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Health Technology Assessment

Extended Research Article

A group psychological intervention for postnatal depression in British mothers of South Asian origin – the ROSHNI-2 RCT

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This article

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Abstract

Background: Postnatal depression is more common in British South Asian women than white women in the United Kingdom. Despite empirical evidence suggesting the effectiveness of cognitive–behavioural therapy as a first line of treatment, little evidence is available regarding its applicability to different minority ethnic groups.

Objectives: Determining the clinical and cost-effectiveness of a culturally adapted group psychological intervention (Positive Health Programme) in primary care for British South Asian women with postnatal depression compared with treatment as usual.

Setting: General practices and children's centres in the North West, East Midlands, Yorkshire, Glasgow and London.

Participants: British South Asian women meeting the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) depression criteria, aged 16 years or above, with infants up to 12 months.

Design: A multicentre randomised controlled trial with an internal pilot and partially nested design to compare treatment as usual plus the Positive Health Programme with treatment as usual in British South Asian women with postnatal depression, with a qualitative study to examine the acceptability and feasibility of the intervention.

Intervention: The Positive Health Programme, a culturally adapted group intervention based on the principles of cognitive–behavioural therapy delivered by facilitators over 12 sessions.

Outcomes measures: The primary outcome was recovery from depression (Hamilton Depression Rating Scale ≤ 7) at end of intervention (approximately 4–6 months). Analysis of the primary outcome and the long-term follow-up (at 12 months) used a logistic random-effects model to estimate the odds ratio of caseness between treatments, adjusting for centre, severity of depression and education at baseline. Cost data were collected using an Economic Patient Questionnaire.

Results: Seven hundred and thirty-two participants across four study centres were randomised by the Manchester Clinical Trials Unit. At 4 months, almost half of patients in the treatment (Positive Health Programme) group were recovered (138 or 49%), whereas 105 (37%) were recovered in the control (treatment as usual) group. By 12 months, the control (treatment as usual) and treatment (Positive Health Programme) group had over 50% recovery at 140 (54%) and 141 (54%), respectively. For the primary outcome, recovery from postnatal depression at end of intervention, we found a significant effect such that the odds of achieving recovery in the treatment group were almost twice as high compared to the treatment as usual group (odds ratio 1.97, 95% confidence interval 1.26 to 3.10). Between the two groups, there was no significant difference in the odds of recovery at 12 months (odds ratio 1.02, 95% confidence interval 0.62 to 1.66), highlighting a need for more intensive therapies and/or longer-term care plans for this group of patients.

Qualitative results: The intervention was considered feasible and acceptable from the perspectives of Positive Health Programme participants, facilitators, and general practitioners. The findings suggest improved emotional and social support and an enhanced sense of well-being.

Economic evaluation: Positive Health Programme implementation was estimated to cost an average of £408 per participant. The intention-to-treat analysis shows that the Positive Health Programme intervention costs £22,198 per quality-adjusted life-year gain. Positive Health Programme was cost-effective on average but with a substantial uncertainty: the probability that Positive Health Programme was cost-effective was 44% (65%) at the willingness to pay £20,000 (£30,000) per quality-adjusted life-year. The Positive Health Programme was highly cost-effective for those who attended 5–8 sessions, costing £9040 per quality-adjusted life-year.

Limitations: The study sample limits generalisability with other ethnic minority groups, and the cost-effectiveness analysis did not explore recall bias.

Conclusions: The results of this study provide robust evidence that the culturally adapted psychological intervention for postnatal depression in South Asian women is effective at the primary end point and acceptable to women.

Future work: Further development of the Positive Health Programme intervention and evaluation, with longer-term outcome follow-ups and exploration of cost-effectiveness of remote delivery of the Positive Health Programme.

Study registration: Current Controlled Trials ISRCTN10697380.

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/KKDS6622).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

ABC	antecedents, behaviour, consequences
A&E	accident and emergency
BSA	British South Asian
CACE	complier average causal effect
CBT	Cognitive Behavioural Therapy
CI	confidence interval
CO-I	co-investigator
COVID-19	coronavirus disease discovered in 2019
CRN	Clinical Research Network
CSO	Clinical Studies Officer
DSM-5	*Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition)
EPDS	Edinburgh Postnatal Depression Scale
EPQ	Economic Patient Questionnaire
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
GAD-7	Generalised Anxiety Disorder Assessment-7
GCP	good clinical practice
GCSE	General Certificate of Secondary Education
GP	general practitioner
HEI	Higher Education Institute
HRA	Health Research Authority
HRDS	Hamilton Depression Rating Scale
HTA	Health Technology Assessment
IAPT	Improving Access to Psychological Therapies
ICC	intraclass correlation
ICD-11	International Classification of Diseases 11th Revision
ICER	incremental cost-effectiveness ratio
IPT	interpersonal therapy
IPV	interpersonal violence
IQR	interquartile range
IRAS	Integrated Research Application System
LCRN	Local Clinical Research Network
MAHSC CTU	Manchester Academic Health Sciences Centre-Trials Coordination Unit
MAR	missing at random
MCAR	missing completely at random
MRC	Medical Research Council
NICE	National Institute for Clinical and Care Excellence
NIHR	National Institute for Health and Care Research
NMR	net monetary benefits
NNT	number needed to treat
NW	North West England
ONS	Office of National Statistics
OR	odds ratio
PHE	Public Health England
PHP	Positive Health Programme
PHQ-9	Patient Health Questionnaire-9
PI	principal investigator
PIS	participant information sheet
PND	postnatal depression
PPI	patient and public involvement
PPIE	patient and public involvement and engagement
PSCS	Parenting Sense of Competence Scale
PSSRU	Personal Social Services Research Unit
PTSD	post-traumatic stress disorder
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	Research Ethics Committee
SCAN	Schedules for Clinical Assessment in Neuropsychiatry
SCID	Structured Clinical Interview for DSM-IV
SD	standard deviation
SFA	social functioning assessment

SUR	seemingly unrelated regression	UKNSC	UK National Screening Committee
TAU	treatment as usual	WHO	World Health Organization
TFA	Theoretical Framework of Acceptability	WTP	willingness to pay
ToC	theory of change		

Plain language summary

The rates of British South Asian women experiencing depression after the birth of a baby are high, causing negative consequences for them, their infants, and their families, with huge costs to society. Due to language and cultural barriers, access to appropriate healthcare services is inadequate for many South Asian women.

The study compared a talking treatment for postnatal depression developed specifically for British South Asian women called the Positive Health Programme, in a group setting, to usual treatment. The aim was to find out if it worked and if it was value for money. Women aged 16 years and over, who were depressed, with a child up to 12 months, were included in the study. We wanted to find out if these women recovered from depression at end of intervention and stayed well for 12 months. We carried out detailed interviews to find out if the talking treatment could be delivered in National Health Service.

A total of 732 participants across four study centres took part in the study. These were allocated completely by chance to either the Positive Health Programme arm or the treatment-as-usual arm. At the end of intervention (approximately 4–6 months), we found that more women in the Positive Health Programme group recovered compared to the treatment-as-usual group. By 12 months, we found that the Positive Health Programme group women continued to stay well, but by that time the women in the usual treatment group also recovered and there was no difference between the two arms of the study.

The results are promising, as more women in the Positive Health Programme group recovered quickly. The study has helped us to understand how to best engage with British South Asian families. We will make recommendations to the people who make health policies for availability of culturally sensitive treatment options for British South Asian women having depression after giving birth.

Scientific summary

Background

Postnatal depression (PND) is considered the leading cause of disease burden for women of childbearing age and is a global public health priority. It is often underdiagnosed and under-treated. Low mood, referred to as 'baby blues', presents as feeling stressed, weepy, lonely, tired, having mood spells, changes in appetite, and insomnia. It is common for women to experience these feelings following the birth of their baby, but these are usually mild and transient. PND is more severe than the 'baby blues' and symptoms usually develop within the first few weeks after giving birth, and can last up to a year after having a baby. PND is defined as a non-psychotic depressive episode meeting standardised diagnostic criteria for a minor, or major, depressive disorder.

Literature suggests British South Asian (BSA) women have high rates of PND but are less likely to receive treatment compared to the White British women population. High rates of PND may be due to social isolation, financial problems, discrimination, deprivation, being a migrant, language difficulties and, most importantly, inequity in access to health care. Women of ethnic minority backgrounds are less likely to seek help from a general practitioner (GP) to discuss mental health issues compared to White British, and evidence about perinatal mental illness in the UK, which includes PND, is based largely on research among white women.

Cultural sensitivity is required to meet the social, cultural and linguistic needs of patients. Research findings from experiences of PND in BSA women have shown that the women often experience 'culture clash', feelings not being understood by healthcare professionals, and there are thus considerable challenges in reporting mental health symptoms. Prajapati and Libeling have cited literature which suggests that, compared to other ethnic groups, GPs are also less likely to recognise mental health difficulties in the South Asian population and, even after recognition, are less likely to refer them to specialist services. Referrals for South Asian primary care patients for talking therapies are also less likely, despite patients reporting a preference for these over psychotropic medications.

The National Institute for Health and Care Excellence emphasises the need to improve access to care for ethnic minorities and tailor health services to make them culturally sensitive to people's cultural identity or heritage. Psychological therapies need to be adapted to improve engagement with people from ethnic minorities. This could facilitate a better understanding of mental health conditions, diverse explanatory models, and idioms of distress, and may improve access and engagement. Failing to understand the implications of ethnicity and culture on mental health can impact the engagement with services with significant cost implications.

Research supports psychological interventions such as Cognitive Behavioural Therapy (CBT) as an effective treatment for PND and is recommended as a first-line treatment. A recent meta-analysis and systematic review of systematic reviews reported CBT to be the most effective evidence-based psychological treatment for PND. The CBT-based interventions for PND are grounded in the theory that thoughts are the key to understanding emotional and behavioural responses to certain situations and that thoughts are often based on a person's previously held experiences and beliefs. Wenzel and Kleiman propose that beliefs, which are manifested through automatic negative thoughts, are activated during stressful periods, including going through transitions or changes and therefore play a key role in the development and maintenance of PND.

The access to psychological interventions for ethnic minority patients, remains limited, despite the Improving Access to Psychological Therapies (IAPT) initiative. Systematic reviews demonstrate the potential role of group CBT as an alternate solution to address access barriers, by utilising an approach where a single therapist offers CBT to a group. But there is limited evidence for the effectiveness of this approach in ethnic minority women, and it requires further research.

Aims and objectives

This study aimed to evaluate the clinical and cost-effectiveness of a culturally adapted group psychological intervention [Positive Health Programme (PHP)] in primary care for BSA women with PND compared with treatment as usual (TAU).

The objectives of the quantitative study

To evaluate the short-term and long-term clinical and cost-effectiveness of the PHP intervention on rates of recovery from PND in BSA women compared to TAU.

The primary outcome

Recovery from depression as measured by the Hamilton Depression Rating Scale (HDRS) (score seven or less) at end of intervention.

Hamilton Depression Rating Scale

The HDRS was administered to measure the severity of depression at 4 months (end of intervention) and 12 months (Hamilton MA. Development of a rating scale for primary depressive illness. *Br J Soc Clin Psychol* 1967;**6**:278–96). The HDRS has been reported to give valid and reliable results in primary care; we have used the HDRS in Manchester with BSA women, in the Research for Patient Benefit (RfPB) exploratory trial, and in Pakistan.

Objectives of qualitative study

1. To examine the acceptability of the group intervention from the perspective of BSA women and their families.
2. To explore the views of the GPs about the group psychological intervention and its impact on practice.
3. To explore the perspectives of PHP group facilitators (group psychological intervention deliverers) about training and delivery of the intervention.

Methods

Design

A multicentre randomised controlled trial (RCT) with a built-in internal pilot and partially nested design to compare TAU-plus-PHP with TAU in BSA women with PND. Participants were randomised via a remote telephone randomisation service, The Manchester Clinical Trials Unit. Nested qualitative studies explored participant, health professional and facilitator perspectives. An additional substudy was incorporated following the pandemic to explore the impact of other associated risk factors related to maternal mental health and specifically in the pandemic's context. We aimed to increase the understanding of the pandemic-related impact on BSA women, including interpersonal violence (IPV) in their communities.

Setting

Participants were recruited from general practices and children's centres in areas of high BSA density in the North West, East Midlands, Yorkshire, Glasgow and London between February 2017 and March 2020.

Target population

British South Asian women meeting the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) (DSM-5) depression criteria, aged 16 years or above, and having an infant aged up to 12 months.

Health technology being assessed

Positive Health Programme, a culturally adapted group intervention, based on the principles of CBT. The manual-assisted intervention has been designed to be delivered by non-specialist mental health professionals. The PHP is a 12-session intervention, approximately 90 minutes each, and its feasibility and acceptability has previously been established.

Measurement of costs and outcomes

The primary outcome was recovery from depression (HDRS ≤ 7) at 4 months (end of intervention). The analysis of the primary outcome and the long-term follow-up (at 12 months) used a logistic random-effects model to estimate the odds ratio of caseness between treatments, adjusting for centre, severity of depression and education at baseline. Cost data were collected using the Economic Patient Questionnaire (EPQ).

For the primary outcome, recovery from PND at 4 months, we found a significant effect such that the odds of achieving recovery in the PHP added to TAU group were almost twice as high compared to the TAU group (OR 1.97, 95% CI 1.26 to 3.10). The improvement was sustained till 12 months in the PHP-plus-TAU group but there was a significant improvement with the TAU group and there was no significant difference in the odds of recovery at 12 months between the PHP-plus-TAU group compared to the TAU group.

Qualitative results

The qualitative study provided indicators of the feasibility and acceptability of the PHP intervention, highlighting underlying processes and contextual influences. The PHP participants, facilitators, and the GPs perceived the intervention as feasible and acceptable. The perceived benefit of increased social relationships during the PHP sessions could have provided an influential therapeutic factor.

The engaging activities that participants found enjoyable and meaningful and discussion and information that resonated with their cultural experience may also have contributed to improvement. Awareness and action to support and improve their low mood and depression were necessary to increase participants' understanding and build their coping skills. Improved emotional and social support, better coping strategies, and an enhanced sense of well-being demonstrate the mediating variables between PHP and the reduction of depression. In addition, the culturally adapted PHP intervention content enabled intervention delivery and was positively received by the PHP participants. The qualitative data supplemented the trial outcomes and provided a contextualised description of how PHP contributed to reduction of depression.

Economic evaluation

The PHP was estimated to cost an average of £408 per participant. The intention-to-treat analysis shows that the PHP intervention costs £22,198 per quality-adjusted life-years (QALYs) gain. PHP was cost-effective on average but with a substantial uncertainty: the probability that PHP would be cost-effective is 44% (65%) if the policy-makers are willing to pay £20,000 (£30,000) per QALY gain. PHP was highly cost-effective for those who attended 5–8 sessions, costing £9040 per QALY gained.

Conclusions

We consider that the results of this study provide robust evidence that the culturally adapted psychological intervention PHP is clinically effective at the primary end point. The results are promising for the wider field, particularly for learning lessons in engagement with this community. This study has led to multidisciplinary deliberations on a broader level across the UK, focusing on the culturally adapted method of engagement and delivery tailored explicitly for 'hard-to-reach' communities. The ethnic minorities community is often labelled as 'hard-to-reach' or as 'easy-to-ignore' as phrased by one of the community partners. Despite a number of policy initiatives, the services lack the uptake of tailoring their approaches to the community they serve, and the level of cultural engagement is limited. The creative methods of recruitment, engagement and commitment to engage with the community to enhance participation in research can serve as a best-practice example for recruitment in future similar studies. The results suggest that some form of maintenance contact and booster PHP sessions, possibly digital within the 1-year period, could be helpful. The focus of future research should be further development of the PHP intervention and evaluation, with longer-term outcomes. The positive results of transition to remote delivery of PHP observed during the pandemic may be a cost-effective way forward.

Study registration

Current Controlled Trials ISRCTN10697380.

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Chapter 1 Background

Postnatal depression

Postnatal depression (PND) is considered the leading cause of disease burden for women of childbearing age,[1] and is a global public health priority. It is often underdiagnosed and under-treated.[2] Low mood, referred to as 'baby blues', can present as feeling stressed, weepy, lonely, tired, having mood spells, changes in appetite, and insomnia. It is common for women to experience these feelings following the birth of their baby,[3] but these experiences are usually mild and transient. PND is more severe than the 'baby blues' and symptoms usually develop within the first few weeks after giving birth and can last up to a year after having a baby. PND is defined as a non-psychotic depressive episode meeting standardised diagnostic criteria for a minor, or major, depressive disorder.[4]

The two key universal classifications, The International Classification of Diseases (ICD-11)[5] and *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) (DSM-5),[6] provide the standards for the measurement of depression. In the ICD-11,[4] episodes are assessed as mild, moderate, or severe depending on the severity of the depressive symptoms and the degree of functional impairment. Nine symptoms of depression are identified in the DSM-5.[5] The standard for a major depressive disorder in DSM-5 requires the identification of either (1) depressed mood most of the day, on a daily basis, with individuals reporting hopelessness, worthlessness, or appearing weepy; or (2) noticeably less attentiveness or desire, alongside at least five of the symptoms, for at least 2 weeks (criteria include: weight loss or gain, insomnia or hypersomnia, psychomotor agitation or retardation, fatigue, feeling worthless or excessive guilt, poor concentration and thoughts of death/suicide). The severity of postnatal depression can vary and can present with the symptoms of both major and minor depression as defined in the DSM-5.

Neither of the two classification systems, the ICD-11 or the DSM-5 provide explicit categories for PND. However, the ICD-11 endorses that depression in the postnatal period could be grouped as one of the usual categories of depression. Nonetheless, if the symptoms do not fall into the other criteria for depression, there is a clause for a mental disorder arising within 6 weeks of the delivery. Specifiers such as 'with peripartum onset' are within the DSM-5, which denotes similar symptoms connected with major depression, however, uses the most current episode arising during pregnancy and the 4 weeks after delivery. The revision in DSM-5, from DSM-IV,[7] is essentially related to the introduction of the postpartum specifier compared to the earlier version, which recognised PND as a mental disorder beginning within 6 weeks of the delivery. However, the latest revision has still not extended the period following delivery and considers the most recent depressive episode until only 4 weeks after having the baby. Evidence suggests that the DSM-5 specifier is restrictive, as clinicians deliberate that depressive episodes in the perinatal period can occur at any time within a year after birth.[8]

Epidemiology and risk factors of postnatal depression

A comprehensive overview of the global epidemiology of PND indicated that PND was found in 17.22% of the female population.[9] Anxiety, comorbid with depression and on its own, is also common during the postpartum period. During the perinatal period the prevalence of any type of anxiety disorder has been estimated to be between 4% and 20%.[10,11] Trajectories of maternal postnatal depressive symptoms suggest these symptoms reduce within a few months from onset,[12] but approximately 30% of women continue to have depression beyond the first year after delivery and are at high risk (40%) of subsequent postnatal and non-postnatal relapse.[13]

The incidence of mental health problems during the perinatal period may increase depending on circumstances and, therefore, have significant implications for the care provided. The latest findings from the National Maternity Survey for women who gave birth in England during the first wave of the COVID-19 pandemic in 2020 highlight an increase in anxiety during pregnancy and an increase in both anxiety and depression in the postnatal period. This increase in mental health problems was significantly higher when compared to findings from National Maternity Surveys conducted in previous years.[14]

The UK is a multiethnic society, and its population's diversity continues to increase.[15] Data from the Office for National Statistics[16] indicate that 7.5% of the total population is classified as 'South Asian', making it the largest ethnic minority. 'South Asian' is defined as people with origins from India, Pakistan, Bangladesh, Nepal, Bhutan and Sri Lanka who share familial or cultural backgrounds.[17] In 2019, UK migrants mostly originated from India and Pakistan.[18]

Ethnicity and culture are considered to have an impact on how and when women seek help for mental health problems during the perinatal period, and many women are reluctant to go for a professional consultation because they feel the services available are not sensitive to their beliefs.[19] Some ethnic minority groups in the UK have a higher burden of mental health disorders, including anxiety and depression, as compared to the majority white population.[20,21] There is also a lesser likelihood of these disorders being detected or treated, including during the perinatal period for people from minority ethnic backgrounds.[22,23] In British Pakistani women living in the North West of England the rate of perinatal depression assessed using the Schedules for Clinical Assessment in Neuropsychiatry (SCAN)[24] was 17% during pregnancy and 19% during the postnatal period.[25]

The target population of the study was British South Asian (BSA) women with postnatal depression and psychosocial difficulties. As mentioned above, ethnic minority groups, particularly women of South Asian origin, are at higher risk for developing PND.[26,27] A secondary analysis of birth cohort data and linked routine care data in the UK by Prady *et al.*[22] found an estimated prevalence of between 9.5% and 14% for common mental disorders (CMD) in British women pre birth. It was found that compared to White British and White Irish populations, the prevalence of PND was significantly higher among South Asian women.[24,28] A recent report on maternal mental health and well-being during the COVID-19 pandemic, published by the Centre for Mental Health,[29] addressed the disparity in maternal mental health outcomes caused by the crisis and outlines how the impact has been unequal.

Additional risk factors of PND are provided in an updated umbrella review,[30] a synthesis of the systematic reviews and meta-analyses focused on risk factors for PND over the past 20 years. The review identifies 25 statistically significant risk factors for PND, including high life stress, lack of social support, current or past abuse, PND, and marital or partner dissatisfaction. These risk factors, particularly marital difficulties, are high in British South Asians.[31,32] Lesser-known risk factors, but equally important, include lifelong depression in the spouse, younger than 20 years, worries related to lack of access to child care, previous miscarriage and birth defects in the baby.[33]

Personal, social and economic costs of postnatal depression

The impact of PND on well-being is well established[34] and includes increased risk of chronic disease and substance misuse, breastfeeding problems, poorer quality of life, relationship problems, increased risk of suicide, as well as the economic burden of loss of earnings and unemployment.[35,36] A recent systematic review on the consequences of PND on maternal outcomes[37] suggests that PND creates an environment that is neither conducive to women's personal development nor for the baby's optimal growth and development. Maternal mental health problems can negatively impact women's capacity to provide care for young children when they are most sensitive to their environments, leading to behaviour difficulties, impaired cognitive and emotional development outcomes for children, and insecure attachment.[38,39] Infants before the age of 1 year, with women experiencing PND, are at a higher risk of developmental vulnerability at school entry.[40]

Women from an ethnic minority are more likely to have preterm and low-birthweight babies and often receive late or no prenatal care compared to the majority white women.[41] The COVID-19 pandemic has highlighted the urgent need to address disparities faced by ethnic minority groups in maternal and infant health specifically and the importance of providing culturally competent care.[42] As stated above, supporting maternal mental health during the postnatal period is crucial for strengthening the well-being of women and reducing the impact of depression on intergenerational transmission of adversity.[43]

The report 'The Costs of Perinatal Mental Health Problems'[44] commissioned by the Maternal Mental Health Alliance[44] suggested that in addition to the human suffering, mental health problems during the perinatal period (period between pregnancy and first year postnatal) carry a total long-term cost to the society. Calculated conservatively in the UK, the cost is more than £8,1B each year. The report highlights that approximately half of all cases of perinatal depression and anxiety are overlooked, and those identified frequently fall short of benefiting from evidence-based treatment. Since the report's publication,[43] the UK has substantially invested in addressing the needs of women with perinatal mental health problems as part of the Five Year Forward View and additional funding commitment in the NHS Long-term Plan.[45] However, major gaps remain, particularly related to making appropriate referrals and supporting women who do not meet the threshold of severity of depression, which, if left untreated, may become more severe in the long term.[46]

A recent report, 'The economic case for increasing access to treatment for women with common mental health problems during the perinatal period', by the Care Policy and Evaluation Centre and London School of Economics and Political Science,[47] emphasises the need for new service models. The need is even stronger now, due to the significant increase in demand for maternal mental health services during the COVID-19 pandemic.[48] These findings necessitate greater investment in improving maternal mental health services since they provide a clinically effective and cost-effective solution with a potential to improve the lives of the women in this generation but has benefits for the next generation.

Current service provision in the United Kingdom

The National Institute for Health and Care Excellence (NICE) guidance for antenatal and postnatal mental health[49] in the UK outlines the recommended care pathway for recognition, assessment, care, and treatment for women with PND, up to 1 year after childbirth. The guidelines suggest that at a woman's first antenatal contact with primary care, and then during the early postnatal period (usually at 4–6 weeks and 3–4 months), healthcare professionals should routinely consider asking two questions ('During the past month, have you often been bothered by feeling down, depressed, or hopeless?' 'During the last month, have you often been bothered by having little interest or pleasure in doing things?') to screen for depression as part of a general discussion about a woman's mental health and well-being. If a woman responds positively to the questions, she should be considered at risk of developing a mental health problem. Alternatively, if there is a clinical concern, the use of either the Edinburgh Postnatal Depression Scale (EPDS)[50] or the Patient Health Questionnaire-9 (PHQ-9),[51] as part of a full assessment, is recommended[48] to assess severity of problems.

In case of identification of a mental disorder, either during pregnancy or the postnatal period, NICE guidance[48] recommends additional assessment, including referral to the GP for further assessment and management. Targeted psychosocial interventions are recommended for women who have symptoms of depression or anxiety but do not meet the threshold for a formal diagnosis. NICE[48] further recommends that for women with a moderate depressive episode or a history of depression, or those with a severe depressive episode during pregnancy or in the postnatal period, high-intensity psychological treatment specifically for depression [cognitive–behavioural therapy (CBT) or interpersonal therapy (IPT)] [Improving Access to Psychological Therapies (IAPT) service] should be considered. Antidepressants should be considered for women with severe depression, and those with mild/moderate depression but not responding to psychological treatment. The antidepressants need to be prescribed cautiously[52] and evidence suggests that women may be reluctant to take psychotropic medications and prefer non-pharmacological treatments, particularly while breastfeeding.[53,54] It is recommended[51] that when a woman with a known or suspected mental health problem is referred during pregnancy or the postnatal period, assessment for treatment within 2 weeks of referral and psychological interventions within 1 month of initial assessment should be provided.

Barriers to help-seeking for women with postnatal depression

The NICE guidelines on antenatal and postnatal mental health recommend that women be asked specific depression identification questions at their first contact with primary care or their booking visit. The findings indicate an estimated 31–46% cases of perinatal depression are missed, suggesting a substantial diagnosis gap and under-recognition in general practice.[55] The gap in diagnosis could be due to a range of factors. For example, women may feel hesitant to share their experience of symptoms with their GP or other primary care clinicians. Reasons include feeling reluctant to acknowledge that they are struggling with their mental health, lack of family support, feeling that they are expected to cope on their own, bringing shame and stigma to the family, and having a fear of being labelled and losing their baby. Secondly, when women share their symptoms, GPs or other primary care staff may sometimes not consider it a task within their scope of work, may not follow up or have delayed follow-up, and may not make a formal diagnosis.[56] A further reason for under-recording in GP records could be that GPs may rely on health visitors to address these aspects of care and when this is not communicated by the health visitors to the GPs, it does not go into primary care records. The fragmented nature of postnatal care, involving several healthcare professionals, could be one of the reasons for missed or delayed identification, as reported by Silverwood *et al.*,[57] for perinatal anxiety.

A report on maternal mental health[52] suggested that most of the women who reported experiencing mental health difficulties were not referred to relevant services or given any advice about which organisations they could contact to seek further help. Lack of cultural sensitivity and other associated factors have also been identified as help-seeking barriers for women with PND. South Asian families may discourage women from seeking help and discussing concerns, such as mental health problems with people external to the family.[58] Evidence suggests that the perinatal needs of women from ethnic minority groups are met less often than White British women.[53,59]

Postnatal depression in British South Asian women

The BSA population continues to be the largest and fastest-growing minority ethnic group in the UK.[60] Literature suggests BSA women have high rates of PND but less likely to receive treatment compared to the White British women population.[30,61] High rates of PND may be associated with social isolation, financial problems, discrimination, deprivation, being a migrant, language difficulties and most importantly, inequity in access to health care.[62] Women of ethnic minority backgrounds are less likely to seek help from the GP to discuss mental health difficulties compared to the majority White British[18] and evidence about perinatal mental illness in the UK, which includes PND, is based largely on research among white women.[58]

Cultural sensitivity is required to meet the social, cultural, and linguistic needs of patients.[63] Research findings from experiences of PND in BSA women has shown that the women often experience 'culture clash', feeling misunderstood by healthcare professionals, and consequently considerable challenges in reporting mental health symptoms.[64] Prajapati and Libeling[17] suggest that, compared to other ethnic groups, GPs are also less likely to recognise mental health difficulties in South Asian people and, even after recognition, are less likely to refer them to specialist services. Referrals for South Asian primary care patients for talking therapies are also less likely, despite a preference over psychotropic medication.[31]

British South Asian women are often considered to be underserved and 'hard-to-reach' due to language and cultural barriers.[27] Many BSA women lack fluency in English and the resources to obtain help[60] and these barriers when accessing psychological services are even greater. Leaving symptoms of maternal depression unrecognised and untreated increases the risk both to the women and their infants of poorer health outcomes.[16,65] Karasz[66] investigated explanatory models of illness and demonstrated that South Asian women interpreted depressive symptoms to be because of situational stress, compared to white women who attributed PND symptoms to hormonal imbalance or biological factors. Such explanatory models may be more responsive to psychosocial approach, but may be difficult to negotiate due to difficulties in communication, cultural stereotypes held by healthcare professionals, little information about culturally sensitive treatment pathways, or differences in explanatory models between the physician and the ethnic minority patients leading to less likelihood of being referred for psychological interventions.[67]

Research demonstrates that South Asian women experience high rates of interpersonal relationship problems compared to the majority White British.[19,30] As mentioned above within the South Asian community, the concept of stigma, shame and the notion of maintaining family honour – 'Izzat' – can make women feel reluctant to discuss and disclose symptoms of PND or access psychological services.[68]

The need for cultural adaptation of psychological treatments

The NICE[48] emphasises the need to improve access to care for ethnic minorities and tailor health services to make them culturally sensitive to people's cultural identity or heritage. Psychological therapies need to be adapted to improve engagement with people from ethnic minorities.[69] This could facilitate a better understanding of mental health conditions, diverse explanatory models and idioms of distress, and may improve access.[70] Failing to understand the implications of ethnicity and culture on psychological health can impact the engagement with services,[71] and this also has cost implications.[68]

Empirical research supports psychological interventions such as CBT as an effective intervention for PND and is recommended as a first-line treatment.[48] A recent meta-analysis and systematic review of systematic reviews reported CBT to be the most effective evidence-based psychological treatment for perinatal depression.[72] CBT-based interventions for PND are grounded in the principle that cognitions are the key to understanding emotional and behavioural reactions to certain situations and that cognitions are typically based on a person's previously held experiences and beliefs. These are manifested through automatic thoughts, which further influence a person's emotional and behavioural reactions.[73,74] Wenzel and Kleiman[74] propose that beliefs, which are manifested through automatic negative thoughts, are activated during stressful periods, including going through transitions or changes, and therefore play a key role in the development and maintenance of PND.

Access to psychological interventions, however, remains limited, despite the IAPT initiative, especially for ethnic minority patients.[75] Systematic reviews[76,77] demonstrate the potential role of group CBT as an alternate solution to address access barriers, by utilising an approach where a single therapist offers CBT to a group. But there is limited evidence for the effectiveness of this approach in ethnic minority women, and it requires further research.

The Positive Health Programme (PHP) was developed as a culturally adapted group CBT intervention for BSA women with PND.[53] PHP was further developed and tested in an exploratory randomised controlled trial (RCT) (ROSHNI-D – NCT01838889[27]). The PHP is a group psychological intervention that uses principles of cognitive–behavioural model and consists of 12 weekly group sessions, that is duration of intervention being 3 months. The approach to addressing cultural barriers to access is partly informed by the Lau *et al.*[78,79] conceptual framework for improving access and cultural adaptation of interventions (*Figure 1*).

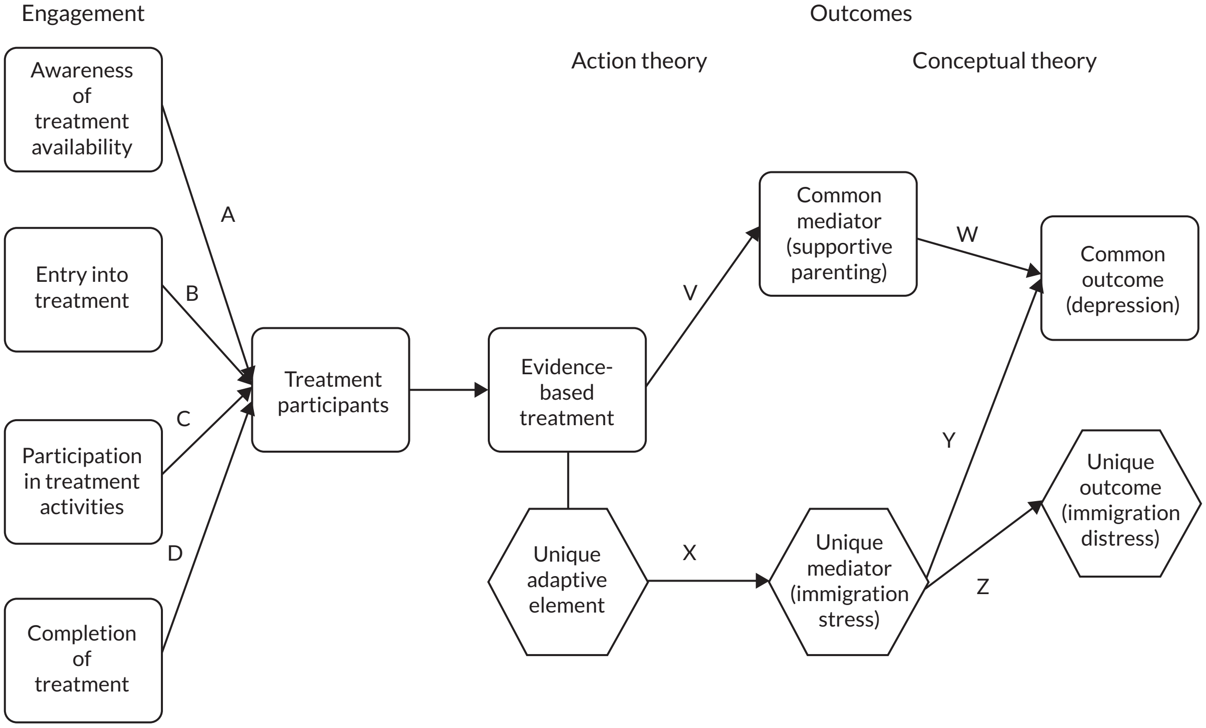

FIGURE 1 A heuristic framework for the cultural adaptation of interventions.

Earlier studies evaluating culturally sensitive psychosocial group interventions for the treatment of depression in BSA women reported an improvement in depression and participants' self-confidence at the end of the intervention.[19,30,31] Studies suggest[27,31,53,80] the relationship between the facilitator and the participants, and sensitivity to local culture are crucial factors for successful engagement. The content of the group sessions was developed with particular emphasis on developing empathy, maintaining confidentiality, and facilitating engagement.

A total of 83 participants were included in the ROSHNI-D exploratory trial, 42 randomised to the PHP intervention and 41 to the routine treatment. Four PHP groups were completed successfully across Manchester and Lancashire with reasonable attendance (64% of the 42 randomised). The recruitment figures of women screened (n = 560) and trial retention figures, at the end of intervention (80%) highlighted the ability of the research team to engage with the population.[27] The findings of a nested qualitative study within the trial showed that interventions targeting PND in BSA women would need to pay particular attention to ways of improving engagement with the family, self-esteem, social support, independent coping strategies, child care, and transport provision, and using the group discussion and communication techniques (storytelling).

Through the ROSHNI-D trial, we learnt how best to recruit and retain BSA women with PND in an RCT. The recruitment of bilingual research assistants and group CBT facilitators via the NHS, newspaper advertisements and the voluntary sector was innovative, leading to high recruitment and follow-up rates. A larger trial was needed to test the findings of the exploratory trial, to test both short- and longer-term outcomes and to answer additional research questions, including the cost-effectiveness of PHP. The focus of the present trial is to test a group CBT intervention (PHP) for BSA women with PND and psychosocial difficulties, using both quantitative and qualitative methods. The UK Medical Research Council (MRC) recommends that both qualitative and quantitative methods are used to evaluate complex interventions[81] and qualitative data gathered from in-depth interviews with trial participants can provide valuable insight into their experiences of the trial and the intervention.[82] The current trial results will provide evidence for the culturally adapted CBT intervention for BSA women and the importance of cultural adaptation for excluded groups with unmet needs. The results are likely to inform the next update of the NICE PND guidelines.

Chapter 2 Aims and objectives

This study aimed to evaluate the clinical and cost effectiveness of a culturally adapted group psychological intervention (PHP) in primary care for BSA women with PND compared with treatment as usual (TAU).

Diagnosis of depression

The full baseline assessment was carried out after the diagnosis of depression using the Structured Clinical Interview for DSM Disorders (SCID).[83] The interview consists of standardised diagnostic questions arranged in modules corresponding to each DSM-5 Axis I disorder. The SCID has been used in a large RCT of a psychological intervention for PND in a multicultural population in Canada.[84] It was used for assessing PND across seven countries.[85] It has been successfully used in a large (*n* = 900) CBT perinatal depression trial in rural Pakistan.[86]

The objectives of the quantitative study were: To evaluate the short-term and long-term clinical and cost-effectiveness of the PHP intervention on rates of recovery from postnatal depression in BSA women compared to TAU.

The primary outcome: Recovery/remission from depression as measured by a Hamilton Depression Rating Scale (HDRS) score of 7 or less at 4 months (end of intervention).

