INFORMATION SHEET AND INFORMED CONSENT

BBenestar

Longitudinal study on mental wellbeing of women and partners during pregnancy and after childbirth. Determining factors.

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INVITATION TO TAKE PART IN A RESEARCH STUDY

We are writing to inform you about a research study in which you are invited to participate. The study has been approved by a Research Ethics Committee. Our intention is that you receive sufficient and correct information so that you can decide whether or not to take part in this study. Therefore, we ask you to read this information sheet carefully and we will clarify any questions you may have. You are also welcome to consult with any other person you consider appropriate.

WHAT IS "BBenestar"?

"BBenestar" is a longitudinal research study that aims to find out the level of mental wellbeing of women and partners during pregnancy and after birth, as well as the factors that may determine this wellbeing. The study will require the participation of 400 pregnant women and 400 partners.

The aim is to collect extensive information on pregnancy, birth and postpartum, lifestyle habits, social support, level of resilience and information on the mental health of the study participants.

WHY HAVE I BEEN INVITED TO PARTICIPATE IN THIS STUDY?

Women and partners between the 18th and 24th week of pregnancy who have at least one follow-up visit in the health centres participating in the study are invited to participate.

WHAT DOES PARTICIPATING IN THIS STUDY INVOLVE?

Participants will have to fill in 6 questionnaires that they will receive by email at different times: 1) at the beginning of the study, 2) at 32-36 weeks of pregnancy, 3) at 6 weeks postpartum and 4) at 3 months after the birth, 5) at 6 months after the birth and 6) at 12 months after the birth.

The different questionnaires have a variable duration between 10 and 25 minutes. In order to obtain more complete data, we kindly ask you to fill in all questionnaires.

WHO CONDUCTS THE RESEARCH?

This research study is carried out by a group of researchers from Blanquerna - Ramon Llull University (URL), together with a team of midwives, obstetricians, psychologists and psychiatrists, all of whom are involved in pregnancy and postpartum care.

CONFIDENTIALITY

Data will be collected on a secure server and will be treated with absolute confidentiality and in accordance with Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (GDPR) and Organic Law 3/2018 of 5 December on the Protection of Personal Data and guarantee of digital rights and any other implementing regulations.

The information collected will only be used for research purposes.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary and you may decide not to participate. By signing the informed consent form you confirm that you want to participate freely and autonomously in this study. You may withdraw your consent at any time by requesting it by e-mail to the Principal Investigator without having to explain the reasons and without affecting the health care you receive.

HOW WILL MY PERSONAL DATA BE TREATED?

You should be aware that the data collected will be identified with a numerical code (pseudonymised), so no information will be included that would allow your identification. They will be protected with security measures to prevent their alteration, loss and unauthorised access.

WHY IS MY PARTICIPATION IMPORTANT?

The information collected can help to better understand the mental health and wellbeing of women and partners during pregnancy and after birth.

WHAT ELSE DO I NEED TO KNOW?

Pregnant women who participate in the study can invite their partner, if they have, to take part in this research. Information on how this should be done will be provided at the time they are informed.

WE APPRECIATE YOUR SELFLESS COLLABORATION IN THIS STUDY. YOU ARE CONTRIBUTING TO A BETTER UNDERSTANDING OF MENTAL HEALTH DURING PREGNANCY AND AFTER BIRTH.

Do not hesitate to ask the healthcare professional who has communicated this information to you about any questions you may have, now or in the future, regarding this consent.

PERSONAL DATA PROTECTION

"BBenestar" RESEARCH TEAM IS COMMITTED TO THE PROTECTION OF YOUR PERSONAL DATA

- Both the centre and the principal investigator are responsible for the respective data processing, with each of them corresponding to the obligations derived from their activity. The centre is responsible for all data that appear in the medical records and that can identify it, and the principal investigator for the data collected in this research study in coded form (pseudonymised).

- The list linking the identification code with the data that identifies you (name, surname, medical records number) will be kept confidentially at your health centre.

- Access to your personally identifiable information will be restricted to the researchers/collaborators, the Research Ethics Committee (REC) and personnel authorised by the principal investigator (study monitors or auditors), when they need to check the data, study procedures and compliance with standards of good clinical practice; but always maintaining your confidentiality. Your identity may be disclosed in exceptional cases, such as situations of medical urgency for your health or legal requirement. The processing, communication and transfer of the personal data of all the participants in the study will comply with the provisions of the applicable regulations.

- All the information we request is necessary to participate in this research study and it is mandatory to provide it in order to guarantee its correct development. The Centre and the Principal Investigator will keep the data collected for the study for 5 years after its completion.

- What rights do I have over my data?

  1. The Right of access: you can ask at any time what data is being stored, who is using it and for what purpose. You can request a copy of your personal data for their use.
  2. The right to data portability: you can request a copy of the personal data provided by you in order to pass it on to other persons.
  3. The right to rectification: you can correct the personal data provided by you and limit the use of inaccurate personal data.
  4. The right to erasure and the right to restriction: it enables to request the deletion or removal of personal data where there is no compelling reason for its continued processing, and also to restrict the processing of their personal data.
  5. There are some limitations in order to ensure the validity of the research and to comply with the legal duties of the sponsor. If you decide to stop participating in the study or withdraw your consent to the processing of your data, the data collected up to that point cannot be deleted. You should be aware that if you decide to withdraw your consent to the processing of your data this may result in the termination of your participation in the study.
  6. To protect your rights we will use as little information as possible.
  7. Please note that you have the right to lodge a complaint with the Data Protection Agency about any action by the Promoter or the Centre that you consider to be in breach of your data protection rights.

- The encrypted data will not be shared for direct marketing purposes or for other purposes that are not legal obligations or are not considered scientific research in accordance with current data protection legislation. In particular, it will not be used to make decisions about future services that may be offered to you, such as insurance.

To exercise your data protection rights, you can contact the Data Protection Officer at your centre, or contact the data protection officer of the promoter.
Contact details of the Data Protection Officer (DPD) of Parc Taulí Hospital: DPD@tauli.cat