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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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Scientific summary

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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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