Hamilton Depression Rating Scale:[87] The HDRS was administered to measure the severity of depression at 4 months (end of intervention) and 12 months. The HDRS has been reported to give valid and reliable results in primary care; we have used the HDRS in Manchester with BSA women,[19] in the Research for Patient Benefit (RfPB) exploratory trial[24] and in Pakistan.[85] The objective is to evaluate the short-term, 4-month (end of intervention) effectiveness of the intervention on rates of recovery from PND . Recovery is a score of 7 or less[88] as measured by the HDRS.[86]

Objectives of the internal pilot qualitative study

1. Explore early barriers/enablers to study participation to optimise ongoing trial recruiter training and trial recruitment rates.
2. Identify reasons for continuing or not continuing with the study.

Objectives of qualitative study for the full trial

1. To examine the acceptability of the group intervention from the perspective of BSA women and their families.
2. To explore the views of the general practitioners (GPs) about the group psychological intervention and its impact on practice.
3. To explore the perspectives of PHP group facilitators (group psychological intervention deliverers) about training and delivery of the intervention.

Success criteria for the internal pilot phase

Success criteria for the pilot were to recruit 200 participants during the internal pilot study phase (months 5–14). The predetermined stop/go criteria were as follows:

- Go if 180 or more participants are recruited into the study (the target minus 10%).
- Implement rescue plan if > 120 (60%) but < 180 (90%) recruited in the study.
- Stop if < 120 (60%) recruited in the study.

Chapter 3 Methods

Trial design

ROSHNI-2 was designed using a multicentre two-arm, rater-blind RCT. The trial compared a culturally adapted CBT-based intervention (PHP) accompanied by TAU with just TAU for BSA women with PND. The primary outcome point for the trial was at post intervention at 4 months, and further follow-up with assessments (secondary outcomes) was conducted at both post intervention and 12-months after randomisation (*Figure 2*). The study included an internal pilot phase (18 months) with clear stop/go criteria, with the success criteria being set at the recruitment of at least 180 participants.

Study approvals

The study sponsor was Lancashire & South Cumbria NHS Foundation Trust, with the study being approved by the North West Health Research Authority [ethics approval number: Integrated Research Application System (IRAS) 187851; 6 January 2017]. Research management and governance arrangements and approval were acquired for each trial centre subsequently. The study was also registered with the International Standard Randomised Controlled Trial Number (ISRCTN10697380). The Manchester Academic Health Sciences Centre-Trials Coordination Unit (MAHSC-CTU) was subcontracted to provide randomisation services, study monitoring and research auditing.

Trial centres

The trial consisted of study centres in areas with high density of South Asians (*Table 1*). These included North West (Blackburn, Burnley, Accrington, Bolton, Greater Manchester, Preston and Oldham), North West, Yorkshire (Bradford, Dewsbury and Keighley), Midlands (Derby and Leicester), London and Glasgow. Each site had a delegated local principal investigator (PI) lead who was responsible for co-ordinating the recruitment of participants into the trial. Staff at each site had responsibility for the day-to-day running of the trial and engagement with participants.

TABLE 1 Ethnic population density across regions[89]

Region	Asian (%)	Black (%)	Mixed (%)	White British (%)	White other (%)	Other (%)
London	18.5	13.3	5	44.9	14.9	3.4
West Midlands	10.8	3.3	2.4	79.2	3.6	0.9
Yorkshire and The Humber	7.3	1.5	1.6	85.8	3	0.8
East Midlands	6.5	1.8	1.9	85.4	3.9	0.6
North West	6.2	1.4	1.6	87.1	3.1	0.6
South East	5.2	1.6	1.9	85.2	5.4	0.6
East	4.8	2	1.9	85.3	5.5	0.5
North East	2.9	0.5	0.9	93.6	1.7	0.4
Wales	2.3	0.6	1	93.2	2.4	0.5
South West	2	0.9	1.4	91.8	3.6	0.3

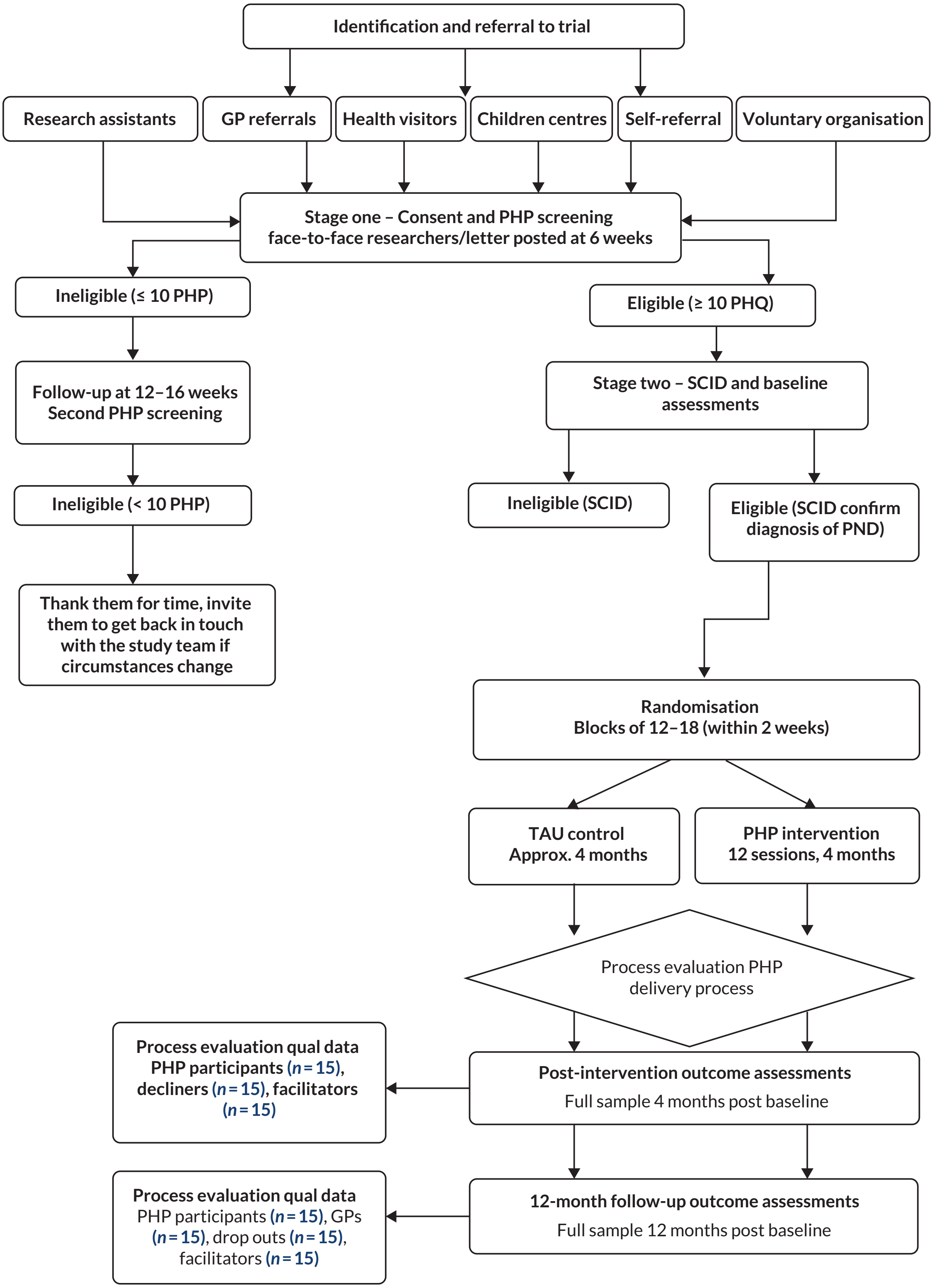

FIGURE 2 Study flow design.

Participant eligibility

Inclusion criteria

- Self-ascribed BSA women [Office of National Statistics (ONS) ethnicity].
- Aged 16 years or above.
- With a child up to 12 months of age.
- Met the DSM-5 [Structured Clinical Interview for the DSM (SCID)] criteria for depression.

Exclusion criteria

- Any diagnosed physical or intellectual disability limiting ability to provide informed consent as determined by the participants care team, GP, or Chief Investigator.
- Post-partum or other psychosis.
- Actively suicidal.

Antidepressant medication and a prior self-reported common mental illness, including prior PND, were not an exclusion criterion. The clinical history of other types of mental health disorders were determined on a case-by-case basis and was informed by the clinical judgement of clinicians with patient safety and potential participants ability to provide informed consent.

Recruitment strategies developed during internal pilot

Participant recruitment

Potential participants were approached through their local GP surgeries, children's centres, baby clinics, local community and voluntary organisations, pharmacies, nurseries, schools, local faith organisations and through attending community health events. To increase awareness of the study and ensure it reached the targeted audience, we used culturally sensitive public facing materials co-produced through patient and public involvement and engagement (PPIE) input. The materials (flyers, posters, banners and social media campaigns) were produced in English and then, translated into Hindi, Urdu, Tamil, Bengali and Gujarati languages. The research team at each study site engaged with local community and voluntary sector organisations and set up regular liaison meetings with the local health visiting teams, GPs, and children's centres to promote the study. This involved attending meetings to raise awareness about the study, enhance engagement, and build rapport to start valuable conversations on maternal mental health in BSA women. The research team made significant efforts to engage GP practices and initiated lunch-and-learn sessions at GP practices and attended business meetings to build rapport and engage with primary care teams. Each site had multilingual research assistants appointed to work on the study who also identified as British South Asian and were trained in cultural sensitivity when working in this context.

Media involvement

The study team worked closely with the media consultant Shakil Salam to promote the study using BSA media. During the pilot period, the Chief Investigator, deputy manager and other research team members made TV appearances on local South Asian TV channels and radio stations. The study team also recorded a radio advert aired across North West from November 2017 onwards; the advert was in both English and Urdu. There were press releases in both local and national newspapers in English and South Asian languages. The CI was interviewed on BBC Radio 5 live to talk about ROSHNI-2 for their maternal mental health summit during the pilot period.

General practices and children's centres

The research team continued to work closely with primary care and children's centres, as these were the key recruiting sites. Regular updates were shared with the GP practice managers, and the research team ensured active engagement by sending e-mails on special occasions, such as Eid and Diwali.

Training and development

Opportunities were created for bilingual volunteers to support the ROSHNI-2 study. The volunteers participated in training away days, including how best to recruit participants to ethnic minority trials delivered by co-app WW. There was also a session on successful recruitment and retention in perinatal mental health trials led by Professor Cindy-Lee Dennis from the University of Toronto and general day-to-day delivery of the trial. There was regular PHP training conducted by the study management team and supervision sessions. A total of 45 facilitators were trained across the sites for the full 2-day training and refreshers. Twenty-two of these delivered PHP sessions across sites. The training was offered widely across the community to develop capacity in psychological therapies and promote a culturally adapted model of delivery and engagement.

Cluster strategy

Across all study centres, 'clusters' with high South Asian density areas and birth rates were identified so that the research team could focus all their efforts on these clusters for maximum primary care and community engagement. A 'cluster' was an area mapped out, capturing approximately potential 350 South Asian women to be invited to the study. Given a conservative 10% rate of depression, we anticipated 35 women being eligible for the study on PHQ-9 (high scorers). Of these 35, we anticipated 12–18 being eligible for randomisation giving us one randomisation group (6–9 mums in intervention and 6–9 mums in TAU).

Recruitment to the main trial

The strategies developed during the internal pilot were incorporated into the recruitment process through the main trial. We ensured that we implemented lessons learnt from our previous work[27,53] with BSA women with PND and the internal pilot. We engaged with women's families (with consent) from the initial screening stage to ensure participation and continuity in the study. Contact details of bilingual senior members of the team were provided to family members for any queries. Further information on the research team's recruitment engagement efforts is published elsewhere.[90] The recruitment period was between February 2017 and March 2020.

Amendments were made as a result of learning from the internal pilot, feedback from the advisory group's PPIE work, and the addition of sites to maximise patient recruitment and retention to the trial. Amendments included adding in a child development measure, new sites, reducing group sizes for randomisation, and more engaging promotional materials. Full details of the amendments can be referred to in the attached *Report Supplementary Material 1*.

Recruitment via general practitioners

Participating GPs sent invitation letters to all British South Asian women who were 6 weeks post natal with study information and an invitation to participate in the study. The invitation note included the PHQ-9[50] (in Urdu and English), a participant information sheet (PIS), a return form for consent to contact and a stamped return addressed envelope. An additional slip was included which asked participants to contact the study team if they required the information in another language, this statement was in all five study languages. Interested participants were instructed to populate the PHQ-9 questionnaire and complete the consent-to-contact form, and requested to post the completed documents to the research team at their allocated study site. Reminders were followed up via post and telephone for those who did not respond within 4 weeks. Furthermore, GP records were examined for non-responders, and the primary care staff (health visitors and community midwives) were asked to include reminders about the study during their routine visits.

Research assistants contacted all women who fulfilled the trial eligibility criteria, completed consent-to-contact forms, who scored 10 or more on the PHQ-9. The potential participants were then contacted to provide further information and invited to provide written informed consent for trial participation and baseline assessments. A mutually convenient meeting time and location (general practice, children's centre or at home, or over the telephone) was arranged with the potential participant to obtain informed consent and discuss any queries raised. All potential participants were given sufficient time to consider participation (up to 48 hours) before signing the consent form.

In addition, the research team had ethics approval and permission from the GPs to work with practice staff to access routine health records, and to identify potential participants eligible for the study. This activity was carried out by general practice administrative staff or NIHR Clinical Research Network (CRN)-funded Clinical Studies Officers (CSOs). Once identified, potential participants were contacted either by phone or in person by the CSO, research nurse or administrative staff to obtain consent to contact for the research team. The research team also attended local children's centre, baby clinics, mums' support groups and playgroups to meet with potential participants, shared information about the study and provided interested individuals with a PIS.

Recruitment via baby clinics

Participants were also approached by trained researchers for the study in person at GP clinics and children's centres. The study PIS was explained to each potentially eligible participant and consent obtained. After obtaining consent from participants, the PHQ-9 was administered by a research assistant, with participants scoring 10 or more progressed to the second eligibility assessment stage. All low scorers on the PHQ-9 at the first screen who had consented were invited to complete a further PHQ-9 after 12–16 weeks to ensure that later-onset PND was not missed. All assessments were conducted in Urdu, Hindi, Bengali, Gujarati and Tamil based on participant preference. On first contact participants were asked what their language preference was and, based on this, the Research Assistant (RA) would be allocated to complete their screening/baseline/follow-up assessments.

Baseline assessment

Individuals who agreed to proceed with the study were taken through the informed consent procedure for second-stage screening to confirm the diagnosis of depression. Diagnosis of depression was confirmed using SCID.[82] The SCID has been used in a multicultural population in Canada.[83] To meet research diagnosis on the SCID, participants had to score a three on either the depressive symptoms (Question 1) or the work and activities (Question 2). In addition to either of these two, they needed to score a 3 on any three items giving a total of five positive scores on the SCID. Further details on the SCID are described in *Chapter 6*. Participants who scored positively on the SCID were also asked to complete a range of additional outcome measures, which consisted of:

- Demographics – information such as age, ethnicity, language spoken, marital status, employment status and qualifications.
- The HDRS[86] treatment response criterion is a reduction of ≥ 50% in the HDRS baseline score of the participants. In this study, the 17-item version was used and integrated within the SCID assessment. The measure has been validated in the Urdu language.[91]
- PHQ-9 items:[50] valid and reliable self-report measure of severity of depression; Urdu and Bengali versions of the PHQ-9 have been validated.[92] A higher score corresponds to more severe depressive symptoms.
- Generalised Anxiety Disorder-7 (GAD-7):[93] a valid and reliable self-report measure of severity of anxiety; an Urdu version of the GAD-7 has been validated.[94] A higher score corresponds to more severe anxiety symptoms.
- Parenting Sense of Competence Scale:[95] a valid and reliable self-report measure of parental competence;[96] Parental competence is measured on two dimensions of satisfaction and efficacy the questionnaire has 16 items (9 on satisfaction and 7 on efficacy) and is scored according to a 6-point Likert scale, ranging from '1, strongly disagree' to '6, strongly agree'. A higher score corresponds to better parenting sense of competence.
- Social functioning: a self-report measure rating difficulty in completing a 10-item measure of daily function. The questionnaire is scored according to a 5-point Likert scale, ranging from '0, no difficulty' to '4, often can't do the task'. A higher score demonstrates a higher social dysfunction.
- Ages and stages questionnaires:[97] a valid and reliable parent-completed measure of childhood development; this series of 11 questionnaires each include 30 closed questions on 5 domains of child development; trial participants completed the questionnaire both at baseline and 12-month follow-up. Higher scores indicate better child development, generally scores above 40 suggest that the child's development is on schedule.
- EuroQol-5 Dimensions, five-level version[98,99] is a health status measure, which has five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression); participants can rate themselves as having no problems, some or moderate problems or extreme problems (for pain/discomfort and anxiety/depression domains), or unable to do an activity (self-care) and usual activity domains or confined to bed (mobility domain).
- Economic Patient Questionnaire (EPQ): health service use data were collected using the EPQ; in addition to the NHS and social care. The cost to the participant for services was collected by capturing information from participants in both arms of the trial that accessed any other treatment or care.
- Improving Access to Psychological Therapies Patient Experience Questionnaire: this self-reported questionnaire gathers participants' experience of the intervention received.

Participant follow-up

Research assistants administered all baseline and post-randomisation questionnaires to participants at each site. All participants were followed up with questionnaires at 4 and 12 months. IAPT Healthy Minds Patient Experience Questionnaire was incorporated at both 4 and 12-month follow-ups, with the Ages and Stage questionnaire included only at 12 months (*Table 2*).

Trial outcome assessments

It has been reported that the validation of clinical assessments should be conducted to meet the needs of diverse population groups to ensure context dependent appropriateness and to determine context specific cut-off scores for use in the study population.[100] It should be noted that despite the growing need to provide clinical care which meets an individual's cultural background, there are considerable barriers to the detection of PND, with many high-income countries, implementing perinatal mental health screening programmes.[99] The delivery of culturally appropriate interventions requires the use of appropriate clinical assessment tools. This is advocated by the World Health Organization (WHO),[101] which recommends the use of screening programmes for conditions which are serious, preventable, and treatable.

Cultural adaptation of clinical assessment tools

The challenge of providing care to vulnerable women from minority backgrounds requires the need for robust research which takes into account the cultural relevance and language needs of this group of women. The present trial was based on the preparatory work in BSA women (ROSHNI-D), with assessment tools being culturally adapted and validated for use in BSA women. The outcome measures and patient information material used in the trial were culturally adapted, and translated using a standardised protocol from the previous work,[54] which

TABLE 2 Schedule of outcome measures

	Visits			
Procedure	**Screening**	**Baseline**	**4 months (end of intervention)**	**12 months**
Informed consent	X			
Demographics		X		
Socioeconomic data		X		
Study assessment				
PHQ-9		X	X	X
HDRS		X	X	X
SCID		X		
GAD-7		X	X	X
EQ-5D-3L		X	X	X
The Parenting Sense of Competence Scale		X	X	X
Social functioning		X	X	X
IAPT Healthy Minds Patient Experience Questionnaire		X	X	X
EPQ		X	X	X

involved stakeholder input from service users, lay members of the public, and back translation through the use of back-translation techniques.[19,26,102–104]

Sample size

The analysis compared those in the PHP intervention group with women in TAU group using a partially nested design.[105] The sample size calculation and data analysis considered clustering because of this partially nested design. Partial clustering was used, due to the trial including women in the intervention arm receiving the group therapy and benefiting from the group interaction. The methods for the partially nested statistical methods are examined elsewhere.[106] The sample size was 720 participants, consisting of 40 groups of 9 participants and 360 participants in TAU. Giving 90% power to detect a clinically significant difference between a 55% recovery rate in the PHP intervention group and a 40% recovery rate in TAU, with an approximation of intraclass correlation (ICC) for group treatment of 0.05, and 75% follow-up at 4 months, 70% at 12 months and a 5% significance level.

Randomisation and blinding process

The Manchester Clinical Trials Unit randomised participants via a remote telephone randomisation service. The PHP intervention required a group size of 5–9 participants. Therefore, randomisation was stratified by study sites using a block size of 10–18 for allocation, contingent on the size of the site, so that 5–9 participants were randomised to PHP-plus-TAU and 5–9 participants to TAU only. Attempts were made so that the duration between the participant's baseline assessment and randomisation was not longer than 6–8 weeks.

GPs were informed by letter about their patient's participation and treatment allocation. Participants were informed about the allocation via phone call. The TAU participants were informed about the follow-up assessments and points at which to expect contact from the team. The PHP participants were contacted by the allocated facilitators and a 'zero' visit arranged to discuss group attendance and logistics. Due to the nature of the intervention, it was not possible to blind participants, their GPs, or practice health visitors. However, researchers masked to treatment allocation collected the outcome measures.

Ineligible participants

Participants whose assessment outcome using SCID did not indicate PND were followed up with a phone call informing them that they were not eligible for the trial. They were, however, invited to join the local PPIE advisory group for ROSHNI-2.

Health technology being assessed

Treatment as usual

Participants allocated to the TAU group had access to usual GP care. They received primary care management of PND if available and accessed through their GP, which could include routine appointments, referral to IAPT and to other services, and antidepressant prescription. The access to services is described further in *Chapter 6* as part of the health economics evaluation.

Positive Health Programme intervention group

Participants in the intervention group received the PHP, a manual-assisted, culturally adapted group psychological intervention based on CBT principles, designed for BSA women with PND[53] in addition to usual care. The PHP intervention consists of 12 group sessions delivered by two trained bilingual facilitators. PHP facilitators ranged from NHS band 4–6 researchers with a psychology/social sciences/related sciences degree. To develop wider capacity in delivery of culturally adapted therapies, several volunteers were trained from the third sector. During the first 2 months of the intervention, PHP sessions were delivered once a week and thereafter fortnightly for the following 2 months. Each group session lasted approximately 60–90 minutes. Participants were reminded about confidentiality and ground rules at each session, and group members were informed that all disclosures remained confidential, except for matters concerning risk to oneself or others or any other safeguarding issues. Any disclosures that constituted a safety/safeguarding risk was reported using the local NHS trust safeguarding policy and a study specific risk assessment completed and signed off by local PI.

The PHP covered culturally relevant topics, including recognising the pressures on South Asian women, understanding and managing self-esteem, 'keeping up with the Chaudhry's (Jones's)', exercise and looking good, religion and spirituality, relaxation and 'taking time out', culturally appropriate assertiveness and confidence building, breaking social isolation and building social networks, practising CBT techniques and assessing change and developing relapse prevention plans.[26,53] (A detailed table of facilitators and their characteristics including their experience, training, cultural backgrounds, language skills and gender is presented in *Report Supplementary Material 1*. The description of each PHP session is also detailed in *Report Supplementary Material 1* with a summary of key points covered in each session.)

The PHP manual is available in English and the participants' preferred languages – Urdu, Hindi, Bengali, Gujarati and Tamil. All facilitators had a good command of English and many bilingual in the study languages; for each group, facilitators were allocated to match the group's language preferences. A PHP supervisor attended 1–2 of the 12 sessions to assess fidelity. The venues for group sessions were kept neutral to avoid a specific ethnic or religious affiliation.[26] Therefore, PHP was delivered at children's centres and other neutral community venues, as preferred by the participants. Expenses for travel and child-care costs were provided, refreshments and reimbursement of a £10 voucher for each session. The intervention group also had access to TAU.

Training, supervision and competency assurance

The recruited PHP facilitators had variable experiences in the psychological background and were from diverse ethnic backgrounds. Facilitators attended 2 days of the 'train the trainer' course to deliver the PHP intervention. The training consisted of soft skills, including activities in engaging with participants, managing the PHP group discussion, and safeguarding issues. The training focused on mastery of facilitation, behavioural activation, and the antecedents, behaviour, consequences (ABC) model. It involved a didactic and Socratic teaching approach with verbalising 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. One-day refresher training sessions were also delivered throughout the study.

No standardised tools were utilised for post-training assessment. Instead, the facilitators' performance was evaluated through role-plays conducted during the training sessions. After each role-play, the facilitators received detailed feedback on their performance.

To assess the competency of the facilitators and the fidelity to the intervention, the trainers/supervisors directly observed the facilitators during the group sessions. Prior to the observed session, the participants were informed about the observation. During the observation, the trainer/supervisor quietly positioned themselves at the back of the group, taking notes on their observations and using the session observation form as a checklist for important aspects to be assessed. After the observation, the trainer/supervisor conducted face-to-face supervisions, providing detailed feedback to the facilitators. Each facilitator underwent at least two observations, and in cases where concerns were identified, additional observations were carried out. A 15-item checklist was devised specifically for the purpose of conducting group observations. Each item on the checklist was evaluated using a three-point Likert scale, which ranged from 'not done' to 'done well,' with the additional option of 'not applicable'.

Co-investigator (CO-I) Karina Lovell and PHP trainers formed the supervisory team and provided regular telephone and Skype monthly supervision and ad hoc meetings as needed. These group supervisions provided a platform for facilitators to share their experiences, learn from one another, and discuss challenging cases with their supervisors. Moreover, facilitators were given the option to communicate with their supervisors if they had any concerns regarding any participant.

Trial completion and withdrawal

During the trial period, participants were considered to have withdrawn from the trial on the following basis:

- withdrew consent (participant wished to leave the trial with no further contact or follow-up)
- clinical decision from a health professional for the participant to be withdrawn from the trial
- serious adverse event (persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions or provide ongoing consent).

Withdrawals

The process of informed consent was considered ongoing for the duration of the study; participants were reminded at each contact point that they had the right to withdraw from the study at any point. With study withdrawal requests, a research assistant explored with the participant to what extent they wished to withdraw from the research and the reason for withdrawal (if they wanted to share). The research assistant logged reasons for withdrawal and whether the withdrawal was from all parts of the study, from the intervention or from the follow-ups. For participants who withdrew from the intervention only, follow-up data continued to be collected. All data collected were retained for all participants until the point of withdrawal unless they explicitly requested their details to be removed, where feasible (until the database was locked).

Clinical risk management protocol

Due to the clinical characteristics of the target population being investigated, there was a risk of suicide or suicidal ideation in this group. The research team adhered to good clinical practice (GCP) in assessing suicide risk during their contact with participants. All participants were registered with the GP and would continue to access care if requested/provided. If acute suicide risk was detected, the protocol for assessing and reporting risk for the study was followed.

Public and patient involvement and engagement

It is also important to note that, in the context of the internal pilot RCT, we continuously asked participating BSA women for their views regarding the study procedures and measures. We introduced several changes as a result of the feedback.

For example, in addition to the face-to-face SCID assessment, the protocol was amended to include the completion of SCID over the phone. This was due to the participant's request to choose the option depending on their circumstances. Either option allowed the participants to decide whether to limit time and travel to the researchers or not to be in the house, avoiding intrusive family members, and maintaining privacy or evading associated stigma.

A key learning point from these events was that BSA women enjoyed contributing to the research, both those who received the intervention and those who did not. Some service users were trained in research methods and attended qualitative research methods training to help with the research study, topic guide and data analysis.

Engagement events

We held numerous community awareness events. These events, 'Chai with ROSHNI-2' and 'Brunch with ROSHNI-2', were successful means of engaging with the BSA community and encouraging significant presence of the BSA women at different study sites. The community events raised awareness about maternal mental health and the ROSHNI-2 study. These included health fairs, school events and community fun days, health seminars and specific seminars to link in with, such as the global women's health seminar to mark 'World Maternal Mental Health week' in which ROSHNI-2 presented. Workshops on depression, particularly PND, were facilitated by third-sector organisations working with the BSA community at the study sites.

Theory of change

We used the workshop to inform the interview topic guides for the qualitative study, particularly on how to address stigma. Theory of change (ToC) workshops were organised to implement various additional strategies during the internal pilot phase which could be carried through to the main trial. The research team utilised the short mid-study closedown period to share the learning with the BSA population across the study sites. The ToC approach provided a robust foundation for impact assessment. The systematic analysis allowed reflection on the trial's contributions to planned changes for the target group. This process allowed the team and stakeholders to understand and report on unexpected/unintended impacts as well as those that were intended. In these workshops, we developed the ToC causal pathway, which visually describes how and why an expected change is likely to occur in a particular context/setting. It describes activities/initiatives (outputs), the sequence of outcomes so that we reach the various milestones that lead to desired goals and articulates the activities and assumptions we have made. The causal pathway ToC provided a detailed and direct understanding of the links between activities that lead to the desired goals. During the proposal stage, we identified a PPIE member (NM) to provide us with a steer on the project concept, aims and objectives and methodology. Furthermore, NM was included on the application as a named PPIE member. The set-up of the project continued to benefit greatly from NM, and she was able to contribute to the development of participant facing materials. NM attended the first ethics committee meeting and was able to answer questions and ensured the approach, recruitment methodology, and materials were appropriate for the community we wanted to work with whilst also being ethically sound. NM was able to contribute to the researcher training and we found it hugely valuable to have the service user input on appropriate terminology, perceived barriers, understanding how to engage with the community and learning from that lived experience of both postnatal depression and research participation.

A male service user researcher, NMO, joined the team during recruitment. NMO joining the team helped us to engage with men/fathers/husbands and the wider South Asian community. It was important to acknowledge the gender roles within this community, the patriarchal society, and the joint family unit that needed to be engaged. Both NM and NMO were able to provide the team with insight on managing this respectfully when working with families. In particular, those living in multi-generational households where decision-makers are often the husbands or elder family members such as the mother-in-law/father-in-law. NMO and NMs involvement allowed the research team to engage widely in the community, providing a platform to change the narrative of a ‘hard-to-reach’ community. NMO supported the research team engage with mosques, temples, gurudwaras, schools, nurseries, charities, and community organisations. NMO shared his story as a South Asian male who had experienced psychosis, accessed treatment, tackled cultural barriers and the recovery journey. His story provided powerful insight into the struggles of a South Asian male experiencing mental health difficulties and the stigma that can be worked on through open conversations.

Patient and public involvement and engagement workshops

The research team utilised the study closedown period to share the learning with the BSA population across the study sites. The ToC approach provided a robust foundation for impact assessment. Systematic analysis allowed reflection on the trial’s contributions to planned changes for the target group. This process allowed us to understand and report on unexpected/unintended impacts as well as those that were planned. In these workshops we developed the ToC causal pathway, which visually describes how and why an expected change is likely to occur in a certain context/setting. It describes activities/initiatives (outputs), the sequence of outcomes so that we reach the various milestones which lead to desired goals and articulates what activities and assumptions we have made. This provides a visual road map to how we achieve the outcomes. In the workshops, in line with theories of change, we explored various elements including stakeholder engagement, developing a shared vision, and defining short-, medium- and long-term goals. This led to better evaluation and measure of progress and an understanding of impact both planned and unplanned. This exercise provided us with the knowledge about what barriers and challenges were faced in the trial and what assumptions were made in defining the goals. Participants and carers as key stakeholders were direct contributors to any planned and unplanned changes, and their experiences and feedback directly influenced any adjustments that had to be made. The ToC aided in monitoring, reflection on developments, and helped us to see and explain any progress during and after the intervention, where impact had not yet occurred.

The study methodology, recruitment and retention have all been largely influenced by insight from the service users, carers, and wider public. The engagement and involvement allowed us to swiftly move to a remote model of working during the pandemic. We were able to have swift consultations with the PPIE members and wider public to understand if the study could continue with adaptations in methodology and providing a virtual intervention. We also managed to understand the impact of coronavirus disease discovered in 2019 (COVID-19) on this population and maternity outcomes to develop an additional add on study. We held four discussion groups with a total of 25 service users to understand what associated factors should be considered as a result of the pandemic and understand the most appropriate methodology to carry out this add on work. The service users gave us valuable insight into factors that affected their mental health, home schooling, access to care, attitudes to vaccination, and much more. We developed this feedback into a survey study and topic guides for semistructured interviews and discussion groups, which is described further in the add-on report.

Clinical effectiveness

Primary outcome measure

The primary outcome measure was collected using HDRS[86] at 4 months, a valid and reliable measure of the severity of depression. A score of ≤ 7 on the HDRS indicated remission/recovery from depression.

Data collection schedule

An overview of the time points at which trial data were collected is presented in *Table 2*.

Statistical analysis

We proposed an intention-to-treat analysis. The statistical analysis adopted a logistic random-effects model to calculate the odds ratio (OR) of recovery between treatment arms, with added covariates of study sites, baseline severity of depression scores using PHQ-9 and education (< 8 years, ≥ 8 years). The analysis was used for both the primary outcome measure (end of intervention at 4 months) and the further outcomes (at 12 months). Random intercepts were included for each group in the intervention arm and individuals (i.e. clusters of size 1) in the control arm, and random intercepts for participants to account for repeated measures. For secondary outcomes of continuous nature, we performed a linear random-effects model with aforementioned covariates, plus baseline measures of the outcome variable. For all analyses, a two-sided $p < 0.05$ was statistically significant.

Internal pilot qualitative study

Objectives

1. Explore early barriers/enablers to study participation in order to optimise ongoing trial recruiter training and trial recruitment rates.
2. Identify reasons for continuing or not continuing with the study.

Methods

Recruitment and sampling

We aimed to interview 15 ‘decliners’ (eligible women who declined to participate in the study), 15 trial participants who attended 4 or more PHP sessions and 15 PHP facilitators. A purposive sampling strategy for interviewing was used across the five sites for the trial, and three participants in each category were anticipated to be interviewed from each site, for each category.

Decliners

Researchers invited decliners for an in-depth interview to discuss their reasons for declining to participate in the study. Researchers made contact by telephone or letter (adhering to their stated contact preferences) to invite them to consider participating in an interview. Participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate. For those who expressed an interest in participating, a convenient meeting place and time was arranged for those who wished to be interviewed face to face.

Trial participants

Researchers contacted trial participants by telephone or letter (adhering to their stated contact preferences) to invite them to consider participating in an interview. Participants who agreed were sent an information pack, which included a PIS. Potential participants were re-contacted after approximately 1 week to confirm whether they would be willing to participate. A convenient meeting place and time was arranged for those who expressed an interest in a face-to-face interview. A convenient time was agreed upon for those wishing to participate in telephone interviews, and suitable equipment was provided (researchers posted earphones to potential participants for privacy in shared households).

Positive Health Programme facilitators

Group facilitators who delivered at least one complete programme of providing the PHP were invited to participate in the interviews. Researchers contacted PHP facilitators by e-mail to invite them to consider participating in an interview. Participants who agreed were e-mailed an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate. A telephone interview was arranged for those who provided consent.

Consent

Prior to the face-to-face interviews, written informed consent to participate in the interview was obtained. For telephone interviews, verbal consent was obtained from participants and audio recorded. Permission was also obtained from trial participants and PHP facilitators to audio record and transcribe the interview verbatim. Interviews were carried out in their preferred language. Where the participants did not speak English as their first language, the interviews were later translated into English for analysis.

Data analysis

Thematic analysis was conducted to analyse the data. This approach was appropriate for analysing data collected through an open-ended procedure, particularly when rich, descriptive data has been gathered. The three researchers [Saadia Aseem (SA), Rebecca Mcphillips (RM) and Jasmin Begum (JB)] met regularly and were responsible for independently carrying out data coding. They received regular supervision from Carolyn Chew-Graham (CCG) and Penny Bee (PB) for the interpretation of the data.

Qualitative study

Objectives

1. To examine the acceptability of the group intervention from the perspective of BSA women and their families.
2. To explore views of the GPs on the group psychological intervention and its impact on practice.
3. To explore perspectives of PHP group facilitators about training and delivery of the intervention.

Methods

Design

Semistructured interviews were conducted with trial participants, withdrawn participants, PHP facilitators and GPs to gather in-depth information on how they perceived the acceptability, engagement, and implementation of PHP intervention. Trial participants shared their views and experiences of receiving PHP, while PHP facilitators shared their experiences and opinions on delivering the PHP intervention. Interviews with GPs explored their experiences of working with BSA women with postnatal depression. Interviews were conducted with trial participants, PHP facilitators and GPs at the end of the intervention period.

Inclusion criteria

- Participants randomised to the intervention arm and withdrew before completing four sessions of the intervention.
- Participants randomised to the intervention arm.
- Participants who attended at least one or more sessions of the PHP.

Positive Health Programme facilitators

- Positive Health Programme facilitator who delivered at least one course of the PHP.
- General practitioners.
- General practitioners whose practices participated in ROSHNI-2.

Trial participants

For the interviews, trial participants were purposively sampled from the PHP intervention trial database, aiming for variation in terms of geographic location, age and socioeconomic status and ethnicity to enable an in-depth exploration of the perceived impact of the PHP intervention.

Withdrawn trial participants

Trial participants who withdrew were purposively sampled from the trial database to further explore the reasons for discontinuing the PHP trial. Qualitative researchers re-engaged with withdrawn participants by telephone or letter (adhering to their stated contact preferences) to ask if they would consider participating in an interview. Those participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate.

Positive Health Programme facilitator participants

Qualitative researchers phoned or e-mailed all GPs and PHP facilitators ask if they would be willing to participate in an interview Interested individuals were e-mailed a PIS with information about the qualitative study.

General practitioner participants

General practitioners involved in the trial were e-mailed to participate in an interview. Interested individuals were e-mailed a PIS with information about the interview study.

Study materials

With input from patient and public involvement (PPI), the research team developed separate sets of topic guides for trial participants, PHP facilitators and GPs during the internal pilot period. These topic guides were further refined after the completion of interviews in the internal pilot to inform the interview topic guides in the main trial.

Data collection

Qualitative researchers conducted interviews at a convenient place and time according to participant preferences, either face-to-face interviews at the participant's home, in neutral settings, such as a children's centres or community centres, or over the telephone. With the consent of participants, all interviews were audio-recorded, transcribed verbatim and anonymised before data analysis. The recruitment period for the qualitative study was from February 2017 to March 2020.

