

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

<b>Submission date</b> 23/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/03/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

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2. Professor Nusrat Husain (scientific)

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## Contact information

### Type(s)

Public

### Contact name

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Scientific

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## 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?
<a href="#">Participant information sheet</a>	version V1	01/07/2016	26/01/2017	No	Yes
<a href="#">Protocol article</a>		01/01/2022	16/09/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Poster results</a>			10/07/2024	No	No
<a href="#">Results article</a>	Economic evaluation	12/10/2024	15/10/2024	Yes	No
<a href="#">Other publications</a>		17/03/2025	21/03/2025	Yes	No