Efficacy of a culturally adapted, cognitive behavioural therapy-based intervention for postnatal depression in British south Asian women (ROSHNI-2): a multicentre, randomised controlled trial

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Lancet 2024; 404: 1430–43

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Summary

Background Postnatal depression necessitates timely and effective interventions to mitigate adverse maternal and child outcomes in the short term and over the life course. British south Asian women with depression are often underserved and undertreated due to stigma, language barriers, and cultural barriers. This trial aimed to test the clinical efficacy of a culturally adapted, group cognitive behavioural therapy (CBT)-based intervention, the Positive Health Programme (PHP), delivered by non-specialist health workers for postnatal depression in British south Asian women.

Methods This study was a randomised controlled trial, with culturally adapted recruitment and an internal pilot, comparing the PHP (intervention group) with treatment as usual (control group) in British south Asian women with postnatal depression. The study was conducted at five centres across the UK. Participants were aged 16 years or older, met the DSM-5 criteria for depression, and had infants aged 0–12 months. Randomisation (1:1) was stratified by centre, with a block size of 18, and was done through an independent remote telephone service. The PHP was delivered over 12 group sessions in 4 months. The primary outcome was recovery from depression (defined as a Hamilton Depression Rating Scale [HDRS] score ≤7) at 4 months after randomisation, and an assessment was also done at 12 months. Analysis was on an intention-to-treat basis including only participants with non-missing outcome data; we used a random-effects logistic regression model including fixed covariates for study site, baseline depression severity (HDRS score), parity, and years in education and a random coefficient for therapy group. This trial is registered with the ISRCTN (ISRCTN10697380).

Findings Of the 9136 individuals approached for recruitment between Feb 8, 2017, and March 29, 2020, 4296 women were eligible for and consented to screening, among whom 732 screened positive and were randomly allocated: 368 (50%) to the PHP group and 364 (50%) to the control group. Participants were mostly of Pakistani (397 [55%] of 719 with available data), Indian (176 [24%]), or Bangladeshi ethnicity (127 [18%]), with an overall mean age of 31·4 years (SD 5·2), with their youngest infants having a mean age of 23·6 weeks (14·2). At 4 months from randomisation, the proportion of participants who showed recovery from depression on the HDRS was significantly higher in the PHP group (138 [49%] of 281) than in the control group (105 [37%] of 281; adjusted odds ratio 1·97 [95% CI 1·26–3·10]). At the 12-month follow-up, this difference was no longer significant (1·02 [95% CI 0·62–1·66]).

Interpretation In British south Asian women with postnatal depression, a culturally adapted group CBT-based intervention could aid in quicker recovery from depression compared with treatment as usual. Further research is needed to identify how to sustain the treatment effect and establish strategies for scale-up.

Funding UK National Institute for Health and Care Research.

Introduction

Postnatal depression affects around one in eight women globally and typically presents within the first few weeks after giving birth.[1,2] It has substantial public health implications due to its association with several adverse outcomes in children, including impaired cognitive, socioemotional, and physical development.[2] Moreover, it contributes considerably to the intergenerational transmission of health and socioeconomic inequalities globally.[3–7] Common perinatal mental disorders, including postnatal depression, are associated with long-term societal costs; in the UK, for example, these costs amount

Research in context

Evidence before this study

Postnatal depression is highly prevalent worldwide, is associated with poor maternal and infant outcomes, and is a significant public health concern. The UK National Institute for Health and Care Excellence (NICE) recommends cognitive behavioural therapy (CBT) as a primary treatment for postnatal depression. Our previous systematic review and meta-analysis of 59 CBT-based interventions showed that group-based CBT interventions were effective for postnatal depression (standardised mean difference –0·67 [95% CI –0·96 to –0·38]; n=4915) in majority populations in high-income societies, even when administered by trained non-specialist health workers. It also showed a scarcity of studies on the acceptability and effectiveness of psychotherapeutic treatments for postnatal depression in women belonging to minority ethnic groups.

Added value of this study

This is the first large-scale randomised trial to test a group CBT-based intervention for postnatal depression in British south Asian women, a group that is underserved by psychological therapy services due to stigma and language and cultural barriers. Our previous exploratory work established the need for cultural adaptation of psychological therapies in the UK especially for south Asian ethnicities to improve access to care, engagement, and uptake. Based on these experiences, we developed a culturally adapted CBT-based approach, the Positive Health Programme (PHP), delivered by non-specialist health workers. Compared with treatment as usual (control), the PHP intervention was associated with a higher proportion of patients recovering from postnatal depression at 4 months after randomisation, suggesting that this intervention can aid in earlier recovery. However, no significant difference in recovery between the PHP and control groups was observed at 12 months.

Implications of all the available evidence

Minority ethnic groups are often excluded from mental health research and can be overlooked if services do not consider their cultural and social contexts. In addition to providing evidence of the feasibility and effectiveness of a culturally adapted, group CBT-based intervention for this population, the study demonstrates methodological approaches for engaging UK-based minority ethnic communities in mental health research. Outreach approaches and stakeholder and service user engagement can help to overcome some of the barriers to accessing services.

to approximately £8·1 billion for each 1-year birth cohort.[3] Bauer and colleagues suggested that the cost of enhancing services to address common perinatal mental disorders could be less than a fifth of the current societal costs associated with these conditions, thereby highlighting the need for improved interventions and support.[4]

Despite postnatal depression being acknowledged as a major public health concern, a substantial treatment gap still exists, whereby a large proportion of those with clinically relevant symptoms do not seek or are unable to access treatment—in the UK, for example, this proportion is as high as 60%.[3,4] Closing such treatment gaps is now a global priority.[8–11] Although progress has been made, considerable disparities remain in providing timely mental health care and addressing inequalities in access, experience, and outcomes.[12] These disparities are particularly pronounced for women from minority ethnic backgrounds, such as south Asian women, the largest minority ethnic group in the UK,[13–15] who, despite higher prevalence, present for mental health treatment at a considerably lower rate than White women. Innovative solutions and approaches are needed to enhance access to perinatal mental health services for minority ethnic groups.[15,16]

Guidance from the National Institute for Health and Care Excellence (NICE) in the UK recommends cognitive behavioural therapy (CBT) for the prevention and treatment of postnatal depression,[17] particularly for women with mild to moderate depression. Although the UK National Health Service (NHS) offers free to access CBT through the NHS Talking Therapies service (previously the Improving Access to Psychological Therapies [IAPT] initiative),[18] access to and acceptability of CBT among minority ethnic groups, especially south Asian people, remains low, both for postnatal depression and more generally.[19,20] Language barriers and ethnic and cultural beliefs can substantially hinder south Asian women's efforts to seek help during the perinatal period. There is, therefore, a pressing need for culturally appropriate models for the effective screening and care for postnatal depression in minority ethnic populations.[21,22]

Our earlier exploratory research identified the need for cross-cultural adaptation of psychological therapies, particularly among south Asian populations in the UK, to improve engagement and uptake.[20] Such adaptation requires not only an appreciation of cultural and linguistic needs, but also an understanding of the unique psychosocial risk factors (eg, family and intimate partner violence) and family dynamics within minority ethnic populations such as south Asian communities.[2] This research informed the development of a culturally adapted, CBT-based intervention: the Positive Health Programme (PHP).[19,20] In a previous feasibility study,[19] we showed that the PHP was feasible and led to improvements in postnatal depressive symptoms, quality of life, and marital relationships, and improved access to services for south Asian women.[19]

The primary objective of the ROSHNI-2 trial (*roshni* meaning "light" in Urdu and Hindi), informed by our

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earlier feasibility study,[19] was to investigate the clinical efficacy of the PHP intervention for postnatal depression in terms of recovery from depression in British south Asian women. Additionally, the trial aimed to examine the intervention's effect on secondary outcomes, such as postnatal anxiety, social functioning, quality of life, access to health services, parenting competence, and treatment satisfaction.