Qualitative data analysis

Initially, the data analysis plan was to utilise a framework analysis. However, the research team employed thematic analysis to discern and highlight significant themes. The themes were subsequently applied to the Theoretical Framework of Acceptability (TFA), specifically focusing on assessing the intervention's acceptability across the seven domains outlined within the framework. This dual methodology facilitated a comprehensive exploration and evaluation of the intervention's acceptability within the study's specific context.

Interviews conducted in English were transcribed verbatim. However, interviews conducted in languages other than English were translated into English and then transcribed verbatim by the qualitative researchers; and analysed by two qualitative researchers. The transcripts were read to identify key themes linked with the qualitative study's aims. An iterative procedure was used to generate new codes, and specified codes were developed as the analysis progressed. After completing the initial coding, the codes were reduced into various themes. The specified key themes focussed on both parts of the study: the support experiences of trial participants and the perceived effectiveness of PHP (trial participants, PHP facilitators and GPs in the intervention arm). After that, transcripts were revisited, and the first qualitative researcher identified developing subthemes within each central theme with the second researcher and through ongoing discussions to agree on, and finalise, themes.

The GP interviews were analysed using only thematic analysis to identify key themes. For the trial participants and the PHP facilitators' interviews, the researchers deductively charted the themes into the seven acceptability domains in the TFA.[107] TFA was used to analyse the trial participant's and PHP facilitators' data. The TFA is a multiconstruct theoretical framework that can be applied to assess the retrospective acceptability of healthcare interventions from the perspective of intervention recipients. TFA consists of seven component constructs. These seven components were used as a framework for analysis: affective attitude; burden; perceived effectiveness; ethicality; intervention coherence; opportunity costs and self-efficacy.

To enhance reliability, all interview transcripts were coded in NVivo (QSR International, Warrington, UK) by the first qualitative researcher; then, transcripts were coded by the second qualitative researcher. The experiences of participants were charted to summarise and link to the matching themes and subthemes. Both qualitative researchers met to discuss the identified themes, and the discussion continued until a consensus was reached. Descriptive quotes were included to support the validity of the findings.

Remote delivery of the Positive Health Programme intervention during COVID-19 pandemic insight study

During the COVID-19 pandemic period, due to the social distancing rules, the research team sought ethical approval to continue the PHP intervention delivery remotely via video-conferencing platforms to ensure research continuity with participants. This substudy aimed to understand participants' views on the perceived feasibility, acceptability, and sustainability of the face-to-face versus remote delivery of the PHP intervention, and the PHP facilitator's perspectives on the mode of delivery of the PHP.

Design

Semistructured interviews with a subsample of trial participants and PHP facilitators were conducted to understand their perceived feasibility, acceptability, and sustainability of the face-to-face versus remote delivery of the PHP intervention.

Sampling and recruitment

We aimed to sample 15 participants. Participants were sampled purposively from 2 larger study sites – London and North West England. Trial participants were invited to include those who attended both face-to-face and video-conferencing sessions of the PHP intervention from different socioeconomic backgrounds, ages, and native languages. PHP facilitators were invited to include those who delivered both face-to-face and video-conferencing sessions of the PHP intervention.

Analysis

We used thematic analysis to identify key themes. Key themes were charted into the seven acceptability domains in the TFA. The seven components were used as a framework for analysis: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy.

Economic evaluation

The health economic evaluation explored the value for money of the PHP intervention compared to TAU from a health and social care sector costs perspective. For the primary economic analysis (cost–utility analysis), health benefits were quantified in the form of quality-adjusted life-years (QALYs). The cost component included costs of the PHP intervention and participants' use of secondary, primary, and community healthcare resources. The secondary economic analysis (cost-effectiveness analysis) considered HDRS scores as the health outcomes.

Health outcomes and healthcare resource use

Health benefits in the form of QALYs were estimated from responses to EQ-5D-3L questionnaire. The EQ-5D-3L is a generic health-related quality-of-life instrument widely used in clinical trials. This system covers (1) mobility, (2) self-care, (3) usual activities, (4) pain/discomfort and (5) anxiety/depression, each rated on a 3-point Likert scale with higher scores indicating more severe problems. The UK general population value set was used to weigh responses to the five dimensions of EQ-5D.[108,109] Such weighting results in a utility index ranging from 0 (death) to 1 (perfect health). The EQ-5D-3L responses were obtained at baseline, 4- and 12-month follow-ups. QALYs were calculated from time-weighted linear interpolation of the baseline, 4- and 12-month follow-ups utility indices.

Participants were asked to complete an EPQ at the baseline and at each follow-up. In addition to information on primary and community healthcare use, they were asked to provide details of any inpatient admissions, outpatient appointments, and emergency department attendances and admissions. The primary cost-effectiveness analyses included secondary, primary and community healthcare use besides the costs of the PHP therapy for the intervention arm. Since most of the PHP sessions were covered in 2018 and 2019, unit costs of 2018–9 were used for costing the use of secondary, primary, and community healthcare resources. Unit costs for the primary and community healthcare resources were collated from the Personal Social Services Research Unit (PSSRU).[105] Secondary care use costs were obtained from the NHS England and NHS Improvement National Cost Collection publications for secondary care.

Missing data

Overall mean values (single imputation) of costs and HDRS scores at the baseline were used to impute the missing baseline values of the respective variables.[110] Since the demographic variables are categorical, a missingness indicator was created for each demographic variable. Using logistic regressions, the missingness indicators of the cost components and utility at the 4 and 12 months were regressed on intervention indicator, demographics, baseline costs, baseline utility, and group and study site indicators.

The missing disaggregated costs, utilities and HDRS scores data at the 4 and 12 months were imputed using the predictive mean matching chained method (multiple imputations). The imputation model included baseline values of costs (both primary and secondary), utilities, HDRS scores, demographic indicators, and group and study site indicators. We have included all available information (variables) in the imputation model. The imputation model works like forecasting, so including more and more information always improves the model fit, resulting in better forecasts.[106] Given the amount of missing data, 50 imputed data sets were created.

Statistical analysis

Regression analysis estimated incremental costs and benefits of PHP intervention over and above the TAU. The cost and effect regressions were jointly estimated using the seemingly unrelated regression (SUR) model. The SUR model overcomes any possible correlation between costs and effects. Given the imbalances in the baseline costs and utilities, regression equations included baseline costs and utilities. The regression equations also included age, qualifications, and study site indicators. Other demographics, such as employment and marital statuses, were highly insignificant (p-value of > 0.3), so they were excluded from the regression analysis. Finally, to account for the partially nested nature of the trial, standard errors were clustered at the PHP group-level to account for a possible within-group correlation with control arm participants treated as clusters of size one.[111]

The results are presented in the form of incremental cost, incremental benefits, incremental cost-effectiveness ratios (ICERs), and incremental net monetary benefits (INMBs). Uncertainty was addressed by extracting 5,000 nonparametric bootstrapped samples from the data. The ICERs of the 5,000 bootstrapped samples were plotted on cost-effectiveness plane, which displays the differences in costs and QALYs between PHP and TAU by plotting costs against QALYs. Cost-effectiveness acceptability curve (CEAC) is drawn based on the distribution of the ICERs on the cost-effectiveness plane. CEAC shows the likelihood that PHP is more cost-effective than TAU as a function of the willingness-to-pay (WTP) for one additional QALY. Since the WTP is generally unknown, the indifference point is set at a probability of 0.5 on the vertical axis. Above this point, PHP is more likely to be preferred over TAU in terms of cost-effectiveness.

Sensitivity analysis

Sensitivity analysis introduced two deviations from the missing at random (MAR) assumption that was used to impute the missing data. Additional sensitivity checks included analysis only on the complete case data and excluding secondary care use from the healthcare utilisation.

Chapter 4 Internal pilot study

We conducted an internal pilot study with nested qualitative research. The study duration was 18 months to demonstrate the viability of the full RCT. Progression to the full trial depended on meeting the key objectives and success criteria (stop/go). Although recruitment methods had been established in the earlier completed ROSHNI-D[26] study, the project team needed to evidence similar engagement across multiple study centres and navigate governance procedures across a range of NHS Trusts and academic partners across the country. The internal pilot phase was conducted in line with NIHR guidelines [recruitment rate progression rules for internal pilot studies for Health Technology Assessment (HTA) trials].[112] However, the internal pilot study was faced with challenges, described below.

Ethics and governance

The study start date was set to 1 July 2016 at the point of funding. The study management team experienced delays in the study set-up phase. One reason for this was staff appointments were taking longer than anticipated and a revised ethics system [Health Research Authority (HRA)] was being implemented at the time. The HRA application was submitted on 29 September 2016. A favourable ethics opinion from the North West Greater Manchester South Research Ethics Committee was received on 28 October 2016. The final HRA approval letter was obtained on 6 January 2017. Confirmation of Capacity and Capability at the sponsor Trust was issued on 9 January 2017. This allowed us to start recruitment, but only for the North West centre.

Collaborators agreement

The study had significant delays in finalising the collaboration agreement between the sponsor and other participating NHS Trusts and Higher Education Institute (HEI) organisations. Initially an NIHR standard template model Non-Commercial Agreement (mNCA) was prepared by the sponsor and circulated, this however was not accepted by all HEI organisations, and they requested to enter into a different collaboration agreement. This meant recruitment could not be started at any of the additional study centres. The final collaboration agreement for all centres was signed and a consolidated copy circulated on 10 May 2017. The London study centre was not included in this agreement as they requested to sign a separate standard collaboration agreement. This was signed on 26 May 2017.

Delays in recruitment of research teams

The above delays meant limited study set-up work at the new centres, considering the research staff could not be recruited without the agreements. These delays meant that the additional centres were not able to make a start for 11 months after the actual study start date. The North West centre was an established centre with contacts with primary care, the community centres, and the wider community from the earlier ROSHNI-D study. The lessons learnt from the North West centre were useful for the additional study centres, particularly how best to engage with the different stakeholders. While waiting for the staff to be recruited across the centres, the Local Clinical Research Networks (LCRNs) started to support the identification of primary care recruitment sites. This was challenging as the practices in areas of high South Asian population density were often not research active. The research team from the North West carried out extensive work to engage primary care, community religious, and voluntary sector organisations at each centre to promote the study. Lunch-and-learn sessions were organised at key general practices (6–8) in each centre, attended by one of the senior investigators to provide information about the study and get support from the GP and practice staff to support the recruitment process.

Changes in infrastructure

During this period, there were changes in the LCRNs and across the NHS including the commissioning of health visiting teams which presented significant challenges. Changes in remit and infrastructure were not easy to negotiate compared to the anticipated pathways to recruitment. Strong working relationships were established with the LCRNs to fully maximise their support for the trial, such as refining the recruitment process and identifying potential recruitment sites. Though there was a strong LCRN willingness to support the study, there was a lack of bilingual CRN CSOs at any of the centres except Bradford, which made engagement with the BSA population and general practices difficult. The solution suggested by the advisory groups was to facilitate screening from resources within the trial team and additional multilingual sessional staff were recruited to undertake screening activities in the larger London and the North West study centres, which required extra time and resources to be put in place.

Study closedown and restart

Due to the delays described above, 11 months of delivery time was lost from the original project plan. There was a delay of further 2 months (November–December 2017) where recruitment and all trial activity were suspended by the NIHR due to concerns about progress and not meeting internal pilot targets. The monitoring panel made a recommendation to the NIHR to close the study. This was successfully challenged with the support of community partners, and the study was reopened in January 2018. The appeal process involved strong efforts and support from the PIs across all sites and other stakeholders, including Members of Parliament and local councillors who submitted letters of support. The HTA chair reversed the decision and appointed a new independent chair of the Trial Steering Committee (Professor Rod Taylor). Due to the setbacks, an extension for the internal pilot recruitment period was granted until June 2018, and recruitment at all study centres was back in place from February 2018. During the closedown period, the research team engaged with the BSA communities across the study sites to share the learning. Theory of Change workshops were organised to implement the various additional strategies during the pilot phase to inform the main trial.

Results

To accomplish the objectives of the pilot study, data were collected to obtain the number of women screened and their refusals at the time of initial screening for the trial and the baseline assessment. The results highlight that key objectives of the internal pilot were achieved (*Table 3*).

Internal pilot – qualitative study

Introduction

Qualitative methods were embedded in the internal pilot to improve recruitment processes and optimise recruitment, as well as the implementation and engagement of both the intervention and the trial methods. The qualitative study

TABLE 3 Internal pilot – RCT study outcome

	Key objectives of the internal pilot	Outcome
1	Recruitment of sufficient number of general practices to support the trial (4–6 general practices with large BSA population at each site)	• During the pilot period, the team held lunch-and-learn sessions in GP practices within the identified clusters. Service-level agreements were set up with key practices in each site with high-density BSA population
2	The proportion of eligible participants recruited across the five study centres, to examine the feasibility of achieving recruitment targets	• A total of 120 participants were recruited (meeting the minimum target) during the internal pilot (*Table 4* – recruitment rate vs. target rate) • Recruitment was slow in Glasgow. The birth rates were lower than those extrapolated during the funding bid process. In consultation with local site leads, the CI decided to close the Glasgow site and allocated resources to the four study centres actively recruiting
3	Quantify the estimated waiting period from recruitment to randomisation, and initiation of the PHP intervention groups	• The team ensured the waiting period from randomisation to initiation of the PHP was no longer than 6 weeks. The average wait time for IAPT was 12–14 weeks, and during the pilot, we determined that initiating PHP within 8 weeks of randomisation was feasible

TABLE 4 Internal pilot RCT study – recruitment rate vs. target rate

Pilot site	Target total (*N*)	Minimum target (*N*)	Actual (*N*)	Percentage of target (%)
London	72	44	76	50
Yorkshire	72	44	44	29
Glasgow	19	10	0	0
Midlands	36	22	31	21
Total	199	120	151	100

was embedded in the internal pilot to improve recruitment processes and optimise recruitment. The objectives were to understand how to improve the recruitment pathways for the study, retention of participants, and learning for the full trial.

Methods

Recruitment and sampling

We aimed to interview 15 'decliners' (eligible women who declined to participate in the study), 15 trial participants who attended four or more PHP sessions and 15 PHP facilitators. A purposive sampling strategy for interviewing was used across the five sites for the trial, and three participants in each category were anticipated to be interviewed from each site, for each category.

Decliners

Researchers invited decliners for an in-depth interview to discuss their reasons for declining to participate in the study. Researchers made contact by telephone or letter (adhering to their stated contact preferences) to invite them to consider participating in an interview. Participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate. For those who expressed an interest in participating, a convenient meeting place and time was arranged for those who wished to be interviewed face to face.

Trial participants

Researchers contacted trial participants by telephone or letter (adhering to their stated contact preferences) to invite them to consider participating in an interview. Participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately one week to confirm whether they would be willing to participate. A convenient meeting place and time was arranged for those who expressed an interest in a face-to-face interview. A convenient time was agreed upon for those wishing to participate in telephone interviews, and suitable equipment was provided (researchers posted earphones to potential participants for privacy in shared households).

Positive Health Programme facilitators

Group facilitators who delivered at least one complete programme of providing the PHP were invited to participate in the interviews. Researchers contacted PHP facilitators by e-mail to invite them to consider participating in an interview. Participants who agreed were e-mailed an information pack, which included a PIS. Potential participants were contacted again after approximately one week to confirm whether they would be willing to participate. A telephone interview was arranged for those who provided consent.

Consent

Prior to the face-to-face interviews, written informed consent to participate in the interview was obtained. For telephone interviews, verbal consent was obtained from participants and audio recorded. Permission was also obtained from trial participants and PHP facilitators to audio record and transcribe the interview verbatim. Interviews were carried out in their preferred language. Where the participants did not speak English as their first language, the interviews were later translated into English for analysis.

Data analysis

Thematic analysis was conducted to analyse the data. This approach was appropriate for analysing data collected through an open-ended procedure, particularly when rich, descriptive data has been gathered. The three researchers (SA, RM and JB) met regularly and were responsible for independently carrying out data coding. They received regular supervision from CCG and PB for the interpretation of the data.

Researchers invited women for semistructured interviews to discuss their reasons for declining to participate in the study. The pilot phase initially aimed to interview 15 decliners, 15 participants who attended four or more PHP sessions, and 15 PHP facilitators. A purposive sampling strategy for interviewing was used across the five sites for the trial, and three participants in each category were invited to be interviewed from each site. However, due to the internal pilot challenges described earlier, including study closedown and restart, the research team could not conduct the target number of interviews with the participants and the facilitators. In total, during the internal pilot a total of seven interviews were conducted, including three trial participants and four PHP facilitators from the North West and London sites. No decliners agreed to be interviewed.

Findings results

Due to the internal pilot challenges described earlier, including study closedown and restart, the research team could not conduct the target number of interviews with the participants and the facilitators. In total, during the internal pilot a total of seven interviews were conducted, including three trial participants and four PHP facilitators from the North West and London sites. No decliners agreed to be interviewed.

Decliners

Study researchers who were in charge of recruiting women for the ROSHNI-2 trial recorded the reasons provided by these women for their decision not to participate in the trial. All study researchers responsible for recruiting women to the ROSHNI-2 documented verbatim reasons that women gave for not wanting to participate in the trial. Out of 397 women who declined to participate in the trial at PHQ-9 screening, 5 women agreed to be interviewed; but then subsequently declined to be interviewed. A total of 46 women declined when approached for SCID assessment, and none agreed to participate in a semistructured interview to explore reasons for declining.

There were various reasons documented given by women who declined to participate in the study. In most cases women gave more than one reason. Most women refused to participate as they were ‘not interested in research’; or ‘don’t have the time’ and ‘don’t’ feel the need to take help’. Some women commented that the proposed group intervention did not appeal to them. *Table 5* presents the multiple reasons given by the BSA women. Researchers noted that, in some cases, the decision to participate in the trial appeared to be made for the woman by her husband, a family member, or her mother-in-law.

Optimising recruitment pathways and retention for study

The embedded qualitative study aimed to understand the experiences and acceptability of PHP from the trial participants’ and PHP facilitators’ viewpoints. The objectives were to understand how to improve the recruitment pathways for the study, retention of participants, and learning for the full trial. Based on the findings of the qualitative pilot study, changes and actions were taken for the main trial, illustrated in *Table 6*.

Discussion

Despite efforts to engage potential participants and collect data, the research team could only conduct limited interviews with trial participants and facilitators. Notably, no decliners (those who declined to participate in the trial) agreed to be interviewed. However, documented notes highlight the reasons for declining participation among eligible BSA women, with collective themes being a lack of interest in research, time constraints and not feeling the need for help. Some women also expressed discomfort in sharing personal information, research mistrust and language difficulties. Family influence, particularly from husbands and mothers-in-law, played a significant role in women’s decisions to participate or decline.

TABLE 5 Internal pilot – RCT study: multiples reasons given for declining participation in PHP trial by eligible BSA participants during the internal pilot period

Types of reason	Number of reasons given for declining participation	Percentage (%)
Not interested in research	342	49.1
Reasons unknown	88	12.6
Don't have time/in a rush	138	19.8
Don't want to share personal information	12	1.7
Don't feel the need to obtain help	59	8.5
Not happy for signing consent	4	0.6
Don't trust research	8	1.1
Not able to communicate in the language offered	5	0.7
Not interested in the intervention/PHP	17	2.4
Need to think	6	0.9
Does not feel comfortable in participating in research	18	2.6
Total	697	100

TABLE 6 Internal pilot – learnings to inform main trial

Themes	Key findings from the pilot trial	Changes and actions taken for the main trial
Barriers to participation	Cultural and language barriers	• The research team established contacts with wider stakeholders to consult on the approaches and methods to help refine and finalise the mechanisms for screening and assessments at each study site
	Challenges identified in recruitment was the need to enable potentially eligible BSA women to engage with research staff in a culturally sensitive manner for further study information and screening. This included overcoming language barriers	• The research team held discussions with the centre leads and bilingual CRNs/primary care staff at each site to establish the best methods for recruitment and retention of participants to time and target at each centre • Recognising that the CRN staff would not be able to support screening and recruitment, bilingual sessional staff were appointed to help with recruitment • The team developed detailed site-specific recruitment strategies and Standard Operating Procedures, which were reviewed by the Clinical Trials Unit and the Data Monitoring and Ethics Committee Chair. This included service level agreements with the third sector working with the BSA population
	'One thing which was a bit of hindrance for me was English language. My English is not fluent and sometimes it took longer for me to understand. Similarly, I was not able to explain myself completely because of the language. There should have been an Urdu facilitator in the group as well. I think there were two other women who struggled as well. I was not able to explain myself completely because of the language' (trial participant NW-12-0024)	• Recognising that the CRN staff would not be able to support screening and recruitment, bilingual sessional staff were appointed to help with recruitment

continued

TABLE 6 Internal pilot – learnings to inform main trial (*continued*)

Themes	Key findings from the pilot trial	Changes and actions taken for the main trial
	Lack of awareness and stigma associated with mental health	• Family-centred recruitment pathways and modification of approaches to study advertising were developed
	'I was a bit reluctant to tell my mom that I have joined the group . . . because she is from the old school of thought and anything about mental health is very stigmatising for her. Also, she will not like that her daughter is suffering from depression nor has any mental health issue' (trial participant NW-13-0030)	We developed how to use a culturally sensitive and confidential family engagement approach. PHP was presented as a problem-solving skills training programme rather than 'therapy', and the word 'stress' was used more rather than depression. The team organised various community engagements such as 'brunch with ROSHNI-2' at all sites. The events were well received in each study site and attended by different community members and postnatal women of South Asian backgrounds
	Participants highlighted that women's lack of trust in health professionals and service providers prevented them from engaging with services	The research team was able to engage key health professionals, such as health visitors and midwives, in all these events
PHP as culturally appropriate	Valued PHP. The group delivery of the PHP was perceived as acceptable and valuable, which helped women to share their experiences with other BSA women, and subsequently which increased their social network support	No changes were required to PHP
Supervision and training	PHP facilitators valued the training sessions they received. Discussed skills they had developed, including listening and communication skills	No significant changes made to training or supervision; however, PHP facilitators were regularly encouraged to contact supervisors as and when needed for queries
'Self explanatory' manual	The usefulness of the 'self-explanatory' PHP manual was perceived as a good guideline for the PHP facilitators	No changes were made to the manual; however, PHP facilitators were given the flexibility to repeat sections of the sessions based on requests made by the women

Key findings and actions were implemented to address these challenges and optimise recruitment pathways for the main trial. These included recognising and addressing cultural and language barriers, developing family-centred recruitment pathways, modifying study advertising and organising community engagement events. The internal pilot phase underscored the importance of tailoring recruitment approaches to the cultural circumstances of BSA women and contending with the stigma and mistrust associated with mental health.

Chapter 5 Results

Sample

A total sample of 732 participants was included in this trial, randomised into two groups: 364 in the TAU group and 368 in the PHP-plus-TAU group (*Figure 3*) . The wait between baseline to randomisation was no more than 4–6 weeks as we aimed to match the NHS Talking Therapies waiting-list time. A total of 15 groups were randomised in London, 21 in North West, 3 in Midlands and 3 in Yorkshire.

During the trial, participants were lost due to following reasons: lost to follow-up (*n* = 189); withdrew on decision of the investigator (*n* = 17); patient request (*n* = 2); withdrawal of consent (*n* = 2); and other (*n* = 1).

Demographic baseline characteristics

Demographic details of study participants are illustrated in *Table 7*.

Age

Mean age of total sample was 31 ± 5.2 years, that is nearly same in both TAU and PHP + TAU group.

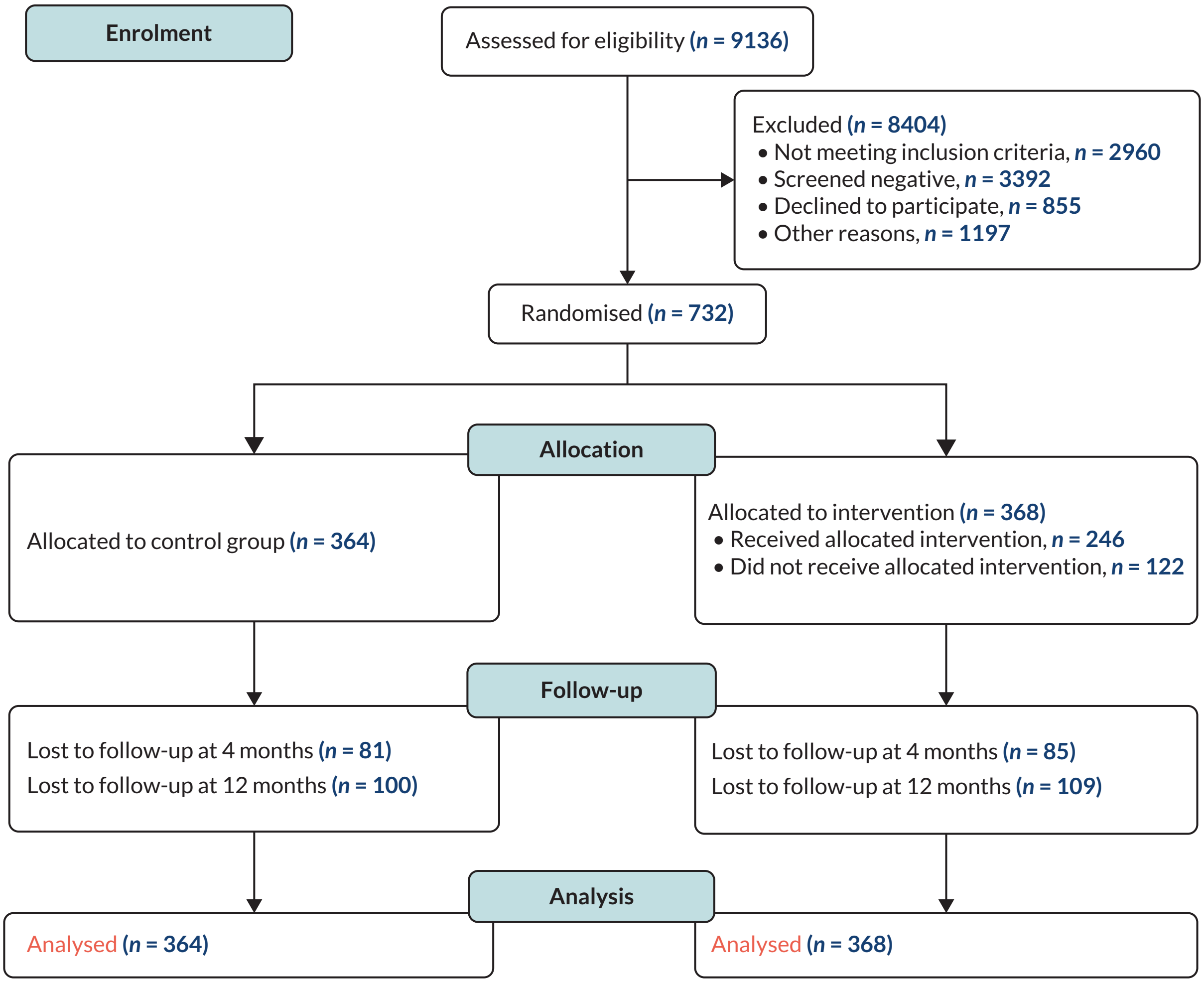

FIGURE 3 ROSHNI-2 study flow design.

TABLE 7 Baseline characteristics

Baseline characteristics		TAU (*n* = 364)	PHP (*n* = 368)	Sample (*n* = 732)
Age, mean (SD)		31.4 (5.2)	31.3 (5.2)	31.3 (5.2)
Ethnicity, *n* (%)	Indian	85 (24)	91 (24.9)	176 (24.5)
	Bangladeshi	67 (18.9)	60 (16.4)	127 (17.7)
	Pakistani	195 (55.1)	202 (55.3)	397 (55.2)
	Other South Asian	7 (2)	12 (3.3)	19 (2.6)
English speaking, *n* (%)	Yes	327 (92.9)	338 (93.1)	665 (93)
	None	25 (7.1)	25 (6.9)	50 (7)
Religion, *n* (%)	Islam	315 (88.2)	322 (88)	637 (88.1)
	Hindu	28 (7.8)	23 (6.3)	51 (7.1)
	Christian	4 (1.1)	2 (0.5)	6 (0.8)
	Buddhism	0 (0)	3 (0.8)	3 (0.4)
	Sikh	9 (2.5)	16 (4.4)	25 (3.5)
	Other	1 (0.3)	0 (0)	1 (0.1)
Generation, *n* (%)	First generation	215 (60.9)	206 (56.6)	421 (58.7)
	Second generation	103 (29.2)	120 (33)	223 (31.1)
	Third generation	35 (9.9)	38 (10.4)	73 (10.2)
Employment status, *n* (%)	Full-time	44 (12.5)	42 (11.5)	86 (12)
	Part-time	43 (12.2)	56 (15.3)	99 (13.8)
	Unemployed	43 (12.2)	39 (10.7)	82 (11.4)
	Sick	0 (0)	1 (0.3)	1 (0.1)
	Home maker	186 (52.8)	197 (54)	383 (53.4)
	Student	3 (0.9)	2 (0.5)	5 (0.7)
	Other	33 (9.4)	28 (7.7)	61 (8.5)
Highest qualification, *n* (%)	Primary	14 (4)	12 (3.4)	26 (3.7)

Ethnicity

Almost half of the total sample was comprised of individuals of Pakistani ethnicity – 397 (55%), while 176 (25%) were from India, 127 (18%) from Bangladesh and 19 (3%) from other Asian backgrounds. Ethnicity between the TAU and PHP group was distributed equally.

Language

Most participants replied that their preferred language was English, by 316 (43%) participants. Urdu was preferred by 234 (32%), Bengali by 71 (10%), Punjabi by 52 (7%) and Gujarati by 30 (4%) participants. A majority of 665 (93%) participants spoke and understood English and only 50 (7%) lacked confidence in fluent English.

Religion

A total majority of 637 (88%) participants were affiliated to Islam, 51 (7%) were Hindu, 25 (4%) were Sikh, 6 (0.8%) were Christian and 3 (0.4%) were Buddhist. The same pattern was observed in both groups, except Sikh individuals that were slightly more in the PHP group (16 or 4.4%) then in the TAU group (9 or 3%).

Generation

The majority of the overall participants were from first generation (421 or 59%), while the rest of them were from second generation (223 or 31%) and third generation (73 or 10%).

Employment status

Of all participants, 383 (54%) were homemakers, there were 99 (14%) part-time employed, 86 (12%) full-time employed, 82 (11%) unemployed and 5 (0.7%) were students.

Qualification

Participants were asked about their highest qualification. From the total sample, 221 (32%) had first degree, 150 (21%) did A-levels, 119 (17%) had a higher degree, 117 (17%) did GCSEs, 26 (4%) did primary schooling and 68 (10%) had some other type of qualification like a diploma or had done certificate courses. The mean years of education was 13.9 ± 3.6 years.

Marital status

A total of 684 (95%) participants of the overall sample were married or cohabiting, 27 (4%) were divorced, and 11 (2%) were single mums. The mean years of marriage was 6.7 ± 4.8 years. Women were also asked about their previous marital status and were able to respond with either divorced, separated, and widowed as 61 (9%), 29 (5%) and 6 (1%), respectively.

Children status

Participating mothers were asked about the age of their youngest child and the median age in months was 5.7 with interquartile range (IQR) as 3.6 months.

Household members

Participants were also asked about total number of households and we found the median number as 5.1 with IQR as 2. From the overall sample, 495 (69%) were not living with extended family while 220 (31%) were living with extended family.

Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition)

Baseline diagnosis of depression was confirmed by a research assistant who was blind to the allocation status of the participants and administered SCID.[92] The SCID is a semistructured interview and in the context of this study it was conducted as a conversation with the participant and interpreted in the language of their preference. The interview consisted of standardised diagnostic questions arranged in modules corresponding to each DSM-5 Axis I disorder. The depression module was used for this study.

Items

There are nine items as follows:

- Depression mood.
- Work and activities.
- Weight and appetite (increase or decrease).
- Sleep (insomnia or hypersomnia).
- Psychomotor agitation or retardation.
- Loss of energy, tiredness or fatigue.
- Worthlessness or guilt.
- Ability to concentrate.
- Suicide.

Each item has four options as follows:

- Absent or false = 1.
- Sub threshold = 2.

- Threshold or present or true = 3.
- Inadequate information = ?

Assessment

At least five of the above items (1–9) were coded '3 (present)' and at least one of these item 1 or 2. Expected outcome was from minimum 5 score to maximum 9 score.

Outcome

The SCID score was assessed and the mean score of all participants found was 7.31 ± 1.05. Out of 9 items, minimum 5 was scored by 56 (8%) participants. Similarly, 6 was score by 95 (13%), 7 scored by 215 (29%), 8 scored by 301 (41%) and 9 scored by 65 (9%) participants as shown in *Table 8*.

Outcome measure completeness by study participants

Table 9 shows the completeness of study outcome measures by study participants. For the outcome assessment at both 4 months and 12 months, the denominator refers to the number of participants who attended the outcome assessment but did not complete a particular measure.

Depression

This measure was completed by 727 (99.6%) participants in both study arms at the time of baseline, 360 (99%) in TAU and 367 (99.7%) in PHP group. At the 4-month follow-up, this measure was completed by 282 (98%) participants in TAU and 281 (95%) in PHP group. Similarly, completeness in TAU group is by 262 (72%) and in PHP group by 259 (71%) participants at the 12-month follow-up.

Depression (Patient Health Questionnaire-9)

At baseline this measure was completed by 362 (99.5%) in the TAU and 368 (100.0%) in the PHP group. The TAU group completed this scale at the 4-month follow-up by 281 (98%) and at 12-month by 261 (72%) participants, whereas completeness of this scale in the PHP group by 282 (96%) participants at the 4-month follow-up and by 258 (70%) at the 12-month follow-up.

Anxiety (Generalised Anxiety Disorder-7)

Completeness of this scale at baseline by 356 (98%) in the TAU group and 364 (99%) in the PHP group. This scale was completed at 4-month follow-up by 279 (97%) and 279 (95%) in the TAU and PHP groups respectively, and at 12-month follow-up by 260 (72%) and 256 (69%) in the TAU and PHP groups respectively.

Parenting (Parenting Sense of Competence Scale)

Participants in TAU group completed this scale at baseline, 4 and 12-month follow-ups as A 322 (89%), 248 (86%) and 226 (62%), respectively. While participants in the PHP group completed this scale at baseline, 4- and 12-month follow-ups as 337 (92%), 252 (85%) and 227 (62%), respectively.

TABLE 8 Structured Clinical Interview for DSM-IV scores as scored by study participants

SCID score	Frequency	Percentage (%)
5	56	7.7
6	95	13.0
7	215	29.4
8	301	41.1
9	65	8.9

TABLE 9 Outcome measure completeness by study participants

Clinical scales	Baseline			4 months			12 months		
	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)
Depression (HDRS)	360 (99.4)	367 (99.7)	727 (99.6)	282 (98.3)	281 (95.3)	563 (96.7)	262 (72.2)	259 (70.6)	521 (71.4)
Depression (PHQ-9)	362 (99.5)	368 (100.0)	730 (99.7)	281 (97.9)	282 (95.6)	563 (96.7)	261 (71.9)	258 (70.3)	519 (71.1)
Anxiety (GAD-7)	356 (98.3)	364 (98.9)	720 (98.6)	279 (97.2)	279 (94.6)	558 (95.9)	260 (71.6)	256 (69.8)	516 (70.7)
Parenting (PSCS)	322 (89.0)	337 (91.6)	659 (90.3)	248 (86.4)	252 (85.4)	500 (85.9)	226 (62.3)	227 (61.9)	453 (62.1)
Social functioning	355 (97.5)	360 (97.8)	713 (97.7)	269 (93.7)	269 (91.2)	538 (92.4)	252 (69.4)	249 (67.8)	501 (68.6)
EQ-5D – health today	350 (96.7)	358 (97.3)	708 (97.0)	269 (93.7)	272 (92.2)	541 (93.0)	259 (71.3)	256 (69.8)	515 (70.5)
IAPT satisfaction	–	–	–	261 (90.9)	267 (90.5)	528 (90.7)	253 (69.7)	254 (69.2)	507 (60.5)

PSCS, Parenting Sense of Competence Scale.

Social functioning

This measure was completed at baseline by 355 (96%) participants in the TAU group and 360 (98%) in the PHP group. At 4-month follow-up this measure was completed by 269 (94%) and 269 (91%) participants in the TAU and PHP groups, respectively. Similarly, at 12-month follow-up by 252 (69%) and 249 (68%) participants in the TAU and PHP groups, respectively.

EuroQol-5 Dimensions – health today

This measure at the time of baseline was completed by 350 (97%) participants in the TAU group and 358 (97%) in the PHP group. Participants in the TAU group completed this scale at 4-month follow-up as 269 (94%) and at 12-month follow-up as 259 (72%). Similarly, in the PHP group 272 (92%) participants completed this scale at 4-month follow-up and 256 (70%) at 12-month follow-up.

Improving Access to Psychological Therapies satisfaction

The satisfaction measure was collected at 4- and 12-month follow-ups. Completeness of this scale at 4-month follow-up was by 261 (91%) in the TAU group and 267 (91%) in the PHP group. At 12-month follow-up this measure was completed by 253 (70%) in the TAU group and 254 (69%) in the PHP group.

Outcome measures

Information about outcome measures is presented in *Table 10*.

Depression (Hamilton Depression Rating Scale)

The mean depression score on the HDRS at baseline in the TAU and PHP groups was 18.0 ± 7.29 and 17.6 ± 7.27, respectively. This score reduced more in the PHP group at both 4- and 12-month follow-ups to 9.0 ± 7.07 and 8.6 ± 6.75, respectively. The HDRS score reduced in the TAU group at 4- and 12-month follow-ups to 11.0 ± 7.85 and 9.4 ± 8.43, respectively.

