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Pregnancy and Wellbeing Study (PAWS)

Submission date
13/10/2011

Recruitment status
No longer recruiting

Registration date
02/12/2011

Overall study status
Completed

Last Edited
20/09/2016

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
Background and study aims
The implications of depression in the perinatal period are considerable for the well-being, safety and the development of the baby, with depression in mothers associated with adverse effects on child health. Antenatal depression is the main predictor of postnatal depression and women may be more depressed in late pregnancy than at any other perinatal time point. There are few studies of antenatal interventions to prevent postnatal depression and none to prevent depression assessed before childbirth.
The purpose of the study will be to evaluate the feasibility, and effectiveness of training community mid wives (CMWs) in a psychological approach to prevent perinatal depression antenatally. Randomly selected CMWs will receive training on a psychological approach and will then subsequently deliver an enhanced delivery of care to consenting women on their caseload.

Who can participate?
300 women will be involved in the study from the Leicestershire and Rutland region.

What does the study involve?
This is a pilot study before a full scale study can take place. The pilot study will address questions of resources needed for recruitment, cognitive behavioural approach (CBA) therapists and midwife involvement. Participants will be asked to complete a number of research questionnaires throughout the study.

What are the possible benefits and risks of participating?
There are no risks to the participants

Where is the study run from?
Leicestershire, Northamptonshire and Rutland

When is the study starting and how long is it expected to run for?
September 2010 to September 2012

Who is funding the study?
The study is funded by the The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care - Leicestershire, Northamptonshire and Rutland (NIHR CLAHRC for LNR)

Who is the main contact?
Prof. Terry Brugha
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Study website
http://www.clahrc-lnr.nihr.ac.uk/pregnancy-and-well-being

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Psychological approach for preventing perinatal depression antenatally pilot of a cluster randomised controlled trial of community midwifery training

Acronym
PAWS

Study hypothesis
Can training of community midwives (CMWs) in a psychological approach to their delivery of care, enhance their standard delivery of care and subsequently, prevent antenatal depression?

We hypothesis that the training of CMWs, in a psychological approach to their delivery of care, we will help prevent antenatal depression and improve the mental health of pregnant women. This pilot is not powered to answer this question definitively. The purpose of the study will be to evaluate, in a pilot of a cluster randomised controlled trial (CRCT), the feasibility, and effectiveness of training CMWs in a psychological approach to prevent perinatal depression antenatally, based on the comparison of community midwife care as usual (standard care) with enhanced assessment and psychological support by CMWs. The study findings, including a qualitative evaluation, will help to inform planning for a larger randomised controlled clinical trial. A planned interim analysis of this pilot study will be conducted, to enable the planning of recruitment to a multicentre study with sufficient power.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Research Ethics Committee, 03/06/2010, ref: 10/H0405/39

Study design
Pilot study of a cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Condition
Pregnancy

Interventions
Control group:
The control group CMWs will continue to provide community midwife care as usual, encompassing the breadth of care currently provided by community midwives. They will be only required to hand out the pilot study information packs at antenatal booking clinics and to complete a womans service contact and activity participant log for each woman consenting to take part in the study.

Intervention group:
The intervention CMWs will receive a total of seven days of training.

They will attend a one day training module on the assessment of women, recognising antenatal depression, and monitoring symptoms of depression. Training will include standardised procedures for administering the EDS (Edinburgh Postnatal Depression Scale) questionnaire covering the use of probe questions to evaluate the clinical importance of the results of the self-completion questionnaire.

The intervention CMWs will also attend a six day training module on the development of midwives skills in the Cognitive Behavioural Approach (CBA) to the delivery of care to prevent antenatal depression, to be used with all intervention group women who have agreed to take part in the pilot study. CBA incorporates cognitive behaviour therapy (CBT) principles and skills which will be delivered by qualified cognitive-behavioural psychotherapists who are based in local National Helath Service (NHS) psychological therapy teams. CMWs will be supported to tailor their care to the womans needs and preferences.

Manuals will be based on materials used in Psychological interventions for postnatal depression: cluster randomised trial and economic evaluation. The PoNDER trial (PoNDER)2, a cluster randomised conrolled trial designed to compare the effectiveness and cost of postnatal health visitor training in depression recognition and psychological care, developed and provided for CMWs in the intervention groups; CMWs will also be given active feedback and guidance on practice in their use by their trainer. Training will focus primarily on depression but will acknowledge the frequent co-existence of symptoms of general anxiety.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The proportion of Edinburgh Depression Scale (EDS) negative women (clinic researcher administered) at study entry, identified at 34-weeks as EDS (clinic researcher administered) positive (EDS ≥12)
2. The primary comparison will be between all EDS negative women who were under the care of CMWs randomised to provide the intervention, versus all EDS negative women under the care of CMWs who were randomised to provide CMW care as usual
3. To assess the feasibility of the study, randomly selected intervention group women, having completed the 34 week pilot outcome, will also be invited to take part in qualitative evaluations of the pilot with an experienced researcher. All intervention midwives will take part in a confidential focus group

Secondary outcome measures
1. The proportion of Edinburgh Depression Scale (EDS) positive women (clinic researcher administered) at study entry, identified at 34-weeks (clinic researcher administered) as remaining EDS positive (EDS ≥12), comparing intervention with control women
2. In all participating women the mean EDS score, state anxiety with the STAI, SF-12 score and the Agnew scale at 34 weeks of pregnancy, comparing intervention with control women
3. Qualitative information on study feasibility including participation of CMWs and study women

Overall study start date
01/09/2010

Overall study end date
30/09/2012

Eligibility

Participant inclusion criteria
All pregnant women on the caseload of participating community midwives, who are also:
1. Registered by the 18th week of pregnancy
2. Over 18 years of age
3. Able to give informed consent
4. Residing in the UK and intend to remain there 6 months after the birth of the baby
5. Able to read and fully comprehend English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
300 pregnant women will be recruited, with the aim of identifying 230 women with an EDSS score, at their dating scan clinic (approximately the 12th week of pregnancy)

Participant exclusion criteria
1. Not able to give informed consent for any reason
2. Not a resident of the UK or will not remain in the UK for 6 months after the birth of the baby
3. Unable to fully comprehend and read English
4. Women who are currently in receipt of treatment from specialist mental health services

Recruitment start date
01/09/2010

Recruitment end date
30/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leicester
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University Hospitals of Leicester (UK)

Sponsor details
NHS Trust Headquarters
Level 3, Balmoral Building
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Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) CLAHRC, Leicestershire, Rutland and Northamptonshire (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2011		Yes	No
Results article	results	01/01/2016		Yes	No