Study Participant Information Sheet

Enjoy Your Bump – Implementation Study

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Having a baby is a big life event which can often have an effect on our mood. Depression is one of the most common complications of pregnancy and is thought to occur in 10-15% of pregnancies. Studies have found that women often do not seek professional support for depressive symptoms due to worry about what others might think, potential long waiting times for face to face counselling and feeling unsure of using anti-depressants while they are pregnant. We have therefore identified a need for an effective intervention to help treat anxiety and depressive symptoms during pregnancy. In this Enjoy Your Bump Study we want to test whether an on-line Cognitive Behavioural Therapy (CBT) based life skills course, that we have designed with input from pregnant women, will help improve symptoms of anxiety and depression in pregnancy.

CBT is based on the concept that your thoughts, feelings, physical sensations and actions are interconnected, and that negative thoughts and feelings can trap you in a vicious cycle. CBT aims to help you deal with current problems in a more positive way by breaking them down into smaller parts. The Enjoy Your Bump programme uses many aspects of CBT in an online format and aims to help change negative patterns to improve the way you feel. For CBT to be effective, committing to the process is important so that you can get the most out of it. This is something to consider when deciding whether to take part.

We intend to enrol about 100 women into our study.

Why have I been invited to take part?

You are a pregnant woman between 8-32 weeks of pregnancy who has some feelings of low mood or anxiety.

Do I have to take part?

No. It is up to you to decide whether or not to take part but before deciding whether to take part or not, you might want to discuss this with your family or friends. It's a good idea to think about it for at least 24 hours before deciding to take part.

If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. Deciding not to take part or withdrawing from the study will not

affect the healthcare that you receive, or your legal rights. If you have any questions about taking part or withdrawing from the study, please email the research team on enjoyyourbump@ed.ac.uk .

What will happen if I take part?

All study participants will be screened to make sure they are eligible to take part in the project. The screening will measure your current mental health status using an approved questionnaire and a few additional screening questions.
There are 2 questions:
1. During the past month have you often been bothered by feeling down, depressed or hopeless?"
2. During the past month have you often been bothered by having little interest or pleasure in doing things?"

If you answer yes to either of these questions, you can access the online study website. As part of the screening process, we will also check your stage of pregnancy and whether you have any severe mental health issues. If you do not meet the criteria to be included in the study, we will make sure we provide you with the relevant information to seek emotional support during your pregnancy should you wish to do so.

If you do meet the criteria and wish to consent to participate in the study, the following process will happen:

i) You will need to read the consent form carefully and give informed consent to become a study participant.

ii) You will need to provide us with some basic personal and demographic information, like your name, date of birth, address, phone number, email address, weight, height, estimated due date, gestation, number of pregnancies, GP practice details, GP name.