Methods

Study design

ROSHNI-2 was a partially nested, multicentre, randomised controlled trial that included an internal pilot study. The trial was conducted at five study centres (including general practices, community settings, and children's centres) in the UK with high south Asian populations, across northwest England, Yorkshire, the

Panel: **Key strategies used to facilitate recruitment**[21]

Community engagement

Bilingual research assistants attended community children's centres or community venues that host children's playgroups. We worked closely and developed service level agreements with a number of third-sector organisations across our study sites. These organisations had community link workers or outreach workers who were trained in study processes to provide information about the study and raise awareness in the community. This upskilled community workers and also ensured those with established community trust and rapport could positively influence study recruitment.

The team collaborated with different organisations to host events involving families, key opinion makers from the local community, and professionals to tackle stigma and raise awareness. Previous research staff and health professionals have labelled minority ethnic community members as "hard to reach", and thus the people in those communities are wary of working with big establishments.[19]

Chai **with ROSHNI-2**

The team arranged regular drop-in sessions open to the community. General practitioners and health visitors were also invited to meet the general members of south Asian community and encourage conversations around mental health in the postnatal period over *chai* (tea). The events were focused on normalising conversations and tackling stigma. Information about the study was given at the end of the events and anyone eligible was able to ask for more information.

Engaging with faith leaders

The team worked to liaise and engage with faith leaders from the key religions practised in this community. Faith leaders from Muslim and Hindu communities joined study advisory groups. Meetings were held with local councils of mosques and Hindu and Sikh associations. They were briefed on the importance and background of the study and asked to support by sharing information with their congregations about the study at events. Some mosques included information on ROSHNI-2 at the end of sermons during the holy month of Ramadhan and encouraged families to engage with the project.

Family engagement

There was a need for educating family members on taboo subjects such as postnatal depression and seeking support from health services in a manner that suited them. Many felt they needed to carry on as normal and not make their situation publicly known. Family members felt that if other people found out, family reputation might be affected. Some participants would not receive permission to attend the groups from extended family or their partner. The team offered to meet with the whole family to explore and discuss the content of the group sessions and the importance of the therapy sessions, not just for the mother but also for the child or children. Family were also included in the consent process to ensure that the team were being sensitive to the power dynamics within south Asian homes and facilitating participation by adapting processes.

Language

Many languages are spoken by the British south Asian population, the common ones being Urdu, Punjabi, Gujarati, Bengali, and Tamil. Each researcher is able to speak English and one of the study languages fluently. Participants are able to communicate in the language that they feel most comfortable in. All the study materials—including promotional posters, information leaflets, and study assessments—were translated into the key study languages.

Cultural competence and staff training

Staff were trained in cultural sensitivity and competence, including awareness of participants' cultural commitments and religious beliefs. Regular team discussions were held on dynamics, respect, understanding, and appropriateness of verbal and non-verbal communications. ROSHNI-2 staff researchers and also participants helped to raise awareness among non-minority ethnic health professionals of cultural differences, including by sharing positive case studies with general practitioners or health visitors.

Social media

Trained research assistants promoted the ROSHNI-2 project via social media platforms including Facebook, Twitter, and Instagram. Promotions included weekly updates and posts on the importance of maternal mental health. The pages were managed by a communications and media intern within the team in line with guidance from the National Institute for Health and Care Research on the use of social media in research. We produced short promotional animated videos, posts introducing members of the team to build trust and rapport within the community, and updates on study progress. Potential participants were able to message with questions or to express interest in participating.

East Midlands, London, and Glasgow. In the intervention group, participants were nested in therapy groups, while those in the control group were not. This rater-blind trial compares the use of the PHP plus treatment as usual with treatment as usual alone. The trial protocol, published previously, provides details about the study design and methods.[23] Recruitment included an 18-month internal pilot phase.

The Northwest Health Research Authority granted ethical approval for the research (approval number IRAS 187851; approval date Jan 6, 2017). The data monitoring and ethics committee collaborated with the trial steering committee to review the quality and safety aspects of the research. Our team developed a comprehensive risk policy to address concerns regarding potential harm to trial participants, especially in the context of the prevalence and stigma regarding mental health in the south Asian community. We followed the safeguarding policies of local NHS trusts to ensure the safety and wellbeing of participants, details of which can be found in our protocol.[23]

NS, a service user collaborator, served as a key member of the research team throughout the project, including during the proposal development stage, acquisition of ethical approval, implementation, and dissemination of results. To develop a comprehensive intervention and protocol, the study team also sought the participation of British south Asian women who had lived experience relevant to the study. Alongside NS, the advisory groups had patient and public involvement, with three individuals supporting the study.

Participants

Eligible participants were south Asian women who met the DSM-5 criteria for depression, were aged 16 years or older, and had an infant aged 0–12 months. Exclusion criteria were a diagnosis of postpartum or other psychosis, active suicidal ideation, and physical or intellectual disability that would limit the ability to provide informed consent. Participants taking antidepressant medication or with a history of common mental illness, such as previous postnatal depression, were not excluded.

General practice records were used to identify eligible participants, who received study invitation letters and consent-to-contact forms. Participants were also identified in children's centres, community venues, and through self-referrals. Screening was done using the nine-item Patient Health Questionnaire (PHQ-9). In women who scored 10 or higher on the PHQ-9, the research diagnosis of postnatal depression was confirmed using the Structured Clinical Interview for DSM-5 (SCID-5), administered by trained researchers. We adapted the PHQ-9 screening procedure from self-report to a standardised conversational approach to address inconsistencies in participant responses. This adaptation had the added benefit of fostering a more open dialogue, building rapport and trust, which led to more honest responses from the mothers

The study used various recruitment strategies (panel), placing a strong emphasis on establishing trust in the research team within the community through frequent discussions with key stakeholders about mental health and the importance of participation in research. Addressing the stigma associated with postnatal depression and increasing awareness about appropriate avenues of care was a key focus. Through various community-engagement activities, including clinic drop-in sessions and participation in health promotion events, the initiative sought to empower the community by highlighting the significance of their involvement in research as a means to drive change and help to address the community's specific needs. Staff training emphasised the importance of flexibility in scheduling, location, and language options, and also addressed the inclusion of family members and the need for adaptable measurement procedures to avoid creating barriers to participation. To maximise reach, trained research assistants actively promoted the ROSHNI-2 project on social media platforms (including Facebook, Twitter, and Instagram) in various south Asian languages, thus ensuring that the recruitment strategy was inclusive and wide reaching.