TABLE 10 Study participants outcome measures scoring by time point

	Baseline			4 Months			12 Months		
Clinical scales	**TAU mean (SD)**	**PHP mean (SD)**	**Overall mean (SD)**	**TAU mean (SD)**	**PHP mean (SD)**	**Overall mean (SD)**	**TAU mean (SD)**	**PHP mean (SD)**	**Overall mean (SD)**
Depression (HDRS)	18.0 (7.28)	17.6 (7.27)	17.8 (7.28)	11.0 (7.83)	9.0 (7.07)	10.0 (7.52)	9.4 (8.41)	8.6 (6.75)	9.0 (7.62)
Depression (PHQ-9)	15.9 (4.21)	15.2 (3.93)	15.5 (4.08)	9.1 (6.34)	7.2 (5.80)	8.1 (6.12)	7.6 (6.81)	6.8 (5.55)	7.2 (6.22)
Anxiety (GAD-7)	11.6 (5.62)	11.6 (5.87)	11.6 (5.73)	7.4 (5.71)	6.1 (5.66)	6.7 (5.72)	6.4 (6.26)	6.0 (5.51)	6.2 (5.90)
Parental sense comp	62.4 (10.92)	63.0 (12.01)	62.6 (11.49)	67.2 (10.77)	69.1 (12.25)	68.2 (11.59)	67.4 (12.61)	69.9 (12.32)	68.7 (12.59)
Social functioning	13.0 (9.67)	12.9 (9.85)	13.0 (9.74)	8.0 (8.75)	6.6 (7.76)	7.3 (8.27)	6.7 (8.77)	6.0 (7.98)	6.4 (8.38)
EQ-5D – health today	55.3 (20.44	55.4 (19.80)	55.4 (20.13)	64.3 (21.55)	66.2 (21.60)	65.2 (21.55)	65.9 (21.71)	68.1 (21.10)	66.8 (21.44)
IAPT satisfaction	–	–	–	3.3 (0.85)	3.6 (0.68)	3.5 (0.78)	3.6 (0.69)	3.7 (0.65)	3.6 (0.67)

Note

The primary outcome is recovery from PND, measured with the HDRS, with lower scores indicating higher recovery. Depression was measured with the PHQ-9, with lower scores indicating fewer depressions. Anxiety was measured with the GAD-7, with lower scores indicating less anxiety. The PSCS measures how competent the patient feels in their parenting ability, with higher scores indicating higher feelings of competence. The social functioning scale measures social dysfunction, with higher scores indicating higher levels of social dysfunction. The EQ-5D is a rating of the patient's health state on the day, higher scores indicate higher health. The IAPT satisfaction scale is a measure of satisfaction of patient experience and higher scores indicate higher satisfaction.

Depression (Patient Health Questionnaire-9)

The mean depression score at baseline on PHQ-9 recoded as 15.9 ± 4.22 in the TAU group and 15.2 ± 3.92 in the PHP group. This score reduced in both groups but more in the PHP group at 4- and 12-month follow-ups. In the TAU group it reduced to 9.1 ± 6.34 at 4-month follow-up and 7.6 ± 6.81 at 12-month follow-up. Similarly, in the PHP group it reduced to 7.2 ± 5.80 at 4-month follow-up and 6.8 ± 5.55 at 12-month follow-up.

Anxiety (Generalised Anxiety Disorder-7)

Both the TAU and PHP groups showed the same mean anxiety score as 11.6 ± 5.6 at baseline. This score reduced to 7.4 ± 5.71 in the TAU group and 6.1 ± 5.66 in the PHP group at 4-month follow-up and to 6.4 ± 6.26 in the TAU group and 6.0 ± 5.51 in PHP group at 12-month follow-up.

The Parenting Sense of Competence Scale

In the TAU group, the mean parenting sense of competence scale (PSCS) score was 62.4 ± 10.89 and 63.0 ± 12.01 in the PHP group at baseline. At 4-month follow-up this score raised to 67.2 ± 10.77 in the TAU group and 69.1 ± 12.25 in the PHP group. A slight increase was observed at 12-month follow-up as 67.4 ± 12.61 in the TAU group and 69.9 ± 12.32 in the PHP group.

Social functioning

At baseline, the mean score for social functioning was 13.0 ± 9.67 and 12.9 ± 9.85 in the TAU and PHP groups, respectively. In the TAU group this score reduced to 8.0 ± 8.75 at 4-month follow-up and to 6.7 ± 8.77 at 12-month follow-up. Similarly, in the PHP group this score reduced to 6.6 ± 7.76 at 4-month follow-up and to 6.1 ± 7.98 at 12-month follow-up.

EuroQol-5 Dimensions – health today

The mean EQ-5D visual analogue score at baseline was 55.3 ± 20.44 in the TAU group and 55.4 ± 19.80 in the PHP group. This score raised to 64.3 ± 21.55 in the TAU group and to 66.2 ± 21.60 in the PHP group at 4-month follow-up. At 12-month follow-up, the score in the TAU group was 65.9 ± 21.71 and in the PHP group was 68.1 ± 21.10.

Improving Access to Psychological Therapies satisfaction

Satisfaction of study participants was assessed at 4- and 12-month follow-ups. The IAPT mean satisfaction score at 4-month follow-up was 3.3 ± 0.83 in the TAU group and 3.6 ± 0.71 in the PHP group. Similarly, the mean score at 12-month follow-up in the TAU and PHP groups was 3.6 ± 0.69 and 3.7 ± 0.65, respectively.

Mobility

At baseline, some problems were reported by 73 (21%) participants in the TAU group and 80 (22%) participants in the PHP group. The number reduced to 47 (17%) in the TAU group and 37 (13%) in the PHP group at the 4-month follow-up. At the 12-month follow-up, 37 (14%) participants in the TAU group and 28 (11%) in the PHP group reported some mobility problems.

Self-care

Some self-care problems were reported by 100 (28%) participants in both the TAU and PHP groups at baseline. The condition improved at the 4-month follow-up, with 53 (19%) participants in the TAU group and 34 (12%) in the PHP group reporting some self-care problems. Further improvement was observed at the 12-month follow-up, with 32 (12%) in the TAU group and 24 (9%) in the PHP group reporting some self-care problems.

Usual activities

Some problems with usual activities were reported by 161 (45%) participants in the TAU group and 170 (47%) participants in the PHP group at baseline. At the 4-month follow-up, it was found that 76 (27%) participants in the TAU group and 51 (18%) participants in the PHP group had some problems with usual activities. Further improvement was observed at the 12-month follow-up, with 57 (22%) participants in the TAU group and 33 (13%) participants in the PHP group reporting some problems.

Pain/discomfort

Extreme pain was reported by 44 (12%) participants in the TAU group at the baseline. Only 18 (7%) TAU group participants reported pain at 4-month follow-up and 19 (7%) participants at the 12-month follow-up. In the PHP group, 36 (10%) had extreme pain at the baseline, 22 (8%) at 4-month follow-up and 12 (5%) at 12-month follow-up.

Anxiety/depression

At baseline, 58 (16%) participants in both groups reported extreme depression. This proportion improved at 4-month follow-up, with extreme depression reported by 23 (8%) participants in the TAU group and 18 (7%) participants in the PHP group. However, at 12-month follow-up, there was an increase in the proportion of participants reporting extreme depression. *Table 11* presents scores on the EuroQoL measure.

TABLE 11 EuroQol-5 Dimensions questionnaire

	Baseline			**4 months**			**12 months**		
Clinical scales	**TAU** *n* **(%)**	**PHP** *n* **(%)**	**Overall** *N* **(%)**	**TAU** *n* **(%)**	**PHP** *n* **(%)**	**Overall** *N* **(%)**	**TAU** *n* **(%)**	**PHP** *n* **(%)**	**Overall** *N* **(%)**
Mobility									
No problems	280 (78.7)	283 (77.5)	563 (78.1)	229 (82.4)	241 (86.4)	470 (84.4)	223 (85.4)	228 (89.1)	451 (87.2)
Some problems	73 (20.5)	80 (21.9)	153 (21.2)	47 (16.9)	37 (13.3)	84 (15.1)	37 (14.2)	28 (10.9)	65 (12.6)

continued

TABLE 11 EuroQol-5 Dimensions questionnaire (*continued*)

	Baseline			4 months			12 months		
Clinical scales	**TAU *n* (%)**	**PHP *n* (%)**	**Overall *N* (%)**	**TAU *n* (%)**	**PHP *n* (%)**	**Overall *N* (%)**	**TAU *n* (%)**	**PHP *n* (%)**	**Overall *N* (%)**
Confined to bed	3 (0.8)	2 (0.5)	5 (0.7)	2 (0.7)	1 (0.4)	3 (0.5)	1 (0.4)	0 (0.0)	1 (0.2)
Self-care									
No problems	251 (70.5)	258 (70.7)	509 (70.6)	221 (79.5)	241 (86.4)	462 (82.9)	227 (87.0)	232 (90.6)	459 (88.8)
Some problems	100 (28.1)	100 (27.4)	200 (27.7)	53 (19.1)	34 (12.2)	87 (15.6)	32 (12.3)	24 (9.4)	56 (10.8)
Unable to wash self	5 (1.4)	7 (1.9)	12 (1.7)	4 (1.4)	4 (1.4)	8 (1.4)	2 (0.8)	0 (0.0)	2 (0.4)
Usual activities									
No problems	179 (50.3)	177 (48.5)	356 (49.4)	197 (70.9)	224 (80.3)	421 (75.6)	201 (77.0)	222 (86.7)	423 (81.8)
Some problems	161 (45.2)	170 (46.6)	331 (45.9)	76 (27.3)	51 (18.3)	127 (22.8)	57 (21.8)	33 (12.9)	90 (17.4)
Unable to perform	16 (4.5)	18 (4.9)	34 (4.7)	5 (1.8)	4 (1.4)	9 (1.6)	3 (1.2)	1 (0.4)	4 (0.8)
Pain/discomfort									
None	110 (30.9)	119 (32.6)	229 (31.8)	139 (49.8)	155 (55.6)	294 (52.7)	165 (63.2)	156 (60.9)	321 (62.1)
Moderate	202 (56.7)	210 (57.5)	412 (57.1)	122 (43.8)	102 (36.6)	224 (40.1)	77 (29.5)	88 (34.4)	165 (31.9)
Extreme	44 (12.4)	36 (9.9)	80 (11.1)	18 (6.5)	22 (7.9)	40 (7.2)	19 (7.3)	12 (4.7)	31 (6.0)
Anxiety/depression									
None	66 (18.5)	92 (25.2)	158 (21.9)	138 (49.8)	156 (55.9)	294 (52.9)	146 (55.9)	146 (57.0)	292 (56.5)
Moderate	232 (65.2)	215 (58.9)	447 (62.0)	116 (41.9)	105 (37.6)	221 (39.7)	89 (34.1)	88 (34.4)	177 (34.2)
Extreme	58 (16.3)	58 (15.9)	116 (16.1)	23 (8.3)	18 (6.5)	41 (7.4)	26 (10.0)	22 (8.6)	48 (9.3)

Note
This table shows the proportion in each category for each domain of the EuroQol questionnaire.

Health service utilisation by study participants during study period

Study participants were asked about health services utilisation at three time points (baseline, 4- and 12-month) during the study. Details of various services utilisation are presented in *Table 12*.

Use of inpatient services

Inpatient services were utilised by 38 (11%) in the TAU group and 37 (11%) in the PHP group at baseline. Similarly, utilisation at 4-month follow-up was by 12 (4%) in the TAU group and by 11 (4%) in the PHP group. At 12-month follow-up it was by 9 (4%) in the TAU group and by 7 (3%) in the PHP group. The mean inpatient days spent by study participants at baseline in the TAU and PHP groups were 2.5 ± 1.76 and 6.7 ± 7.43, respectively; at 4-month follow-up were 1.4 ± 1.19 and 1.7 ± 1.25; and at 12-month were 3.0 ± 2.08 and 2.0 ± 1.41, respectively.

TABLE 12 Service utilisation by study participants during study period

	Baseline			4 months			12 months		
Description	**TAU**	**PHP**	**Overall**	**TAU**	**PHP**	**Overall**	**TAU**	**PHP**	**Overall**
Use of inpatient services – Yes *n* (%)	38 (11.4)	37 (10.9)	75 (11.2)	12 (4.3)	11 (4.0)	23 (4.2)	9 (3.5)	7 (2.7)	16 (3.1)
Impatient days – mean (SD)	2.5 (1.76)	6.7 (7.43)	4.6 (5.76)	1.4 (1.19)	1.7 (1.25)	1.5 (1.19)	3.0 (2.08)	2.0 (1.41)	2.5 (1.79)
Use of outpatient services – Yes *n* (%)	22 (6.6)	22 (6.5)	44 (6.6)	31 (11.2)	26 (9.4)	57 (10.3)	19 (7.3)	30 (11.8)	49 (9.5)
Number of visits – mean (SD)	2.0 (1.24)	1.6 (1.12)	1.8 (1.18)	1.9 (1.19)	3.6 (5.12)	2.7 (3.64)	2.1 (1.64)	1.8 (1.29)	1.9 (1.41)
Within last month – mean (SD)	1.6 (1.70)	0.9 (1.04)	1.3 (1.43)	1.0 (0.96)	2.0 (3.80)	1.4 (2.66)	1.8 (1.68)	1.2 (1.41)	1.4 (1.52)
Hospital visits – Yes *n* (%)	11 (3.3)	11 (3.3)	22 (3.3)	9 (3.3)	16 (5.8)	25 (4.5)	6 (2.3)	12 (4.7)	18 (3.5)
Number of visits – mean (SD)	1.8 (0.97)	1.4 (1.51)	1.6 (1.23)	2.0 (2.51)	1.5 (0.97)	1.7 (1.68)	2.0 (1.15)	2.2 (1.30)	2.2 (1.21)
Within last month – mean (SD)	0.8 (0.75)	0.7 (0.52)	0.8 (0.62)	1.0 (1.10)	0.8 (0.67)	0.9 (0.83)	1.0 (1.73)	1.2 (0.84)	1.1 (1.13)
A&E visits – Yes *n* (%)	16 (4.8)	14 (4.1)	30 (4.5)	15 (5.4)	16 (5.8)	31 (5.6)	8 (3.1)	8 (3.1)	16 (3.1)
Number of visits – mean (SD)	0.9 (1.09)	0.8 (0.93)	0.8 (1.00)	0.6 (1.27)	0.7 (1.17)	0.6 (1.21)	0.5 (0.74)	1.0 (1.76)	0.7 (1.33)
Within last month – mean (SD)	0.3 (0.46)	0.3 (0.56)	0.3 (0.51)	0.2 (0.42)	0.3 (0.74)	0.2 (0.60)	0.3 (0.44)	0.5 (1.01)	0.4 (0.75)
A&E inpatient visits – Yes *n* (%)	4 (1.2)	5 (1.5)	9 (1.4)	3 (1.1)	5 (1.9)	8 (1.5)	3 (1.2)	4 (1.6)	7 (1.4)
Number of visits – mean (SD)	1.0 (0.00)	1.7 (1.15)	1.4 (0.89)	1.0 (0.00)	2.7 (2.08)	2.0 (1.73)	1.0 (0.0)	1.5 (0.71)	1.3 (0.58)
Within last month – mean (SD)	0 (0)	0.7 (0.58)	0.7 (0.58)	0.5 (0.71)	0.0 (0.00)	0.3 (0.50)	1.0 (0.0)	1.0 (0.0)	1.0 (0.00)
Use of GP services – Yes *n* (%)	175 (52.6)	168 (50.3)	343 (51.4)	128 (46.2)	136 (49.1)	264 (47.7)	94 (36.4)	93 (36.6)	187 (36.5)
Number GP visits – mean (SD)	2.0 (1.70)	2.2 (1.61)	2.1 (1.66)	2.2 (1.78)	2.1 (1.72)	2.1 (1.75)	1.5 (1.33)	1.9 (1.76)	1.7 (1.56)
Within last month – mean (SD)	1.1 (1.01)	1.3 (1.14)	1.2 (1.08)	1.0 (1.09)	1.0 (1.01)	1.0 (1.05)	1.0 (1.22)	1.1 (1.27)	1.1 (1.24)
Number of home visits – mean (SD)	0.3 (0.59)	0.7 (1.37)	0.6 (1.13)	0.1 (0.27)	0.0 (0.00)	0.0 (0.19)	0.1 (0.50)	0.1 (0.28)	0.1 (0.41)
Within last month – mean (SD)	0.1 (0.32)	0.0 (0.20)	0.1 (0.25)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Number of nurse surgery visit – mean (SD)	0.6 (1.25)	0.6 (1.21)	0.6 (1.21)	0.2 (0.49)	0.2 (0.58)	0.2 (0.54)	0.3 (0.75)	0.4 (0.50)	0.4 (0.63)
Within last month – mean (SD)	0.4 (0.70)	0.0 (0.21)	0.2 (0.50)	0.1 (0.26)	0.0 (0.17)	0.0 (0.22)	0.1 (0.37)	0.1 (0.37)	0.1 (0.36)
Number of nurse home visits – mean (SD)	0.4 (0.89)	0.5 (1.71)	0.5 (1.38)	0.1 (0.38)	0.7 (3.49)	0.4 (2.60)	0.1 (0.33)	0.5 (1.10)	0.3 (0.81)

continued

TABLE 12 Service utilisation by study participants during study period (*continued*)

Description	Baseline			4 months			12 months		
	TAU	PHP	Overall	TAU	PHP	Overall	TAU	PHP	Overall
Within last month – mean (SD)	0.1 (0.34)	0.2 (0.71)	0.2 (0.57)	0.0 (0.00)	0.0 (0.17)	0.0 (0.13)	0.1 (0.25)	0.3 (0.45)	0.2 (0.37)
Number of walk-in visits – mean (SD)	0.3 (0.82)	0.4 (0.99)	0.4 (0.91)	0.9 (2.28)	0.5 (0.93)	0.7 (1.74)	0.6 (0.64)	0.6 (0.96)	0.6 (0.78)
Within last month – mean (SD)	0.7 (1.62)	0.2 (0.54)	0.4 (1.14)	0.3 (0.75)	0.2 (0.59)	0.3 (0.67)	0.4 (0.59)	0.3 (0.46)	0.3 (0.53)
Number of counsellor visits – mean (SD)	1.6 (2.94)	1.2 (2.92)	1.4 (2.90)	1.1 (4.49)	0.5 (1.69)	0.8 (3.30)	1.1 (3.99)	1.0 (2.35)	1.0 (3.18)
Within last month – mean (SD)	0.7 (1.17)	0.5 (1.12)	0.6 (1.14)	0.5 (1.61)	0.2 (0.58)	0.3 (1.18)	0.1 (0.50)	0.2 (0.56)	0.2 (0.53)
Number of community-based mental health service visits – mean (SD)	0.0 (0.74)	0.0 (0.20)	0.0 (0.54)	0.0 (0.19)	0.0 (0.23)	0.0 (0.21)	0.0 (0.37)	0.0 (0.05)	0.0 (0.26)
Within last month – mean (SD)	0.0 (0.32)	0.0 (0.05)	0.0 (0.23)	0.0 (0.06)	0.0 (0.00)	0.0 (0.04)	0.0 (0.16)	0.0 (0.00)	0.0 (0.11)
Number of community-based mental health service visits – mean (SD)	0.0 (0.74)	0.0 (0.20)	0.0 (0.54)	0.0 (0.19)	0.0 (0.23)	0.0 (0.21)	0.0 (0.37)	0.0 (0.05)	0.0 (0.26)
Within last month – mean (SD)	0.0 (0.32)	0.0 (0.05)	0.0 (0.23)	0.0 (0.06)	0.0 (0.00)	0.0 (0.04)	0.0 (0.16)	0.0 (0.00)	0.0 (0.11)

SD, standard deviation.

Use of outpatient services

Outpatient services at the time of baseline were utilised by 22 (7%) participants in the TAU group and 22 (7%) in the PHP group. At 4-month follow-up services were utilised by 31 (11%) in the TAU group and by 26 (9%) in the PHP group. Similarly, 19 (7%) in the TAU group and 30 (12%) in the PHP group utilised this service at 12-month follow-up. Details of the mean number of visits are illustrated in *Table 12*.

Hospital visits

Hospitals visits at baseline were done by 11 (3%) each in both the TAU and PHP groups. Frequency of visits by participants in the TAU and PHP groups at 4-month follow-up was 9 (3%) and 16 (6%), respectively, while at 12-month follow-up was 6 (2%) and 12 (5%), respectively. *Table 12* describes the mean number of days this service was utilised at different time points in study.

Accident and emergency visits

When participants were asked about accident and emergency (A&E) visits at the time of baseline, 16 (5%) in the TAU group and 14 (4%) in the PHP group were affirmative. At 4-month follow-up, 15 (5%) participants in the TAU group and 16 (6%) in the PHP group did the A&E visit. Likewise, at 12-month follow-up, 8 (3%) participants in the TAU group and 8 (3%) in the PHP group did the A&E visit. Further details about the mean number of visits are provided in *Table 12*.

Accident and emergency inpatient visits

Participants also have inpatient visit, 4 (1%) in the TAU group and 5 (1%) in the PHP group at baseline. Of those in the TAU group, 3 (1%) said yes and in the PHP group and 5 (2%) said yes at 4-month follow-up. At 12-month follow-up, 3 (1%) participants in the TAU group and 4 (2%) in the PHP group said yes. Details of the mean number of visits are available in *Table 12*.

Use of general practitioner services

The most utilised service by study participants is a GP service. For the TAU group, participants who visited a GP at baseline were 175 (53%), at 4-month follow-up were 128 (46%) and at 12-month follow-up were 94 (36%). Similarly, among the PHP group, 168 (50%) participants visited a GP at baseline, 136 (49%) at 4-month follow-up and 93 (37%) at 12-month follow-up. The mean number of visits by participants are briefed in *Table 12*.

Outcome classification

Primary outcome

The primary outcome was recovery from PND. Patients were considered recovered if they had a HRDS score of 7 or less. If they scored above 7, they were considered to still be depressed. At 4 months, almost half of patients in the treatment (PHP) group were recovered 138 (49%) whereas 105 (37%) were recovered in the control (TAU) group. By 12 months, the control (TAU) and treatment (PHP) group had over over 50% recovery as 140 (54%) and 141 (54%), respectively (*Table 13*).

Secondary outcome

One of the secondary outcomes was regarding whether we observed a treatment response on the HRDS measure. A treatment response was considered a reduction of 50% or more from baseline score on the HRDS. In the treatment (PHP) group, we observed 158 (56 %) of participants experiencing a treatment response and 112 (40%) of the control (TAU) group experiencing a treatment response, at 4 months. At 12 months, 158 (61%) of the treatment (PHP) group had a treatment response and 151 (58%) of the control (TAU) group had a treatment response.

Depression and anxiety scores using the PHQ-9 and GAD-7 can be further categorised into groups depending on severity of symptoms. *Table 14* shows the proportion in each classification, at each time point, within the treatment groups and overall. On PHQ-9, severity of symptoms was classified as minimal symptoms, minor depression, major depression and major depression severe. Major depression was reduced from baseline as 129 (36%) to 36 (13%) at 4-month follow-up and 34 (13%) at 12-month follow-up in the TAU group. Similarly, in the PHP group major depression reduced from baseline as 119 (32%) to 30 (11%) at 4-month follow-up and 26 (10%) at 12-month follow-up.

Primary outcome analysis – recovery

We used a logistic regression, partially nested, random-effects model to appraise the OR of recovery in connection with treatment clusters. We adjusted for baseline depression, parity and education, and included a random intercept for therapy group. At 4 months, we have seen a significant difference in the odds of recovering for those in the treatment group, who were almost twice as likely to recover at 4 months than Group A (OR 1.97, 95% CI 1.26 to 3.10). At 12 months, we no longer observe a significant difference in the odds of recovering from postnatal depression (*Table 15*).

Table 16 shows the differences in continuous outcomes between groups. For depression, measured by the PHQ-9 score, we see that the treatment group has a significantly lower depression score than the group at 4 months (β = 2.05, 95% CI −3.18 to −0.92). There was no significant difference observed at 12 months. At 4 months, the treatment group had significantly lower anxiety compared to the control group (β = 1.45, 95% CI −2.66 to −0.25). At 12 months, we do not see a significant difference in anxiety between groups.

TABLE 13 Outcome classification – primary outcome

Clinical scales	Baseline			4 months			12 months		
	TAU	PHP	Overall	TAU	PHP	Overall	TAU	PHP	Overall
	n (%)	*n* (%)	*N* (%)	*n* (%)	*n* (%)	*N* (%)	*n* (%)	*n* (%)	*N* (%)
Depressed	336 (94.9)	338 (93.1)	674 (94.0)	176 (62.6)	143 (50.9)	319 (56.8)	121 (46.4)	118 (45.6)	239 (46.0)
Recovered	18 (5.1)	25 (6.9)	43 (6.0)	105 (37.4)	138 (49.1)	243 (43.2)	140 (54.4)	141 (54.4)	281 (54.0)

TABLE 14 Outcome classifications – secondary outcome

Outcome		Baseline			4 months			12 months		
		TAU, *n* (%)	PHP, *n* (%)	Overall, *N* (%)	TAU, *n* (%)	PHP, *n* (%)	Overall, *N* (%)	TAU, *n* (%)	PHP, *n* (%)	Overall, *N* (%)
Reduction in HRDS	< 50% reduction	–	–	–	167 (59.9)	123 (43.8)	290 (51.8)	109 (41.9)	101 (39.0)	210 (40.5)
	50% or more reduction	–	–	–	112 (40.1)	158 (56.2)	270 (48.2)	151 (58.1)	158 (61.0)	2309 (59.5)
PHQ classification	Minimal symptoms	0 (0.0)	1 (0.3)	1 (0.1)	159 (56.8)	200 (70.9)	359 (63.9)	170 (67.5)	183 (72.3)	353 (69.9)
	Minor depression	150 (41.6)	183 (49.7)	333 (45.7)	63 (22.5)	43 (15.3)	106 (18.9)	31 (11.9)	40 (15.5)	71 (13.7)
	Major depression	129 (35.7)	119 (32.3)	248 (34.0)	36 (12.9)	30 (10.6)	66 (11.7)	34 (13.1)	26 (10.1)	60 (11.6)
	Major depression severe	82 (22.7)	65 (17.7)	147 (20.2)	22 (7.9)	9 (3.2)	31 (5.5)	20 (7.7)	5 (1.9)	25 (4.8)
GAD classification	Minimal symptoms	38 (10.7)	46 (12.6)	84 (11.7)	10.7 (38.6)	138 (49.5)	245 (44.1)	132 (51.0)	133 (52.0)	264 (52.0)
	Mild anxiety	96 (27.0)	94 (25.8)	190 (26.4)	72 (26.0)	72 (25.8)	144 (25.9)	57 (22.0)	63 (24.6)	120 (23.3)
	Moderate anxiety	113 (31.7)	102 (28.0)	215 (29.9)	64 (23.1)	38 (13.6)	102 (18.4)	35 (13.5)	31 (12.1)	66 (12.8)
	Severe anxiety	109 (30.6)	122 (33.5)	231 (32.1)	34 (12.3)	31 (11.1)	65 (11.7)	33 (13.5)	29 (11.3)	64 (12.4)

In terms of parenting competence (PSCS), there was no significant difference in parenting sense of competence scores at 4 months between groups. However, at 12 months, the control group had a higher score, on average by 3.32 points (95% CI 1.10 to 5.54), indicating significantly higher sense of competence than the control group. There was no significant difference in social functioning between groups at 4 or 12 months. Regarding the patient's health state on the day, there was no significant difference in scores between groups at each time point.

Secondary outcome analysis – recovery

We used a logistic regression model to estimate the association between the intervention and whether a women had a response to treatment. A treatment response was defined as a decrease in HRDS score by 50% or more from baseline. We adjusted for parity and education and included a random intercept for therapy group. At 4 months, we saw that the treatment group were over twice as likely to experience a treatment response than the TAU group. This was a significant difference in odds (OR 2.49, 95% CI 1.38 to 4.52). However, at 12 months, we did not observe a significant difference in the proportion of patients experiencing a treatment response between groups (OR 1.07, 95% CI 0.59 to 1.95) (*Table 17*).

TABLE 15 Primary outcome analysis – recovery from postnatal depression

Outcome	TAU, *n* (%)	PHP, *n* (%)	OR (SE); *p*-value (95% CI)
Baseline	19 (5.3)	25 (6.8)	–
4 months	105 (37.4)	138 (49.1)	1.97 (0.45); *p* = 0.003 (1.26 to 3.10)
12 months	140 (53.6)	141 (54.4)	1.02 (0.27); *p* = 0,80 (0.62 to 1.66)

TABLE 16 Secondary outcomes

	TAU; Unadjusted mean (SD)	PHP; Unadjusted mean (SD)	Adjusted difference[a] (SE); *p*-value (95% CI)	Cohen's *d* (95% CI)
PHQ				
Baseline	15.85 (4.21)	15.21 (3.93)	–	
4 months	9.09 (6.34)	7.22 (5.80)	−2.05 (0.58); *p* <0.0001 (−3.18 to −0.92)	
12 months	7.60 (6.81)	6.77 (5.55)	−0.89 (0.59); *p* = 0.13 (−2.05 to 0.27)	
GAD				
Baseline	11.60 (5.62)	11.56 (5.87)	–	
4 months	7.37 (5.71)	6.05 (5.66)	−1.45 (0.62); *p* = 0.018 (−2.66 to −0.25)	
12 months	6.40 (6.26)	5.95 (5.51)	−0.24 (0.63); *p* = 0.71 (−1.46 to 0.99)	
PSCS				
Baseline	62.36 (10.92)	63.00 (12.01)	-	
4 months	67.19 (10.77)	69.13 (12.25)	1.76 (1.109); *p* = 0.11 (−0.37 to 3.89)	
12 months	67.43 (12.61)	69.88 (12.32)	3.32 (1.13); *p* = 0.0034 (1.10 to 5.54)	
SFA				
Baseline	12.98 (9.67)	12.91 (9.85)	–	
4 months	8.04 (8.75)	6.62 (7.76)	−1.57 (1.11); *p* = 0.16 (−3.74 to 0.59)	
12 months	6.73 (8.77)	6.05 (7.98)	−0.34 (1.11); *p* = 0.76 (−2.51 to 1.83)	
EQOL5				
Baseline	55.28 (20.44)	55.43 (19.80)	–	
4 months	64.26 (21.55)	66.20 (21.60)	3.303 (1.86); *p* = 0.0077 (−0.35 to 6.95)	
12 months	65.93 (21.71)	68.12 (21.10)	3.48 (1.92); *p* = 0.069 (−0.28 to 7.23)	

a Adjusted for therapist (random effect) and baseline HDRS, parity, education and baseline value of the outcome variable.

TABLE 17 Secondary outcome – treatment response on HRDS (50% or more reduction in baseline score)

	TAU	PHP	
Outcome	*n* (%)	*n* (%)	OR (SE); *p*-value (95% CI)
Baseline	–	–	–
4 months	112 (40.1)	158 (56.2)	2.49 (0.76); *p* = 0.003 (1.38 to 4.52)
12 months	151 (58.0)	158 (61.0)	1.07 (0.33); *p* = 0.82 (0.59 to 1.95)

Secondary outcome – improving access to psychological therapies

As of *Table 18*, at 4 months, the treatment (PHP) group were significantly more likely to be satisfied than the TAU group. At 12 months, there was no difference in satisfaction between groups.

TABLE 18 Secondary outcome – IAPT

	OR (SE); *p*-value (95% CI)
Baseline	–
4 months	2.72 (1.33); *p* = 0.0.40 (1..05 - 7.09)
12 months	2.03 (1.01); *p* = 0.16 (0.77 to 5.40)

Ages and stages questionnaire

The ages and stages questionnaire is a parent completed measure of childhood development in five domains. These data were collected at baseline and 12 months to evaluate the feasibility of using the questionnaire in future studies with British South Asians. However, there are limited data on this variable as it was included later in the study and was lengthy to complete. It was collected only at follow-up for 47 children. *Table 19* shows the average age and score for the children in each domain and in each allocation group. Higher scores indicate better child development; generally scores above 40 suggest that the child's development is on schedule.

TABLE 19 Ages and stages descriptive statistics

	Follow-up – 12 months		
	TAU	PHP	Overall
	(*n* = 18)	(*n* = 19)	
	M (SD)	*M* (SD)	*M* (SD)
Age of child (months)	8.9 (5.74)	8.7 (5.29)	8.8 (5.44)
Communication	45.8 (19.57)	48.2 (11.21)	47.0 (15.66)
Gross motor skills	43.3 (18.15)	50.8 (11.21)	47.2 (15.25)
Fine motor skills	50.0 (14.55)	49.2 (13.77)	49.6 (13.96)
Problem solving	52.2 (10.46)	50.3 (15.14)	51.2 (12.93)
Personal social	49.2 (12.16)	52.9 (10.58)	51.1 (11.37)

TABLE 20 Sensitivity analysis – recovery from depression

	TAU, *n* (%)	PHP, *n* (%)	OR (SE); *p*-value (95% CI)
Baseline	0 (0)	0 (0)	–
4 months	105 (29)	138 (38)	1.63 (0.34); *p* = 0.020 (1.08 to 2.46)
12 months	140 (38)	141 (34)	0.97 (0.20); *p* = 0.87 (0.65 to 1.43)

Compliance analysis

We defined compliance as attending at least one session of therapy. Out of those in the treatment group, three-quarters of the participants were considered compliers (*n* = 246). The group of compliers, on average, attending 8.94 sessions. Due to randomisation, we assumed that the proportion of compliers in the treatment group were identical to the proportion of compliers in the treatment group. Using this assumption, we could find the complier average causal effect (CACE) of the primary outcome. The CACE analysis found that the treatment group were 68% more likely to recover from postnatal depression than Group A at 4 months (95% CI 1.06 to 2.65).

Predictors of missing data in primary outcome

The primary outcome at 4 months, recovery from PND, had 23% missing data (*n* = 170). The missing data were approximately equal between allocation groups, with 83 participants having missing data in the control group (23%) and 87 participants with missing data in the treatment group (24%). A series of logistic regression models were run to find if baseline covariates predicted missingness in the primary outcome. The covariates considered were baseline social functioning (SFA), parental competence (PSCS), health rating (EQol5), depression (PHQ-9), postnatal depression (HDRS), anxiety (GAD-7), education, parity, mother's age, marital status, generation and whether the patient spoke English. None of these variables significantly predicted missingness in the primary outcome, suggesting these data were not MAR. There was a borderline significant effect of baseline parenting sense of competence in missingness of the primary outcome (OR 1.017, 95% CI 1.000 to 1.00; *p* = 0.050).

Sensitivity analysis

A sensitivity analysis was performed with the missing data in the primary outcome. All participants with a missing primary outcome (recovery from depression) were assumed to have not recovered and were coded as depressed. A partially nested, logistic regression random-effects model was performed to estimate the OR of recovery between treatment groups, when missing outcome data were assumed to be a negative outcome. The sensitivity analysis found that at 4 months, those in the treatment group were 63% more likely to recover from PND than the control group, even when assuming all those with missing outcomes were depressed (OR 1.63, 95% CI 1.08 to 2.46). At 12 months, there was no significant difference in the odds of recovery between groups, under this assumption (*Table 20*).

Chapter 6 Health economic evaluation

Cost of Positive Health Programme intervention

The costs of PHP intervention are reported in *Table 21* by categories of cost across the four study sites and the number of groups covered in each study site. The major PHP cost component was PHP facilitators' payment. They were paid according to PWP bands 4, 5 and 6 for 2.5 hours per session (preparation and session). The second significant cost of PHP intervention was for creche, costing a total of £41,560 for the study. More than 50% of the sessions were delivered in children's centres which did not charge any cost for their spaces. Since using children's centres has opportunity costs for the health and care system, the economic evaluation analysis costed children's centres at the average (mean) costs charged by community venues in the respective site, with a total venue use costs of £25,000. Supervisors were paid at a fixed rate of £25 per hour for 3.5 hours per group, incurring costs of £3670. Training PHP facilitators costed a total of £6620, which includes refreshment costs, venue costs, and PHP trainers pay (two bands seven trainers with an hourly wage of £20.49 for 6 hours per day) and travel. In terms of sites, the major intervention cost was in the North West (£66,660), covering 21 study groups. Adding all together, the PHP implementation costed £151,020, which becomes £3560 per study group. PHP implementation costed an average of £408 per person. For those who attended at least one session, per session costs were £84. Since the economic evaluation is conducted from the health and social care sector perspectives, the PHP cost does not include the £10 per session paid to each PHP arm participant, nor the participants' travel expenses, as these are generally not covered by health and social care in the UK.

Health and social care resource use

Participants were asked to complete an economic patient questionnaire at the baseline and at each follow-up. In addition to information on primary and community healthcare use, they were asked to provide details of any inpatient admissions, outpatient appointments, type of department/disease and any emergency department attendances. The primary cost-effectiveness analyses included all secondary, primary, and community healthcare use besides the costs of the PHP therapy for the intervention arm.

TABLE 21 Positive Health Programme intervention costs (thousand pounds) by cost categories and study sites

	North West	Yorkshire	London	Midland	Total
Venue	4.63	0.83	13.66	5.84	24.95
Supervision	1.84	0.26	1.31	0.26	3.67
Supervisor travel	0.34	0.14	1.63	0.62	2.72
Printing	1.48	0.25	0.93	0.22	2.87
PHP facilitators	25.88	1.76	15.29	3.27	46.20
PHP facilitators' travel	4.16	0.52	1.29	0.00	5.96
Catering	6.91	1.01	7.08	1.47	16.47
Creche	19.19	6.00	14.62	1.75	41.56
Training	2.24	1.11	2.76	0.51	6.62
Total	66.66	11.86	58.56	13.94	151.02
Number of groups	21	3	15	3	42
Per group cost	3.174	3.953	3.904	4.647	3.596
Per person cost	0.3944	0.3826	0.4039	0.5574	0.4082

Since most of the PHP sessions were covered in 2018 and 2019, unit costs of 2018–9 were used for costing the use of secondary, primary and community healthcare resources (see *Table 22*). Under the 'Other community and social health services' heading in *Table 22*, few participants mentioned an initial psychiatric assessment or psychiatrist. These were costed at the unit cost of 'mental healthcare clusters initial assessments' from National Cost Collection 2018–9. Other resource uses such as visits to religious places and support workers were costed at the hourly rate of 'support and outreach worker' from PSSRU 2019. Elective and non-elective inpatient admissions were costed at the respective average unit cost on a finished consultant episodes basis.