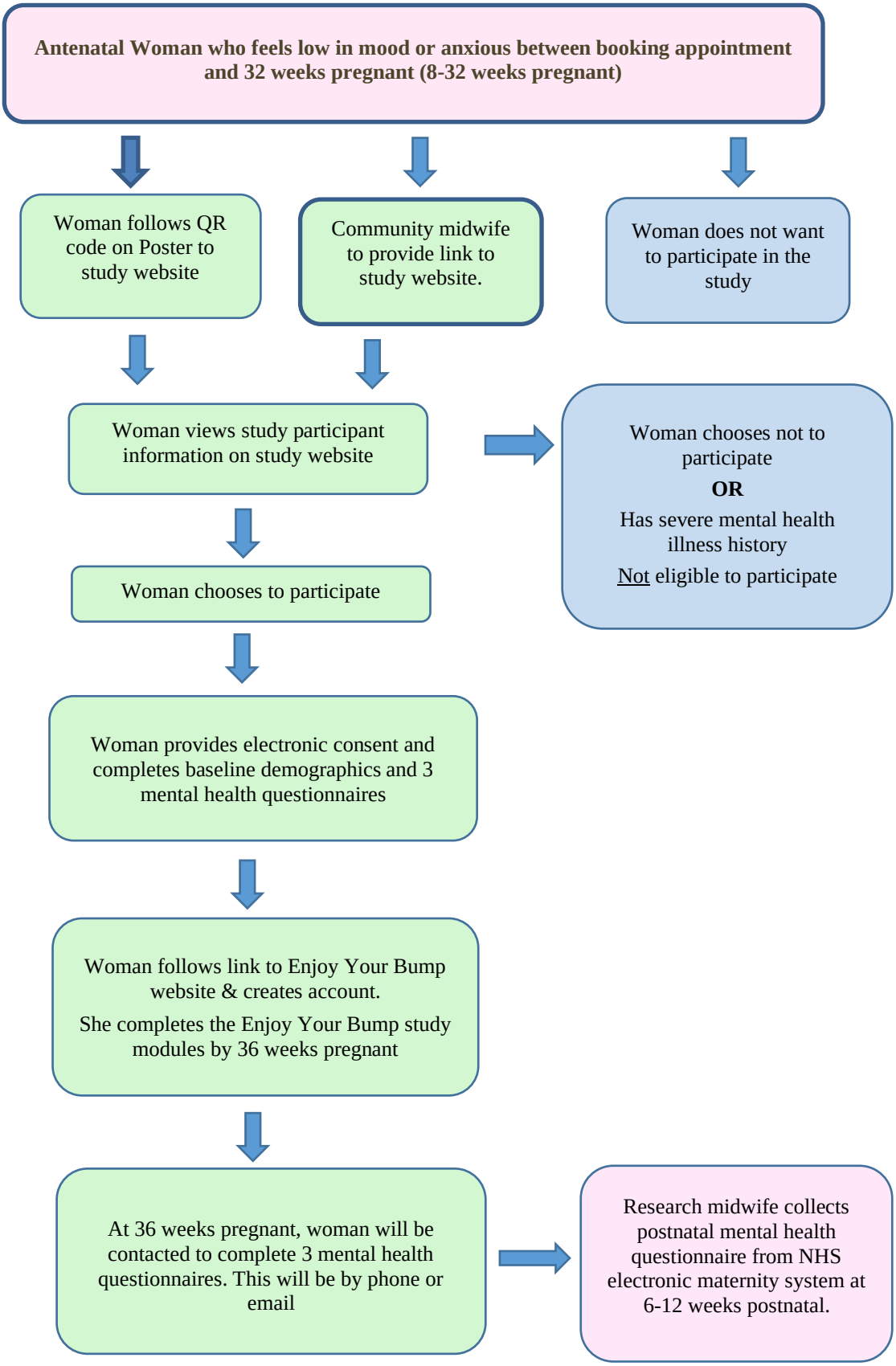
iii) You will be asked to complete 3 wellbeing assessment questionnaires. These are online and can be completed on a smart phone, iPad, kindle, laptop or PC. These questionnaires will take approximately 10 minutes to complete.

iv) You can complete the 5 Enjoy Your Bump study computer modules at your own pace, with the aim of completing the course by 36 weeks of pregnancy. There will also be 12 optional topics and 9 short "You Time" exercises available to you to complete if you want. You can complete the modules at your own pace. We anticipate that it would take between 6 to 12 weeks. The modules cover topics such as: understanding your feelings, managing expectations, planning for the arrival, bonding with your baby. The programme is also set up to send you personalised automatic emails from the research team once a week for up to 12 weeks to motivate you to carry out the modules. You can switch off these reminders if you prefer.

v) At approximately 36 weeks pregnant, all participants will be asked to complete the 3 short questionnaires again (those are the same

questionnaires that you were asked to complete at the beginning of the study). You will be contacted by a member of the Research Team by phone or you will receive an email link to the study website. The contact preference will be part of the consent procedure. These questionnaires will take approximately 10 minutes. The Research Team will make no more than three attempts at contacting you to complete the questionnaires.

vi) At 6-12 weeks following the birth of your baby, you will complete a short wellbeing questionnaire with the health visitor as part of standard NHS postnatal care. As part of the consenting process, we will ask you to consent to the research midwife looking at the score of this assessment and use this information help inform our research.


