RELAX – REducing Levels of AnXiety - in pregnancy and after birth. A study to see if a new online training (RELAX) can reduce anxiety in pregnant women and new mothers.

Chief Investigator: Professor Colette Hirsch, King's College London

Invitation and brief summary

We would like to invite you to participate in this research. The study will help us find out whether online training can help to reduce anxiety and negative thinking during pregnancy and after birth.

You can choose whether or not to take part. Your decision will not influence any other aspects of your pregnancy, birth, or postnatal care.

We use the term *'women'* throughout our website and our online training intervention to refer to those who are pregnant. We acknowledge that not all people who are pregnant and give birth identify as women, and it is important that evidence-based care for maternity, perinatal and postnatal health is inclusive. Our study is open to anyone who is currently pregnant however they choose to identify, and we welcome all those who are eligible.

If you are interested in taking part in the study, please take time to read the following information carefully and discuss it with others if you wish. If you have any questions about the study, please contact us via email at relaxstudy@kcl.ac.uk or via telephone on [TELEPHONE NUMBER TO BE INSERTED].

What is the study for?

Anxiety is common during and after pregnancy and is very distressing for women. Anxiety can be fuelled by negative thoughts such as worry about the future or mulling over negative events from the past (rumination), such as *'will my baby be healthy?*' or '*why did I feel so exhausted by the end of the weekend?'*. Using what we have learnt from past research, we have produced a simple, online training programme called RELAX (REducing Levels of AnXiety) that aims to reduce anxiety and negative thinking in pregnant women and new mothers.

We will test if completing RELAX leads to lower levels of worry and anxiety through this randomised controlled trial where pregnant women are offered either (i) their usual maternity care plus the RELAX programme, or (ii) their usual maternity care only. Women will be randomly assigned to either group ('randomly assigned' means that a computer decides which of these two options you will be offered and no one involved with the research or a woman's care decides which option she gets). This will make the results of the study a reliable test of how effective the training is. RELAX involves 12 online training sessions which last about 15-20 minutes each where women listen to short stories (scenarios) about everyday events and answer questions.

What would taking part involve?

We are looking for women who are 16-28 weeks pregnant who frequently have negative thoughts (worry and rumination) and mild to moderate levels of anxiety to participate in this study. If you decide to take part in the study, you will:

- complete some screening questionnaires about yourself, your pregnancy, negative thinking, mood, and anxiety to find out if you are suitable for the research. If you are eligible, we will invite you to a short screening phone call so we can tell you more about the study at a time that is convenient for you.
- if you consent to take part, you will complete assessments (sets of questionnaires), online at home, at the start of the study and then four, eight and 36 weeks later. The final assessment will also ask you your thoughts about the birth and life with your baby. The screening questionnaire and all assessments can be completed on a computer, laptop, tablet, or mobile phone. We will send you reminders to complete your assessments via email, text message or telephone.
- if you are offered RELAX, you will be invited to complete 12 online training sessions over a 4-week period, which involve listening to short stories (scenarios) about everyday situations, thinking about them in particular ways and answering questions. The first training session will last around 30 minutes and the rest will each last about 15-20 minutes. The RELAX training sessions can be completed at home (or the most convenient place for you) and they must be completed using a computer, laptop, or tablet. It is best to do the RELAX sessions using a device that has a screen size of at least 8.3 inches. You are able to select the days and time you wish to complete the training sessions. If you are falling behind on the sessions, we will send you reminders to complete your sessions via email, text message or telephone. Once the 4-week period is over, you will not have access to the online training sessions.
- after the final session, you may be invited to take part in a recorded phone interview about the training. The recordings will be given a code to make them anonymous and a sample of the interviews will be sent to a transcription service to be typed up in full. Any personal information that might identify you, such as the name of your midwife or any family members, will be taken out, so the documents are entirely anonymous.

What are the possible benefits of taking part?

We hope that you find it interesting to take part in this study and try a new online approach to prevent and reduce anxiety, which is not yet UKCA marked, publicly or commercially available. RELAX offers participants an opportunity to re-train their thinking style to respond to situations with less negative thinking than is usual for people who tend to worry or feel anxious. We hope that engaging with the programme will feel like a useful way to help prevent or reduce anxiety, with lasting benefit.

We have had people with high levels of anxiety take part in similar research studies before and they found the training helpful and were pleased to have contributed to mental health research. For more information on our past research, please visit our website: relax.healthmachine.io. If you wish, you can also read the research paper for our previous pregnancy study here: https://cpe.psychopen.eu/index.php/cpe/article/download/3781/3781.pdf/. The information we get from this study will help us work out whether anxiety and negative thinking can be reduced in pregnant women and whether this online intervention offers the best way to provide the training.

