ISRCTN12754931 https://doi.org/10.1186/ISRCTN12754931

Reducing levels of anxiety in pregnancy and after birth: a study to see if a new online training can reduce anxiety in pregnant women and new mothers

Submission date
06/04/2023

Recruitment status
No longer recruiting

Registration date
25/05/2023

Overall study status
Completed

Last Edited
14/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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 they have learnt from past research, researchers 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.
This study will test if completing RELAX leads to lower levels of worry and anxiety by offering pregnant women 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 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.

Who can participate?
Women aged 18 years and older who are 16-28 weeks pregnant who frequently have negative thoughts (worry and rumination) and mild to moderate levels of anxiety

What does the study involve?
Participants complete some screening questionnaires about themselves, their pregnancy, negative thinking, mood, and anxiety to find out if they are suitable for the research. If they are eligible, they will be invited to a short screening phone call to tell them more about the study. Participants will complete assessments (sets of questionnaires), online at home, at the start of the study and then 4, 8 and 36 weeks later. The final assessment will also ask for their thoughts about the birth and life with their baby. The screening questionnaire and all assessments can be completed on a computer, laptop, tablet, or mobile phone. The researchers will send reminders

to complete the assessments via email, text message or telephone.
Participants who are offered RELAX 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. Participants are able to select the days and times they wish to complete the training sessions. If they are falling behind on the sessions, the researchers will send reminders to complete the sessions via email, text message or telephone. Once the 4-week period is over, participants will not have access to the online training sessions. After the final session, participants 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 the midwife or any family members, will be taken out, so the documents are entirely anonymous.

What are the possible benefits and risks of participating?
It is hoped that participants will find it interesting to take part in this study and try a new online approach to prevent and reduce anxiety which is not yet 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. It is hoped that engaging with the programme will feel like a useful way to help prevent or reduce anxiety, with lasting benefits.
The researchers 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 their past research, please visit their website: https://relax.healthmachine.io/. Participants can also read the research paper for the previous pregnancy study here: https://cpe.psychopen.eu/index.php/cpe/article/download/3781/3781.pdf/. The information from this study will help to 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, participants 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. As this study is for women with mild to moderate anxiety and negative thinking, it 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, the researchers will direct these women to local services offering help designed for their level of need. Also, 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.
Taking part in this study will not affect 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. In 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 anxiety 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, participants will be able to discuss these with a member of the research team who will tell them where they can get further support and if they agree can also tell their midwife or doctor of any concerns about their mental health.

Where is the study run from?
1. King's College London (KCL) (UK)
2. Guy's and St Thomas' NHS Foundation Trust (UK)
3. King's College Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2022 to November 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) Efficacy and Mechanism Evaluation (EME) programme (UK)

Who is the main contact?
relaxstudy@kcl.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Colette Hirsch

ORCID ID
https://orcid.org/0000-0003-3579-2418

Contact details
P 1.06 Henry Wellcome Building for Psychology
Institute of Psychiatry, Psychology and Neuroscience
King's College London
De Crespigny Park
London
United Kingdom
SE5 8AF
+44 (0)2078480697
colette.hirsch@kcl.ac.uk

Type(s)
Public

Contact name
Dr Brittannia Volkmer

Contact details
King's College London
Henry Wellcome Building for Psychology, Room P1.16
Institute of Psychiatry, Psychology and Neuroscience (IoPPN)
16 De Crespigny Park
London
United Kingdom
SE5 8AF

+44 (0)207 848 0665
brittannia.volkmer@kcl.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
307468

Central Portfolio Management System (CPMS)
54789

Study information

Scientific Title
A randomized controlled trial of a web-based early intervention targeting repetitive negative thinking in pregnant women: an evaluation of its impact on perinatal anxiety and the mechanism of change

Acronym
RELAX

Study objectives
The purpose of this randomised controlled trial is to determine whether pregnant women with high levels of repetitive negative thinking (RNT) who complete an early intervention, RELAX, alongside receiving usual care, experience significantly lower levels of anxiety later in the perinatal period, compared to those who receive usual care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/02/2023, West Midlands - South Birmingham Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8345; southbirmingham.rec@hra.nhs.uk), ref: 22/WM/0273

Study design
Two-arm parallel-group multicentre superiority randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pregnant women (16-28 weeks gestation) with high levels of repetitive negative thinking and up to a moderate level of anxiety

Interventions

Randomization will take place via Avegen's randomization system. Participants will be randomized individually with equal allocation to the two arms, stratified by site (GSTT vs KCH vs KCL), parity (0 vs not 0) and pregnancy complications (no pregnancy complications vs pregnancy complications (current and/or past)), using a random permuted block design. Participants will be allocated to the intervention arm (receive usual care + RELAX) or control arm (usual care) at a ratio of 1:1 via an online system independently developed and hosted by Avegen.