Randomisation and masking

Eligible consenting women were randomly allocated through an independent remote telephone service managed by the Manchester Academic Health Sciences Centre Trials Coordination Unit, stratified by centre, with a block size of 18. The therapy for the intervention group consisted of groups of nine patients. After recruiting each set of 18 women at each centre, participants were block randomised into the two groups, resulting in nine women in the intervention group and nine in the control group.

Efforts were made to ensure that the period between consent and randomisation did not exceed 4 weeks. General practitioners (GPs) were notified of their patient's participation in the trial. It was not possible to mask the participating mothers, their GPs, or practice health visitors to the treatment group.

Procedures

The PHP is a structured intervention consisting of 12 group-based sessions, combining CBT-based strategies with culturally relevant adaptations for British south Asian women with postnatal depression.[19,20,24] Initially, sessions were held weekly for 2 months, then every 2 weeks for an additional 2 months, with each session lasting 60–90 min. The sessions were delivered in languages preferred by the trial participants; following randomisation, the individuals were contacted to understand language preference and any other barriers to participation, and this would determine the allocation of facilitators, such that at least one facilitator was usually allocated who spoke the most common language reported by the participants. The PHP

educated participants about depression and addressed nine culturally specific topics, including the challenges of being a British south Asian woman, the role of religion and spirituality in mental health, issues affecting self-esteem and their management, exercise, relaxation, assertiveness, self-confidence, and tackling social isolation, all aimed at raising awareness and improving wellbeing. The PHP was delivered by non-specialist workers, who were trained NHS band 4–7 researchers, with backgrounds in psychology, social sciences, or related fields, but no experience in delivering CBT. Details about the intervention content, training, and supervision procedures for non-specialist workers are summarised in the appendix (pp 1–2) and can be found in the protocol.[23] The training of non-specialist workers for intervention delivery focused on mastery of facilitation, behavioural activation, and the ABC model of CBT. It involved a didactic and Socratic teaching approach, with verbalisation of the contents of the intervention via presentations, role-plays, and dialogue in discussions. PHP trainers observed facilitators for at least one session, provided practical feedback, and suggested improvement where required.

See Online for appendix

Treatment as usual for the control group involved routine mental health assessments, care by the GP, routine management and monitoring of the condition, referral to talking therapies, and antidepressant medications as needed. More details about the use of health services are provided in the appendix (pp 3–5).

Following the introduction of physical distancing measures in the UK during the COVID-19 pandemic, the team swiftly implemented a continuity plan to ensure delivery to time and target could be maintained with regard to all governance and operational aspects. At a time of particular vulnerability for an already disadvantaged group, the research team, in coordination with the participants and experts on participant and public involvement and engagement, ensured measures could be put in place that allowed contact to be maintained in line with the study protocol.

On March 23, 2020, Public Health England (PHE) guidance was issued and lockdown procedures were implemented across all sites, and it was not possible to deliver the above without some changes. We held remote 1:1 discussions with the study participants to understand their views and suggestions for possible solutions, and the consensus was they did not want the study to be paused or for intervention delivery to not go ahead as planned.

To comply with PHE guidance and follow physical distancing guidelines, the PHP intervention was delivered remotely via Zoom, Microsoft Teams, or Google Meet, rather than in in-person groups. Updated ethical approvals, guidance, and delivery materials to facilitate the change in format were developed, together with comprehensive training of research team members under supervision of senior investigators.

Assessments were done at baseline (ie, randomisation), immediately post-intervention (around 4 months from randomisation), and at 12 months from randomisation and were conducted at participants' homes or other preferred locations, and in the participant's preferred language, including Urdu, Bengali, Gujarati, Punjabi, Hindi, and Tamil. Research assistants administered all questionnaires at baseline, post-intervention (4 months), and 12 months, except for the SCID-5 which was administered only at baseline. Assessments included the Hamilton Depression Rating Scale (HDRS) to assess the severity of depression, with higher scores indicating higher severity and scores of 7 or lower considered to indicate remission;[25] the PHQ-9, a self-report measure of depression scored from 0–27 (categorised as minimal depression [score 0–9], minor depression [10–14], major depression [15–19]; and severe depression [20–27]);[26] the seven-item Generalized Anxiety Disorder (GAD-7) scale (with scores categorised as minimal anxiety [0–4], mild anxiety [5–9], moderate anxiety [10–14], and severe anxiety [≥15]);[27] social functioning score,[28,29] a self-report measure of daily functioning based on ten items, with questions scored on a 5-point Likert scale from 0 (no difficulty) to 4 (often cannot do the task) and overall scores ranging from 0 to 40, where higher scores indicate higher social dysfunction; the EuroQol EQ-5D-3L scale to evaluate quality of life and health status across five dimensions (mobility, self-care, usual activity, pain or discomfort, and anxiety or depression) for which participants rated themselves as having no, some, or extreme problems, in addition to giving a 0–100 rating of their overall health state on a visual analogue scale (VAS), where higher scores indicated a better health state;[30,31] and the Parenting Sense of Competence Scale (PSCS) to measure perceived parenting competence across 16 items (nine on satisfaction and seven on efficacy), scored on a 6-point Likert scale from 1 (strongly disagree) to 6 (strongly agree), with overall scores ranging from 16 to 96 and higher scores indicating a higher sense of competence.[32] All measures were available in Urdu, Hindi, Bengali, Gujarati, and Tamil languages. The IAPT Patient Experience Questionnaire was also used to record individuals' experiences of the intervention at the 4-month and 12-month follow-ups; patients self-reported their level of satisfaction from not at all satisfied to completely satisfied. The trial protocol provides details about the outcome assessments used in the trial.[23]

Outcomes

The primary outcome measure was remission or recovery from depression post-intervention, defined by a HDRS score of 7 or lower at 4 months.[25] Treatment response was also assessed as a prespecified secondary outcome, defined as a reduction of at least 50% in depressive symptom severity as measured by the HDRS across the three timepoints (baseline, post-intervention, and 12 months). Other prespecified secondary outcomes included depressive symptom severity on the PHQ-9, anxiety symptom severity on the GAD-7, and psychosocial health indicators: social functioning, quality of life (EQ-5D-3L score), and parenting competence (PSCS score). Two prespecified

outcomes pertaining to cost-effectiveness and child outcomes will be reported elsewhere.