Table 23 reports the headline mean per person secondary, primary and community healthcare resource utilisation costs. Except for the GP surgery attendances, the use of primary and community health care remained very low in both the intervention and control arms. The mean attendance of GP surgery was 1.10 per person at the baseline in the intervention arm versus 1.07 in the control arm. In the post-intervention period, GP surgery attendances fell by 0.03 points in each arm. The mean number of counsellor visits was 1 per 100 persons in the intervention arm versus 2 per 100 persons in the control arm at the baseline. In the post-intervention period, it became zero for the intervention arm versus 1 per 100 persons in the control arm. There was no change in the use of other community mental health services in the intervention arm over the study period, whereas the use increased from zero to 1 per 100 persons in the control

TABLE 22 Unit costs of secondary, primary and community healthcare resource (2018–9)[a]

Service type	Unit costs (£)	Source
GP surgery	39.1	PSSRU[111] 2019 (GP cost per surgery consultation lasting 9.22 minutes, including direct care staff costs, including training)
GP home	78.92	PSSRU 2014 and PSSRU 2019 [£156 per hour of GMS activity, 11.4 minutes visit, 1:0.61 direct-to-indirect time ratio (7.0 minutes indirect), 12 minutes travel]
Practice nurse surgery	12.43	PSSRU 2014 and PSSRU 2019 (£37 per hour, 15.5 minutes per contact, 1:0.30 direct-to-indirect time ratio)
Practice nurse home	39.68	National Cost Collection 2018–9 (N02AF – district nurse, face to face)
Walk-in centre	21.00	PSSRU 2019 (assume 15 minutes of band 6 nurse time)
Counsellor	45.00	PSSRU 2019 (agenda for change band 6 for 1 hour)
Other community mental health services	44.00	PSSRU 2019 (community occupational therapist 1 hour)
Other community and social health services	62.90	If physiotherapy: National Cost Collection 2018–9 (A08A1 – physiotherapist, adult, one to one)
	304.00	If psychiatric assessment: National Cost Collection 2018–9 (mental healthcare clusters initial assessments)
	24.00	Others: PSSRU 2019 (support and outreach worker for 1 hour)
Inpatient admissions	4077.93	National Cost Collection 2018–9 [national average unit cost of elective inpatients (FCEs)]
Outpatient visits	126.85	National Cost Collection 2018–9 (national average unit cost of outpatient attendances)
Day cases	751.90	National Cost Collection 2018–9 (national average unit cost of day cases)
A&E attendances	166.05	National Cost Collection 2018–9 (national average unit cost of A&E attendances not leading to admission)
Emergency admissions	3292.75	National Cost Collection 2018–9 [national average unit cost of non-elective inpatients (FCEs)]

PSSRU, Personal Social Services Research Unit

a Primary and community care unit costs and length of visits are taken from different PSSRU issues and converted to the year 2018–9 prices.

TABLE 23 Mean secondary, primary and community healthcare costs by trial arms and time points (2018–9£)

	PHP arm			Control arm		
	Mean	SD	Participants	Mean	SD	Participants
Baseline						
Elective and A&E admissions	507	1466	338/338	485	1347	333/334
Outpatient/day case/A&E attendances	47	238	338/338	61	299	333/334
Secondary care total cost	554	1515	338/338	546	1452	333/334
Primary care	49	70	336/338	45	65	333/334
Community care	3	16	338/338	2	17	333/334
Total healthcare cost	606	1531	338/338	593	1462	333/334
4-month follow-up						
Elective and A&E admissions	288	1654	276/338	201	928	276/334
Outpatient/day case/A&E attendances	111	421	277/338	81	420	278/334
Secondary care total cost	398	1892	277/338	280	1024	278/334
Primary care	47	72	279/338	51	84	276/334
Community care	3	21	278/338	3	13	277/334
Total healthcare cost	445	1918	279/338	334	1048	278/334
12-month follow-up						
Elective and A&E admissions	151	806	255/338	154	836	260/334
Outpatient/day case/A&E attendances	98	432	256/338	46	247	261/334
Secondary care total cost	248	976	256/338	199	922	262/334
Primary care	32	57	254/338	27	45	260/334
Community care	4	21	256/338	4	17	262/334
Total healthcare cost	284	996	256/338	229	930	262/334

arm. The use of secondary care was higher in the intervention arm compared with the control arm both at the baseline and at each follow-up.

Health outcomes

Health benefits were quantified by QALYs estimated from responses to the EQ-5D-3L questionnaire. QALYs were calculated from time-weighted linear interpolation of the baseline, 4- and 12-month follow-ups utility indices. *Table 24* gives a summary of the resultant utility index and QALYs by trial arm and time points of the study. The mean baseline utility of the intervention arm is 2 points lower than the mean utility of the control arm. The difference increased to 3 points in favour of the PHP group at the 4-month follow-up but decreased at the 12-month follow-up. *Figure 4* plots the mean utilities for each point in time. This figure contains data for complete cases at each time point, so the difference in utilities in *Figure 4* is partly due to differences in the number of participants at the 3 points of time caused by missing data.

TABLE 24 Utility scores and QALYs by trial arm and time point (complete cases across time)

	Mean	SD	Median	Minimum	Maximum	Participants	Missing data (%)
Intervention arm							
12 months	0.78	0.26	0.85	−0.18	1.00	214	42
4 months	0.75	0.30	0.81	−0.59	1.00	214	42
Baseline	0.58	0.30	0.69	−0.35	1.00	214	42
QALY	0.73	0.21	0.77	0.03	1.00	214	42
Control arm							
12 months	0.78	0.30	0.85	−0.22	1.00	214	41
4 months	0.72	0.29	0.80	−0.18	1.00	214	41
Baseline	0.60	0.32	0.69	−0.48	1.00	214	41
QALY	0.72	0.23	0.78	−0.04	1.00	214	41

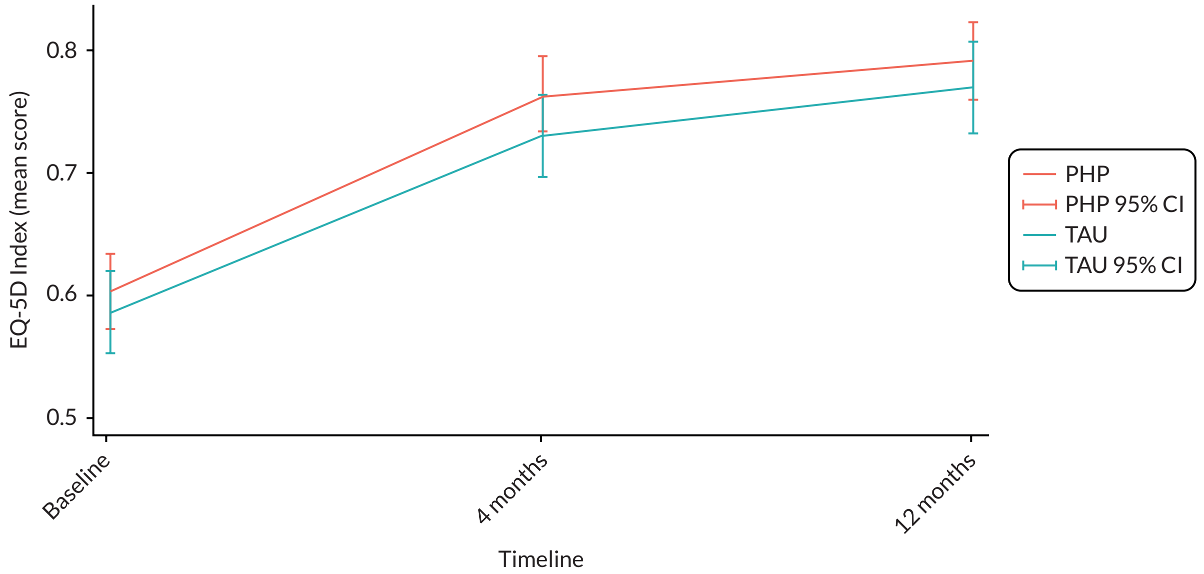

FIGURE 4 Trends in utility scores by trial arms (complete cases at each time point).

Missing data

Logistic regressions showed that missingness indicators of the cost components and utility at the 4- and 12-month follow-ups were not associated with baseline demographics like employment, qualification, and marital status. Some of the missing cost components and utilities at the 4- and 12-month follow-ups were associated with the baseline inpatient admission costs and baseline costs of GP surgery. Nevertheless, the association was statistically significant only at a 10% significance level. In some regressions, missingness was significantly different across study sites, with proportionally more missing data in two study sites. This suggests that the data were not missing completely at random (MCAR).[110] Covariates-dependent missingness or MAR seemed to be a more plausible assumption.[112] The sensitivity analysis then introduced two deviations from the MAR assumption to see how the results of the multiply imputed data are affected.

Given the amount of missing data, 50 imputed data sets were created. For comparison, *Table 25* reproduces the utility and QALYs statistics on the imputed data. Comparing *Tables 24* and *25*, the mean of the imputed data is greater than the respective mean in the unimputed data only for the intervention arm. This seems to suggest that at the 12-month follow-up, the missing data in the intervention group were mostly for those with higher utility values at the baseline. The difference in *Tables 24* and *25* remained irrespective of whether the imputations were carried on the utility index or the responses to EQ-5D-3L five dimensions.

Incremental cost and effects (QALYs)

Table 26 reports incremental costs, incremental QALYs, incremental cost-effectiveness ratio (ICER) and incremental net monetary benefits of PHP intervention. The PHP resulted in a 0.02 increase in QALYs per person over the 12 months. The associated incremental cost of the PHP group was £549.68 per person. This means that the average person in the PHP group cost £549 more than the average person in the TAU group. Most of this cost was due the cost of PHP implementation (£408 per person). Based on the QALY health gains, the mean incremental cost per incremental QALY was £22,198. This indicates that gaining one additional QALY with PHP versus TAU is associated with a mean total cost of £22,198. The uncertainty analysis indicates that the probability that PHP would be cost-effective is 44% (56%) if decision-makers are prepared to pay £20,000 (£25,000) to gain one QALY. At £25,000 willingness to pay, the mean net monetary benefits from PHP were £69 (*Table 26*).

Uncertainty

To assess uncertainty of estimates, incremental costs and QALYs were non-parametrically bootstrapped with 5000 replications. *Figure 5* presents the cost-effectiveness plane to depict the uncertainty around the mean incremental costs and QALYs. The bootstrapped results suggest that 96% of the replications lie within the northeast quadrant. This suggests that PHP intervention for PND increased both costs and QALYs in most of the replications. In 4% replications, PHP intervention increased cost but had no or negative effects on QALYs. *Figure 6* presents the likelihood that PHP was cost-effective at different willingness-to-pay values. With reference to NICE range, the probability that PHP would be cost-effective is 44% at £20,000 and 65% at £30,000.

Incremental cost and effects (remission)

Cost-effectiveness analyses were run with the primary clinical outcome measure (HDRS score of ≤ 7 vs. HDRS score of > 7) at the 4- and 12-month follow-ups to explore the cost per remission from PND. The cost and effects regressions were jointly estimated, but now the effects regression was estimated with logistic regression as the outcome measure is a binary indicator. The results are reported in *Table 27*. The PHP intervention was found to have significant effects on remission from PND after 4 months of PHP intervention. The odds of remission from depression in the PHP intervention group were higher by a factor of 1.71 compared with the TAU group at the 4-month follow-up. This suggested an incremental cost of £4550 per remission from PND among South Asian women at the 4-month follow-up.

TABLE 25 Utility scores and QALYs by trial arm and time point (imputed data)

	Mean	SE	90% lower CI	90% upper CI	Participants
Intervention arm					
12 months	0.8011	0.0017	0.7982	0.8039	368
4 months	0.7659	0.0020	0.7626	0.7693	368
Baseline	0.6039	0.0022	0.6002	0.6075	368
QALY	0.7506	0.0014	0.7483	0.7529	368
Control arm					
12 months	0.7665	0.0022	0.7629	0.7702	364
4 months	0.7341	0.0020	0.7307	0.7374	364
Baseline	0.5870	0.0023	0.5832	0.5909	364
QALY	0.7204	0.0016	0.7178	0.7230	364

TABLE 26 Regression results of incremental costs and QALYs

	Costs estimate		QALYs estimates	
	Coefficients	**95% CI**	**Coefficients**	**95% CI**
PHP	549.68	231.18 to 868.19	0.02	−0.01 to 0.06
Baseline costs	0.11	−0.01 to 0.24	−0.00	−0.00 to 0.00
Baseline utility	−444.80	−899.09 to 9.48	0.31	0.26 to 0.35
Age	3.73	−16.90 to 24.36	−0.00	−0.00 to −0.00
Primary/GCSE/A level	−184.96	−607.31 to 237.40	0.04	−0.00 to 0.09
First/higher degree	−381.95	−802.57 to 38.66	0.06	0.02 to 0.11
Site 2	235.96	−190.49 to 662.40	−0.09	−0.15 to −0.04
Site 3	−47.92	−370.60 to 274.76	−0.07	−0.12 to −0.01
Site 4	−150.21	−547.25 to 246.83	−0.07	−0.13 to −0.00
Incremental cost/QALY gained		£22,198		
Net benefit (95% CI) WTP = £20,000		£−54 (£−776 to £667)		
Probability PHP cost effective at WTP = £20,000		0.4411		
Net benefit (95% CI) WTP = £25,000		£69 (£−791 to £930)		
Probability PHP cost effective at WTP = £25,000		0.5630		
Net benefit (95% CI) WTP = £30,000		£193 (£−809 to £1195)		
Probability PHP cost effective at WTP = £30,000		0.6476		

WTP, willingness to pay.

Note

Standard errors are partially clustered (at PHP group level) to account for within PHP group correlation. Both equations are simultaneously estimated using Seemingly Unrelated Regression.

However, the PHP incremental effects on HDRS scores remained lower and statistically insignificant at the 12- month follow-up, with an ICER of £60,221.98. The higher ICER at the 12-month follow-up is not surprising, as the difference in remission does not persist at this point.

Sensitivity analysis

Table 28 contains different sensitivity analyses. The loss to follow-up or missing observations might not be random. Among other reasons, the participants might not participate at the follow-ups due to either remission from PND or deterioration in their health. Columns 1 and 2 of *Table 28* introduce two deviations from the MAR assumption that was used to impute the missing data. Column 1 (best-case scenario) assumes that the missing utility values are 10% higher than the ones imputed through multiple imputations, and the missing costs are 10% lower than the imputed costs. Column 2 (worst-case scenario) deviation from MAR is the opposite of column 1. The PHP under the best-case scenario resulted in a 0.03 increase in QALYs per person over the 12 months. Compared to *Table 26*, ICER now dropped to £20,733, and the probability that PHP is cost-effective is 48% (60%) if decision-makers are prepared to pay £20,000 (£25,000) to gain one QALY. Under the worst-case scenario in column 2, ICER jumped up to £23,879, and the probability PHP is cost-effective dropped to 40% (52%) at the willingness to pay of £20,000 (£25,000) to gain one QALY.

Incremental costs, effects and ICER for the complete cases are reported in column 3 and incremental costs, effects and ICER estimates after excluding secondary care use are reported in column 4 of *Table 28*. In complete case analysis, the PHP intervention resulted in a positive incremental cost and incremental QALYs gains. The resultant ICER is £29,459. Nevertheless, as discussed earlier, the missing data were not likely to be MCAR. Thus, we would not recommend relying

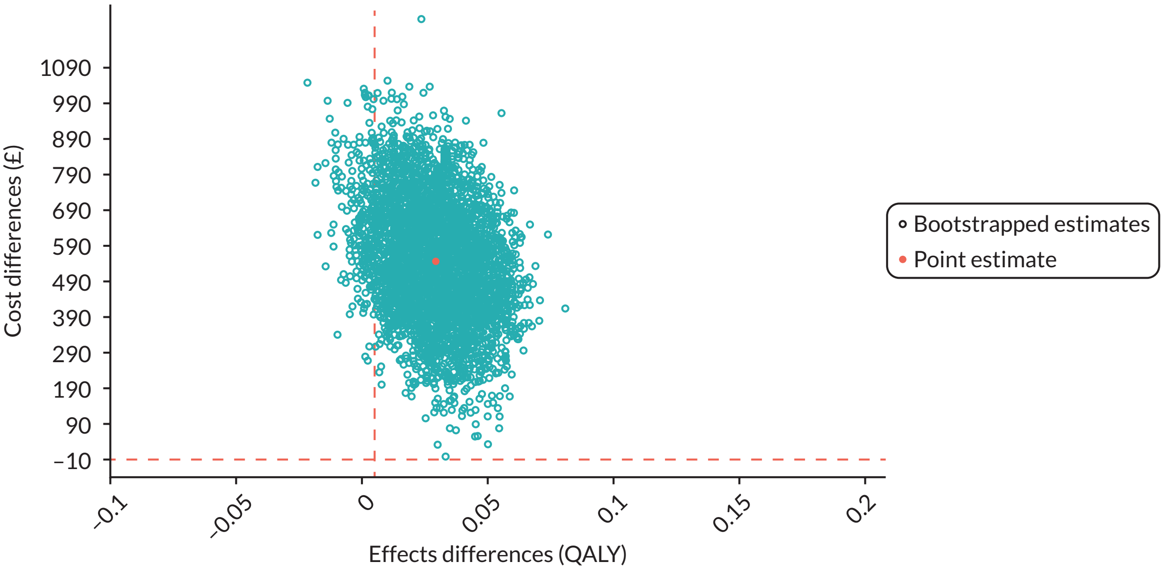

FIGURE 5 Cost-effectiveness plane (bootstrapped with 5000 replications).

on the results of the complete cases. After excluding secondary care use costs, the ICER dropped to £16,961. This is because of the relatively higher secondary care use among the PHP arm participants.

Additional analysis

The PHP intervention comprised 12 sessions and was delivered in a group format. In such programmes, the group size and the optimal number of sessions are important factors in cost-effectiveness. One key question, therefore, is whether there is any minimum threshold of sessions that must be met for the PHP intervention to be effective. Similarly, what might be the maximum number of sessions beyond which the incremental health effects of additional sessions become insignificant, or the costs become increasingly high. The latter question is fundamental in any group learning environment. As the programme progresses, the number of participants will likely fall either because they will recover or the intervention might not fit their purpose. But the costs would not fall by the

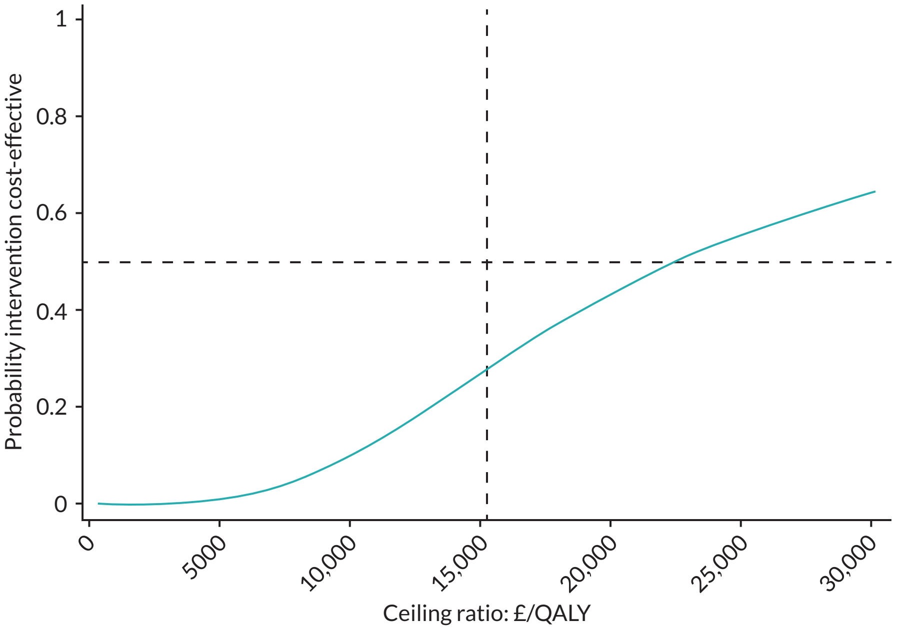

FIGURE 6 Cost-effectiveness acceptability curve for the cost per QALY gain.

TABLE 27 Regression results of incremental costs and HDRS

	Costs effects estimate		HDRS effects estimates	
	Coefficients	**95% CI**	**Odds ratios**	**95% CI**
Effects at the 4-month follow-up				
PHP	569.08	255.74 to 882.43	1.71	1.17 to 2.50
Incremental cost/remission		£4550.73		
Effects at the 12-month follow-up				
PHP	551.55	232.68 to 870.41	1.04	0.72 to 1.51
Incremental cost/remission		£60,221.98		

Note
Standard errors are partially clustered (at PHP group level) to account for within PHP group correlation. The estimations adjust for baseline HDRS, costs, age, qualification and study sites (to save space all covariates are not reported).

same ratio or might not change at all. This will mean increasing per-person costs if the group continues to shrink. Similarly, existing literature suggests that postpartum patients must attend 5–8 sessions to realise the positive effects of such therapies.[113] Depression and QALYs being strongly linked imply that the healthcare use and quality of life effects of PHP might be different for those attending varying numbers of sessions.

TABLE 28 Deviations from missing at random assumption and complete case analysis

	1[a]	2[b]	3[c]	4[d]
Incremental QALY effects	0.03	0.02	0.02	0.02
95% CI	−0.01 to 0.06	−0.01 to 0.05	−0.02 to 0.06	−0.01 to 0.05
Incremental cost effects	548.66	550.71	652.49	405.00
95% CI	242.11 to 855.20	219.44 to 881.98	262.11 to 1042.87	364.23 to 446.00
ICER	£20,733	£23,879	£29,459	£16,961
NMB at WTP = £20,000	£−19	£−89	£−209	£73
95% CI	£−758 to £720	£−801 to £622	£−1199 to £780	£−525 to £670
Probability PHP cost-effective	0.48	0.40	0.34	0.59
NMB at WTP = £25,000	£112	£25	£−98	£192
95% CI	£−771 to £997	£−821 to £873	£−1281 to £1083	£−552 to £936
Probability PHP cost-effective	0.60	0.52	0.43	0.69
NMB at WTP = £30,000	£245	£141	£12	£311
95% CI	£−786 to £1277	£−844 to £1126	£−1366 to £1390	£−580 to £1203
Probability PHP cost-effective	0.68	0.61	0.51	0.75

NMB, net monetary benefits.
[a] Best-case scenario: missing costs = 0.9 × model predicted cost, missing utility = 1.1 × model predicted utility.
[b] Worst-case scenario: missing costs = 1.1 × model predicted cost, missing utility = 0.9 × model predicted utility.
[c] Estimations based on complete cases only.
[d] Estimations excluding secondary care use.

Note
Standard errors are partially clustered (at PHP group level) to account for within PHP group correlation. The estimations adjust for baseline utility, costs, age, qualification and study sites. Both equations are simultaneously estimated using Seemingly Unrelated Regression.

Following the findings in Forde *et al.*,[113] we have divided the PHP participants into three groups based on the number of attended PHP sessions. *Figure 7* presents mean utility scores for three different bands of completed sessions. Those who completed up to four sessions had a better mean utility score at baseline compared with the baseline mean scores of the other two bands. Nevertheless, the one with more than four completed sessions had better outcomes in the post-intervention period. This implies that participants with greater need (with poorer health at the baseline) had taken more sessions than those with relatively better health, and seemed to benefit more from the PHP intervention.

To formally check the dose–response relation and the associated costs, the incremental cost and effects regressions were rerun with the intervention indicator now replaced by a categorical variable on the completed sessions. From *Table 29*, four or fewer completed sessions have no incremental effects on QALY. Thus, this group is strictly dominated by the control arm. For the group who participated in 5–8 sessions, the PHP resulted in a 0.04 increase in QALYs per person. The associated incremental cost of PHP was £387 per person. Based on the QALYs health gains, the ICER was £9,040. At £15,000 WTP to pay, the mean net monetary benefits from PHP were £255 for this group (*Table 29*). For uncertainty check, *Figure 8* plots cost-effectiveness acceptability curves for each of these groups of participants. From the figure, one can see that the probability of PHP is cost-effective for the group with 5–8 sessions is 73% (81%) if decision-makers are prepared to pay £15,000 (£20,000) to gain one QALY. This analysis indicates that QALYs continue to increase with the number of attended PHP sessions. Nevertheless, the incremental positive effects get smaller with additional sessions. Resultantly, 5–8 therapy sessions are more cost-effective than 9–12 sessions.

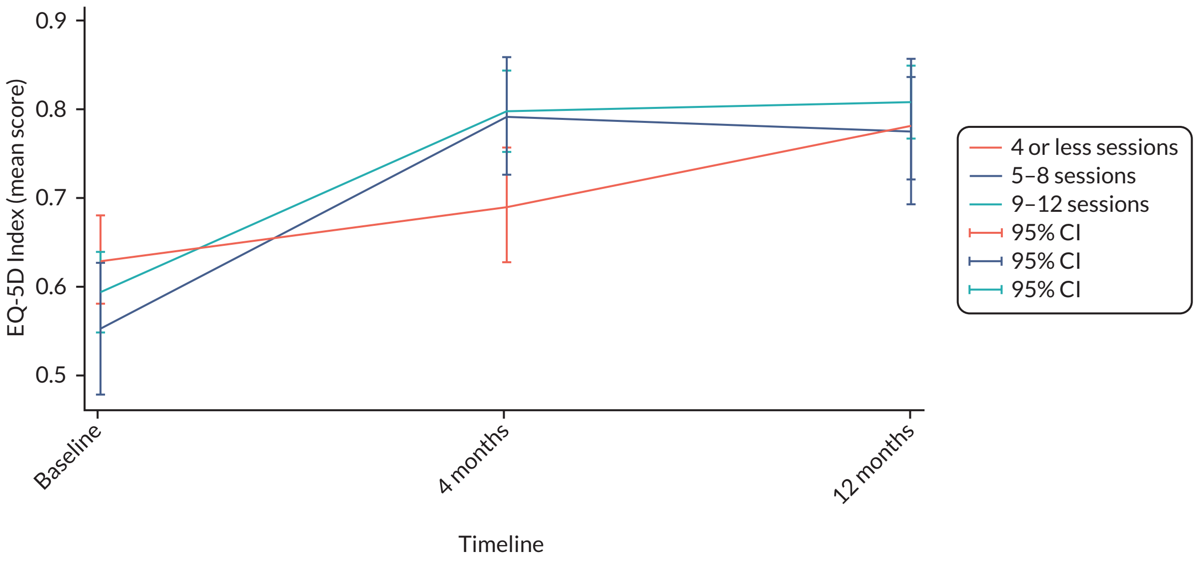

FIGURE 7 Utility scores by completed sessions and time.

TABLE 29 Regression results of incremental costs and QALYs with completed sessions

	Costs effects	QALYS effects	ICER	NMB (WTP = £15,000)
4 or fewer sessions	528.94	−0.00	–	–
95% CI	175.20 to 882.68	−0.05 to 0.04		
5–8 sessions	387.26	0.04	£9040	£255
95% CI	−30.83 to 805.36	−0.00 to 0.09		£−584 to £1095
9–12 sessions	667.54	0.05	£13,127	£95
95% CI	162.78 to 1171.27	0.02 to 0.08		£−658 to £848

Note
The standard errors are clustered at group level to account for within group correlation. The estimations adjust for baseline utility, costs, age, marital status and employment status of the study participants. It includes group-level random intercepts to correct for any within group nesting.

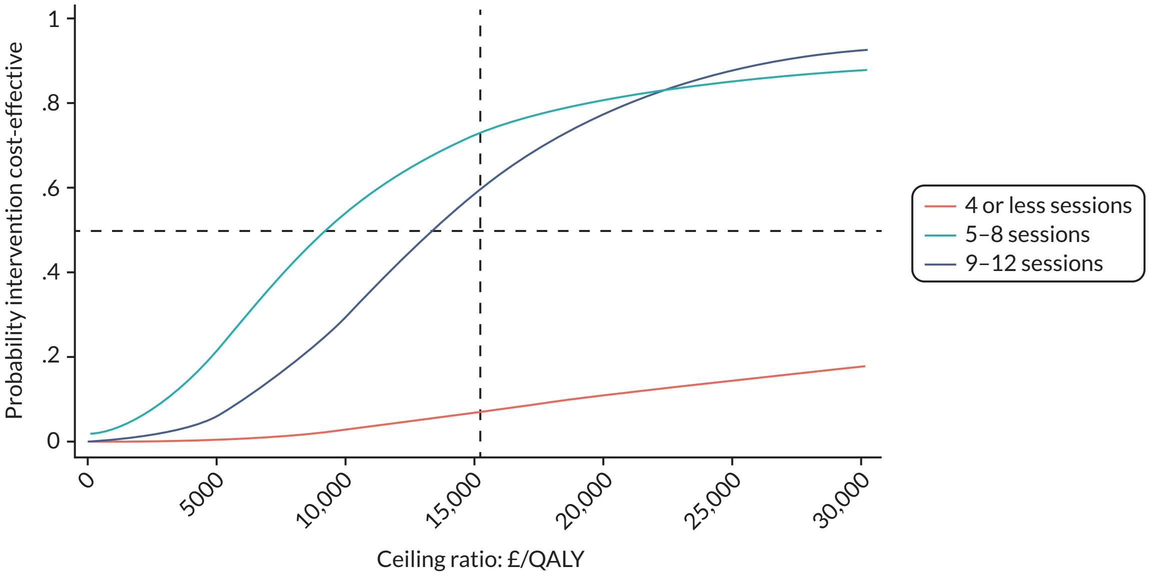

FIGURE 8 Cost-effectiveness acceptability curves by number of sessions.

Since PHP intervention costs were incurred at the group level and were equally divided among the group members, the low cost for 5–8 sessions means that they have either low healthcare use or belongs to groups of low PHP costs. Looking at the data indicated that the per person PHP costs for those with 9–12 sessions were £433 compared to PHP costs of £407 for those with 5–8 sessions. The healthcare uses costs were also higher for those with 9–12 sessions compared with participants who attended 5–8 sessions.

Chapter 7 Qualitative study – (main trial) findings

Introduction

The aim of this qualitative study was to explore the views and perspectives of BSA women, PHP facilitators and GPs on the usefulness of the PHP intervention and how participants experienced it. The study examined the PHP's perceived feasibility, acceptability, and sustainability for managing PND in BSA women in primary care settings. The findings from the PHP RCT (see *Chapter 5*) revealed a statistically significant difference in the primary outcome of depression severity (PHQ-9) between trial arms at 4-month follow-up in support of PHP intervention but not at 12-month follow-up. The qualitative data reported here provides an understanding of acceptability of the intervention components using TFA:[105] affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Objectives

1. To examine the acceptability of the group intervention from the perspective of BSA women and their families.
2. To explore views of the GPs on the group psychological intervention and its impact on practice.
3. To explore perspectives of PHP group facilitators about training and delivery of the intervention.

Methods

Design

Semistructured interviews were conducted with trial participants, withdrawn participants, PHP facilitators and GPs to gather in-depth information on how they perceived the acceptability, engagement, and implementation of PHP intervention. The participants shared their views and experiences of receiving PHP, while PHP facilitators shared their experiences and opinions on delivering the PHP intervention. Interviews with GPs explored their experiences of working with BSA women with PND. Interviews were conducted with trial participants, PHP facilitators and GPs at the end of the intervention period.

Inclusion criteria

Withdrawn trial participants

- Participants who were randomised to the intervention arm and withdrew before completing four sessions of the intervention.

Trial participants

- Participants who were randomised to the intervention arm.
- Participants who attended at least one or more sessions of the PHP.

Positive Health Programme facilitators

- Positive Health Programme facilitator who delivered at least one course of the PHP.

General practitioners

- General practitioners whose practices participated in ROSHNI-2 study.

Trial participants

For the interviews, trial participants were purposively sampled from the PHP intervention trial database, aiming for variation in terms of geographic location, age, socioeconomic status, and ethnicity to enable an in-depth exploration of the perceived impact of the PHP intervention.

Withdrawn trial participants

Trial participants who withdrew were purposively sampled from the trial database to further explore the reasons for discontinuing the PHP trial. Qualitative researchers re-engaged with withdrawn participants by telephone or letter (adhering to their stated contact preferences) to ask if they would consider participating in an interview. Those participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate.

Positive Health Programme facilitator participants

Qualitative researchers phoned or e-mailed all GPs and PHP facilitators to ask if they would be willing to participate in an interview. Interested individuals were e-mailed a PIS with information about the qualitative study.

General practitioner participants

General practitioners involved in the trial were e-mailed to participate in an interview. Interested individuals were e-mailed a PIS with information about the interview study.

Study materials

With input from patient and public involvement, the research team developed separate sets of topic guides for trial participants, PHP facilitators and GPs during the internal pilot period. These topic guides were further refined after the completion of interviews in the internal pilot to inform the interview topic guides in the main trial.

Data collection

Qualitative researchers conducted interviews at a convenient place and time according to participant preferences, either face-to-face interviews at the participant's home, in neutral settings, such as a children's centres or community centres, or over the telephone. With the consent of participants, all interviews were audio-recorded, transcribed verbatim, and anonymised before data analysis. The recruitment period for the qualitative study was from February 2017 to March 2020.

Qualitative data analysis

Initially, the data analysis plan was to utilise a framework analysis, however, the research team employed thematic analysis to discern and highlight significant themes. The themes were subsequently applied to the TFA, specifically focusing on assessing the intervention's acceptability across the seven domains outlined within the framework. This dual methodology facilitated a comprehensive exploration and evaluation of the intervention's acceptability within the study's specific context.

Interviews conducted in English were transcribed verbatim. However, interviews conducted in languages other than English were translated into English and then transcribed verbatim by the qualitative researchers; and analysed by two qualitative researchers. The transcripts were read to identify key themes linked with the qualitative study's aims. An iterative procedure was used to generate new codes, and specified codes were developed as the analysis progressed. After completing the initial coding, the codes were reduced into various themes. The specified key themes focussed on both parts of the study: the support experiences of trial participants and the perceived effectiveness of PHP (trial participants, PHP facilitators and GPs in the intervention arm). After that, transcripts were revisited, and the first qualitative researcher identified developing subthemes within each central theme with the second researcher and through ongoing discussions to agree on, and finalise, themes.

The GP interviews were analysed using only thematic analysis to identify key themes. For the trial participants and the PHP facilitators' interviews, the researchers deductively charted the themes into the seven acceptability domains in the TFA.[107] The TFA was used to analyse the trial participant's and PHP facilitators' data. The TFA is a multiconstruct theoretical framework that can be applied to assess the retrospective acceptability of healthcare interventions from the perspective of intervention recipients. The TFA consists of seven component constructs. These seven components were used as a framework for analysis: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

To enhance reliability, all interview transcripts were coded in NVivo by the first qualitative researcher; then, transcripts were coded by the second qualitative researcher. The experiences of participants were charted to summarise and link to the matching themes and subthemes. Both qualitative researchers met to discuss the identified themes, and the discussion continued until a consensus was reached. Descriptive quotes were included to support the validity of the findings.

Results findings

A total of 61 participants were purposively sampled for interview purposes (32 trial participants, 13 withdrawn participants, 11 PHP facilitators and 5 GPs). These participants were chosen based on their relevance and significance to the research objectives.

Interviews with participants lasted between 30 and 60 minutes. Interviews with PHP facilitators and GPs took place over the phone and face to face. PHP facilitators and GPs' interviews lasted between 30 and 60 minutes. Where appropriate, women who did not speak English were interviewed in their preferred language with either an interpreter or a bilingual interviewer. Following the interview, trial participants were offered a £20 shopping voucher to thank them for participating.

In total, 35 interviews were conducted as part of the study. These interviews encompassed a diverse range of participants, including 17 trial participants and 2 withdrawn participants, 11 PHP facilitators and 5 GPs. The trial participants demographics is detailed in *Table 30* and details of the PHP facilitators in *Table 31* and GPs across the different regions in *Table 32*.

The findings are reported under the seven domains of the TFA:[105] affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy. These are explored in detail below, and descriptive quotations illustrate the interview data findings.