Participants in the intervention arm will complete RELAX, which consists of 12 web-based Cognitive Bias Modification for Interpretation (CBM-I) training sessions (of 15-20 minutes duration), over a period of 4 weeks alongside receiving usual care. The RELAX sessions involve listening to short, ambiguous scenarios (30 per session) that can be interpreted in both negative and positive ways. Participants in the intervention arm complete RELAX alongside receiving usual care.

Those in the control arm will only receive usual care and if accessing the RELAX platform, a message will appear indicating the date on which their next assessment is due. Usual care typically involves monitoring by maternity services and contact with a health visitor. Women may also be offered information on self-referral to local psychology services where they will be on a 4-week waitlist or be offered generic interventions (e.g., group treatment, computerised CBT).

Intervention Type
Device

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
REducing Levels of AnXiety (RELAX)

Primary outcome(s)
T2 anxiety measured by the Generalised Anxiety Disorder Questionnaire-7 (GAD-7) at 8 weeks post-randomisation; 24-36 weeks gestation

Key secondary outcome(s))
Secondary clinical endpoints will all be presented as mean differences in outcomes between the intervention (RELAX + usual care) and control (usual care) arms adjusting for baseline. These endpoints are:
1. Anxiety measured using GAD-7 at 36-weeks post-randomisation (T3)
2. Depression measured using Patient Health Questionnaire-9 (PHQ-9) at 8 weeks post-randomisation (T2)
3. Depression measured using PHQ-9 at 36 weeks post-randomisation (T3)
4. RNT measured using Repetitive Thinking Questionnaire-10 (RTQ-10) (trait) at 8 weeks post-randomisation (T2)
5. RNT measured using RTQ-10 (trait) at 36 weeks post-randomisation (T3)
6. Trait worry measured using Penn State Worry Questionnaire (PSWQ) at 8 weeks post-randomisation (T2)
7. Trait worry measured using PSWQ at 36 weeks post-randomisation (T3)
8. Perinatal depression measured using Edinburgh Postnatal Depression Scale (EPDS) at 8 weeks post-randomisation (T2)
9. Perinatal depression measured using EPDS at 36 weeks post-randomisation (T3)
10. Perinatal anxiety measured using Perinatal Anxiety Screening Scale (PASS) at 8 weeks post-

randomisation (T2)
11. Perinatal anxiety measured using PASS at 36 weeks post-randomisation (T3)
12. Work and social functioning measured using Work and Social Adjustment Scale (WSAS) at 8 weeks post-randomisation (T2)
13. Work and social functioning measured using WSAS at 36 weeks post-randomisation (T3)

Completion date
30/11/2025

Eligibility

Key inclusion criteria
1. Pregnant women between 16-28 weeks gestation
2. Aged 18 years or older
3. Based in the United Kingdom
4. High levels of RNT (RTQ-10 [trait] ≥32; McEvoy et al., 2014)
5. Anxiety up to only a moderate level (GAD-7 <15)
6. Ability to understand oral and written English
7. Normal or corrected-to-normal hearing and vision
8. Ability to access the internet on a PC, laptop, or tablet (rather than a mobile phone)
9. Provision of an email address and phone number for contact with the team

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
288

Key exclusion criteria
1. Current psychiatric diagnosis (this will be assessed via the clinical interview schedule revised (CIS-R; Lewis & Pelosi, 1992) which participants will complete as part of the screening questionnaire as well as via general questions about a current diagnosis of a psychotic disorder, eating disorder, substance use disorder or personality disorder)
2. Past diagnosis of a psychotic disorder (e.g., schizophrenia), bipolar disorder, an eating disorder, a substance use disorder (e.g., alcohol dependence) and/or a personality disorder (e.g., borderline personality disorder)
3. Current or recent history of risk: current suicidal intent (PHQ-9 item 9 >1), suicide attempt <2 years and/or self-harm <1 year

4. History of stillbirth, neonatal death, or multiple (i.e., ≥3) miscarriages
5. Current participation in another study that is investigating a treatment for a mental health problem
6. Not registered with a GP in the UK

Date of first enrolment
07/06/2023

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
King's College Hospital NHS Foundation Trust
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
King's College London
Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
16 De Crespigny Park
London
United Kingdom
SE5 8AF

Study participating centre

Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
Efficacy and Mechanism Evaluation Programme

Alternative Name(s)
NIHR Efficacy and Mechanism Evaluation Programme, Efficacy and Mechanism Evaluation (EME), EME

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the King's Open Research Data System (KORDS), which is a repository that allows data sets to be shared openly (https://www.kcl.ac.uk/researchsupport/managing/preserve).
The data shared will be anonymised, final datasets of the end of trial data, as agreed by the Trial Management Group nearer to the time of the deposit.
The local Research and Development office has reviewed these plans and advised that the participant consent is currently appropriate for this data sharing, i.e., with the participant clause in the consent form: "I understand that the research team may use my data for future research and that my data may be shared anonymously with other researchers".

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/10/2024	24/10/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1.5	10/02/2023	24/10/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes