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Multi-centre randomised controlled trial for postnatal depression in British South Asian women - ROSHNI-2

Submission date
23/01/2017

Recruitment status
No longer recruiting

Registration date
26/01/2017

Overall study status
Completed

Last Edited
21/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Postnatal depression (PND) is a type of depression that some mothers experience after having a baby. It can cause disability and suffering in women, negative consequences for their infants and their family with huge costs to society. Rates of PND in British South Asian (BSA) women are higher than the general population. Due to language and cultural barriers, BSA women often do not access appropriate health care services. This has been highlighted as a major contributor to unequal healthcare across the UK populations. Mothers of South-Asian backgrounds (Bangladesh, Pakistan and India) account for a large number of births in the UK. There is a growing concern about ethnic inequalities in the provision and access to postnatal depression services, which is an identified priority in both England and Scotland. The Positive Health Programme (PHP) is a new culturally adapted treatment program that has been developed to help women with PND. Smaller studies have shown that it may lead to improved mood, and successfully engages and supports women from a South Asian background. The aim of this study is to look at the effectiveness and cost-effectiveness of PHP in the treatment of BSA women with PND.

Who can participate?
British women of South Asian origin with PND who have had a baby within the last year.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the PHP programme as well as standard treatment. This involves 12 group sessions which last for 60-90 minutes every week for two months and then fortnightly for a further two months. The sessions involve learning life skills and having the opportunity to meet other women in similar circumstances. Those in the second group receive usual care only. At the start of the study and then after four and 12 months, participants in both groups complete a questionnaire to measure their depression levels. At the end of the study, the costs of delivering the programme are also calculated from questionnaires completed by participants at the start of the study and after four and 12 months.

What are the possible benefits and risks of participating?
Participants who receive the programme may benefit from improvements to their mood. There are no major risks involved with participants, although some women may find taking about experiences and feelings to be difficult.

Where is the study run from?
Lancashire and South Cumbria NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2016 to August 2022

Who is funding the study?
National Institute for Health Research (UK) - HTA programme

Who is the main contact?
1. Dr Farah Lunat - project manager
farah.lunat@lscft.nhs.uk
2. Professor Nusrat Husain (scientific)
nusrat.husain@manchester.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Farah Lunat

ORCID ID
http://orcid.org/0000-0003-4091-6139

Contact details
Lantern Centre
Vicarage Lane
Fulwood
Preston
United Kingdom
PR2 8DW
+44 (0)1772 773498
farah.lunat@lscft.nhs.uk

Type(s)
Scientific

Contact name
Prof Nusrat Husain

Contact details
University of Manchester & Lancashire Care NHS Foundation Trust
3rd Floor, Jean Mcfarlane Building University of Manchester
Oxford Road

Manchester
United Kingdom
M13 9PL
+44 (0)161 306 7921
nusrat.husain@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 32313

Study information

Scientific Title
Multi Centre RCT of a group psychOlogical intervention for poStnatal depression in britisH mothers of south asiaN origIn - ROSHNI-2

Acronym
ROSHNI-2

Study objectives
The aim of this study is to investigate the clinical and cost-effectiveness of a culturally adapted group psychological intervention called the Positive Health Programme (PHP) in British South Asian (BSA) women with post-natal depression.

Added 16/09/2022:
An add-on study was included in August 2021. The aim of this additional work is to explore and understand the wider consequences of the global pandemic on BSA women during the perinatal period in the context of mental health, isolation, education, interpersonal relationships, child development and views on the vaccination and wider impacts. The pandemic has resulted in the closure of parent support groups including baby play, breastfeeding support and child health clinic drop-in sessions. The researchers will also explore the nature and intensity of breastfeeding problems encountered, help-seeking behaviours and sources of support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/01/2017, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8235; nrescommittee.northwest-gmsouth@nhs.net), ref: 16/NW/0727

Study design

Randomized; Interventional; Design type: Treatment, Screening, Diagnosis, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Charity/Voluntary sector, Community, GP practice, Medical and other records

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Postnatal depression, maternal mental health, interpersonal violence

Interventions
Consenting, eligible women will be randomized via an independent remote randomisation service based at the King's College Clinical trials unit (CTU). After each block of 18 women have been recruited into the trial in each centre, women will be block randomised to the two treatments to give 9 intervention and 9 control participants.