Affective attitude – how an individual feels about taking part in the intervention

Trial participants reflected on how they initially felt about being invited to participate in the PHP. They discussed initial concerns about confidentiality and, how the members of their community and family network would perceive them, and developing self-confidence to talk about themselves with others in a group setting:

> *I thought people would judge me … I never attended group counselling … everyone else will know your problems and I know they are not supposed to share it, but they might share it.*
>
> *Trial participant MD-003*

Most of the trial participants we interviewed expressed positive attitudes about the intervention. Participants highlighted the specific positive therapeutic content of the intervention. Also, they voiced a general appreciation of the non-therapeutic specific elements such as child-care facilities, refreshments, time away from their daily routine and the opportunity to meet with other women:

> *It was a treat honestly … good food, childcare I made friends learnt some very good things which help me in my daily life … Truly it was time for me, I will always remember it. Everything was really good. Can't be thankful enough, these sessions have really changed my life.*
>
> *Trial participant LO-003*

TABLE 30 Qualitative study – trial participants' characteristics (including withdrawn participants)

Characteristics	*N* = 19
Age	
18–25	1
26–35	14
36–45	4
46 +	0
Ethnicity	
Bangladeshi	2
Pakistani	11
Indian	5
Sri Lankan	1
Trial region	
North West	4
East Midlands	5
London	6
Yorkshire	4

TABLE 31 Qualitative study – PHP facilitators' characteristics

Characteristics	*N* = 11
Ethnicity	
Bangladeshi	3
Pakistani	6
Indian	2
Sri Lankan	0
Trial region	
North West	1
East Midlands	4
London	5
Yorkshire	1
Educational attainment	
Postgraduate	4
Master’s and postgraduate certificate	3
Competence-based qualification	3
Information missing	1

TABLE 32 Qualitative study – GPs' characteristics

Characteristics	*N* = 5
Ethnicity	
Bangladeshi	0
Pakistani	4
Indian	0
Sri Lankan	1
Trial region	
North West	3
East Midlands	0
London	2
Yorkshire	0

PHP facilitators with South Asian heritage discussed how they were inclined to apply for the advertised PHP facilitator's role to work specifically with BSA women. They highlighted their interest in the project due to its explicit nature in targeting BSA women and maternal mental health, highlighting this as an area requiring greater attention and health support from health professionals:

> *When I applied for the job, it sorts of appealed to me because it was working with the ethnic minority community. I think that's an area that we do need to sort of tackle and raise awareness of the stigma that is associated with mental health and especially maternal mental health. So that's sort of like why I wanted to sort of go forward for the role.*
>
> *PHP facilitator WY-008*

Similarly, another PHP facilitator reported:

> *I just generally think it's a good piece of intervention especially in terms of developing and helping the South Asian community and whenever I've gone out and have talked to people about it to some participants or even if it's a professionals or community they always kind of seen it as a really a good therapy which is something needed out there. So, I just think it's a really good initiative.*
>
> *PHP facilitator LO-009*

Participants perceived the intervention as providing a better understanding and resonating with their value systems, whether from the PHP facilitator's or trial participants perspective. Most participants agreed with the idea of the design and strategies used for delivering the intervention:

> *It's just very good, obviously, to have that manual with us because the manual has everything in it. Every part, every exercise, everything even after this is my fifth group as still; I am referring to the manual sometimes. The manual obviously gives us you know readymade guide to deliver the sessions. Quite good obviously the manual is arranged in a way that all of the women can be part of the session.*
>
> *PHP facilitator LO-001*

The data extracts used to illustrate the affective attitude from the PHP facilitator's interviews reflect that PHP facilitators generally felt confident and well equipped to deliver the intervention effectively to ensure that knowledge and understanding are transferred to the women. Their satisfaction with the intervention and connectivity to the individuals' value system shows that such a programme requires invested time and engagement. The intervention was perceived by most participants as acceptable and could produce impactful results for BSA women with PND in the context of inclusivity and raising awareness.

Ethicality – the extent to which the intervention has a good fit with an individual's value system

Many participants discussed the perceived stigma associated with mental ill-health and postnatal depression in the BSA community. A trial participant used the term 'narrow-minded' to describe the BSA community. However, in this context, PHP was primarily seen as a culturally sensitive intervention addressing their value systems and viewed as beneficial:

> *In the Asian community it's a stigma definitely and even people don't understand mental health and they don't look after it as they do about their physical health ... yes, I think they should open up and should tell their family to engage and especially husband and wife can both work together and should support each other.*
>
> *Trial participant WY-003*

> *These sessions were beneficial for me that they kept my confidentiality but also provided me with right support that I was looking at that time. I had family support, but I am talking about professional support as I also work in health care, and I know the importance of professional support, so these sessions benefited me a lot.*
>
> *Trial participant WY-004*

Intervention coherence – the extent to which the participant understands the intervention, and how the intervention works

Prior to starting the intervention, most participants' viewed PHP as a support tool that would enable them to address their condition and/or facilitate problem-solving and understood its intended purpose:

> *I thought then that I am depressed, and it might help me as I was looking for some support to get me out of my poor situation.*
>
> *Trial participant LO-003*

Participants reflected on what they had understood about PHP through the sessions they had attended:

> *Each session was about a different topic … so it explored different things, one I think was assertiveness, saying no to certain things I think that helped me a lot … it was basically working on yourself, and trying to identify the problems you have to build your self-esteem back up, so that helped yeah. I did work on my self-esteem and also started saying 'No' when I wanted to.*
>
> *Trial participant MD-003*

In addition, most PHP facilitators reiterated the importance of the intervention for BSA women. One PHP facilitator shared her thoughts on how her own life experiences resonated with trial participants' circumstances:

> *When I heard about this study, I said this is something very close to my heart and I want to work with at that, and being a mum, being a British Asian woman I can understand what it feels like, don't have your family here and the challenges and the problems one faces when we have a baby without any support and sometimes we have support but it's what we go through so it's quite close to me as well.*
>
> *PHP facilitator MD-013*

Most of the PHP facilitators stated the importance of improving the mental health of the BSA community, especially the needs of participants who recently immigrated and were tasked with the families' household chores and responsibilities:

> *The South Asian British women, who are coming, I mean, from the group we had, I realised that, when mums, mostly mums have come from Bangladesh or India or Pakistan. And then they come here, they don't have a family support over here, so that they have to do everything on their own and there's already too much on their plate that they have to look after the family they have to do household chores and then the baby. The mother is already so tired and there is so much psychological adjustment to motherhood, that no one, no one else is able to understand that.*
>
> *PHP facilitator LO-009*

Positive Health Programme facilitators talked about their satisfaction with the training, which added value to their understanding of the intervention. Subsequently, many seemed to understand the aim of the intervention clearly and felt confident in delivering the intervention. PHP facilitators viewed the objective of the PHP to help BSA women to be active, and a few PHP facilitators highlighted that particular session on confidence building, assertiveness and self-esteem were favoured highly by many of the trial participants:

> *I think most of the women at the end of our sessions in the last two sessions we ask if they want to repeat any sessions? That they really enjoyed and want to go back to and for me I think it has been the confidence and assertiveness and the self-esteem one, these are the two areas that mums really like to focus on.*
>
> *PHP facilitator NW-001*

Burden – the perceived amount of effort that is required to participate in the intervention

Managing attendance at the sessions and balancing child-care needs was perceived as challenging by a number of trial participants; which was reflected in their limited availability to attend all sessions:

> *I have other kids, and I was concerned about them although they provided the taxi and as well as crèche which was really very good. It was just that I was concerned about my kids, so I became less interested, and this made me skip the sessions.*
>
> *Trial participant WY-001*

In contrast, PHP facilitators perceived their attendance as requiring little effort and not very difficult overall to attend and deliver PHP sessions, mainly due to the group delivery approach used:

> *It was not that difficult for facilitating because most of the women who were part of the group where you know recruited by myself, sometimes by myself and sometimes by others and we went to zero visits. For zero visits where you go and invite them, and that part made me familiar with these women and obviously made me confident to go in front of them and obviously facilitate the training.*
>
> *PHP facilitator LO-001*

Opportunity costs – the extent to which benefits, profits, or values must be given up engaging in an intervention

Although child-care and benefits such as taxi fares for transportation and refreshments were provided to trial participants, PHP facilitators indicated that a few women could not attend some sessions for various other reasons:

> *And that's just down to individual circumstances, you know the babies falling ill or the mums are or falling ill but there were a few mums who didn't attend all the session you know when you just can't be bothered.*
>
> *PHP facilitator NW-002*

Some PHP facilitators highlighted how it was easier to engage the women and retain them during the intervention; however, they struggled with a lack of co-operation from the trial participant's family members, head of household, especially spouses of women.

Perceived effectiveness – the extent to which the intervention is perceived as likely to achieve (or have achieved) its purpose

Most trial participants perceived the PHP intervention as likely to achieve its purpose:

> *I am feeling so much better … I got a lot of confidence, and I was a bit hesitant to communicate with other people in public, but I don't hesitate now … I don't even fight with my husband anymore, only thing to complain about was I wake early and sleep late.*
>
> *Trial participant LO-005*

However, other trial participants reflected that although PHP was perceived as effective, their low mood still persisted:

> *I feel good but sometimes you just feel like … you don't have the support there when sometimes you feel low … it's made me think how to improve myself, help myself so I think that same time it helped me with my depression so it's made me do more things … it will take some time obviously to deal with everything but it's getting better.*
>
> *Trial participant MD-003*

Closely linked to trial participants' views on intervention coherence, PHP facilitators also observed that group intervention helped trial participants. The group interaction with other BSA women with similar experiences, motivated each other to increase their physical activity and boost their self-esteem, and establish trusting relationships:

> *The research study and the results prove from the feedback of women and the way we noticed changes in them when we see them on the screening and during SCID assessment and on celebrations day, session eleven and celebration day we could tell the difference from majority of moms.*
>
> *PHP facilitator NW-002*

Self-efficacy – that participant's confidence in change of behaviours using Positive Health Programme

Participants talked about their learning from PHP, for example, using time more effectively, being assertive, and planning self-care. Self-efficacy findings defined the PHP facilitator's confidence in delivering the intervention sessions. Most PHP facilitators reported feeling confident about providing and completing the sessions effectively. PHP facilitators' views were consistent in delivering the sessions confidently and taking control of the sessions that brought an unprecedented change in the participants and improved their self-esteem.

Positive Health Programme facilitators reported satisfaction in terms of training that prepared them effectively in delivering the sessions and appreciated the opportunity to be trained before delivering the sessions:

> *At the beginning I was a bit apprehensive like to run a group because I hadn't really done that before so I was wondering like would I be able to do it. Like we had the manual as well so we just worked through that and most of the time I was co-facilitator but there were parts when the lead facilitator was off sick and stuff, so I had to do the group on my own. So, I think that really developed my confidence and I was able to run the programme.*
>
> *PHP facilitator NW-001*

The PHP facilitators noted that most women found the PHP intervention appealing, positively influencing their willingness to attend the sessions. However, a small minority of women exhibited hesitancy towards participation. Additionally, when these women did take part, their engagement in the group activities appeared limited or lacking in enthusiasm.

General practitioners' perspectives

Five semistructured interviews with GPs were conducted to understand their experiences working with BSA women with PND. The interviews also explored GPs' insight on the perceived feasibility, acceptability, and sustainability of the PHP in managing depression in primary care. The interviews were conducted in the North West (n = 3) and London (n = 2).

Four key themes from the interviews centred on: PND and its associated factors of stigma and culture, challenges experienced interacting with BSA women, increased support for BSA women and engaging BSA women though the ROSHNI-2 trial. The emerging themes from the interviews with the GPs reported below were similar to those conducted with the BSA women and the PHP facilitators, particularly related to the stigma of seeking help for PND.

Theme 1: postnatal depression and its associated factors of stigma and culture

The majority of the GPs discussed the barriers they faced when interacting and consulting with BSA women who might have a diagnosis of PND. They described that women hesitated to approach primary care services due to the stigma of PND. They suggested that even though women may have symptoms that may represent a depressive illness, they did not openly express themselves and 'kept up with appearances' in front of the family because they did not want to get labelled:

> *It is very much common in South Asian women, but the stigma is there because as soon as you tell someone that you have mental instability and you need some help they get very scared about it because you know there is a stigma and they don't want to get labelled.*
>
> *GP NW-001*

The GP explained further the concerns that many patients might deny feeling depressed or have a lack of awareness of PND:

> *I have worked in different areas there are religious and culturally sensitive areas and supporting women from such backgrounds is very different because they are not very much open about it and as Asian women never come to us and say that I am feeling depressed, and I need your help. They do more with more somatic problems like my tongue is numb, my throat is numb, my hands are numb. They come with different issues they are related to more physical rather than psychological and they do not recognise that they are going through postnatal depression because there is a stigma behind it.*
>
> *GP NW-001*

One GP viewed PND from a cultural viewpoint where the expectation is that depression should be internalised and not disclosed:

> *I think it all comes down to the fact that you know what, in that culture, you've had baby, you're a mum, it's a happy occasion and if you're not feeling happy, there is something wrong, therefore, you hide it, you don't tell people, you cover it up. It's just the way the culture is.*
>
> *GP LO-004*

General practitioners suggested that women from South Asian backgrounds typically kept personal problems to themselves and did not take conversations and feelings out of the boundary of the house. GPs postulated that this stopped many women from actively seeking out support even if they were feeling low in mood:

> *There is also pressure not to disclose mental health problems and just to bear the problems and get on with things.*
>
> *GP LO-004*

The GP continued:

> *There are cultural issues as in they won't always bring certain things to the forefront, for example, postnatal depression. It's not a thing in this community to talk about and bring it up. So unless you've got high suspicion or somethings happened, it's not they are willing to bring forward.*
>
> *GP LO-004*

General practitioners suggested that the stigma of postnatal depression was even more pronounced for women who had immigrated from South Asian countries to the UK as compared to women of South Asian descent who were born and raised in the UK:

> *Very few women specially women who are moving from Pakistan they don't really actually connect here in the system but those girls who are born and bred here in this country they are slightly different they are a bit more open up.*
>
> *GP NW-001*

The interviews with the GPs suggest that the stigma associated with PND prevents BSA women from actively seeking help. The associated stigma acts as a hindrance; even though women might feel the need to seek professional help for depression, they hesitate and instead try to internalise their feelings.

Theme 2: challenges experienced interacting with British South Asian women

This theme highlights the unique challenges experienced by the GPs when interacting with women from South Asia or of South Asian descent. These include following an indirect versus a direct approach to build rapport, discomfort interacting with male GPs, not having enough psychologists from ethnic minority backgrounds, and missed appointments. As mentioned in the first theme, the GPs reported the initial barrier of fear of stigmatisation and labelling that BSA women faced while approaching primary care services. For those women who did approach the GP, the doctors faced several challenges in building rapport with them and setting an appointment for follow-up discussions.

Indirect versus direct approach

The first challenge was related to the number of follow-up appointments until the time the women finally opened up about depression and the need for help. GPs suggested that women often avoided talking about their own negative emotions, and most of the GP participants reported having to take an indirect rather than a direct approach when asking the women about their PND symptoms:

> *The biggest challenge is to engage them. They need help and when they come regularly to the surgery bringing their child in and if they are going through any psychological issues they will try linking to their somatic problems and they don't accept and agree that this is postnatal depression problem they don't accept the fact. They don't actually tell you openly that they are depressed.*
>
> *GP NW-001*

The GPs felt that culture had a strong influence on the way the women presented their problems and had discussions with their doctors:

> *Well it's interesting, the people from the Asian communities will present things in a different way, whereas people from the white community may come and tell you things much more straightforward.*
>
> *GP LO-005*

In recounting their experience of women not seeming to disclose their problems, GP participants said they followed an indirect approach to help the women feel comfortable and discuss their symptoms:

> *We have to be very careful and we cannot put anything on risk so we carefully phrase the question to find out they are feeling depressed like a routine check of the baby in 2 to 3 weeks' time and try to see how Mum is getting along.*
>
> *GP NW-002*

The indirect approach was also recommended by another GP, who commented:

> *Not to ask direct questions like are you feeling low or are you feeling depressed … like we ask the new baby has arrived how you are getting along with your sleep.*
>
> *GP NW-001*

Perspectives of male general practitioners

The male GPs interviewed felt that cultural perceptions about not disclosing feelings openly, especially in front of a male GP, made it difficult for the doctors to establish a connection with the women. This became even more difficult because most of the women were accompanied by their family members for the appointment and could not openly speak up about matters which were troubling them:

> *But sometimes they don't make eye contact but making a full eye contact with a male GP is rare however it is difficult to get them engage sometimes we can sometimes we cannot or we get a translator even when they come along with any family member it can [be] difficult to speak and voice out. Also, difficult to talk about the domestic abuse and they are not comfortable to speak to a male GP or somebody else's presence.*
>
> *GP NW-002*

Lack of psychologists of ethnic minority backgrounds

General practitioner participants suggested that many BSA women did not approach primary care services because of the lack of availability of an adequate number of psychologists and translators from similar ethnic minority background in the healthcare system. This made the women lack enough confidence to share their feelings:

> *Well it's not PND alone … and one of the reasons is there is not enough psychologists with ethnic minority backgrounds and experience, trying to get a psychologist with that is challenging.*
>
> *GP LO-005*

Language was considered a barrier by a GP participant since the women at times were not able to make a GP appointment:

> *So sometimes ringing at the surgery and making appointment is difficult for them because there has to be somebody who can speak the language we don't have all the receptionists who speak their language. So I feel people who really need to see the GP there is a barrier to access the service due to language.*
>
> *GP NW-003*

Given the stigma of PND perceived by women and their families, the GPs faced challenges in building rapport with the women during the initial appointments due to the lack of acknowledgement by the women feeling depressed. The GPs took an indirect rather than a direct approach to enable the women to acknowledge their emotional difficulties and the need to actively seek counselling. However, there were several barriers faced by GPs in ensuring the BSA women accessed mental health services. These included not wanting to see a male GP, language barriers, the women's lack of education, insufficient translators, or lack of psychiatrists and mental health practitioners from an ethnic minority background.

Theme 3: increased support for British South Asian women

A key issue highlighted by GPs was that support seeking for postnatal mental health problems needed to be prioritised, since many BSA women struggled to accept that they were depressed due to the associated stigma and fear of being labelled. The GPs interviewed had a practice of not prescribing antidepressants straight away but rather advising follow-up appointments or meeting with the counsellor or community mental health team:

> *I try not to prescribe them straight away because some of the mums are breastfeeding and it is not good to prescribe such medicine. I don't actually start antidepressants straightaway and I tried to speak to them and discuss the issues they are going through that is the approach I take.*
>
> *GP NW-001*

However, GPs felt that the current assessment and support that was being offered was not optimal because of a lack of adequate follow-ups and not knowing whether the women did take up the counselling services that were offered to them:

> *I'm not aware of anything in the community that I can refer them to or any services. We can signpost them to midwives and health visitors. If they're antenatal, I know they've had a history we've flag it up to the midwives but we don't really have much input with the midwives. Again, I think its funding shortages, there is not much of a dialogue with health visitor.*
>
> *GP LO-004*

Some GP participants suggested group psychological intervention as an appropriate form of delivery for women to help them discuss more openly about PND and increase awareness and acceptance:

> *I think it (group therapy) works for everyone because women do not open up about their issues easily however if they are in a group they will be is they will get the support that helps them to discuss their issues and can talk to each other and make friends regarding baby and their other issues and can become more socialize.*
>
> *GP NW-001*

The GPs were also asked about their opinion on the place of delivery of group interventions for women. A GP participant felt that a community versus a formal hospital setting would be more appropriate:

> *I think community setting would be better because many time they have travel issues because if they don't drive they depend on someone to take them to that place so within the community it will be convenient plus travel cost is also an important part is here. So if they have to pay for a taxi and travel to a distant place they may probably would not go.*
>
> *GP NW-003*

Theme 4: engaging British South Asian women though the ROSHNI-2 trial

The GPs interviewed were supportive of the ROSHNI-2 trial as a possible way forward to engage with BSA women facing PND:

> *Yes, I have come across (patients) and have got some very positive experiences and I have not come across anyone who had negative experience of Roshni.*
>
> *GP NW-002*

The GP highlighted that the group therapy format of the ROSHNI-2 programme made it particularly appealing because it was reminiscent of the kind of peer support typically available in South Asian countries for women after the birth of their baby:

> *I think it would (work) because it draws cultural relations of peer support South Asia and community anyways back home which they expect to have access to. There is different mentality but it's about community raising children so extended family network and can break us down over the time and if the networks will be there and the support for the new participants. So, I think this new model works very well from the culture support perspective and peers support of the other participants who are going through the same situation.*
>
> *GP NW-002*

One GP participant reflected on initial reservations about whether the PHP intervention and the group therapy format would generate interest for participation but later realised the benefit of such a format:

> *I think when you first started I had my doubts about people getting involved with that but with time I realised there are a lot of people open to it because nothing much happens specific to BME patients so people are happy to get involved with this. So I think people just need to get used to the idea of groups and speaking to health professionals.*
>
> *GP LO-005*

General practitioners perceived that women's participation in the ROSHNI-2 trial had led to fewer *women with postnatal depression being seen in the practice:*

> *Yes, I think so and it has (ROSHNI-2 trial) deflected so many GPs appointments and so many issues that we probably would have taken ourselves as we had very positive feedback from Roshni. When I see patients bringing their children in and talk about their health and how their mental health is progressing, they provide such a positive feedback and are doing wonderful. So, in other ways it is impacting our workload and helping us to support these mums.*
>
> *GP NW-002*

Taking different approaches in the place of delivery and piloting the PHP intervention was discussed by GPs:

> *GP would be one because that's where they're all going to. If it was highlighted in the community, and then you work alongside the GP units, it can be delivered in the community, it can be delivered one to one, it can be delivered as groups. If it's a community venue that everyone goes to, it can be done there.*
>
> *GP LO-004*

Discussion

The qualitative study for the main trial explores the experiences of BSA women participating in the PHP. Initially, participants had concerns about confidentiality and feared judgment from their community, but as they engaged with PHP, their outlooks loosened positively. They valued the therapeutic content and practical components like child care support and the opportunity to associate with other women facing similar challenges. PHP facilitators, mainly those with South Asian heritage, were drawn to the project due to its focus on maternal mental health and its potential to reduce stigma. Regardless of challenges like child care and family co-operation, participants and facilitators perceived the intervention as culturally sensitive and beneficial, posing valuable skills and support to improve mental health.

In addition, GPs supported the ROSHNI-2 trial as an encouraging approach to engaging BSA women facing postnatal depression. The group therapy arrangement of the ROSHNI-2 programme was viewed positively. The study highlights the potential of interventions like PHP to address mental health issues in this community effectively and reduce the stigma surrounding PND, offering hope for improved well-being among BSA women.

Chapter 8 Qualitative substudy

Remote delivery of the Positive Health Programme intervention during COVID-19 pandemic

Introduction

During the COVID-19 pandemic period, due to the social distancing rules, the research team sought ethical approval to continue the PHP intervention delivery remotely via video-conferencing platforms to ensure research continuity with participants. This substudy aimed to understand participants' views on the perceived feasibility, acceptability, and sustainability of the face-to-face versus remote delivery of the PHP intervention, and the PHP facilitator's perspectives on the mode of delivery of the PHP.

Method

Design

Semi-structured interviews with a subsample of trial participants and PHP facilitators were conducted to understand their perceived feasibility, acceptability, and sustainability of the face-to-face versus remote delivery of the PHP intervention.

Sampling and recruitment

We aimed to sample 15 participants. Participants were sampled purposively from two larger study sites – London and North West England. Trial participants were invited to include those who attended both face-to-face and video-conferencing sessions of the PHP intervention from different socioeconomic backgrounds, ages, and native languages. PHP facilitators were invited to include those who delivered both face-to-face and video-conferencing sessions of the PHP intervention.

Analysis

We used thematic analysis to identify key themes. Key themes were charted into the seven acceptability domains in the TFA. The seven components were used as a framework for analysis: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Results insight findings

A total of 10 trial participants and seven PHP facilitators took part in the study (*Table 33*). The findings informed the changes in the mode of delivery of the PHP sessions during the COVID-19 pandemic from face to face to a video-conferencing platform.

TABLE 33 Interview participants

Location	Trial participants	PHP facilitators
North West	8	5
London	2	2
Total	10	7

Findings

Affective attitude – how an individual feels about taking part in the intervention

Trial participants reflected on their feelings about engaging remotely in the PHP sessions and compared the experiences with face-to-face participation in earlier sessions. The responses shared by trial participants for the virtual delivery platform indicated that they had initial reservations about confidentiality and felt hesitant to speak about themselves in front of others in the household. They also felt that, compared to the virtual sessions, in the face-to-face format, they had a chance to enjoy some 'me-time' with other mothers who were going through similar experiences. They mentioned they missed the non-therapeutic elements, such as child care facilities, which were offered in the earlier sessions, refreshments, time away from daily routine, and the opportunity to meet with other women:

> *Firstly you get a change of environment, freedom of speech because when you are home the kids and husband is home so you cannot speak openly and secondly we need to attend the kids simultaneously as we are attending the sessions, and on top of it the most important thing is that when we see each other we have snack time or casual me time and we can go a little bit early or a little bit late, we have a play area for kids there and when the session finishes we can talk to each other or can have more interaction. So, I think face to face is helpful.*
>
> *Trial participant NW-033*

Elaborating further on the comparison between the two modes of delivery, trial participants appreciated the personalised connection built by seeing each other face to face and felt this was missing during the online sessions:

> *I would prefer face to face because the way you can talk face to face it's much better you can be more friendly you can like when you're in front of somebody its different to when you're over the phone like you cannot see each other's faces that much and you can't see the person you are talking to properly so I would prefer face to face you can have a better connection face to face.*
>
> *Trial participant NW-033*

Burden – the perceived amount of effort that is required to participate in the intervention

Due to the online format of the intervention, the usual support service, such as child care, was unavailable during the session to the trial participants. Many participants found it challenging to attend these sessions and the other household responsibilities. As a result, some of them struggled to attend the sessions with complete attention and found it challenging to fully engage where they could learn new skills effectively:

> *I think it is like when we are attending the online sessions it happened to me like I was sometimes cooking while attending the sessions and which is sometimes very distracting and sometimes kids used to attack me and it was only that time which was my me time when I used to attend the class however there was a lot of other stuff going around which was unavoidable and what other participants also said about it that it was difficult at times to attend the sessions with complete concentration. So, I think online sessions have a lot of distraction.*
>
> *Trial participant NW-05*

The trial participants reflected on how they felt about engaging remotely in PHP sessions and reported that in face-to-face sessions, they could express themselves better and get a change of environment:

> *The face to face is better actually, because in a face-to-face session you were able to leave the house and could go out of the house in a different environment and speak with freedom and can express your problem in a better way.*
>
> *Trial participant LO-04*

The PHP facilitators expressed their concern as well related to the constant challenge of keeping the participants engaged for up to 90 minutes when many of the mothers were multitasking, such as looking after the baby or doing some household chores while attending the sessions. Though the facilitators maintained the protocol by sending reminders to the participants for these sessions regularly, however, it appeared a burden:

> *As the sessions are delivered remotely it is difficult to keep the attention of the mums on the session for a longer time and is very challenging to engage the mum while she is taking care of the baby. So it is difficult to suggest anything, however, most of the mums attended these sessions regularly.*
>
> *PHP facilitator NW-047*

The majority of the PHP facilitators who delivered the virtual intervention sessions expressed their concerns in terms of the technical aspects of having to shift to virtual sessions since they felt the trial participants were not very comfortable with using technology:

> *I would not say virtual sessions are better than face to face because we had a couple of mums who did not know how to go about managing Google hangout joining the conversation knowing that they have to mute not every mother was equipped technology-wise.*
>
> *PHP facilitator NW-011*

Likewise, most of the PHP facilitators preferred face-to-face sessions over the remote delivery of the PHP sessions for a number of reasons, such as lag in response time after a task because the trial participants were not there physically, and they had to wait for their responses as well as persistent connectivity problems:

> *There is a lot of difference like online we say something and then wait for the response than we need to be prepared for things that may go wrong like internet issue or connection issues.*
>
> *PHP facilitator NW-032*

Some of the PHP facilitators, however, acknowledged that the remote sessions were useful and stated that such sessions facilitated participation for trial participants who were unable to travel or were bound to their house due to their responsibilities. They felt that because of the online nature of the sessions, participation became possible for them. One of the trial participants mentioned:

> *I can say that remote one is good in a way that if you do not have time and cannot go out of the house you can still attend the session as when the baby is young you need to arrange so many things before you move out of the house so I think remote delivery is better than face to face.*
>
> *Trial participant NW-006*

The views of the trial participants and the PHP facilitators reflect that even though the study helped the trial participants engage during the lockdown, the virtual sessions were not always easy to manage due to internet connectivity, initial hesitation in using technology, and multitasking. There was a clear preference for attending face-to-face sessions over remote sessions.

Ethicality – the extent to which the intervention has a good fit with an individual's value system

Trial participants were positive about receiving PHP intervention and considered it as an important step forward to address postnatal depression. Most trial participants agreed that discussion about mental health in South Asian communities is challenging, as it is perceived as a stigma. Some of the participants also explained that the community usually has no awareness about postnatal depression and simply disregards its existence or labels a woman facing postnatal depression as a mad or psychotic person (NW-005). The participants considered PHP to have a good fit with their value system:

> *I think we should have more open seminars and more open sessions or open talks about this problem like Roshni-2 is doing a research-based work or session. So I believe there should be more studies like that which is more open to mums moreover, there is a language barrier there is an approach barrier and education barrier so I think the best way is that say for example I have been part of the group and if I have been by one of the Roshni members that we need more mums I will spread the word out and will assist in getting the help to the mums who need it.*
>
> *Trial participant NW-033*

However, there were a few confidentiality issues raised in conducting the remote sessions. As the term depression is stigmatised in the BSA community, some of the trial participants felt it was a great challenge to speak openly and maintain confidentiality during the remote sessions:

> *I did not feel comfortable especially when I used to discuss my in-laws in front of my husband. It's not that he does not understand but I used to feel bad and I avoid talking about his family and he understands, and he knows what I have gone through because of them and I think it is kind of insensitive to speak about his family in front of him so that was the only part I think.*
>
> *Trial participant NW-005*

The PHP facilitators reported that though postnatal depression is a stigma in BSA communities, the content of the intervention supported the value system of the mothers and helped them to connect more effectively with their values:

> *I think culturally adapted therapies for mental health are beneficial. The reason is that there are a few times when we speak to mums they open and say that the reason I am speaking to you is that you are speaking my language and this intervention is doing the same. It gives you a sense of understanding and not being judged. So, I think this kind of intervention is very important and further narrows it down to a certain community to be able to interact and learn their needs.*
>
> *PHP facilitator NW-032*

The PHP facilitators and the trial participants appreciated the PHP since it was culturally adapted and prioritised all the needs desirable to address the cultural norms of the South Asian community.

Intervention coherence – the extent to which the participant understands the intervention, and how the intervention works

Before the intervention began, participating mothers, in both face-to-face and online formats, perceived PHP as something that would address their low mood and/or enable them to solve problems:

> *I found every session very enlightening by listening to everyone's experience. It was just nice talking to other people. I was able to explore myself and I said to myself that I can do this. These sessions empowered me in some way which I liked that all scenarios should have been about, and I believe life is all about empowering each other.*
>
> *Trial participant NW-005*

The PHP facilitators emphasized that because the PHP sessions, both face to face and online, were culturally adapted, it helped address the emotional needs of the mothers as well and to take better care of themselves:

> *I would say these sessions were helping because one, it deals with the issue of isolation providing them with group support secondly who neglected themselves can care about themselves, thirdly I have seen that CBT works. Cognitive therapy was culturally adapted and was delivered as a positive health program in ROSHNI.*
>
> *PHP facilitator NW-011*

Opportunity costs – the extent to which benefits, profits, or values must be given up engaging in an intervention

This construct reports the compromises a trial participant had to make to participate in the intervention. Some of the trial participants reported that due to the remote sessions, they were unable to participate with complete attention since they were involved in multiple other activities at home, along with attending the online sessions. They missed the earlier, carefree environment of the face-to-face sessions and felt they had to compromise on their freedom and liberty to have open discussions:

> *Firstly you get a change of environment, freedom of speech because when you are home the kids and husband is home so you cannot speak openly and secondly we need to attend to the kids simultaneously as we are attending the sessions and on top of it the most important thing is that when we see each other we have snack time or casual me time and we can go a little bit early or a little bit late, we have a play area for kids there and when the session finishes we can talk to each other or can have more interaction.*
>
> *Trial participant NW-033*

Positive Health Programme facilitators indicated that due to the remote delivery of the sessions, the intervention did not offer the opportunity of having 'me time' for the mothers that used to be provided to them in the face-to-face sessions. With additional supports, such as child care and snack time; however, this did not impact the attendance to the remote sessions.

Perceived effectiveness – the extent to which the intervention is perceived as likely to achieve (or have achieved) its purpose

This construct is interpreted as the extent to which the intervention will likely attain its aim. This becomes even more important to understand during the present times when the mode of delivery is remote via virtual sessions:

> *It has provided me with the right direction the right answers to the questions that we were thinking about on our own and speaking to other mums. I think if I would not be invited to that group, I would have gone for counselling, however, due to COVID and lockdown I would be stuck at home but being home, speaking online, and having that support and interaction was helpful for me. If I would not be invited to the group, I do not think I would be the same person I am today.*
>
> *Trial participant NW-033*

Most of the women acknowledged the effectiveness of these sessions and how they improved their low mood and made them feel confident in improving their skills. The statements that were recorded were 'I started feeling that I am worthy' (NW-005):

> *Though it was not providing the complete support that I was looking for it was providing the partial support like the emotional support that I was looking for and learning from the experience of the other mums and listening to the doctor as well. It supported me in a way that I was able to socialize, and I thought it is a great opportunity to see and talk to new people and it was kind of a blessing in disguise for me.*
>
> *Trial participant NW-005*

The PHP facilitators also agreed that even though the virtual sessions may not be the best way to deliver the sessions, given the times and lack of alternatives, they were helpful to the trial participants by enhancing their online social networks and boosting their confidence and self-esteem:

> *Even though the session was online, but they were able to connect and keep in touch with each other. So, all in all, no matter due to lockdown they are all connected, and we had a very positive response from the mums.*
>
> *PHP facilitator NW-032*

Self-efficacy – that participant's confidence that they can perform the behaviours required to participate in the intervention

Trial participants, in both face-to-face and online formats, felt empowered by learning new skills, such as time management, learning to say no, and making more time for themselves. They also reported improved communication skills:

> *My communication skills were poor previously and through these sessions, I improved my communication skills I speak very little and take time to get comfortable with others, however, these sessions increased my confidence and helped me to improve my communication skills.*
>
> *Trial participant NW-047*

However, it was noted by trial participants that they could not express themselves openly and discuss their issues freely around family members in a shared household, especially when the conversation was about a particular family member. Although the PHP facilitators made efforts to maintain confidentiality by providing trial participants with headphones, some of the participants felt uncomfortable engaging in lengthy conversations due to the proximity of the family members:

> *I generally had my mother-in-law around me sometimes, so I did not talk much.*
>
> *Trial participant NW-033*

The PHP facilitators played a vital role in engaging with the trial participants during the sessions and helping maintain confidentiality. Trial participants were given options of putting down their feelings in the chat box if someone was around and later having a follow-up after the virtual session. As one of the PHP facilitators explained:

> *We said to the mums that if they could not talk or could not be honest about something or felt uncomfortable or if there is someone in the room, they could just put a comment in the comments box and so they knew how to do that, so some mums did type in that I cannot talk now and we were all aware of that and we tried to follow them up later through the phone call to check on them.*
>
> *PHP facilitator NW-004*

Positive Health Programme facilitators reported overall satisfaction and confidence in delivering the sessions remotely. Initially, the PHP facilitators were sceptical about the remote sessions, but with adequate training, they felt prepared to deliver the sessions effectively:

> *I would say there were lots of issues and we felt at the beginning and it was quite challenging there was a bit of anxiety, there was a bit of uncertainty, there was a bit of apprehension that how would the sessions are going to turn out. And whether the Internet is going to work or not and how mums are going to deal with it. However, the results were quite surprising in the first session we had six mums in the second session we had eight mums and by the end of the third session, the mum had their own WhatsApp group.*
>
> *PHP facilitator NW-011*

Furthermore, adequate training before the sessions helped them better understand the programme, especially in the new format of remote delivery:

> *Our trial manager provided us with all the due information and prepared the slides on PowerPoint that assisted in understanding the sessions we were delivering. We were provided with a zoom session to practice a trial session with our co-facilitators to know how we can manage things to work.*
>
> *PHP facilitator NW-047*

Discussion

The findings highlight the multifaceted interplay of factors shaping participants' experiences in the PHP programme. Participants had mixed feelings about engaging in remote PHP sessions compared to face-to-face ones. They articulated initial uncertainties about confidentiality, the lack of personal connections, and the non-therapeutic elements that face-to-face sessions provided, such as child care and socialisation. The burden of contributing remotely was evident as participants grappled to balance household responsibilities, child care, and focus during the sessions. Technical challenges and connectivity issues added to the difficulties of remote participation.

On the other hand, while some participants faced challenges sustaining open discussions due to distractions at home, others valued the convenience and accessibility of remote sessions. Regardless of these challenges, participants and PHP facilitators acknowledged the intervention's positive impact on participants' mental health, self-esteem, and communication skills. Satisfactory training helped PHP facilitators familiarise themselves with remote delivery, improving the programme's overall effectiveness.

Chapter 9 Discussion

Postnatal depression is a substantial public health concern, affecting approximately 17% of mothers globally.[9] This area of research has been prioritised by the NIHR across all programmes in accordance with the 'Best Research for Best NHS' guidance by the NIHR.[114] The ROSHNI-2 trial is the first large-scale evaluation has been undertaken to examine the clinical and cost-effectiveness of a culturally adapted group psychological intervention for postnatal depression in ethnic minorities living in high-income countries. We determined the clinical and cost-effectiveness of the PHP in a multicentre RCT across England. The main findings of the ROSHNI-2 study will now be discussed in relation to (1) the estimates of the clinical effectiveness, (2) estimates of cost-effectiveness and (3) qualitative examination of the acceptability and feasibility of the PHP group-based intervention.

Trial-based estimate of the clinical effectiveness of the Positive Health Programme for postnatal depression in British South Asian women

The RCT compared a culturally adapted CBT-based intervention, the PHP-plus-TAU, with TAU for BSA women with PND. The participants met the DSM-5 criteria for depression, confirmed by the SCID-5. The primary outcome assessment was at 4 months and subsequent follow-up assessments (secondary outcomes) conducted at 12 months after randomisation. The SHAPER-PND trial looked at a community singing intervention for PND, follow-up was conducted at week 6 (mid-intervention), week 10 (end of intervention), week 20 and week 36.[115]A large cohort study, the Avon Longitudinal Study of Parents and Children, reported measurement of PND on a continuum of symptoms rather than a dichotomous diagnosis of PND.[116]

The findings of the study illustrate the evidence for its effectiveness in primary care to deliver a group psychological intervention PHP.[54] The trial also addressed the need for an approach which takes into account cultural awareness while developing and delivering interventions for women in the UK from ethnic minority backgrounds; this is important considering the high rates of maternal depression in this group of women.[58,117] In addition, the ROSHNI-2 trial aimed to address the limitations of earlier trials which mainly consisted of small, non-representative sample size, high attrition and short follow-up,[118] making this trial the first major investigation with ethnic minority women living in high-income countries.