Statistical analysis

Previous studies on psychological treatments for postnatal depression indicate that a 20 percentage points decrease in the proportion of trial participants meeting the criteria for depression on the HDRS is clinically meaningful.[33] As such, we sought 90% power to identify a more conservative 15 percentage points difference between a 55% recovery rate in the intervention group and a 40% recovery rate in the control group. Assuming an intraclass correlation of 0·05 for group treatment,[33] a 75% follow-up rate at 4 months, a 70% follow-up rate at 12 months, and a 5% significance level, we estimated that the target sample size was 720 participants, with 360 in the intervention group (consisting of 40 groups of nine participants each) and 360 in the control group.

All statistical analyses were done according to a predefined statistical analysis plan (appendix p 2). Intervention effects were analysed on an intention-to-treat basis. For the primary efficacy endpoint (odds of recovery from postnatal depression at 4 months), we fitted a random-effects logistic regression model to account for the longitudinal nature of the data, including fixed covariates for study site, baseline depression severity (HDRS score), parity, and years in education. Based on the work by Roberts and Roberts,[34] random intercepts were also included for each individual (ie, clusters of size 1) in the control group. Similar logistic random-effects models were also implemented for secondary outcomes, including odds of recovery from postnatal depression at 12 months and treatment response on HDRS at 4 months and 12 months. For continuous secondary outcomes, we used a linear random-effects model with the aforementioned covariates plus the baseline measure of the outcome. For all analyses, two-sided $p<0·05$ was considered statistically significant.

For psychometric measures, when data were missing for fewer than half of the questions, the mean value was imputed. Following this, there remained a high proportion of patients with missing data for the primary outcome. Logistic regression models were used to investigate whether baseline covariates predicted missingness, and showed little evidence of a departure from being missing completely at random (see appendix p 2 for further details on this analysis). Therefore, all the main analyses were conducted on those with non-missing outcome data. We also did a sensitivity analysis in which all participants with a missing primary outcome were assumed to have not recovered and were coded as having depression.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

9136 individuals were approached for recruitment between Feb 8, 2017, and March 29, 2020 (with the final participant consenting on Dec 16, 2019). 6176 (68%) of these individuals were eligible for screening, of whom 4296 (70%) gave informed consent and completed the PHQ-9. 1064 (25%) of those assessed scored 10 or higher on the PHQ-9 and were eligible for the second stage assessment with the SCID-5. 741 (70%) of 1064 participants scored positively on the SCID-5, of whom 732 (99%) continued consent for participation and were randomly allocated: 368 to the PHP group and 364 to the control group (figure 1). 283 participants in each group had at least one response on the HDRS at 4 months.

All randomly allocated participants were included in the intention-to-treat analysis. Of the 368 participants in the treatment group, 246 (67%) were considered compliant with the treatment (attending at least one session). A breakdown of participants' adherence to the sessions is provided in the appendix (p 9). Baseline demographic data are presented in table 1. Participants were mostly of Pakistani (397 [55%] of 719 with available data), Indian (176 [24%]), or Bangladeshi ethnicity (127 [18%]), with an overall mean age of 31·4 years (SD 5·2), with their youngest infants having a mean age of 23·6 weeks (14·2).

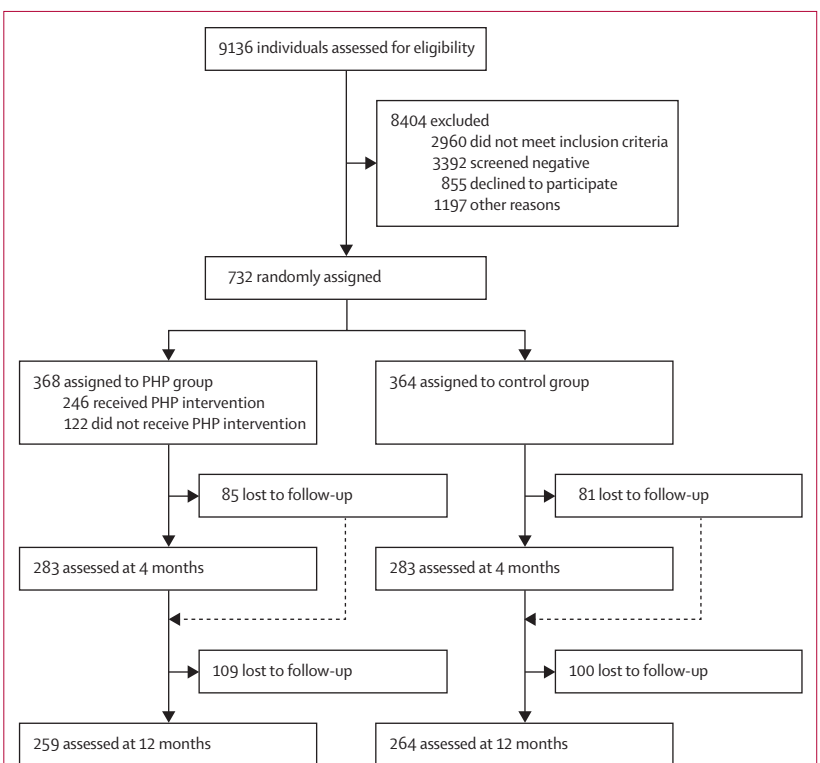

Figure 1: **Trial profile**
Numbers shown as assessed at 4 months and 12 months are those who had at least one response on the Hamilton Depression Rating Scale at that timepoint; however, the analyses included only participants with responses to at least half of the questions (see table 2 for numbers). PHP=Positive Health Programme.

	Positive Health Programme group (N=368)	Control group (N=364)
Age, years	31·3 (5·2), N=364	31·4 (5·2), N=355
Years in education	13·9 (3·6), N=300	13·7 (4·0), N=301
Years married (if married)	6·7 (4·8), N=345	7·0 (5·0), N=326
Age of youngest child, weeks	23·7 (14·1), N=307	23·6 (14·3), N=306
Number of people living in household	5·0 (1·9), N=359	5·2 (2·1), N=351
Hamilton Depression Rating Scale score	17·6 (7·3), N=367	18·0 (7·3), N=361
Ethnicity		
Indian	91/365 (25%)	85/354 (24%)
Bangladeshi	60/365 (16%)	67/354 (19%)
Pakistani	202/365 (55%)	195/354 (55%)
Other south Asian	12/365 (3%)	7/354 (2%)
English speaking		
Yes	338/363 (93%)	327/352 (93%)
No	25/363 (7%)	25/352 (7%)
Religion		
Islam	322/366 (88%)	315/357 (88%)
Hinduism	23/366 (6%)	28/357 (8%)
Christianity	2/366 (1%)	4/357 (1%)
Buddhism	3/366 (1%)	0/357
Sikhism	16/366 (4%)	9/357 (3%)
Other	0/366	1/357 (<1%)
Generational status*		
First generation	206/364 (57%)	215/353 (61%)
Second generation	120/364 (33%)	103/353 (29%)
Third generation	38/364 (10%)	35/353 (10%)
Employment status		
Full-time	42/365 (12%)	44/352 (13%)
Part-time	56/365 (15%)	43/352 (12%)
Unemployed	39/365 (11%)	43/352 (12%)
Sick	1/365 (<1%)	0/352
Housewife	197/365 (54%)	186/352 (53%)
Student	2/365 (1%)	3/352 (1%)
Other	28/365 (8%)	33/352 (9%)
Nature of employment at time of assessment		
Current employment	97/364 (27%)	93/349 (27%)
Previous employment	2/364 (1%)	2/349 (1%)
Partner employed	1/364 (<1%)	4/349 (1%)
Not applicable	264/364 (73%)	250/349 (72%)