As a thank you for participating in the RELAX study, you will be given a £25 voucher after completing each assessment (£100 in total). Women who are not eligible after the

screening call will be given a £5 online voucher to thank them for speaking to us. As this study is for women with mild to moderate anxiety and negative thinking, we cannot involve women with more severe anxiety in this study since they need to be offered a different type of help. Following the screening questionnaire, we will direct these women to local services

offering help designed for their level of need. Additionally, all individuals who complete the screening questionnaire will be entered into a prize draw offering them a chance to win a £50 voucher. This prize draw will occur every 3 months and you can only be entered into it once.

What are the possible disadvantages and risks of taking part?

Taking part in this study will not affect your midwifery or medical care in any way. The risk of taking part is small. A similar online training to RELAX has been used in non-pregnant populations before without any negative effects. If you are offered the RELAX intervention, the scenarios will describe situations that could be worrying (e.g., scan appointments, fetal movements). This may lead to temporary increases in anxiety. It is possible that completing the forms may also lead to a temporary increase in anxious or low mood. Based on previous research, such mood changes are expected to dissipate quickly, though you can stop or pause the sessions at any time. Furthermore, if the sessions bring up any concerns, you will be able to discuss these with a member of the research team and we will tell you where you can get further support. If you agree, we can also tell your midwife or doctor of any concerns about your mental health.

Further supporting information

You will be asked to provide consent just before completing the screening questionnaire and before filling in the first assessment online.

King's College London (KCL) and Guy's and St Thomas' NHS Foundation Trust are co-sponsoring the study, and the study is funded by the National Institute for Health and Care Research (NIHR) Efficacy and Mechanism Evaluation (EME) programme. The study has also been reviewed and approved by the Health Research Authority (HRA), Medical and Healthcare products Regulatory Agency (MHRA) and the NHS Research Ethics Committee (NHS REC).

Your GP and midwife /maternity service will be notified about your involvement in the study and they may be contacted if you are identified to be at risk, suffer a significant adverse event or report feeling very distressed during the study (including the telephone interview) or at screening. In some cases, your GP may also have to share information about you with the research team. Women who experience pregnancy loss (e.g., miscarry), terminate pregnancy, or need inpatient care will be asked if they would like to withdraw from the study.

If you have any questions about any aspect of this study, now or at any stage, please contact the research team via email at relaxstudy@kcl.ac.uk or telephone on [TELEPHONE NUMBER TO BE INSERTED].

How to sign up to take part?

Please visit relax.healthmachine.io to register your interest and we will be in touch to complete a short screening call with you, lasting about 20 minutes, informing you more about the study and what to do next to get started. We will find a time to call that is convenient for you.

What will happen to the results of the research study?

The results of this study will be published in scientific journals and shared at medical and psychological conferences. We will use quotes from the phone interviews when writing about the research but these will be anonymised and you will not be identified in any reports or publications.

A plain English summary will be sent to participants after the end of the full study and findings will be shared via social media, a workshop for people who work with pregnant women and new mothers, and in a policy briefing report that will be shared widely in the NHS and government.

Who has reviewed the study?

This study has been checked by the West Midlands - South Birmingham Research Ethics Committee (Reference Number: 22/WM/0273) and the MHRA, an independent group of people, to protect your safety, rights, wellbeing and dignity.

How will we use information about you?

If you hear about the study through Guy's and St Thomas' NHS Foundation Trust or King's College Hospital NHS Foundation Trust, we will need to use information from you and your medical records for this research project.

For all individuals taking part in the study, we will need to collect the following personal information:

- Name
- Contact details (phone number and email address)
- Date of birth
- Sex at birth
- Estimated due date
- GP contact details
- Maternity service details (midwife name and hospital)

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 data 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.

We need to manage your records in specific ways for the research to be reliable. This means that we will not 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 (email: relaxstudy@kcl.ac.uk; telephone: [TELEPHONE NUMBER TO BE INSERTED]**.**
- by sending an email to info-compliance@kcl.ac.uk
- by ringing us on 020 7848 7816

What if there is a problem?

If you have a concern about any aspect of this study, you should contact Professor Colette Hirsch (email: colette.hirsch@kcl.ac.uk; telephone: 020 7848 0697) who will do their best to answer your questions. If you were recruited through Guy's and St Thomas' NHS Foundation Trust or King's College Hospital NHS Foundation Trust, and remain unhappy and wish to complain formally, you can do this by contacting the relevant Patients Advice and Liaison Service via the details provided below:

- Guy's and St Thomas' Patients Advice and Liaison Service (PALS) - 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.
- King's College Hospital Patients Advice and Liaison Service (PALS) - 020 3299 3601, kch-tr.palsdh@nhs.net. The PALS team are located on the ground floor of Hambleden Wing (King's College Hospital), near the main Bessemer Road entrance.

The study is co-sponsored by King's College London (KCL) and Guys and St Thomas' NHS Foundation Trust (GSTT). The sponsors will, at all times, maintain adequate insurance in relation to the study. KCL through its' own professional indemnity (Clinical Trials) and no fault compensation, and the GSTT having a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of negligence by its employees, brought by or on behalf of a study participant.