Primary outcome

A total of n = 732 participants were recruited across 4 study centres in the UK and were randomised to one of the trial arms. The primary outcome being recovery from PND. Participants were considered recovered if they had a HRDS score of 7 or less. The results indicate that at 4 months (primary end point), half of the participants in the PHP group (49%) recovered, compared to 37% in the TAU group. These improvements were smaller than the anticipated clinically meaningful ARR of 15% (albeit with a large degree of uncertainty and a 95% CI that includes this). However, after adjusting for centre, severity of depression, and education at baseline, the odds of achieving recovery in the PHP group were nearly twice as high compared to the TAU group (OR 1.97, 95% CI 1.26 to 3.10). Applying this adjusted estimate to a population recovery rate of 38% results in an ARR of 0.17% and a NNT of 6; meaning that, for every six patients who are treated, one will recover. By 12 months, the difference in recovery rates became statistically non-significant, with the TAU group also improving and recovering.

Secondary outcomes

On analysis of the secondary outcome measures, one of the secondary outcomes was related to a treatment response on the HDRS measure, which showed a reduction of 50% or more from the baseline score on the HDRS. In the treatment (PHP) group, 56% of the patients experienced a treatment response compared to 40% of the control (TAU) group. At 12 months, the treatment response was 61% (PHP group) and 58% for the control (TAU) group.

For depression symptom severity, measured by the PHQ-9 total scores, the treatment group had a significantly improved total scores at 4 months (β = -2.05, 95% CI -3.18 to -0.92); however, at 12 months there was no meaningful difference (consistent with the recovery at 12 months). At 4 months, the treatment group also scored significantly lower on anxiety in comparison to the control group (β = -1.45, 95% CI −2.66 to −0.25) but again this was not different at 12 months. In addition, the parenting competence measure, although there was found to be no significant difference in parenting sense of competence scores at 4 months between groups, However, at 12 months the intervention (PHP) group had a higher score, on average by 2.32 points (95% CI 1.10 to 5.54), indicating a significantly higher sense of competence than the control group. There was no significant difference in social functioning between groups at 4 or 12 months.

Cost-effectiveness of the Positive Health Programme

The PHP implementation for PND was estimated to cost an average of £408 per participant. The PHP intervention was found to lead to higher incremental costs and QALYs gains among South Asian women. The intention-to-treat analysis revealed that the PHP intervention costs £22,198 per QALY, with a probability of cost-effectiveness of 56% at the willingness to pay of £25,000. A disaggregated analysis by the number of completed PHP sessions, revealed that four or fewer completed sessions have no incremental effects on QALYs. Participation in 5–8 sessions of the PHP resulted in a 0.04 increase in QALYs per person compared with the control arm, and participation in 9–12 sessions resulted in a 0.05 increase in QALYs per person. Participation in 5–8 sessions was relatively cost-effective compared with 9–12 sessions. For those who attended 5–8 sessions, PHP intervention costs £9040 per QALY gained, with a probability of cost-effectiveness of 71% at the willingness to pay of £15,000 and associated mean net monetary benefits of £255.

We believe that the cost-effectiveness estimates given in this report are conservative and provide the upper bound of costs per QALY gained. Healthcare usage for some conditions is hard to change in the shorter term as in the current case. For example, the data show that most secondary care uses were less likely due to the participants' mental health. After excluding secondary care from the cost calculations, the intention-to-treat analysis revealed that the PHP intervention costs £16,961 per QALY. The probability of cost-effectiveness is 59% at the willingness to pay of £20,000. Second, the primary and secondary care costs were higher among the PHP arm at the baseline. Similarly, the PHP intervention involved developing assertiveness skills and helping participants to build confidence, improving communication, and overcoming social isolation by creating new relationship and fostering new social networks. This might lead to overcoming the fear of stigma, leading to more healthcare use and self-reporting, at least in the shorter term. Finally, children's centres were costed at the rent charged by community centres, which may charge higher rates in some instances. Note also that the participants were paid £10 per session. However, that amount was not included in the economic valuation, as the economic evaluation used a healthcare perspective, and the healthcare system in the UK does not cover such costs in practice.

Stevenson *et al.*[119] combined clinical-effectiveness results from Honey *et al.*[120] and data from PoNDER trial to estimate the cost-effectiveness of group CBT for PND in the UK. The mean cost per QALY from the stochastic analysis was estimated to be £36,062; however, there was considerable uncertainty around this value. Camacho and Shields[121] report seven studies, excluding Stevenson *et al.*,[119] assessing the cost-effectiveness of interventions for prevention, treatment, or screening and treatment of postnatal depression. These studies assess different forms of treatments: access to psychiatric day hospitals, counselling and support delivered by trained health visitors, cognitive–behavioural therapy, collaborative care for depression, psychosis in partnership with a psychiatrist, etc. In these studies, the interventions ranged from dominant (rare) to ones costing more than £30,000 in 2015. Similarly, the cost per recovery ranged from low to as high as £56,865. Thus, the PHP intervention's QALY gains and cost per QALY appear to lie within the middle (if not below) of the gains and cost of interventions reported in the existing literature.

Need for culturally adapted psychological interventions

The ROSHNI-2 study was developed based on extensive previous research and builds on an earlier PhD study by Khan *et al.*[54] and ROSHNI-D study[26] and several systematic reviews,[76] which call attention to the immediate need for well-researched studies that can answer crucial questions about PND and the need for culturally adapted psychological interventions. The gaps in research, as reported in *Chapter 1*, include:

- The limited number of well-planned RCTs in the UK for ethnic minorities.

- The dearth of up-to-date studies examining the effectiveness of culturally adapted interventions specifically for the BSA population.
- The need to improve health outcomes of South Asian women in the UK facing PND by assessing the effectiveness of NICE recommended psychological interventions.
- Limited evidence and evaluation from the current research base related to economic costs culturally adapted interventions.

The present study is an important step to improving current understanding on conducting research with a hard-to-engage group, with an elevated risk of PND. The findings of the study further highlight the experiences and acceptability of a culturally adapted intervention (PHP) by the South Asian population in the UK, which is also the largest ethnic minority group. The results are largely comparable with clinical trials on postnatal depression. An important point to be considered while discussing the results with previous research findings is that there are few available studies of trials with ethnic minority women as a point of comparison.

The challenges of delivering care differently

This study highlights the compelling evidence that delivering group therapy within a health service setting offers efficiencies over usual care. Similarly, a meta-analysis focusing on community studies demonstrated the effectiveness of psychological interventions, deliverable in primary care, at reducing symptomatology of PND.[122] In addition, a 2013 meta-analysis of 28 trials involving close to 17,000 pregnant women and new mothers (< 6 weeks post partum) reported that women were less likely to progress to postpartum depression if they received the psychosocial intervention or psychological therapy compared with usual care.[123] The NICE guidelines[51] recommend CBT and IPT as the first-line management approach for PND. The PHP intervention evaluated in the ROSHNI-2 trial is modelled on CBT principles. The psychological intervention was culturally adapted for use with BSA women through the use of cultural adaptation methodologies and previous research.[26,53,66,104] A recent network meta-analysis for different subtypes of psychotherapies points to recurring positive results about CBT, and points out whether done as a combination or on a standalone basis, it generates a more enduring response than the usual treatment for major depression.[124]

Furthermore, the ROSHNI-2 trial showed benefits related to the primary outcome measure, recovery from PND, and other secondary outcomes, including improvements in anxiety symptoms. These improvements were seen at 4 months and continued by the PHP group; however, at 12 months there were no differences between the groups. In the short term, the greatest benefits were apparent for the PHP group, which is in line with research on achieving a treatment response to depression[125] and predictors of variability of depressive symptoms in the long-term in long-term trajectories of depressive symptoms, including, among others, being a woman, a mother, having a low income/education, and belonging to a non-white race.[125] The important finding is that the improvement in depression in the PHP group was sustained up to 12 months after randomisation.

Compliance analysis results indicated that that three-quarters of the participants met compliance to treatment attendance (n = 246) (a participant attending at least 1 therapy session), indicating that most participants engaged well in the PHP intervention. Moreover, participants also completed, on average, 8.94 sessions, with findings similar to the ROSHNI-D[26] that mother who attended 1 session, were likely to continue to engage with the PHP group. Forde *et al.*[113] reported that for reducing depression, attending 6–8 sessions offers more benefits than attending 1 –5 sessions. The high level of engagement in this trial could be due to several reasons despite the barriers highlighted by trial participants, such as the stigma attached to poor mental health in the South Asian community. Qualitative evaluation of the PHP interventions suggests possible reasons for the success of PHP, and these include the targeted community engagement events, which were conducted across the study period to increase awareness, in addition to active meaningful PPIE for the study and public-facing materials. The intervention was presented as a life-skills training programme rather than therapy. For engagement with the wider family the focus was more on the child rather than the mother. The internal pilot provided us the opportunity to increase awareness about the benefits of PHP at the different study sites. The intervention was culturally adapted, which could have influenced its positive take-up and effectiveness. The importance of cultural adaptation of interventions has been confirmed by various reviews, highlighting that culturally adapted psychological interventions provide better outcomes compared to interventions that are not culturally adapted.[126]

Acceptability of the Positive Health Programme

Overall, the qualitative data suggest the acceptability of the PHP from perspectives of trial participants, PHP facilitators and GPs. Trial participants and PHP facilitators expressed satisfaction with session content being culturally acceptable, with the frequency and format of the PHP intervention delivered and considered as relevant to their culture.

Several processes observed in the qualitative study can explain the reduction in depression and anxiety observed in the trial, particularly at the 4-month follow-up. The findings support previous research,[127–129] which suggests that participation and interaction in a group provides participants with a forum to interact with others and in the process develop skills which can help cope with low mood and move forward. The trial participants reported that PHP group members provided feedback and supported each other during and outside the group session by staying in touch and building their social network. The group setting provided participants with a sense of support through shared understanding and acceptance. It is plausible that increased social relations and networks may directly affect depression.[130]

Trial participants described perceived benefits of developing new skills to improve their well-being; leading to being more confident and increase in self-esteem.[131] This could explain the better observed outcomes in the trial at the 4-month follow-up period. Therefore, it is also reasonable to consider that increased social support may have mitigated the impact of social stressors, such as maladaptive coping and stigma.

The findings support previous research,[132] which proposes benefits of participation in a trial, including reduction in associated stigma and improved care for mental health difficulties that participation in a trial can help reduce stigma and improve care for mental health difficulties, such as depression and anxiety. Before starting the PHP intervention, participants were concerned about stigma associated with their experience of PND and the concerns about community 'grapevine'. However, the women and PHP facilitators reported that women gained confidence and developed greater assertiveness skills after the PHP intervention. This resulted in improvement in their relationships with others and making time for self-care. Women reported that they better understood their feelings and more self-awareness. They were able to implement newly learnt coping strategies and engaging in pleasant activities suggested by the facilitator. However, for some trial participants, low mood persisted at the end of intervention and the women suggested that there should be booster sessions. PHP facilitators also noted that the engagement in the intervention was dependent on the level of support from family members and trial participants' intent to address their own problems.

All participants clearly described the value of assisting BSA women in engaging them in activities that they find enjoyable and meaningful, and which resonates with their cultural experiences. Awareness and action to support and improve their low mood and depression are important as it is fundamental to a women's well-being.[18,127] Yet, engagement in existing support services and the lack of culturally sensitive services were identified by participants as one of their major unmet needs.[16] Therefore, as an intervention, PHP made sense to trial participants and PHP facilitators. This is relevant to implementation; according to the TFA,[105] one of the thresholds for positive implementation of a new intervention is to be 'coherent' or make sense to those involved in delivering and receiving the intervention. Implementation literature suggests strategies should focus on known barriers to behaviour or practice change.[133] Therefore, therapists' training in the use of PHP extends to understanding the target population and the cultural barriers associated with stigma and shame, concerns about referral to health professionals, and exploring approaches to enhance the relevance and acceptability of PHP for families and broader engagement with South Asian communities. Implementation of new interventions such as PHP also necessitates health professionals to understand what the intervention involves in sufficient detail to allow the impartial presentation of information, ensuring BSA women and their family members make an informed decision about participation.[134]

The South Asian cultural focus of the PHP intervention and group therapy approach made it particularly appealing. The GPs were hopeful about the long-term benefits of the intervention, with the PHP potentially bridging the gap that GPs describe in the support and management of BSA women in primary care. Continuing with community engagement and awareness, and 'success stories' for PHP and tailoring messages for different stakeholder groups will therefore be important in the take up of the PHP intervention.

Impact of COVID-19

The COVID-19 extension qualitative work aimed to understand the acceptability of the PHP, delivered during the COVID-19 pandemic, from the perspective of South Asian mothers in the UK with PND. We also examined the experiences of community facilitators and therapists in the planning and implementation of the remote therapy sessions and the differences they felt in delivering the remote versus in-person sessions. The women were already attending the PHP sessions before the nationwide lockdown and were in a unique position to compare the advantages and disadvantages of the online sessions. The overall results provide rich learning and include lessons on how best to optimise services for remote therapy, particularly for those groups which are hard to reach.

In-depth interviews with participants and therapists indicated that in-person format was a clear preference as a mode of delivery of the PHP intervention when compared with the online sessions. Women had some reservations in expressing their feelings effectively due to sometimes family members being around. Similar conclusions in research on limitations of video-based/online interventions and remote care for mental health also advocate the distinctiveness of face-to-face sessions over remote care, particularly related to confidential conversations.[134]

Another factor that had an impact on the quality of engagement in remote delivery sessions was multi-tasking. Due to the lockdown some women were looking after the children and carrying out household chores alongside attending the intervention. Other barriers in delivery of the online sessions included unstable internet connection, and initial hesitation for use of technology for some of the participants. Comfort in using the technological platform can sometimes underpin the successful delivery of online therapy sessions.[135] However, participants frequently reported difficulties with the inadequate technological arrangement and poor internet connectivity issues, such as speed and strength of network bandwidths, thereby creating issues with delivery of a smooth session.

Many participants valued the flexibility provided by remote delivery of the sessions, particularly for those who felt that household responsibilities had earlier prevented them from attending the face-to-face sessions. They felt that the online format, even though not ideal, helped them navigate the difficult times during the lockdown, supported their personal development, and provided a network to the women by helping them share experiences and get advice in a non-judgmental setting. Majority of the facilitators who delivered the online intervention were of South Asian background with bilingual skills, accommodating the diverse needs of the participants, which was appreciated by the participants. Some reservations, as expressed by the facilitators for the online sessions, also included not having a 'me time' for the women which was there in the face-to-face sessions, like child-care facility and snack time where women used to get a chance to socialise. Having a meal/snack together, especially in the Asian culture, is considered as a meaningful activity which promotes social interaction.[136] However, this did not affect the attendance of the participants. Social cognitive theories like the theory of planned behaviour,[137] commonly used to understand dietary behaviour in health psychology, further explain how eating together evokes positive emotions of togetherness in people.

The qualitative study suggested that the PHP intervention was perceived as feasible and acceptable by the trial participants, PHP facilitators and GPs' perspectives. The perceived benefits of increased social networks and behavioural activation could have been the therapeutic factor, engaging in activities that participants found enjoyable and meaningful and discussion and information that resonates with their cultural experience. Awareness and action to support and improve their low mood and depression were necessary to increase participants' understanding and utilise coping skills where needed. In addition, culturally adapted PHP intervention content enabled intervention delivery and was positively received by the South Asian population. The qualitative data helped in a better understanding of the context and expanded the learnings from the trial outcome of how PHP contributed to reducing depression.

Strengths and limitations

This study is unique, given the stigma surrounding mental health in South Asian communities. The study has demonstrated a high level of recruitment and retention [approached n = 9135, screened n = 4319, randomised n = 732, 4 months follow-up n = 578 (79%)]. The ROSHNI-2 trial is a crucial step forward in trial knowledge and working with hard to engage groups. Learnings and knowledge gained from the trial will assist in further formulating and modifying current guidelines related to PND, especially for ethnic minorities in the UK. The recruitment of ROSHNI-D and now ROSHNI-2 highlight the team's ability to engage with a 'hard-to-reach' community. The key adaptations made to the

PHP intervention are the use of culturally appropriate language and intervention resources. Care was taken to ensure that all the study materials and final delivery of the intervention was made in Urdu, Bengali, Gujarati, Punjabi, Hindi and Tamil languages, and in an easy-to-use manner via relatable stories to apply the principles of CBT. To our knowledge, this is the first RCT in the UK working across five different languages.

As the results state, recovery from PND is more rapid in the PHP group immediately post intervention; however, there is also recovery in the TAU group over the 12-month period. This could potentially be explained partly as a result of the additional methods employed by the study team for recruitment and retention of participants. For example, engagement events were held in which workshops were focused on increasing awareness and psychoeducation in this study population. It was important for the team to do this level of community engagement in order to increase research participation in this community and tackle stigma about maternal mental health and also build trust in services and research involvement. Further research is also needed to explore the role of brief follow-up contact in this study population.

A limitation of the study was the relatively high level of missing data: overall, 23% of participants had missing data for the primary outcome. There was no association between baseline characteristics and whether or not a participant had missing outcome data, therefore we did not have evidence that excluding those with missing data biased the results. In addition, the results were robust to a sensitivity analysis that assumed participants with missing data had not recovered. Regardless of bias, while a statistically significant effect was detected, the high level of missingness limits the precision in the final estimate. A further limitation was that we report only a relative measure of effectiveness, whereas an absolute measure of change – for example, the NNT – may be a more appropriate measure for assessing the intervention's public health benefit. The challenge in calculating this statistic is that models used to estimate this tend to be more difficult to fit, and doing this should be the focus of future work.

Introducing different deviations to the multiply imputed data in the sensitivity analysis revealed that such deviations bring minute changes in the costs and effects estimates, and the primary analysis's results still hold.

This trial also makes a unique contribution to the limited scientific literature examining the processes and development of culturally adapted psychological interventions, with a focus on PND, for ethnic minority women.

Mixed methods was a particular strength of this trial and it allowed us to gather both quantitative and qualitative data, thereby adding perspectives to the research questions. Interviews conducted with the participating mothers, PHP facilitators and GPs enabled exploration in detail of culturally adapted intervention. There is typically a paucity of usage of theory and frameworks in perinatal health research,[138] therefore, employing the thematic framework of acceptability is an important contribution to the literature. The remotely delivered PHP intervention during the pandemic provided an online platform for participating women during the lockdown when ongoing restrictions made it difficult to carry on with the face-to-face sessions. It provided a sense of continuity for the women who were engaging well with the PHP sessions earlier and a sense of support for those participants who had joined for the first time.

The ROSHNI-2 trial also provided estimates of the cost-effectiveness of the intervention, helping plan future services particularly for excluded groups. This is important as there are few cost-effectiveness analyses of culturally adapted interventions for PND. A possible limitation of this trial is that the sample of the study includes only BSA women; hence, the study findings cannot be generalized to the other ethnic minority groups. In addition, the geographical proximity of many of the participants can lead to the assumption that they were acquainted with each other and could share their experiences of participation in the intervention as well. Potential contamination can, therefore, be expected.

In an attempt to be inclusive, we did not limit the sample to only first-time mothers and included experienced mothers as well. The challenges faced by first-time mothers can be very different from those experienced mothers, which is a limitation we did not consider. Further information on social deprivation, poverty, and family composition are also likely to impact mothers' experiences. The experiences of different generations of BSA women are also likely to be different. Finally, concerning the cost-effectiveness analysis, the current analysis did not explore recall bias, which may have been introduced due to collecting data using self-report methods at 4- and 12-month duration. Additionally, the economic evaluation used only a healthcare perspective and does not cover the cost of medication.

Chapter 10 Conclusions and future research recommendations

The study has been successful in initiating a multidisciplinary dialogue on a wide scale across the UK and addressing the urgent need for a culturally adapted model of engagement and delivery while working with 'hard-to-reach' communities. Overall, the non-specialist delivered group-based PHP was effective in treating PND among BSA women in the short term. Integrating and implementing PHP group sessions into existing health systems was feasible and acceptable. The ethnic minorities community that is often considered 'hard to reach' has been expressed by one of the community partners as 'easy to ignore' since services are not tailoring their approach and the process of mapping communities and cultural engagement is limited. The results suggest some form of maintenance contact and additional maintenance treatment to further improve recovery in the form of additional PHP sessions should form the basis of future research with a longer-term follow-up. The creative methods of recruitment and engagement and dedication to working with the community to enhance participation in research can serve as a best practice example for recruitment in future studies.[139]

The benefits seen in the primary outcome were sustained at 12-month assessment in the PHP group; however, there was no significant difference with improvement in the TAU group. There is ample clinical trial evidence that this is a typical longer-term outcome, which is a well evidenced but rarely discussed limitation of depression treatment evaluations.[125,140] The value of benefits of faster recovery of depression even in the short term cannot be underestimated for the PHP group participants, and arguably, crucially for the baby and possibly also other family members. Whether it further improves the longer-term course and trajectory of depression is not well understood; a significant proportion of cases of depression have a long past history of depressive symptoms and a poor outcome with either fluctuating or continuous trajectories.[125] Funders and researchers should be examining this and reconsidering research priorities for improving future years lived free of depression and though important, not only just the short-term outcomes that are almost ubiquitous in treatment evaluation research.[141,142]

The present findings suggest that a form of maintenance contact and, where indicated, further treatment, possibly in the form of additional PHP sessions, should be the focus of future research intervention development and evaluation, importantly with much longer-term outcome follow-ups as is accepted without question in cancer trials. We are currently carrying out a test of remote brief PHP intervention, which may be a cost-effective intervention for sustained long-term impact.

We are also exploring adaptation for treating PND in British mothers of African/Caribbean heritage. The model of cultural engagement and delivery that has been learnt from ROSHNI-2 can be applied to other ethnic groups that require a culturally sensitive approach. Feedback from ROSHNI-2 participants highlighted the need for future interventions addressing interpersonal violence (IPV) using a format similar to the PHP.

Positive Health Programme implementation was estimated to cost an average of £408 per participant. The intention-to-treat analysis showed that the PHP intervention costs £22,198 per QALY gain. The probability that PHP would be cost-effective is 44% (65%) if the policy-makers are willing to pay £20,000 (£30,000) per QALY gain. Nevertheless, PHP was highly cost-effective for those who attended at least 5 PHP sessions. For those who participated in 5–8 sessions, the PHP cost £9,040 per QALY gain. At £15,000 willingness to pay, the mean net monetary benefits from PHP were £255 for those attending 5–8 PHP sessions.

Equality, diversity and inclusion

This project has centred on the NIHR vision to 'provide better health and care through more inclusive research'. All efforts were made to develop a recruitment and retention strategy through the project to ensure engagement of this under-represented group. The research team were predominantly from ethnic minority backgrounds and through their time on the project the CI and trial management group worked to develop skills in research capacity and capability. Text and pictures, used as part of participant and public engagement, were inclusive and accessible to this research group. All study materials were translated and available in key South Asian languages (Urdu, Punjabi, Gujarati, Hindi, Bengali and Tamil).

Chapter 11 Add on study report – impact of COVID-19

Summary

The additional work stream is an add-on study to the ROSHNI-2 project (14/68/08, HTA) (IRAS 187851). The work was shaped by suggestions made by participants in the main ROSHNI-2 study for a follow-up and re-engagement to explore associated risk factors related to maternal mental health and specifically in the context of the pandemic. The NIHR HTA programme funded the study following a call for additional work building on existing grants.

We aimed to increase the understanding of the pandemic-related impact on BSA women, including IPV. The add-on study research design and survey tool were informed by an MRC-funded international survey study.[143]

Background

Pre-pandemic health disparities have been exacerbated by the impact of COVID-19, which has raised concerns that disparities in maternal health outcomes have also worsened. A recent study indicates that BSA women are four times more likely than white women to be admitted to a hospital with COVID-19-related complications during pregnancy (MBRRACE-UK, 2022). Public Health England (PHE) reiterates the importance of funding culturally competent health promotion and disease prevention programmes. Recently, an 'improving equity and equality in maternity and neonatal care' strategy led by NHS England (Maternity Transformation Programme, September 2021) was launched.

In addition, IPV remains a major public health concern in the UK. Despite growing recognition of the problem, it is an under-researched area. The current crisis of IPV has been heightened further with the COVID-19 pandemic. IPV is a highly prevalent phenomenon in BSA communities but under-reported. BSA women who face IPV are not only at a higher risk of depression and post-traumatic stress disorder but may also remain entrapped in violent relationships to maintain the family 'honour'.

Aim and objectives

This study aims to increase the understanding of the pandemic-related impact on BSA women and IPV in BSA communities. The objectives are as follows:

- To explore and understand the wider consequences of the global pandemic on BSA women during the postnatal period in the context of mental health, isolation, education, child development and views on the vaccination and wider impacts.
- To examine BSA women's experience of IPV to understand: risks, protective factors, barriers to help-seeking, challenges and IPV interventions for BSA survivors.

Methods

Design

We used a mixed-method study using an online survey adapted from *Psychological impact of COVID-19 pandemic and experience: an international survey* (IRAS PROJECT ID: 282858; Rathod *et al.* 2021, 2020) and one-to-one interviews (January–August 2022). The sampling approach used for online surveys and one-to-one interviews was purposive sampling of the participants screened on the ROSHNI-2 trial in the five study centres (North West, Yorkshire, East Midlands and London).

Online survey

An online survey platform [Qualtrics® (Qualtrics, Provo, UT, USA)] was created to collect data from participants. The survey was launched on 3 January 2022 and remained open until 31 August 2022.

Consent

The ROSHNI-2 sample group had previously consented to the ROSHNI-2 trial and provided consent to be contacted for future research opportunities. The aim of the survey was explained in an introductory statement on privacy and confidentiality, and voluntary participation was made clear by reminding participants that they could leave the survey at any stage by closing it and that their answers would be kept anonymous. Full consent was obtained from all participants for the online survey.

Recruitment

The ROSHNI-2 sample of women were invited via an invitation e-mail and text messages with a link to the online survey. Research assistants contacted participants with no digital access via telephone. In addition, the survey link was promoted using various social media sites, including Instagram, Twitter, Facebook and WhatsApp channels.

Research assistants from each of the five study sites accessed secure databases to retrieve ROSHNI-2 participant information. The method of contact depended on factors including – time of day (using text messages during busy periods, including school pick-up times, evenings and weekends) and language (using phone-call to communicate with women who did not speak or read English). The IPV screening tool (HITS) was integrated into the survey. Those who scored high were then prompted to complete additional IPV assessments and were asked to provide contact details (optional) for a one-to-one interview.

All participants were provided with a Qualtrics link to the COVID-19 substudy to complete their questionnaire in their own time. Participants that requested support with the questionnaire were guided via a phone call, and questions were translated and marked accordingly on the online system. The survey was accessible in all study languages. All participants were offered an opportunity to enter a prize draw on completing the questionnaire.

Procedure

To ensure the responses were only from those who had previously taken part in the ROSHNI-2 project, participants were asked to indicate their level of engagement and contact with ROSHNI-2 (e.g. 'Have you previously completed a questionnaire for the ROSHNI-2 Project?'). This allowed any responses from those outside the target sample to be omitted from the final analysis.

Measures

Participant attitudes to the COVID-19 pandemic/restrictions were first measured, followed by levels of IPV, drug use, access to mental health support, impact on communication, loneliness and impact on child-care support. As well as measuring participant responses to these topics, the PHQ-9 and GAD-7 were also completed as part of the survey.

One-to-one in-depth interviews

The study team developed a topic guide for ROSHNI-2 participants and stakeholders (health professional and service providers) with input from PPIE groups.

Consent

Participants provided consent for the one-to-one interview using an electronic link prior to the interview. Participants with no digital access provided consent verbally on an audio recorder. All telephone interviews were audio recorded and transcribed verbatim with participant consent.

Potential stakeholders were identified using the research teams existing contacts and snowball sampling. Stakeholders were sent an e-mail with the details of the study inviting them to participate in the study, a copy of the PIS, and a link to a digital consent form (developed using Qualtrics). Participants were eligible to participate if they had had experience working with BSA women during the perinatal period and women exposed to IPV. All participants provided full consent using the electronic link. All participants completed interviews online using Zoom (Zoom Video Communications, San Jose, CA, USA) or MS Teams. The interviews lasted roughly 1 hour.

Data analysis

Interviews were video recorded on MS Team or Zoom platforms with the auto-transcriptions feature enabled. Research assistants checked, edited, and confirmed verbatim auto-transcriptions recordings. Telephone interviews were transcribed verbatim into written text. Interviews conducted in languages other than English were translated and transcribed. All interview transcripts were imported into the Nvivo software application to manage and organize the coding of the data; transcripts were coded jointly by two researchers and reviewed as a group to achieve reliability.

The data were analysed using framework analysis, using the five stages to analyse the qualitative data: familiarisation; constructing an initial thematic framework; indexing and sorting; reviewing data extracts; and data summary and display, monitored by process of abstraction and interpretation.[144] The preliminary groupings were developed based on particular transcripts selected to categorise the themes. After that, the descriptive framework was reviewed to identify any connection and likeness between categories. The final stage of the analysis involved examining the level of matching between the occurrences distributed across the whole data set. The framework analysis identified key themes to explain the BSA women's experience of pandemic-related impact and IPV.

Patient and public involvement

We consulted with four PPI groups across Bolton, Manchester, London and Lancashire. The groups consisted of 25 BSA mothers with lived experience (previous ROSHNI-2 participants) in Bolton, Manchester, London and Lancashire. The PPI activities aimed to gain insight into the participants' opinions to develop a topic guide for the one-to-one interviews with ROSHNI-2 participants, health professionals and service providers on how we conduct the study and the viability of online survey and the one-to-one interviews. We conducted hybrid (face to face and virtual) group discussions (two hours) to inform us of the study design, research topic and outcomes. Two bilingual facilitators were allocated to each PPI group according to language preferences.

The group feedback helped shape, refine and confirm the research topic guide for the one-to-one interview and the contents and format of the online survey. PPI activity outcome included changes in the interview topic guide for women with lived experience and professionals' perspectives. Participants prioritised needs and discussed feedback drafts. The need for clear, valuing, non-stigmatising language in the interview was identified, particularly highlighting the sensitive nature of how the COVID-19 pandemic affected BSA women differently. PPI contributors had an overall positive attitude towards the study design and using online platforms for the data collection.

Results

Online survey

Researchers contacted potential participants for this add on work from the original cohort of ROSHNI-2 participants. Participants were contacted via text message with a link to the survey study and also with follow-up calls. A total of 1485 participants were sent text messages with details of the study by a ROSHNI-2 researcher and 387 of these were followed up with a phone call as per their request. In total, 267 responses were received, 27 of which were later omitted from the study due to not meeting the criteria of being from the original ROSHNI-2 sample of participants. Thus, a total of 240 responses was used for the final analysis. The baseline demographic characteristics of study participants are presented in *Table 34*. More than half of the study participants were between 25 and 34 years. Pakistani (n = 106, 44%) and Indian (n = 104, 43%) were the two most common ethnicities who completed this survey. The majority of the participants (n = 223, 93%) identified themselves as Muslim followed by Hindus (5%) and Sikhs (1.7%). About 96% (n = 231) of the survey participants were married and about half of the study participants (n = 122, 51%) had attended university. Of all who completed this survey, 177 (74%) were from North West of England and 47 (19%) from London. Regarding living status of survey participants, 126 (53%) owned their home, 75 (31%) had rented accommodations and 30 (13%) lived with an extended family (*Table 34*).

TABLE 34 Demographic characteristics of survey participants

Baseline characteristics		Frequency	Percentage (%)
Age group	21–24	2	0.8
	25–34	140	58.3
	35–44	90	37.5
	45–55	8	3.3
Ethnic group	Indian	104	43.3
	Pakistani	106	44.2
	Bangladeshi	20	8.3
	Sri Lankan	4	1.7
	Any other South Asian background	4	1.7
	Prefer not to say	2	0.8
Religion	Islam	223	92.9
	Sikhism	4	1.7
	Hinduism	12	5.0
	No religion	1	0.4
Marital status	Married	231	96.3
	Separated	4	1.7
	Divorced	3	1.3
	Civil partnership	1	0.4
	Prefer not to say	1	0.4
Level of education	Left school before the age of 16	29	12.1
	Left school aged 16	17	7.1
	Left education aged 18	52	21.7
	Attended university	122	50.8
	Other (please specify)	13	5.4
	Prefer not to say	7	2.9
Location	North East	6	2.5
	North West	177	73.8
	Midlands	5	2.1
	London	46	19.2
	South East	1	0.4
	Prefer not to say	5	2.1
Living status	Own home	126	52.5
	Extended family (parents or in-laws)	30	12.5
	Rented accommodation	75	31.3
	Shared housing	1	0.4
	Other	6	2.5
	Prefer not to say	2	0.8

Participant's health during COVID-19

Survey participants were asked about COVID-19-related restrictions in their area and 197 (82%) said there were no more any restrictions, 10 (4%) said there were still restrictions, and 33 (14%) were unsure about it. Since the start of the COVID-19 pandemic till the time of survey, 90 (38%) of the participants and 125 (52%) of the family members of the study participants had been diagnosed with COVID-19. Also, 18 (8%) of the participants had experienced 'long COVID' and 43 (18%) had been diagnosed with one of the variants. Regarding COVID-19 vaccination, 33 (14%) participants had received first dose and 172 (72%) had received both doses of the vaccine. Regarding the booster dose, 80 (33%) women in the sample had received the booster vaccination, while 25 (10%) opted not to take the available COVID-19 vaccine. Of all those who had received the vaccination, 71 (30%) felt more relaxed, while 65 (27%) felt worried or anxious after receiving the COVID-19 vaccine.

Participants were asked about their attitude towards receiving the vaccine and 71 (30%) had a positive attitude towards it, 42 (18%) felt quite uneasy, 36 (15%) were neutral, 20 (8%) were very keen, 19 (8%) were not sure, 10 (4%) preferred not to say, and 8 (3%) were against it. Regarding participants willingness to get the vaccine, 102 (43%) were willing to get it, 43 (18%) were eager to get it, 24 (10%) were not bothered to get it, 24 (14%) were not willing to get it, and 6 (3%) were against the vaccination. When questioned regarding opinion of their family or friends about getting the vaccine, 64 (27%) stated they would encourage them, 63 (26%) strongly wanted to encourage them, 43 (18%) would not say anything to them, 12 (5%) felt their family/friends would suggest them to not get the vaccination, and 3 (1%) would ask them to delay getting the vaccination. The importance of the COVID-19 vaccination was also assessed among survey participants. The responses were: considered important by 71 (30%), really important by 67 (28%), neither important nor unimportant by 35 (15%), unimportant by 9 (4%), really unimportant by 3 (1%) participants, whereas 'Don't know' and 'Prefer not to say' was reported by 26 (11%) and 11 (5%) participants, respectively. Survey participants were asked about taking the COVID-19 vaccine during pregnancy and 84 (35%) said 'Definitely not', 31 (13%) said 'Probably not', 26 (11%) said 'Probably yes', 20 (8%) said 'Definitely', 13 (5%) said 'May or may not', while 25 (10%) said 'Don't know'. Participants were also asked if they took the vaccine during the first year after giving birth or during breastfeeding and the responses were 'Definitely yes', 'Probably yes', 'May or may not', 'Probably not', 'Definitely not' and 'Don't know' by 38 (16%), 38 (16%), 18 (8%), 27 (11%), 62 (26%) and 17 (7%) participants, respectively.

Domestic violence

Participants were asked if they had experienced (witnessed or suffered from) domestic violence in their home during COVID-19: 220 (92%) said 'No', 12 (5%) said 'Yes but not currently', 2 (1%) said 'Yes within past month' and 6 (3%) preferred not to say. *Table 35* illustrates the types and frequency of domestic violence experienced by survey participants.

Psychological impact of COVID-19 on survey participants

Among all, two (0.8%) participants had used medication other than that required for medical reasons, and one (0.4%) participant used more than one medication at a time. Of the total survey participants, 26 had a diagnosed mental health

TABLE 35 Types and frequency of domestic violence experienced by survey participants

Domestic violence	Never, *n* (%)	Rarely, *n* (%)	Sometimes, *n* (%)	Fairly often, *n* (%)	Frequently, *n* (%)	Prefer not to say, *n* (%)
How often does your partner physically hurt you?	7 (2.9)	4 (1.7)	2 (0.8)	0	0	1 (0.4)
How often does your partner insult or talk down to you?	2 (0.8)	1 (0.4)	2 (1)	6 (2.5)	2 (0.8)	1 (0.4)
How often does your partner threaten you with physical harm?	5 (2.1)	2 (0.8)	4 (1.7)	3 (1.3)	0	0
How often does your partner scream or curse at you?	1 (0.4)	2 (0.8)	3 (1.3)	6 (2.5)	1 (0.4)	1 (0.4)

condition and these included 18 (8%) participants having anxiety, 17 (7%) depression, 7 (3%) panic attacks, 5 (2%) post-traumatic stress disorder and 1 (0.4%) attention deficit disorder and PND each. Diagnosis of mental health disorder was before COVID-19 pandemic among 16 (6.7%) study participants and after pandemic among 8 (3.3%) participants.