(Table 1 continues in next column)

(Continued from previous column)

	Positive Health Programme group (N=368)	Control group (N=364)
Highest educational qualification		
Primary	12/352 (3%)	14/349 (4%)
GCSE	49/352 (14%)	68/349 (19%)
A-level	80/352 (23%)	70/349 (20%)
Undergraduate degree	121/352 (34%)	100/349 (29%)
Postgraduate degree	60/352 (17%)	59/349 (17%)
Other	30/352 (9%)	38/349 (11%)
Marital status		
Single	4/366 (1%)	7/356 (2%)
Married or cohabiting	349/366 (95%)	335/356 (94%)
Divorced or separated	13/366 (4%)	14/356 (4%)
Previously separated or widowed		
Divorced	31/330 (9%)	30/318 (9%)
Separated	15/330 (5%)	14/318 (4%)
Widowed	1/330 (<1%)	5/318 (2%)
Not applicable	283/330 (86%)	269/318 (85%)
Number of male children		
0	93/357 (26%)	103/344 (30%)
1	166/357 (46%)	158/344 (46%)
2	72/357 (20%)	64/344 (19%)
3	22/357 (6%)	14/344 (4%)
≥4	4/357 (1%)	5/344 (1%)
Number of female children		
0	107/350 (31%)	88/336 (26%)
1	143/350 (41%)	142/336 (42%)
2	70/350 (20%)	76/336 (23%)
3	25/350 (7%)	24/336 (7%)
≥4	5/350 (1%)	6/336 (2%)
Living with extended family		
Yes	111/363 (31%)	109/352 (31%)
No	252/363 (69%)	243/352 (69%)

Data are mean (SD) or n/N (%). GCSE=General Certificate of Secondary Education. A-level=General Certificate of Education Advanced Level. *Generations since a family's migration from south Asia to the UK, where "first generation" refers to those who immigrated to the UK during their lifetime, "second generation" to their children, and "third generation" to their grandchildren.

Table 1: **Baseline characteristics of study participants**

The completeness of study outcome measures (ie, participants with at least half of the questions answered on a given scale) at the three assessment timepoints of the study (baseline, 4 months, and 12 months follow-up) is indicated in table 2.

Clinical outcomes at different timepoints are presented in table 2. In terms of the primary outcome of recovery from depression (HDRS score ≤7) at 4 months, 138 (49%) of 281 in the PHP group recovered, compared with 105 (37%) of 281 in the control group (figure 2). Adjusting for baseline covariates, participants in the PHP group were estimated to be almost twice as likely to have recovered at 4 months than those in the control group (adjusted odds ratio [aOR] 1·97 [95% CI 1·26–3·10]).

By 12 months, 141 (54%) of 259 in the PHP group and 140 (54%) of 261 in the control group showed recovery from depression on the HDRS, with no significant difference between groups (aOR 1·02 [95% CI 0·62–1·66]; table 2; figure 2). Absolute values for primary and secondary outcomes pertaining to depressive and anxiety symptom measures at the three timepoints are presented in the appendix (p 7).

	Positive Health Programme group		Control group		Adjusted OR* or difference† (95% CI)	p value
	N	n (%) or mean (SD)	N	n (%) or mean (SD)		
Primary outcome						
Recovery from depression (HDRS score ≤7)						
4 months						
Yes	281	138 (49%)	281	105 (37%)	1·97 (1·26 to 3·10)	0·0030
No	281	143 (51%)	281	176 (63%)	1 (ref)	..
12 months						
Yes	259	141 (54%)	261	140 (54%)	1·02 (0·62 to 1·66)	0·80
No	259	118 (46%)	261	121 (46%)	1 (ref)	..
Secondary outcomes						
Treatment response on HDRS‡						
4 months						
Yes	281	158 (56%)	279	112 (40%)	2·49 (1·38 to 4·52)	0·0026
No	281	123 (44%)	279	167 (60%)	1 (ref)	..
12 months						
Yes	259	158 (61%)	260	151 (58%)	1·07 (0·59 to 1·95)	0·82
No	259	101 (39%)	260	109 (42%)	1 (ref)	..
PHQ-9 score						
Baseline	368	15·21 (3·93)	361	15·85 (4·21)	..	..
4 months	282	7·22 (5·80)	280	9·09 (6·34)	−2·05 (−3·18 to −0·92)	<0·0001
12 months	258	6·77 (5·55)	260	7·60 (6·81)	−0·89 (−2·05 to 0·27)	0·13
GAD-7 score						
Baseline	364	11·56 (5·87)	356	11·60 (5·62)	..	..
4 months	279	6·05 (5·66)	277	7·37 (5·71)	−1·45 (−2·66 to −0·25)	0·018
12 months	256	5·95 (5·51)	259	6·40 (6·26)	−0·24 (−1·46 to 0·99)	0·71
PSCS score						
Baseline	337	63·00 (12·01)	321	62·36 (10·92)	..	..
4 months	252	69·13 (12·25)	247	67·19 (10·77)	1·76 (−0·37 to 3·89)	0·11
12 months	226	69·88 (12·32)	225	67·43 (12·61)	3·32 (1·10 to 5·54)	0·0034
Social functioning score						
Baseline	352	12·91 (9·85)	337	12·98 (9·67)	..	..
4 months	262	6·62 (7·76)	267	8·04 (8·75)	−1·57 (−3·74 to 0·59)	0·16
12 months	246	6·05 (7·98)	250	6·73 (8·77)	−0·34 (−2·51 to 1·83)	0·76
EQ-5D-3L VAS score						
Baseline	354	55·43 (19·80)	342	55·28 (20·44)	..	..
4 months	271	66·20 (21·60)	268	64·26 (21·55)	3·30 (−0·35 to 6·95)	0·077
12 months	256	68·12 (21·10)	257	65·93 (21·71)	3·48 (−0·28 to 7·23)	0·069
Satisfaction with treatment						
4 months						
Yes	260	242 (93%)	257	222 (86%)	2·72 (1·05 to 7·09)	0·040
No	260	18 (7%)	257	35 (14%)	1 (ref)	..
12 months						
Yes	252	235 (93%)	248	224 (90%)	2·03 (0·77 to 5·40)	0·16
No	252	17 (7%)	248	24 (10%)	1 (ref)	..