Intervention: Participants receive a CBT-based culturally adapted group psychological intervention called the Positive Health Programme (PHP) added to the Treatment As Usual. The manual assisted intervention PHP has been designed to be delivered by non-specialist mental health professionals. The 12 groups/sessions are educational life skills classes, based on a CBT model. Each PHP session will last for 60-90 minutes and will be delivered weekly for two months, and then fortnightly for further two months.

Treatment as usual (TAU): Participants undergo study assessments along with routine assessment and management as usually conducted by the participating general practices.

The assessments for both the arms will be at baseline, at 4 months (end of intervention) and then 12 months after baseline. The duration of the assessment will not be more than 45-60 minutes.

Added 16/09/2022:
An additional work stream was included in November 2021 as an add-on study to the ROSHNI-2 project (14/68/08, HTA). The proposed work is shaped by the suggestions made by participants in the current ROSHNI-2 study for a follow-up and re-engagement to explore other associated risk factors related to maternal mental health and specifically in the context of the pandemic. We aim to increase our understanding of the pandemic-related impact on BSA women including Interpersonal Violence (IPV) in BSA communities. The add-on study is supported by an ongoing MRC-funded international survey study - Psychological impact of COVID-19 pandemic and

experience: An International Survey (IRAS Project ID 282858). The project is led by Southern Health NHS Foundation Trust and The University of Portsmouth. It aims to investigate and explore the psychological impact of COVID-19, the resultant restrictions and the impact on behaviours and changes in mental wellbeing across the global population.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Recovery from postnatal depression is measured using the Hamilton Depression Rating Scale (HDRS) at 4 months (end of intervention)

Secondary outcome measures
1. Treatment response is measured using the Hamilton Depression Rating Scale (HDRS) at baseline, 4 and 12 months
2. Cost data will be collected using an Economic Patient Questionnaire at baseline, 4 and 12 months

Overall study start date
01/07/2016

Completion date
26/08/2022

Eligibility

Key inclusion criteria
1. Self-ascribed British women of South Asian origin as defined by Office of National Statistics (ONS, 2011)
2. Over the age of 16 years and living with their infants up to the age of 12 months (1-Year)
3. Meet the criteria for DSM-V depression

Participant type(s)
Patient, Service user

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned Sample Size: 720; UK Sample Size: 720

Total final enrolment
732

Key exclusion criteria
1. Women with diagnosed learning disability that will impact on capacity to consent
2. Postpartum psychosis
3. Any other diagnosed psychosis
4. Actively suicidal (previous history of self-harm or suicide attempt).

Date of first enrolment
08/02/2017

Date of final enrolment
26/08/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancashire and South Cumbria NHS Foundation Trust
The Lantern Centre
Vicarage Lane
Preston
United Kingdom
PR2 8DW

Sponsor information

Organisation
Lancashire Care NHS Foundation Trust

Sponsor details
Sceptre Point
Sceptre Way
Bamber Bridge
Preston
England
United Kingdom
PR5 6AW

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/03zefc030

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 10/07/2024:
The study protocol has been published (https://doi.org/10.1192/bjo.2021.1032). The full study report is being published in the NIHR HTA journal https://www.journalslibrary.nihr.ac.uk/hta/#/ in September 2024.

Further planned publication in high-impact peer-reviewed journals at the end of the recruitment and final results in the year 2024.

An output on lessons learnt and strategies from this trial is attached for wider sharing.

Previous publication and dissemination plan as of 16/09/2022:
The study protocol has been published (https://doi.org/10.1192/bjo.2021.1032). Further planned publication in high-impact peer-reviewed journals at the end of the recruitment and final results in the year 2022.

Previous publication and dissemination plan:
The study protocol will be published before the end of 2017 and there is further planned

publication in high-impact peer-reviewed journals at the end of the recruitment and final results in the year 2022.

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	01/07/2016	26/01/2017	No	Yes
Protocol article		01/01/2022	16/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Poster results			10/07/2024	No	No
Results article		12/10/2024	15/10/2024	Yes	No
Other publications	Economic evaluation	17/03/2025	21/03/2025	Yes	No