(s) are too personal or if talking about them makes you uncomfortable. Photographs may be taken during the study; these will be used for scientific purposes only and will not contain any other personal information.

Benefits

There may be no direct benefit to you, but your participation is likely to help us find out more about how to improve the Infant feeding practices in your community.

Reimbursements

You will not receive any monetary reimbursements for participating in the study; your participation will be voluntary.

Confidentiality

Your confidentiality will be respected. No information that discloses your identity will be released. All the information taken from you will be kept safely and no person other than authorized local key investigators will be able to trace the information to your name or your address. The de-identified data will be shared to Women's and Children's Health Research Unit, KLE University JNMC, BEST4Baby working group in Belagavi and Thomas Jefferson University's BEST4Baby working group in USA for further analysis and interpretation. However, data will not contain any personal identifiers.

Whom to contact with questions about the study

We have given you information about the study called "BEST4Baby Study/' We have discussed the risks and benefits of the study and you understand that you do not have to agree to be in the study or may decide later not to be part of the study. This will not affect your or your baby's care in any way.
If you have any questions, please call:

Dr. N S Mahantshetti

Dr. Shivaprasad S Goudar

Dr. Roopa M Bellad

If you have questions about your rights as a study participant, please contact Dr Subarna Roy, Chairman, JNMC Institutional Ethics Committee on Human Subjects Research at +91 94490 33133.

I have read this consent form or it has been read to me in presence of a witness in my vernacular. I was given opportunity to ask questions and they were answered to my satisfaction. By signing this document I declare that I have consented to participate in this study.

_____

Signature or Thumbprint of Person Providing Consent Date

_____

Signature or Thumbprint of Witness Date

_____

Signature of Person Obtaining Consent Date

Person requesting consent, please check applicable boxes:

☐Consent obtained (for adult respondent)

☐ Assent (for minor respondents)

☐ Consent from authorized person of minor respondent