Antenatal Woman who feels low in mood or anxious between booking appointment and 32 weeks pregnant (8-32 weeks pregnant)
Woman follows QR code on Poster to study website
Community midwife to provide link to study website.
Woman does not want to participate in the study
Woman views study participant information on study website
Woman chooses not to participate
OR
Has severe mental health illness history
Not eligible to participate
Woman chooses to participate
Woman provides electronic consent and completes baseline demographics and 3 mental health questionnaires
Woman follows link to Enjoy Your Bump website & creates account.
She completes the Enjoy Your Bump study modules by 36 weeks pregnant
At 36 weeks pregnant, woman will be contacted to complete 3 mental health questionnaires. This will be by phone or email
Research midwife collects postnatal mental health questionnaire from NHS electronic maternity system at 6-12 weeks postnatal.

What are the possible benefits of taking part?

Completing Enjoy Your Bump CBT based life skills course could improve your pregnancy experience. Some of the skills you will learn from the modules could be helpful in your daily life and in maintaining healthy mental wellbeing. The answers from the questionnaires are very important to the overall results of the study and we hope comparing these results will help to prove that Enjoy Your Bump on-line CBT based life skills course has the potential to improve the mental health of pregnant women. It could reduce health inequalities by overcoming many of the barriers preventing treatment access to standard therapies and enabling the most 'hard to reach' vulnerable pregnant women to access support packages.

What are the possible disadvantages of taking part?

It is not thought that there are any disadvantages of taking part in this study. If you find that you are not enjoying or benefitting from participating in the study, you can withdraw at any moment.

What if there are any problems?

It is vital that if you feel that you need more support, or if your mental wellbeing becomes a concern to you or others around you, that you contact your community midwife, GP, local hospital, or a mental health service provider. During the study, if the researcher has any concerns regarding your mental wellbeing out with his/her scope of practice they will make the appropriate referral to your GP.

If you have a concern about any aspect of this study please contact the research team at enjoyyourbump@ed.ac.uk who will do their best to answer your questions. If you wish to make a complaint about the study, please contact NHS Lothian using the contact details at the end of this information sheet.

Also there will be a link available on the EYB dashboard to allow you to ask for additional email support regarding the online course. The dashboard link submits the information directly to a University of Edinburgh study support email. The research team will check this email inbox routinely and will answer within 3-5 working days.

In the unlikely event that you feel you have been harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study

You are free to withdraw from this study at any point without giving a reason. Withdrawing will not affect the healthcare that you receive, or your legal rights. To withdraw from the study, you will need to contact the study team via enjoyyourbump@ed.ac.uk and they will withdraw you from the study. You won't need to take any further action. You will have the option of withdrawal from:

(i) Withdrawal from the CBT modules and questionnaires but we will retain the data collected from you up to that point.

OR

(ii) Withdrawal from the CBT modules and questionnaires but we will retain the data collected from you up to that point and also collect the routine NHS data at 6-12 weeks at the postnatal check by your health care professional.

What happens when the study is finished?

At the end of the research we will analyse the data and publish the results. We will also publish a summary of the results online. This will give you the information about what we found through undertaking this trial. The data generated from the study will be stored on a secure server for at least 3 years. Anonymised data will be made available to accredited researchers for additional analyses.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. No data will be shared with the Five Areal Ltd, the online course provider. We will, however, receive anonymised data from Five Areas Ltd on participant usage of the course resources.

How will we use information about you?

We will need to use information from you and from your medical records (TRAK system) for this research project.

This information will include:

name
date of birth
estimated delivery date
weight
height
address
email address
phone number
computer IP address
GP practice details
GP name

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your personal details will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your TRAK system records. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from [**www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to enjoyyourbump@ed.ac.uk, or
- by contacting a Data Protection Officer:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net

What will happen to the results of the study?

The study will be written up as a paper and/or presented at a conference. You will not be identifiable in any published results. A general summary of the study's findings will be available on the Centre for Reproductive Health website. If you would like to receive anonymised results at the end of the study, please contact us at enjoyyourbump@ed.ac.uk.