N values show the number of participants who answered at least half of the questions for the given scale and were included in the analysis. Binary outcomes (recovery, treatment response, and satisfaction with assessment) are presented as n (%) per group, with adjusted ORs (95% CI) for between-group comparisons. All other outcomes are presented as mean score (SD) per group, with adjusted differences (95% CI) for between-group comparisons. HDRS=Hamilton Depression Rating Scale. OR=odds ratio. PHQ-9=nine-item Patient Health Questionnaire. GAD-7=seven-item Generalized Anxiety Disorder. PSCS=Parenting Sense of Competence Scale. VAS=visual analogue scale. *Adjusted for therapist (random effect), baseline HDRS score, parity, and years in education. †Adjusted for therapist (random effect), baseline HDRS score, parity, education, and baseline value of outcome variable. ‡Defined as a ≥50% reduction in HDRS score compared with baseline.

Table 2: **Summary statistics by follow-up timepoint and adjusted effect sizes for primary and secondary outcomes**

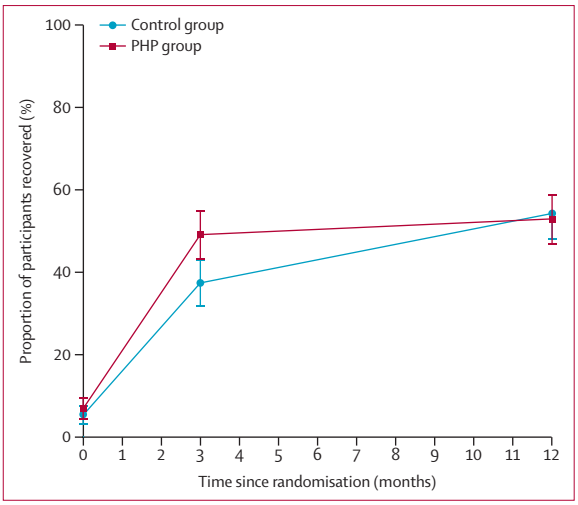

Figure 2: **Recovery from postnatal depression (primary outcome)**
Proportions of patients who had recovered from depression (defined as a score of ≤7 on the Hamilton Depression Rating Scale) at the three assessment timepoints. PHP=Positive Health Programme.

At 4 months, treatment responses (defined as ≥50% reduction in HDRS score from baseline) were observed in 158 (56%) of 281 participants in the PHP group and 112 (40%) of 279 participants in the control group (aOR 2·49 [95% CI 1·38–4·52]). At 12 months, 158 (61%) of 259 participants in the PHP group and 151 (58%) of 260 in the control group had a treatment response on the HDRS, with no statistically significant difference between groups (table 2).

Significantly lower depression scores on the PHQ-9 were recorded in the PHP group than in the control group at 4 months (adjusted difference –2·05 [95% CI –3·18 to –0·92]; table 2). In the PHP group, the frequency of participants with major depression or severe major depression (defined as a PHQ-9 score ≥15) reduced from 184 (50%) of 368 at baseline to 39 (14%) of 282 at 4 months and 31 (12%) of 258 at 12 months. By comparison, the frequency of control group participants with major depression or severe major depression reduced from 211 (58%) of 361 at baseline to 58 (21%) of 280 at 4 months and 54 (21%) of 260 at 12 months (appendix p 7). The PHP group also had significantly lower GAD-7 scores (indicating reduced anxiety) compared with the control group (adjusted difference –1·45 [–2·66 to –0·25]). No statistically significant effects of the intervention on the reduction of anxiety and depressive symptoms were observed at 12 months (table 2).

Regarding parenting competence outcomes, there was no significant difference in PSCS scores at 4 months between the PHP and control groups. However, at 12 months, the PHP group had a significantly higher mean score (adjusted difference 3·32 points [95% CI 1·10–5·54]), indicating a higher sense of competence in parenting compared with the control group. There were no significant differences in EQ-5D-3L VAS scores, measuring the patient's health state on the day of assessment, between the groups at any timepoint (table 2). At 4 months, based on the IAPT Patient Experience Questionnaire, the PHP group was significantly more likely to be satisfied with the treatment offered than the control group (aOR 2·72 [95% CI 1·05–7·09]), while social functioning score did not differ significantly between groups. At 12 months, there was no significant difference in satisfaction or social functioning score between groups (table 2).

At 4 months, 170 (23%) of 720 participants had missing data for the primary outcome of recovery from postnatal depression, with approximately equal distribution between the two study groups (data missing for 87 [24%] of 368 participants in the PHP group and 83 [23%] of 364 in the control group). The sensitivity analysis found that at 4 months, those in the PHP group were more likely to have recovered from postnatal depression than those in the control group, even when assuming that all those with missing outcomes had depression (aOR 1·63 [95% CI 1·08–2·46]; appendix p 8). At 12 months, there was no significant difference between the two groups in the proportions of patients who were recovered in this sensitivity analysis (0·97 [0·65–1·43]).

Discussion

This trial presents evidence of the clinical efficacy of a group-based CBT intervention, the PHP, delivered by non-specialist workers among south Asian women in the UK. Compared with treatment as usual, we observed a higher proportion of participants recovering from postnatal depression 4 months after the start of the PHP intervention, as measured on the HDRS. At 12 months (ie, around 8 months after the intervention ended), the proportion of participants who had recovered did not significantly differ between the two groups. Similar trends were observed in the severity of anxiety and depressive symptoms based on the GAD-7 and PHQ-9, respectively, as well as in treatment satisfaction. The PHP programme showed significant improvement over treatment as usual in the participants' sense of parenting competence at 12 months, but not at 4 months. Our findings suggest that the PHP intervention could considerably reduce the duration of a depressive episode as compared with treatment as usual in the postnatal period, a crucial time when maternal depression is likely to impact various infant outcomes. These findings are therefore important from a public health perspective.

The ROSHNI-2 trial addresses the existing treatment gap in postnatal depression by establishing that non-specialist workers can successfully engage and deliver CBT to underserved minority ethnic groups. There is evidence from the global literature on the benefits of involving non-specialist workers in mental health care,[9,35,36] but studies examining non-specialist worker-delivered CBT for minority ethnic groups in

high-income countries are few in number. A cluster-randomised controlled trial by Morrell and colleagues in the UK showed the efficacy of non-specialist worker-delivered CBT and counselling-based interventions;[37] trained health visitors were proficient in identifying women with postnatal depression and providing effective cognitive-behavioural or counselling-based approaches.[37] A systematic review, focusing primarily on studies from low-income and middle-income countries, also supports the effectiveness of group CBT for postnatal depression, showing moderate to large treatment effect sizes.[36]

The scarcity of research on the effectiveness of psychological interventions for minority ethnic groups might be a reflection of the barriers faced by these groups in accessing such care. Our preliminary work with south Asian women in the UK uncovered several such barriers to care,[19,20,24] including a scarcity of culturally informed care and the huge stigma against mental disorder in south Asian communities. Psychological interventions that do not address these key barriers are unlikely to be accessible to south Asian minority ethnic groups.[19,20,24] The ROSHNI-2 trial supports the observations from our formative work, showing that culturally sensitive approaches are successful in engaging minority ethnic groups with research and interventions, and that such interventions are clinically effective.