Participants responded to who currently supported them with their mental health and 13 (5.4%) of the participants mentioned a counsellor/psychologist/psychotherapist, 12 (5%) GP, 1 (0.4%) family, therapist, and work, while 7 (3%) said they had no support currently. During the time of COVID-19 pandemic, when questioned about what impact the support had on their mental health, nine (4%) participants said it stayed the same, seven (3%) said it decreased, six (2.5%) said increased, while four (1.7%) were not sure. Regarding method of support and whether it changed from face to face to other types, 12 (5%) were affirmative, 4 (1.7%) said there was no change, 6 (2.5%) were not sure while 1 (0.4%) participant said that the support did change for a while but currently face-to-face support had resumed (*Table 36*).

Participants were also asked if ever in the past 3 months, they had wished they were dead or had wished to go to sleep and not wake up. To this, 18 (7.5%) participants said yes while 6 (2.5%) preferred not to say. Further, 10 (4.2%) of the participants confirmed that they had a thought of harming themselves during the last 3 months. When asked if these thoughts had worsened or increased since the time of restrictions, 6 (2.5%) were affirmative while 19 (7.9%) were not sure.

COVID-19-related worries

Various COVID-19-related scenarios had been presented to survey participants to assess how worried they felt, and participants responded they were extremely worried about transmitting the virus to a vulnerable person (*n* = 93, 38.8%), the virus impacting their long-term physical (*n* = 57, 23.8%) and mental health (*n* = 45, 18.8%). A quarter of the participants were worried how COVID-19 was impacting their finances (*n* = 60) and how it would impact the society (*n* = 59). There was an additional worry related to experiencing another wave of the pandemic (*n* = 63, 26.3%).

Patient Health Questionnaire-9

The mean PHQ-9 score of survey participants was 5.37 ± 5.65. Severe depression was found in 8 (3.3%), moderately severe depression in 9 (3.8%), moderate depression in 35 (14.6%), mild depression in 60 (25%) and 128 (53.3%) had no or minimal depression.

Generalised Anxiety Disorder-7

The participants' mean score for anxiety on GAD-7 was 3.4 ± 4.8. Of all the participants, 170 (70.8%) had minimal or no anxiety, 42 (17.5%) had mild, 17 (7.1%) had moderate, whereas 11 (4.6%) had severe anxiety.

Impact of Events Scale – revised

The mean score of participants on the Impact of Events Scale was 11.2 ± 17.9. About 191 (79.6%) of the participants had no post-traumatic stress disorder (PTSD) while 19 (7.9%) had partial PTSD, 7 (2.9%) had probable diagnosis of PTSD and 23 (9.6%) had PTSD.

TABLE 36 Participants response to type of consultation they received and preferred

Type of consultation	Type of consultation received, *n* (%)	Preferable type of consultation, *n* (%)
Telephone consultations	7 (2.9)	5 (2)
Video consultations	1 (0.4)	1 (0.4)
Face-to-face contact	1 (0.4)	3 (1.3)
A mixture of telephone and video consultations	1 (0.4)	0
A mixture of telephone and face-to-face consultations	1 (0.4)	2 (0.8)
A mixture of video and face-to-face consultations	1 (0.4)	0

Ways of coping

Participants were asked how often they communicated with friends or family and were presented different methods of communication as options. A majority used messaging services such as WhatsApp, text messages, Facebook messenger, etc., several times a day (*n* = 93, 38.8%) to stay connected. Phone calls (21.7%), video calls (14.2%), and face-to-face interactions (10.8%) were other ways to stay connected. The impact of COVID-19 on a participant's relationship with family and friends was also asked in the survey. A total of 81 (33.8%) participants said they felt closed to family and friends, 80 (33.3%) felt isolated, 73 (30.4%) said that they were talking more, 60 (25%) said they had not noticed any change, while 9 (3.8%) said they were having more arguments. Participants were also asked how confident they were in coping with pandemic-related stress and these responses are presented in *Tables 37–39*.

Loneliness was assessed among survey participants and the results indicated that 148 (61.7%) did not feel lonely, 85 (35.4%) felt lonely, while 7 (2.9%) preferred not to say. Participants were also asked their opinion about perceived social support and in this regard various statements were given to them. Their responses are presented in *Table 6*. In this regard various statements were offered. Their responses indicated that most of the participants had a special person around them when needed (*n* = 108, 45%), with whom they could share their joys and sorrows (*n* = 114, 48%). They also agreed that their family tried to help them (*n* = 177, 65.4%) and that they got the emotional support and help needed from the family (*n* = 152, 63.4%). The participants also had friends with whom they could share their problems and joys (*n* = 130, 54.2%) (*Tables 35* and *36*).

TABLE 37 Participants' response to how worried they feel about various scenarios in relation to COVID-19

Scenarios	Not at all, *n* (%)	A little bit, *n* (%)	Moderately, *n* (%)	Quite a bit, *n* (%)	Extremely, *n* (%)
Getting COVID-19 yourself	58 (24.2)	70 (29.2)	39 (16.3)	36 (15)	34 (14.2)
Transmitting COVID-19 to someone else	51 (21.3)	54 (22.5)	28 (11.7)	47 (19.6)	56 (23.3)
Transmitting COVID-19 to your friends/family	45 (18.8)	49 (20.4)	31 (12.9)	44 (18.3)	66 (27.5)
Transmitting COVID-19 to a vulnerable person	42 (17.5)	40 (16.7)	24 (10)	37 (15.4)	93 (38.8)
COVID-19 impacting on your long-term physical health	57 (23.8)	52 (21.7)	37 (15.4)	37 (15.4)	57 (23.8)
COVID-19 impacting on your mental heath	76 (31.7)	45 (18.8)	29 (12.1)	45 (18.8)	45 (18.8)
COVID-19 impacting on your employment	120 (50)	32 (13.3)	16 (6.7)	18 (97.5)	42 (17.5)
COVID-19 impacting on your ability to care for others, including animals	62 (25.8)	63 (26.3)	29 (12.1)	38 (15.8)	47 (19.6)
COVID-19 impacting on your finances	74 (30.8)	38 (15.8)	19 (7.9)	46 (19.2)	60 (25)
COVID-19 impacting on your friends/family	35 (14.6)	59 (24.6)	44 (18.3)	52 (21.7)	47 (19.6)
COVID-19 impacting on society as a whole	39 (16.3)	57 (23.8)	33 (13.8)	47 (19.6)	59 (24.6)
Experiencing another wave of the pandemic	48 (20)	52 (21.7)	28 (11.7)	45 (18.8)	63 (26.3)
Things opening up too soon	99 (41.3)	46 (19.2)	36 (14.6)	37 (15.4)	16 (6.7)
Others not wearing masks	107 (44.6)	38 (15.8)	36 (15)	21 (8.8)	28 (11.7)
Going into your place of work	141 (58.8)	26 (10.8)	21 (8.8)	18 (7.5)	16 (6.7)
Mixing with those who have not been vaccinated	125 (52.1)	34 (14.2)	29 (12.1)	23 (9.6)	19 (7.9)

TABLE 38 Participants' ways of coping during the COVID-19 pandemic

(a) Participants' method of communication with family and friends

Communication method	Several times a day, *n* (%)	Daily, *n* (%)	Every few days, *n* (%)	Not at all, *n* (%)
Messaging services (such as WhatsApp, text messages, Facebook messenger, etc.)	93 (38.8)	88 (36.7)	51 (21.3)	6 (2.5)
Telephone calls	52 (21.7)	99 (41.3)	78 (32.5)	9 (3.8)
Video calls	34 (14.2)	73 (30.4)	94 (39.2)	36 (15)
Social media	50 (20.8)	63 (26.3)	57 (23.8)	66 (27.5)
Face to face	26 (10.8)	55 (22.9)	99 (41.3)	56 (23.3)

(b) Participants' response on how confident they were when faced pandemic-related stress

	Not at all, *n* (%)	A little bit, *n* (%)	Moderately, *n* (%)	Quite a bit, *n* (%)	Extremely, *n* (%)
Support yourself to cope well in the situation	22 (9.2)	44 (18.3)	52 (21.7)	46 (19.2)	69 (28.8)
Support those around you to cope well in the situation	17 (7.1)	43 (17.9)	56 (23.3)	54 (22.5)	66 (27.5)

(c) Loneliness among survey participants

Items for loneliness scale	Hardly ever, *n* (%)	Some of the time, *n* (%)	Often, *n* (%)
How often do you feel that you lack companionship?	129 (53.8)	67 (27.9)	35 (14.6)
How often do you feel left out?	132 (55)	63 (26.3)	34 (14.2)
How often do you feel isolated from others?	131 (54.6)	67 (27.9)	35 (14.6)

TABLE 39 Participant response regarding COVID-19-related perceived social support

	Very strongly disagree, *n* (%)	Strongly disagree, *n* (%)	Mildly disagree, *n* (%)	Neutral, *n* (%)	Mildly agree, *n* (%)	Strongly agree, *n* (%)	Very strongly agree, *n* (%)
There is a special person who is around when I am in need	15 (6.3)	11 (4.6)	9 (3.8)	24 (10)	23 (9.6)	41 (17.1)	108 (45)
There is a special person with whom I can share my joys and sorrows	16 (6.7)	9 (3.8)	11 (4.6)	17 (7.1)	28 (11.7)	38 (15.8)	114 (47.5)
My family really tries to help me	11 (4.6)	12 (5)	10 (4.2)	24 (10)	20 (8.3)	55 (22.9)	102 (42.5)
I get the emotional help and support I need from my family	14 (5.8)	8 (3.3)	14 (5.8)	22 (9.2)	25 (10.4)	47 (19.6)	105 (43.8)
I have a special person who is a real source of comfort to me	13 (5.4)	10 (4.2)	11 (4.6)	18 (7.5)	28 (11.7)	45 (18.8)	109 (45.4)
My friends really try to help me	14 (5.8)	16 (6.7)	15 (6.3)	38 (15.8)	24 (10)	55 (22.9)	66 (27.5)
I can count on my friends when things go wrong	17 (7.1)	19 (7.9)	18 (7.5)	34 (14.2)	33 (13.8)	46 (19.2)	64 (26.7)
I can talk about my problems with my family	10 (4.2)	20 (8.3)	11 (4.6)	28 (1.7)	323 (13.3)	47 (19.6)	87 (36.3)

TABLE 39 Participant response regarding COVID-19-related perceived social support (*continued*)

	Very strongly disagree, *n* (%)	Strongly disagree, *n* (%)	Mildly disagree, *n* (%)	Neutral, *n* (%)	Mildly agree, *n* (%)	Strongly agree, *n* (%)	Very strongly agree, *n* (%)
I have friends with whom I can share my joys and sorrows	15 (6.3)	15 (6.3)	14 (5.8)	27 (11.3)	33 (13.8)	59 (24.6)	71 (29.6)
There is a special person in my life who cares about my feelings	18 (7.5)	8 (3.3)	4 (1.7)	19 (7.9)	38 (15.8)	41 (17.1)	103 (42.9)
My family is willing to help me make decisions	13 (5.4)	10 (4.2)	8 (3.3)	33 (13.8)	28 (11.7)	42 (17.5)	101 (42.1)
I can talk about my problems with my friends	16 (6.7)	8 (3.3)	20 (8.3)	28 (11.7)	36 (15)	41 (17.1)	85 (35.4)

Child care, homeschooling, infant feeding and development

Survey participants were asked about child-care arrangements prior to pandemic, for which 48 (20%) participants mentioned home-based care, 39 (16.3%) said grandparents or other relatives, 26 (10.8%) said other options, 3 (1.3%) said in home nanny, whereas 89 (37.1%) said that they had no child care. With regard to the number of hours per week for child-care arrangements utilised by participants and how they were affected during the pandemic restrictions, 49 (20.4%) of the participants said that these child-care restrictions impacted productivity at work level, while 29 (12.1%) said that there was no impact. Further, 53 (22.1%) participants said that these restrictions on child care had impacted their stress and anxiety levels, while for 26 (10.8%) there had been no impact.

For managing household chores with child care restrictions, 56 (23.3%) said it had been impacted and 22 (9.2%) said it had not. Regarding children's home-schooling arrangements during the lockdown, 34 (14.2%) participants said they had used content created and shared only by the school, 59 (24.6%) said they had used both school- and parent-created content, while 104 (43.3%) said other (i.e. out of school or homeschooled prior to the pandemic).

The closure of children's centres and support groups affected 99 (41.3%) of the participants, while 130 (54.2%) said they had not been affected. In addition, 119 (49.6%) of the participants experienced concerns about their child's development during the pandemic. When the participants were further asked about the specific area of child development in which they had concerns, 89 (37.1%) said in social, 62 (25.8%) in language, 57 (23.8%) in emotional, 53 (22.1%) in cognitive/learning outcomes and 45 (18.8%) in physical area of development.

Of all participants, 133 (55.4%) breastfed their child, 97 (40.4%) had not, and 10 (4.2%) preferred not to say. Of those who breastfed, 32 (13.3%) did it for < 6 months and 98 (40.8%) did for more than 6 months. There were 76 (31.7%) participants who had breastfed their baby during the pandemic. When questioned about how the pandemic had impacted their breastfeeding practices, 20 (8.3%) participants mentioned the impact on frequency, 9 (7.9%) duration of breastfeeding, and 18 (7.5%) said that their plan of breastfeeding was impacted due to the pandemic. Participants were also asked about the possibility of testing positive with COVID-19 and if it would impact their concern about breastfeeding their child and chances of transmission. Of the participants, 145 (60.4%) said no, while 22 (9.2%) said yes. However, 63 (26.3%) felt they would have benefitted from additional support/advice with breastfeeding from the mid-wife team/health visitors.

One-to-one interviews – health professional and service providers' perspectives

A total of 10 interviews were conducted with health professionals and service providers (*Table 40*); all participants were female; eight participants were of BSA background, and two were of White British background; eight were based in the North West and one in South Yorkshire and one in London.

TABLE 40 Stakeholder interviews

Health discipline/service	
Midwife	3
General practitioner	1
Domestic abuse service	3
Third sector organisation	2
Children's services	1

Increase in interpersonal violence referrals and reporting

Although the lockdowns were implemented for protecting public health, these also created unintended impacts. The majority of participants perceived the lockdown as heightening the risk factors for IPV due to various reasons: increased financial strains due to loss of income as a result of unemployment and the lack of space or opportunities to avoid situations for those in unsafe relationships:

> *So one of the women I was talking to lived with her husband and his family, and during that first period of lockdown she was saying that she because her child was then not in school and not obviously not in childcare and that she, that the abuse from the husband's family really escalated and she would just keep herself and her child upstairs in in her bedroom, and like every time that she went downstairs, whether it was to get food or do washing or anything she knew that she was kind of open to abuse from husband's family.*
>
> *Third-sector organisation (NW-007)*

Social distancing and isolation meant IPV victims were at a higher risk and greater vulnerability, as many were forced to isolate with violent partners or family members. Many who were dependent on others for their immigration status were threatened and are often at risk of IPV. Participants talked about how for many BSA women, the limited private space isolated victims of IPV from their social support system as victims/survivors, limiting access to family and friends, the people they rely on, so increasing the risk of further violence.

> *… and across all of the clients that we've got, you know it's being stuck at home with the perpetrator 24/7 which is all of them have reported was the worst. And we know, I mean we've not got the statistics but you know reports to the police increased. Which, and you know the knock-on effect of living with the perpetrator and things so that has been.*
>
> *Domestic abuse service (NW-002)*

Although it was perceived that the increase in IPV reporting was due to the increased risk factors with lockdowns and pandemic restrictions, interestingly, a few participants highlighted that the lockdown provided the opportunity for many IPV victims the opportunity to report the abuse and seek help, which otherwise may not have been reported:

> *… And so she talked about having a consultation with the GP. The GP over the telephone. GP asked her is everything all right at home and she said no, she disclosed domestic violence, which she hadn't done before. Because every time she'd been to the GP surgery before her husband had been with her and she'd never been able to make a disclosure so that again it was a situation where the abuse she was experiencing had escalated because all this, all these people in his house were brought together. But the flip side of that was because of the difference in her GP appointment. She was able to make a disclosure, and she left the, so she did access support and she left an abusive relationship. So there was loads of kind of unexpected stories, I guess, from the women I spoke to.*
>
> *Third-sector organisation (NW-007)*

> *The ones that have, like I said, we gave the option if it's not safe for them to speak at home, come to the doctors surgery and we would get the receptionist to ring and say we need to check your bloods or something and call them in that way so we were quite fortunate because we've got those connections and those links.*
>
> *Domestic abuse service (NW-002)*

Participants also highlighted that BSA women with no recourse to public funds were at an exceptionally high risk due to their inability to access benefits and many statutory services. This also presented a barrier to disclosing personal circumstances, for example, mental well-being and IPV.

> *Even before the outbreak of COVID-19, women's access to specialist refuge provision in the UK was severely limited. These victims and survivors spend much longer in insecure, temporary accommodation than other groups.*
>
> *Third-sector organisation (LO-009)*

It was also highlighted that not all IPV victims can reach out for help, this was raised as a concern, particularly in the case of South Asian women, where the women are repeatedly deemed accountable for safeguarding the family 'honour', which has generated a history of under-reporting over the years and are forced to remain in abusive environments.

Increased home and care responsibilities

Many women were expected to take on domestic responsibilities such as cooking, cleaning and other obligations. Due to the lockdown, these women were additionally burdened with the expectation of educating their children and also looking after their in-laws and husband:

> *I think, staying inside, isolation, staying in the home, I think that made them think, that made them realize more on loads of things probably were just, you know, some time, usually in a, in a typical Asian family sort of set up, where woman look after children, cook food and stay home and husband goes out for work. But then, then people started working from home, then I think that it kind of sort of a reflection time to give, give them a more understanding that where the relationship is actually.*
>
> *Third-sector organisation (SY-003)*

Participants reflected that the overwhelming strain of additional household roles may have led to potential mental health difficulties for many South Asian women. Participants highlighted that previous to the lockdown, many young BSA women were able to use their independent lives (through work, friends, relationships, etc.) as a form of escape from the controlling environments often found at home; due to the lockdown, many found themselves entrapped without a release from the difficult home environment.

Mental health support

Participants who came in contact with service users highlighted their observation that service users faced many challenges due to the pandemic, ranging from loss in income and problems accessing healthcare services and other statutory services to difficult relationships at home and child-care-related challenges had played a part leading to a deterioration in their mental wellbeing. A participant highlighted:

> *We have seen depression which is more than normal, anxiety was more than normal because people were housebound and not working so we were getting more calls … I did notice there were more forms which the midwives were doing and expressing concerns.*
>
> *General practitioner (NW-006)*

Access to healthcare services

The COVID-19 pandemic essentially changed how patients accessed primary care; participants talked about the overnight rearrangements of patient contact, moving to remote consultations from face-to-face appointments. For some, this method provided accessibility; however, it also presented difficulties highlighted by participants as language and cultural barriers, which were more difficult to manage via remote consultations. Participants also highlighted that most did not have regular access to digital devices or were IT literate and may have limited access:

> *There were barriers like people were finding it difficult to access GPs. They wouldn't come to the surgery, even when sometimes we when we thought we had to see the patient face to face for examination … But yes in White population they try their best to engage with health services. So they would attend accident and emergency, they would contact the GP.*
>
> *General practitioner (NW-006)*

The GP participant (NW-006) further highlighted the challenges in access of mental health services for patients:

> *Mental health is the I think the worst service I've got lots of friends who are psychiatrist, and I keep saying this. That been mental health was the most difficult, it still is even pre-COVID and after COVID just now also. If you refer to mental health, it takes ages, and most of the time the referrals are declined. That we are not suitable for this service referred to local like self-help, group mindful and mindfulness, and all those type of things with the sign posters to those services, plus even with the during the COVID time all of us have experience that even contacting mental health team for crisis was a nightmare. You have to ring 3, 4 numbers before you can find the right person.*

A participant highlighted the need for clear, accessible, locally relevant public information for BSA women, ensuring engagement in the continuity of maternity care provision measures, reassuring BSA women with regard to maternity care and seeking help with any concerns about their health and maternity care.

Interpreting services

Participants also highlighted the need for adequate regulation and standards agreed to ensure the use of appropriately trained interpreters.

> *Sometimes you know professionals still don't recognize that speaking to the woman alone, getting an independent interpreter is so important to do. Not trusting the smiling mother-in-law who looks like a lovely nice cute little old lady with her head scarf on. Its such a stereotype isn't it, that they believe that no she's a loving caring grandma and we thought it was okay to speak to her and we've closed the case because she said everything was fine. So I think a lot of work still needs to be done about awareness about honour based violence, about multiple perpetrators as well.*
>
> *Domestic abuse service (NW-002)*

Need for cultural competency and training

Cultural understanding and competence were highlighted as key factors ensuring the individual is respected, and the individual's culture is acknowledged and valued. On this note, another important point highlighted was recognising the different cultural practices or views within the South Asian community and recognising the intersectionality. Understanding the beliefs and their learnt notions of health and how their religious beliefs, traditional values and upbringing may play a role in their interactions with and access to health care or services.

A participant highlighted that cultural competence education for healthcare professionals would influence improved health outcomes for interacting and working with diverse patient groups to increase their empathy and by being able to understand and communicate effectively and help reduce health disparities:

> *I also think that that practitioners need cultural awareness. And that's really hard, because there isn't just one culture for any group of people. So you know, I think there's a danger in saying that British South Asian women all have the same culture, and therefore the same needs, or risks, or whatever. And yes, there's a danger of kind of homogenizing and logging people together, so understanding that level of difference in diversities is really hard. But on the flip side I think there is something about cultural competence, and people need to understand that there are differences. Similarly, if you're an older woman to a younger woman, there are additional aspects of your circumstances. And bits of your identity that that will come into play. If you, you know, if you are domestic violence victim.*
>
> *Third-sector organisation (NW-007)*

Challenging implicit bias and prejudice

A few participants stressed the importance of recognising the role of implicit biases of health care professionals creating disparities in healthcare as implicit bias and prejudice may undermine the goal of delivering impartial care: highlighting that a patient should not receive a lower standard of care due to her ethnicity or cultural background:

> *There are issues with care provided to South Asian women, there's a lot of issues. And I've had bias and prejudice and presumptive conversations around South Asian communities by healthcare professionals. It's sadly, one of those things that I historically didn't challenge because I didn't feel like I was able to. And now I have a way of challenging it in a respectful professional manner, and now people don't talk a lot about that around me anymore, so I'm not going to think that oh we've cured it, I just know that they know I will not let them have such conversation in my presence and. And that should tell them that it's a wrong conversation to have and the fact that they're saying that is incorrect because if they have to edit themselves, just because I'm in the room, then they should have the realization that it's wrong to say in the first place.*
>
> *Midwife (NW-001)*

The danger of BSA women being considered homogeneous and overlooking their intersectionality of socioeconomic status, ethnicity, religion, gender and immigration status was highlighted by participants. Furthermore, the need for conversation and to do it consistently was stressed by a participant, highlighting the depth and breadth of South Asians as a community with different subsets and cultural notions, which cannot be addressed by mainstream services in its totality to address all the different intricacies. Still, proactive engagement encourages open, consistent conversations can help to address such challenges.

Intervention

Participants made suggestions for IPV interventions, tailoring interventions to meet the needs of individuals, and ensuring culture-specific and trauma-informed strategies could be helpful for South Asian women. Culturally sensitive interventions comprising of meaningful understanding of the IPV contexts in which BSA women are placed, the community understanding, and experiences of mental health would help with engagement in interventions by BSA women:

> *I think one of the things that I worry about when we talk about standardizing or having a universal way of doing something, is that each family and each individual as much as we have things that link us they're all different and experiences are different so as much as we can standardize and we can have those practices. We also need to be conscious about having a personalized aspect of it, and understanding individual needs for people that might be in that group of that session.*
>
> *Midwife (NW-001)*

Although the value of involvement of the family in the intervention was recognised by participants, in the context of South Asian women, many participants felt that it would not work as, from their experiences, many perpetrators included intimate partners and BSA women's in-laws, extended family members and own family members.

One-to-one interviews – ROSHNI-2 participant's perspectives

The interviews with trial participants for the add-on study focused on gaining a better understanding of the effect of global pandemic on BSA women in the postnatal period and also aimed at getting the participants' perspectives on how future trials should be informed to address IPV. The findings are reported under the themes of mental health during the pandemic, perceived isolation, education, interpersonal relationships, child development, perspective on COVID-19 vaccination and future interventions.

Mental health during the pandemic

Due to the pandemic and the lockdown, the participants reported higher anxiety and pressure. The anxiety was considerable because of the unknown nature of the virus and limited information available related to it. There was the added fear that perhaps the virus would never go away and that things will never get back to normal:

> *We did not know what was happening … perhaps this would remain like this forever … things would never improve … something bad is going to happen.*
>
> *Trial participant (NW-0192)*

Along with limited information available, the experience of having to stay within the confines of the home and not going out at all made the participants feel upset even more:

> *Getting to stay at home … it felt like it was a prison … with the complete lockdown, the children also became very upset and then not being able to do shopping … there were too many problems that came during that time and my depression really increased.*
>
> *Trial participant (NW-0192)*

The women explained that they struggled to get support from the GPs due to the closure of the surgeries and this was particularly difficult for those women who gave birth during this time. One of the participants reflected:

> *The COVID-19 obviously started in 2020 officially … I gave birth to my child in 2019 December. So for me, it was the hardest year to be honest. Because everything got changed the way you actually get help, the way you actually get your midwives, or anything like that, especially with the childbirth or postnatal care, everything has been changed and you got all your kids at home. So, to be honest, since 2020 it has been really really roller coaster ride for me, or any mother like me with kids. There was no appointments, you can't see your doctor. you can't speak to anybody, everything has been closed.*
>
> *Trial participant (NW-0173)*

The statement above identifies how the participants were struggling as they found it difficult to get the right kind of support. This affected their mental health, and some found it difficult to cope:

> *I'm a freak, I get a lot of anxiety with everything, it gives me a lot of stress and also my kids that get a lot of allergies like seasonal, so it was really difficult for me to you know this distinguish between if it's the virus or if it's just normal in our daily everyday sniffles so it was really difficult in the beginning but I was so panicky.*
>
> *Trial participant (LO-01)*

Another participant reported:

> *I remember being very anxious, as my husband has leukopenia so he has low white cells, and his cousin was on a ventilator from the flu because he has the same condition. So I was quite worried and scared for my husband.*
>
> *Trial participant (NW-0193)*

Perceived isolation

The pandemic was associated with a number of challenges including social isolation. One participant explained:

> *We used to feel upset, as we were not allowed to meet anyone in person, nor we were allowed to go at anybody's house. Neither anybody could come to your house. In the past we were very social, so it was difficult for us to live in isolation.*
>
> *Trial participant (NW-142)*

However, some of the participants also reported not feeling too much of a difference related to socialising or going out. This was because of their lifestyle even before the pandemic where they did not step out much out of the house, and therefore did not find things very different during the pandemic:

> *It did not impact me that much … actually I do not go to anybody's home … I do not talk also with many people … I don't also have any close friend here as such … with whom I can talk or go to her place every day … there is nothing like that.*
>
> *Trial participant (NW-0094)*

Another participant similarly mentioned:

> *To tell you the truth we generally do not meet many people … I do not have that much of a social life … it is not that much at all.*
>
> *Trial participant (NW-00192)*

Child education

Similar to other areas of life, the pandemic greatly impacted schooling and education. Children were at home due to school closures and, even though they were connected to the schools through online classes, had different routines from what they were used to. Almost all of the women who were asked about the distant learning responded that they favoured face-to-face classrooms rather than home schooling during the pandemic. One of the women shared:

> *It is best that children should attend school physically in a routine. There they learn more in contrast to home schooling.*
>
> *Trial participant (NW-00142)*

Similarly, another participant responded:

> *No, I believe online schooling was not very successful, my children sometimes used to pay attention to their online session, however, they use to put the laptop at a side while the teacher was still teaching. My son who is at the age of 13–14 was not very much interested in the online session and did not focus on his education as he should be doing.*
>
> *Trial participant (NW-00175)*

One of the women responded about the online schooling mentioning that she found this entire time particularly stressful due to managing so many things simultaneously and balancing housework with the children's schooling. She said:

> *Oh don't ask … it was very very difficult … you know managing house work and then this was something totally new for me … I have three kids and I have to sit down with three of them at different times … and I can't explain how I spent that time … sometimes I was fed up … and sometimes we used to miss some homework as well.*
>
> *Trial participant (NW-001)*

Some participants also felt that it was a good opportunity for them to spend time with their children and help them in their learning process.

> *I have never spent that much time with my son in his learning but now I managed to help him with handwriting and his spelling, because I felt he is not getting that kind of help from the school now with the closures. State schools were unfortunately not able to help like independent schools.*
>
> *Trial participant (NW-002)*

Interpersonal relationships

The add-on study interviews also focused on the relationship between the participants and their spouses and the extended family members during the pandemic. Many participants reported that they did not come across any issues with their own spouse and did not report any incident of interpersonal violence, though they did mention incidents in their circle of acquaintance and hearing about increase in interpersonal violence through media reports.

One of the participants explained:

> *No really, I do not have my own personal experience of it, however, I used to learn from the news that this happened that happened, and actually come across through news that the divorce rate has gone up.*
>
> *Trial participant (NW-00173)*

A participant who mentioned physical violence with her spouse during the lockdown reported:

> *I think it did get physical only once, and that situation was only, like he's not a violent person. It was like he had his own health issues or due to his brain condition, I think, which why the incident occurred. That's one incident that we had where things did get physical.*
>
> *Trial participant (LO-01)*

A participant reported feeling a strain in her relationship with her husband during the pandemic which was heightened due to the fact that he lost his job whereas she still had hers. This had an impact on their interpersonal relationship:

> *Because you don't have a job and that it is very difficult for any British South Asian man to accept no matter how little they may be earning or how educated … he was getting very agitated over small things …*
> *if my daughter would come out of the room without socks it suddenly was my fault, because I should have put the socks on and suddenly she is walking around and sneezing while I am in a meeting and he is observing me working. I know I can't snap back because if I do, I might end up losing my marriage during the pandemic but he is getting quite difficult to deal with every time.*
>
> *Trial participant (NW-002)*

The same participant went on to add:

> *It very nearly got physical … my husband was under immense pressure to send money home which he couldn't because he was furloughed … so all the long hours on phone calls with his family while I was working in my room … added to his frustration and he took it all out on me … he was constantly blowing up on small things.*
>
> *Trial participant (NW-002)*

Stress on children

During the lockdown, children were confined to their house with online classes/distance learning. The closure of the schools for a seemingly indefinite period and the pandemic caused frustration and anxiety among children.

As a participant shared:

> *No, they didn't like the closures. My oldest one wanted to go to the school and needed some support in some subjects. He used to get stressed and used to start to cry saying that I don't know how to do it and teacher did not explain me. I know the teacher didn't have much time as well. So, he was getting a bit stressed on that side, he said no I don't like online schooling I want to go to the school so that they can help me.*
>
> *Trial participant (NW-0013)*

Furthermore:

> *H]onestly now, it makes me sad when I see my kids like when they're out and about and it's my little one that she almost four not even four yet and if she touches, anything, even you know when they walk in the park and she touches a bar that is around the lake, and my son, and even now my daughters like that do not touch this it is a coronavirus you need to disinfect your hand. That is wrong like this age, they were supposed to be free, and not you know pressurized by a virus and they going to get sick or eventually people will die.*
>
> *Trial participant (NW-LO1)*

A participant mentioned her child getting more aggressive and anxious during the pandemic:

> *Many people were mentally effected, one of my sons also use to feel agitated, he use to shout a lot and fight with his sibling very often. This could be clearly noticed that they also got fed up with the social isolation and if in the future the world will face anything like this, I believe it will be very painful for them.*
>
> *Trial participant (NW-04)*

Getting additional help from online tutors was also considered by a participant, although she did mention that she was not too happy, but there was not any choice. She felt that getting the children in a structured routine would be helpful since the children were spending too much of time on social media and video games:

> *Honestly, I was not too happy with it … we were paying per hour to this girl who used to give some worksheets to my son … but it was better than nothing. My children were frustrated, they were scared, they kept asking me questions… x box became a normal part of the day … my biggest job was to get them off the xbox … my children are very difficult to deal with, they know my every move … constantly they were on i-phones like hours are going by.*
>
> *Trial participant (NW-002)*

Perspectives on COVID-19 vaccination

Many of the participants had concerns and reservations about the vaccination and were not pleased to have it. Especially when it was inquired about the booster, they declined to have one nor showed any interest in getting one in the future.

One of the participants expressed her doubts about the effectiveness of the vaccine. She shared:

> *No, I didn't want to have, and it was the same thing that you are actually playing with the body, so this is something that you are not doing it right. Your body immunity is very strong, and it fight itself. So, you are actually playing with the immunity rather than anything else. I'm not well in any way, and that's what's been happening with me as well since I got my second vaccination. I am not good, I have so many issues so many problems so many things that I never experienced before. So yeah, I wouldn't say that this is a good option.*
>
> *Trial participant (NW-0173)*

While feeling hesitant to take the vaccination, one of the participants felt she took it in order to comply with the travel guidelines and regulations:

> *Yes, many rumours circulated but I was compelled to have the vaccination as I was not able to travel without it and I have family outside the UK so it was more of a compulsion then a choice.*
>
> *Trial participant (NW-01)*

One participant felt that even though there were several rumours about the vaccination, she took it because she fell into the vulnerable category:

> *There were a lot of stories that circulated about the vaccination. Some people said they are putting in the chip in the body to control the human being. But I had no choice as I am a diabetic patient and I got a call from the NHS that I am vulnerable and should get the vaccination.*
>
> *Trial participant (LO-04)*

Vaccine hesitancy was particularly noticed in pregnancy and breastfeeding women as a participant spoke:

> *I did not take the vaccine because I am pregnant at that time and now I am breastfeeding so I am not sure whether to take it or not … there is also not much information available about how it impacts the baby … so I don't want to cause any harm to the baby. Actually, my husband has also not got it. He keeps saying that he will get it but he has not done so far … he has gone 4–5 times but always good back … I think he is scared.*
>
> *Trial participant (NW-0094)*

Future interventions

The participants were asked about how future interventions be informed, particularly addressing interpersonal violence. They were reminded about the PHP on which the ROSHNI-2 intervention was based, on the principles of CBT, and two further interventions were presented: (1) trauma-focused CBT – *Basid ki kahani* and (2) the Learning through Play parenting intervention. These interventions have been reported to be effective in South Asia. The participants were then requested to share what they thought needed to be included in addition to the content discussed with them.

Most of the participants said that the future interventions should be universal so that more people can benefit from them:

> *I like the idea of involving fathers as well as mothers, and generally as I suppose it should be open to everyone and everyone can benefit from it. Even foster parents or carer should also have access to it. These sorts of programmes would be so beneficial.*
>
> *Trial participant (NW-04)*

Another participant agreed to extend the intervention besides just women in the perinatal period:

> *I guess it depends who you are trying to target because I think interpersonal violence is not just for women, though is it. I think it effects both genders and I guess if we are seeing a bigger problem for women then I guess it is good for women only but I think children should also be included but it depends on the ages of the children.*
>
> *Trial participant (NW-0175)*

> *I think it should be universal, everyone should benefit from it.*
>
> *Trial participant (NW-0018)*

The participants also felt that including delivery of some sessions by religious leaders within the modules might prove to be beneficial for the participants:

> *I think if a maulvi or father from the church delivers some of the sessions, then more participants might listen or might attend because out of respect they want to agree with them.*
>
> *Trial participant (NW-0094)*

A participant felt that getting to know about one's rights and assertiveness training is very important for women, particularly to stand up against interpersonal violence:

> *It is extremely important that British South Asian women know their rights … they should know what their value is … this is something that is not often talked about … we should be able to stand up for ourselves … these kind of things should be included in the therapy sessions*
>
> *Trial participant (NW-00192)*

Next steps for impact and dissemination

- The differences in demographics and costs suggest that further work and research are needed to establish how best to ensure equitable services within primary care.
- Further research is necessary to support a better understanding of cultural competence to help improve cultural knowledge among healthcare professionals and IPV service providers.
- Health providers can help to mitigate the risk of IPV against women and help reduce its impact by signposting to many locally available support services (hotlines, crisis centres, shelters, legal aid, and protection and counselling services) for IPV survivors and referring BSA women to these services by strengthening engagement with the community.

Additional information

Contributions of authors

Nusrat Husain (https://orcid.org/0000-0002-9493-0721) (Consultant psychiatrist, director of research global mental health, professor of psychiatry) was the study CI with overall responsibility of the study. He also developed the initial drafts of each chapter and had input and review from each of the authors.

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All listed authors have been with the project team from the initial bid submission for funding to the development of the protocol, delivery of the project and the write up of this monograph

All authors have contributed to the development and approved the final version of this monograph.

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Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

Data-sharing statement

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.

Ethics statement

The study was approved by the NorthWest Health Research Authority (ethics approval number: IRAS 187851; 6th January 2017), with each trial site granting individual NHS Trust approvals prior to recruitment at each site.

Information governance statement

Lancashire & South Cumbria NHS Foundation Trust is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

Under the Data Protection legislation, Lancashire & South Cumbria NHS Foundation Trust is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here www.lancsteachinghospitals.nhs.uk/privacy-notice.

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Primary conflicts of interest: Bhui has membership with HS&DR Funding Committee (Bevan) from November 2020 to present. Davies has membership with HTA Clinical Evaluation and Trials Committee (date unknown), Williams has membership with HTA Commissioning Sub-Board (EOI) April 2016 to March 2017, HTA Funding Teleconference Members April 2015 to December 2015, HTA Commissioning Committee August 2011 to September 2017. Emsley has membership with NIHR CTU Standing Advisory Committee January 2020 to January 2024 and membership with the HTA Clinical Evaluation and Trials Committee. Gire is a member of the NIHR PHR Funding Committee from 2022 to present. Morriss has participation on the NIHR EME, HTA and HSDR trial steering committees and Data monitoring ethics committees.

Publication

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