Who is organising and funding the research?

This study has been organised/sponsored by the University of Edinburgh and NHS Lothian and funded by Tommy's, the baby charity. Edinburgh Clinical Trials Unit, which is part of the University of Edinburgh, provides database support for the study. The online CBT based life skills course is provided by an established company - Five Areas Ltd. It is a private company

that offers a wide range of online mental and physical well-being resources including online courses, digital books, video, and worksheets – all based on the Cognitive Behavioural Therapy approach.

Who has reviewed the study?

The study proposal has been reviewed by the University of Edinburgh and NHS Lothian Sponsor representatives. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from South East Scotland Research Ethics Committee **. NHS management approval has also been obtained.

Researcher Contact Details

If you have any further questions about the study please contact the research study email address at enjoyyourbump@ed.ac.uk or contact Professor Rebecca Reynolds at R.Reynolds@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Dr Sarah Murray (Clinical Lecturer in Obstetrics) at Sarah.Murray@ed.ac.uk.

Complaints

If you wish to make a complaint about the study please contact NHS Lothian:

Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
feedback@nhslothian.scot.nhs.uk
0131 536 3370

Help and Support

As you will be aware, our mood can go up and down over time and we acknowledge that pregnancy can be a very emotional time for many women. We hope that you will find the 'Enjoy Your Bump' modules helpful during your pregnancy. However, if you feel you would like more help and support with your mood, then please see the list below of people to contact:

- Make an appointment to see your GP to discuss your concerns.
- Phone and speak to your midwife and ask for an urgent referral to be made to Perinatal Mental Health Services.
- Phone NHS 24 on 111 for non-urgent situations.
- Phone 999 in case of an emergency.

Participant ID: **Centre ID (if applicable)**

CONSENT FORM

Enjoy Your Bump – Implementation Study:

(View only version. Consent form is completed electronically on the study database.)

In order to be eligible to take part in the study, you need to be able to agree to the below listed mandatory points. If you are not able to agree to the mandatory points below, you will not be eligible to take part in the study.

	Please select your answer:
1. I confirm that I have read and understand the information sheet (XX-XXX-XXXX) for the above study and have understood the content.	Yes ☐ No ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected.	Yes ☐ No ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by the trial researchers and individuals from the Sponsor (University of Edinburgh and NHS Lothian), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records.	Yes ☐ No ☐
4. I consent for the research team to access the results of my Edinburgh Postnatal Depression Scale questionnaire on the NHS Lothian Maternity TRAK system.	Yes ☐ No ☐
5. I agree to my General Practitioner being informed of my participation in the study and I agree to my General Practitioner being contacted if a significant risk to my wellbeing was identified.	Yes ☐ No ☐
6. I would like to complete the follow up questionnaires by (please select the preferred option):	Phone ☐ Electronically ☐
7. I give permission for my personal information (including name, address, date of birth, telephone number, GP and consent form) to be passed to the University of Edinburgh and Edinburgh Clinical Trials Unit for administration of the study.	Yes ☐ No ☐
8. I understand that my IP address will automatically collected by the study database when completing the consent form online.	Yes ☐ No ☐
9. I agree to my anonymised data being used in future studies.*(Not mandatory.)	Yes ☐ No ☐
10. I understand that the 'Enjoy Your Bump' course and website is owned by a company (Five Areas Ltd) who are independent of NHS Lothian and the University of Edinburgh. I am aware that I will be given the opportunity to read and decide whether to accept their Terms and Conditions and Privacy Policy before registering my details on the website.	Yes ☐ No ☐
11. I agree to anonymised website usage information of the Enjoy Your Bump course being reviewed by researchers from the University of Edinburgh.	Yes ☐ No ☐
12. I agree to take part in the above study.	Yes ☐ No ☐

Participant ID: **Centre ID (if applicable)**

Please select your answer:

Name of Person Giving Consent	Date	Signature

Name of Person Receiving Consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record