Although there was no significant difference in improvement compared with the control group at the 12-month assessment, the earlier recovery in the intervention group is important. This is primarily because postnatal depression affects optimal childcare and is associated with poor child development outcomes.[2,5,6,36] The intervention further showed a sustained, positive effect on crucial areas such as perceived parental childcare competency. These improvements are important as they help to mitigate the potential intergenerational effects associated with postnatal depression.[6,35] Furthermore, participants who received the intervention reported higher satisfaction with their treatment than those receiving treatment as usual.

The faster recovery from postnatal depression for participants in the PHP group holds considerable value for the participants themselves and potentially for their infants and other family members. It is notable that a substantial proportion of cases of depression are characterised by a prolonged history of depressive symptoms and poor outcomes, exhibiting either fluctuating or sustained patterns.[35,38,39] A more timely and rapid recovery from depression could help alleviate its chronic progression patterns.[35,38,39] Besides this observation, the focus of intervention for postnatal depression should extend beyond the commonplace short-term efficacy outcomes in treatment evaluation research, towards enhancing the quality of life, social functioning, and mother–infant relationship.[40–42]

Although this trial presents evidence for an accessible and acceptable intervention that generates real benefits for an underserved group, future research is needed to develop strategies for maintaining sustained benefits in a scalable way. Potential strategies could concentrate on maintaining contact to further extend the treatment effects, and testing whether providing such extended treatment is helpful and what frequency is optimal. The prioritisation of intervention development and long-term outcome evaluation should be embraced, mirroring standard practice in the evaluation of complex interventions.[43] Currently, we are exploring a remote PHP intervention, which could offer a cost-effective solution for ensuring a long-term impact.

Our findings are supported by trials of similar interventions tested among postnatal women in south Asia, including two major trials[33,44] of the Thinking Healthy Programme delivered by community health workers in Pakistan and by peers (local lay women with a similar sociodemographic profile to the target mothers) in both Pakistan and India. In a cluster-randomised trial, Rahman and colleagues found that 16 sessions of the Thinking Healthy Programme delivered by community health workers yielded strong effect sizes for reduced postnatal depression at 6 months (aOR 0·22 [95% CI 0·14–0·36]) and sustained remission of postnatal depression at 12 months (0·23 [0·15–0·36]).[33] Small improvements were also observed when this intervention was delivered by peers in India, where 89 (73%) of 122 women in the intervention group attained remission, compared with 77 (60%) 129 in the control group.[44] This intervention was also found to be relatively cost-effective by reducing health-care costs, time costs, and productivity costs.[33,44] WHO has endorsed these interventions for preventing and treating postnatal depression in recent guidelines.[9–11] Additionally, in Pakistan, the Learning Through Play Plus programme, an integrated intervention that combines the Thinking Healthy Programme approach with child psychostimulation, has shown statistically significant improvements in maternal depression, enhanced maternal and child functioning, and better child health outcomes.[45,46]

The strengths of the ROSHNI-2 trial were its robust design, large sample size, and participation of multiple UK trial sites, reflecting a diverse population for better generalisability. The application of clinical interviews for diagnosis, and rater-blind standardised assessments of outcomes, further bolster the study's validity. Moreover, considerable efforts were invested in formative research to ensure that the intervention was culturally informed. Our investigator team included global experts with extensive experience of developing interventions in the south Asian context. The lessons learned from this formative and consultative work, including participatory approaches, cultural adaptation of CBT, and strategies for engagement (panel), offer generalisable insights applicable to south Asian populations in the UK.[19,20,23,24]

These insights could serve to diversify research participation in future studies.

The ROSHNI-2 trial is one of the largest trials to date conducted to evaluate a psychological intervention for underserved populations. It marks a considerable advancement in trial methodology, generating knowledge of how to increase engagement with research and address stigma in underserved groups where such engagement can be challenging, which is a priority for the UK Department of Health and Social Care.[18,47–49] The development of the PHP intervention was centred around co-production with service user groups, leading to a high rate of recruitment and retention. Considering that minority ethnic groups were particularly susceptible to poor COVID-19 outcomes and a higher risk of postnatal depression during the COVID-19 pandemic,[13] the study adapted by shifting from in-person to remote delivery, thereby maintaining the continuity of intervention sessions online and minimising dropouts. Moreover, 67% of those in the PHP group adhered to the intervention by attending at least one session.

Efforts made to facilitate recruitment and engagement with research (panel)[24] included strategies for adapting recruitment, screening, and assessment procedures. This work can provide valuable insights for research studies, especially those emphasising inclusivity and enhanced access for socioeconomically disadvantaged groups. While this model was initially implemented with British south Asian women, some of the methods used for community engagement are applicable to other minority ethnic groups globally and other socioeconomically disadvantaged populations in the UK. These strategies can be beneficial beyond the research setting, potentially improving service pathways and facilitating greater access.

The study has several limitations. It was not possible to mask the study participants to treatment allocation due to the nature of the intervention. However, outcome assessments were done by independent team members not involved in intervention delivery or group allocation. Recruitment across sites was not uniform, with one study site (Glasgow) having relatively low recruitment due to its smaller south Asian population and a lower birth rate. Another shortcoming is that the study's findings, based solely on a cohort of British south Asian women, might not be generalisable to other minority ethnic groups elsewhere in the world. However, the results were informed by and in line with other international studies globally.[36] Furthermore, the geographical closeness of many participants could imply potential acquaintance, and the sharing of intervention experiences could inadvertently introduce a contamination bias.

Our study had a relatively high proportion of missing data. However, the consistency of findings between our primary and sensitivity analyses is encouraging.

For sample size calculation, we identified a 20 percentage point difference as clinically meaningful based on previous literature, particularly the Thinking Healthy Programme,[33] with a conservative estimate set at 15 percentage points. However, the primary outcome revealed a difference of 12 percentage points, with recovery in 49% of patients in the PHP group compared with 37% in the control group at 4 months. While this observed effect size is smaller than our conservative estimate, it remains statistically significant and clinically relevant. Several factors could have contributed to this variance. The heterogeneity within our study population, including variability in baseline characteristics such as symptom severity and comorbid conditions, could have influenced individual responses to the intervention. Furthermore, despite our efforts to maintain high fidelity in the delivery of both PHP and treatment as usual, electronic delivery of the intervention during the COVID-19 pandemic period might have attenuated the expected effect. These limitations suggest the need for further refinement in future studies to optimise the effectiveness of the interventions.

The scalability of our approaches to bolster engagement with research and services might be a challenge within a budget-constrained, publicly funded service. Providing childcare facilities or reimbursing travel expenses for group participants might not be financially viable at scale. Further research is also needed to compare online versus face-to-face delivery of interventions, as the former are likely to be cost-effective. However, virtual delivery requires some familiarity with technology and could increase inequalities due to the digital divide.

