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A randomised, controlled trial of a community-based perinatal intervention for postnatal depression in India

Submission date
06/11/2002

Recruitment status
No longer recruiting

Registration date
06/11/2002

Overall study status
Completed

Last Edited
17/02/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims.
Research has identified that significant numbers of women in South Asia can experience postnatal (postpartum) depression. Various effective interventions have been described for women with postnatal depression in high income countries, but at the time of starting this study, no effective intervention had been described for postnatal depression in South Asian women. We aimed to develop a low-cost intervention, based on the evidence-based treatment of 'listening visits' offered by Health Visitors in the UK. We adapted the listening visit intervention to allow it to be provided by experienced mothers who did not have any clinical qualification. We aimed to test the effectiveness of lay psychological intervention. We recruited pregnant women at high risk for postnatal depression, and our hypothesis was that women receiving the intervention would be less likely to develop postnatal depression than women receiving usual care.

Who can participate?
The study was based in Goa, India. We identified a community sample of women in the final months of pregnancy, and we used known risk factors for postnatal depression in Goa to identify women at high risk of developing postnatal depression. Only high-risk women were recruited into the study.

What does the study involve?
The active intervention was a package of 5-6 listening visits, delivered by a lay health worker. Participants in the control group received usual care from local health services.

What are the possible benefits and risks of participating?
All participants in the study were screened for symptoms of depression. Any women with worrying levels of depression during the study were referred to an independent local psychiatrist for a free consultation to discuss treatment options. The same applied to women who were identified as having suicidal thoughts. There are no known side effects of the psychological intervention.

Where is the study run from?
The study was based in a community district of Goa, India. The local research base was the Sangath Centre, a non-governmental organisation providing clinical services to the local population, as well as being the centre for several community health and mental health research projects. The associated UK academic base of the researchers is the Institute of Psychiatry, Kings College London.

When is the study starting and how long is it expected to run for?
The study ran from 2002 to 2003. We ran a pilot study from 2001 to 2002.

Who is funding the study?
The Wellcome Trust (UK).

Who is the main contact?
Dr Marcus Hughes, research fellow (2001-2004)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
060174

Study information

Scientific Title
A randomised, controlled trial of a community-based perinatal intervention for postnatal depression in India

Acronym
SMIPS (Supporting Mothers in Pregnancy Study)

Study objectives

The primary objective is to determine whether a brief perinatal intervention can reduce the prevalence of postnatal depression at three months postpartum, in a group of women identified as being at high risk for the condition, compared to a control group of high risk women. Risk status will be determined using data from an earlier cohort study.

The secondary objectives are:
1. To determine whether the growth and developmental outcome for the infants of women receiving the intervention is improved compared to the infants of women in the control group
2. To determine whether the prevalence of chronic depression, at six months postpartum, is reduced by the same intervention
3. To determine whether levels of maternal disability and health care usage are influenced by the intervention
4. To examine the effect of putative socio-demographic risk factors on response to the intervention
5. To identify the relationship between outcome (both maternal and infant) and adherence to the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postnatal depression; child development

Interventions
A home-based, perinatal psycho-social intervention is given to a random half of the participants. It is based on 'listening visits' used for postnatal depression by UK health visitors, culturally adapted and piloted in Goa. One specific aspect of the intervention is a component to challenge male-child preference, and the psychological pressure that exists for some women to bear a male heir. This pressure has been shown in a recently published cohort study from Goa to be an important risk factor for postnatal depression. The intervention is delivered over five or six sessions (two antenatal, three to four postnatal).

The control group receives usual care from local medical and obstetric services.

The trial was conducted in collaboration with Sangath (http://www.Sangath.com), a non-governmental organisation, conducting research and providing mental health services to children and families in Goa, India.

Intervention Type

Other

Phase
Not Specified

Primary outcome(s)
1. Depression at three and six months postnatal (using Edinburgh Postnatal Depression Scale)
2. Primary infant outcome: mental development score on the Developmental Assessment Schedules for Indian Infants (DASII), measured at six months postnatal

Key secondary outcome(s))
1. Maternal depression according to International Classification of Diseases (ICD-10) criteria (Revised Clinical Interview Schedule [CIS-R]), measured at three and six months postnatal
2. Disability (WHO Disability Assessment Schedule, version II [WHO-DAS II]), measured at three and six months postnatal
3. Costs of healthcare (Modified Client Services Receipt Inventory [CSRI]), measured at three and six months postnatal
4. Infant growth, measured at three and six months postnatal
5. Maternal-infant interaction (Global Rating Scale of maternal-infant interaction [GRS]), measured at three months postnatal

Completion date
30/06/2004

Eligibility

Key inclusion criteria
1. Pregnant women, between 26 and 34 weeks gestation at recruitment
2. At high risk of postnatal depression. A pre-recruitment screening interview is used to identify high risk women, based on:
2.1. Presence of psychological symptoms
2.2. Reporting the current pregnancy to be unplanned, and
2.3. Being vulnerable to excessive pressure to bear a male child (see interventions)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria

1. Women who did not speak the study language (Konkani)
2. Women who planned to move away from the project area during the period of the study
3. Women with a health problem of such seriousness that it would prevent them from participating in the study

Date of first enrolment
01/08/2002

Date of final enrolment
01/09/2003

Locations

Countries of recruitment
United Kingdom

England

India

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/04/2004		Yes	No