While our study aimed to demonstrate the feasibility and benefits of engaging British south Asian women in culturally adapted CBT to reduce postnatal depression, it is important to recognise several other social determinants contributing to postnatal depression that cannot be addressed by our intervention. Some studies show that domestic violence and abuse is prevalent in this community, as in many others, and has major implications for the health of mothers, babies, and families.[50,51] Within the PHP interviews used to develop the intervention, the presence of domestic violence and abuse was evident, often referred to as "marital disharmony", and was identified by women as a major cause of their depression. Further research is necessary on the incorporation of strategies to tackle domestic violence and abuse into multicomponent preventive and treatment interventions for postnatal depression.

Future research should also focus on the integration and implementation of the PHP within existing health-care frameworks, particularly the NHS Talking Therapies service and third-sector services. Conducting theory-of-change studies will be crucial in identifying the necessary steps and resources required to adapt and scale the PHP intervention effectively within these structures.[52] Additionally, using the concepts of implementation science, we propose designing implementation-focused trials that address crucial aspects for successful deployment.[53] These trials should assess the reach of the

intervention to ensure it effectively targets the intended population, measure its impact on desired outcomes (effectiveness and efficacy), and evaluate its acceptance and uptake by staff, settings, systems, and communities (adoption). Furthermore, monitoring the consistency of delivery, associated costs, and any adaptations made during implementation will be essential. Finally, investigating the long-term maintenance and sustainability of the intervention effects in individuals and settings over time will provide comprehensive insights. These implementation-focused trials could offer valuable information on the practical aspects of deploying the PHP model, ensuring its effective and sustainable integration into existing health-care and community support systems.

This study has several policy implications. Therapeutic approaches such as CBT and interpersonal therapy have been shown to be effective for managing postnatal depression and are recommended as first-line treatments in NICE guidance.[17] Nevertheless, there is a well established ethnic disparity in the research and provision of and access to postnatal depression services in the UK, particularly in British south Asian women. These women frequently live in economically disadvantaged areas and, due to numerous psychosocial issues, language barriers, and cultural obstacles, are often deemed easy to ignore and difficult to engage. This situation constitutes a substantial public health issue given that this demographic group represents the largest minority ethnic group in the UK and has one of the highest birth rates in the country.[54]

An important consideration when comparing these results with previous studies is the scarcity of research involving women of minority ethnic backgrounds, which limits direct comparisons. The heightened birth rates and increased disparities, particularly underscored during the COVID-19 pandemic, emphasise the need for culturally appropriate interventions that cater to the specific needs of this community. The PHP could be an effective addition to publicly funded talking therapies for treating depression and anxiety in women of south Asian minority groups and other populations. The ROSHNI-2 team's adeptness in recruiting participants, transitioning the PHP from in-person to remote delivery, and retaining participants reflects a deep understanding of and ability to navigate the complexities of cultural engagement, a skill honed during the ROSHNI-2 project. These outcomes suggest the potential for developing and testing models of care aimed at addressing treatment effectiveness of remote interventions. Future research should prioritise strategies to expand the PHP, incorporating similar interventions into public mental health-care frameworks, with the aim of long-term benefits.

Contributors

All listed authors have been with the project team from the initial bid submission for funding to the development of the protocol. FL, NH, AW, and DS drafted the paper, and all other authors critiqued the output for important intellectual content. NH is the study chief investigator with overall responsibility for the study and the decision to submit for publication. FL was part of the exploratory phase of this trial and contributed to the submission of the bid, delivery and management of the project, and stakeholder and patient and public engagement and dissemination. SA is the qualitative researcher on the project alongside JMi and DS. WW supported in the development of culturally adapted recruitment methodology and training of researchers in recruitment to this study population. NM supported the team in community engagement, tackling stigma, and promoting family involvement by sharing his lived experiences and the development of outputs from this work. NZ contributed to the data management plan and statistical analysis plan and management of all data from the project. CAC-G and PBe are the qualitative research methods leads. RE is the study trial statistician and the study statistical analysis and write-up was supported by MP and AW. KL is the lead for supervision of the intervention training and delivery. RM is the site lead for the Midlands supported by TB and JK. IM and KB are the site leads for the London site. CW and JMo are site leads for the Glasgow site. NS is the site lead for Yorkshire. AU and LD were responsible for the health economics component of the project including analysis and write-up. RE, MP, and AW accessed and verified data as part of analysis. FL and NZ accessed and verified data as per the data management, data cleaning, and preparation for data analysis steps of the trial. AR contributed in an advisory capacity to conceptualisation, design, and running of the study. All authors had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Declaration of interests

CW has written two CBT-based self-help resources for postnatal low mood and class-based and online postnatal low mood courses unrelated to the PHP; and is the Director of Five Areas, a limited company that commercialises these resources and of which he is a shareholder. NH has been a past Trustee of the Pakistan Institute of Living and Learning, Abaseen Foundation UK, Lancashire Mind UK, and Manchester Global Foundation; is an executive member of the Academic Faculty at the Royal College of Psychiatrists, London; and is an NIHR Senior Investigator. All other authors declare no competing interests.

Data sharing

Reasonable requests for patient-level data should be made to the corresponding author and will be considered by the ROSHNI-2 trial management group. The ROSHNI-2 management team and sponsor will consider the sharing of data on a case-by-case basis in line with the ethics approval and patient information sheets. Any presented data do not contain any direct identifiers.

Acknowledgments

This project was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (14/68/08). The project sponsor is Lancashire and South Cumbria NHS Foundation Trust. This work represents independent research supported by the NIHR Research Professorship (RE; NIHR300051) and the NIHR Maudsley Biomedical Research Centre, part of the NIHR and hosted by South London and Maudsley NHS Foundation Trust in partnership with King's College London. NH is funded by the Mental Health Research for Innovation Centre and supported by the NIHR Manchester Biomedical Research Centre, and is an NIHR Senior Investigator. RM is funded by NIHR Applied Research Collaboration, Nottingham NIHR Biomedical Research Centre, and the NIHR Mental Health (MindTech) HealthTech Research Centre. MP is funded by a Henry Dale Fellowship from the Wellcome Trust and the Royal Society (224243/Z/21/Z). KB is part supported by Oxford Health NIHR Biomedical Research Centre and Thames Valley NIHR Applied Research Collaboration. AU is funded by The NIHR Applied Research Collaboration Greater Manchester. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care in the UK. We acknowledge and thank all the participants who took part in this trial; all primary care teams across participating general practices; the chair and members of our Trial Steering Committee and Data Monitoring and Ethics Committee; each of our advisory group members, community and charity organisations, schools, nurseries, children's centres, and community interest groups across the country who have supported this work; and the dedicated

research team across all our study centres for their passion, commitment, and hard work on the project.

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