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Development and evaluation by randomised trial of a community-based Early Multimodal Intervention for depressed mothers and their infants in rural Rawalpindi, Pakistan

Submission date
08/06/2006

Recruitment status
No longer recruiting

Registration date
08/06/2006

Overall study status
Completed

Last Edited
26/08/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
071548

Study information

Scientific Title
Development and evaluation by randomised trial of a community-based Early Multimodal Intervention for depressed mothers and their infants in rural Rawalpindi, Pakistan

Acronym
EMI Trial

Study objectives
The main aim of the study is to develop and then test in cluster randomised design an early multimodal psychosocial intervention targeting mothers with antenatal and postnatal depression. Our hypothesis is that infants of mothers having the intervention will have significantly better growth than the infants of mothers who do not have the intervention. The secondary aim is to investigate the mediating effects of maternal mood, social functioning, health-seeking behaviour, and the moderating effect of maternal education and socio-economic status on the intervention outcome.

The overall trial end date was extended from 15/04/2006 to 30/06/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised single-blind study with two parallel groups

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depressive disorder

Interventions
The groups are randomised on the basis of union council (smallest rural administrative area with population of approximately 10 - 15,000).

Study area and population:
The study will be conducted in two rural sub-districts of Rawalpindi district in Northern Punjab, Pakistan. The study area consists of 40 union councils with a population of 500,000. All women in the study area, in their third trimester of pregnancy, will form the study population. Randomisation of the union councils will be carried out by the trial centre in Rawalpindi.

All recruited subjects will be interviewed by trained and clinically experienced members of the research team using the Structured Clinical Interview for Diagnostic and Statistical Manual of

Mental Disorders IV (SCID DSM-IV), a semi-structured interview for the diagnosis of psychiatric disorder. Recruitment will continue for about one year until 450 women meeting the SCID criteria for current major depressive episode are recruited into each arm of the study.

The intervention group will receive a 16-session Early Multimodal Intervention (EMI) delivered by 40 trained Lady Health Workers (LHWs) to mothers in the intervention group. Control group will receive an enhanced antenatal and postnatal follow-up by a different group of LHWs (16 structured visits monitored by the research team).

Proposed methods for protecting against sources of bias: the outcome data will be collected by an outcome assessor unaware of treatment allocation, and the mother will be asked not to reveal anything about treatment.

Sample size calculations:
Our earlier epidemiological study shows a difference of -0.62 Standard Deviation (SD) in weight for Age Z (WAZ) between case and control. The unit of randomisation is the union council. With 20 union councils in each arm (control and intervention) and 18 mothers per union council and assuming intercluster correlation of 0.05, sample size of 360 in each group would give 80% power to detect the above effect size at the same significance level. Over a period of 12 months we will recruit 450 subjects in each arm, which will allow for infant deaths, families moving out of the study area, and dropouts (our participation rate is likely to be high because:
1. The intervention is delivered at the subjects' homes
2. Participation where existing health care is rudimentary is likely to be high
3. Subjects will be given a small incentive to allow outcome measures to be taken

Planned analysis:
Analysis will be undertaken independently by the Health Care Trials Unit, University of Manchester, under the supervision of the trial statistician, Chris Roberts. Primary analysis will be based on intention to treat, but a secondary analysis will examine the relationship between participation in the treatment and outcome. The primary outcome measure will be the growth over the postnatal year. A cost-effectiveness analysis that compares the incremental costs and outcomes (secondary as well as primary) of the intervention group relative to the control group will be carried out using a random-effects model.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Growth velocity of infants will be compared by assessing development at four time points over one year (at birth and at three, six and 12 months of age). The infants of all three groups will be weighed and measured using standard techniques. Anthropometry will be converted into standard deviation scores.

Key secondary outcome(s))
1. Maternal depression will be assessed using the SCID
2. The level of severity of depression will be assessed using the Hamilton Depression Rating Scale
3. Disability will be assessed using the Brief Disability Questionnaire (BDQ), an eight-item

questionnaire that rates current problems in carrying out daily activities
4. Data will also be collected on demographic, socio-economic, social support and health care-seeking characteristics of the study population
5. Service inputs will be converted into local currency units (Pakistani rupees) via unit cost templates used in earlier mental health economic studies in India and Pakistan

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. The age range for inclusion in the study is 17 to 40 years
2. All subjects should intend to stay in the study area for at least six months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Subjects will not be included in the trial if they:
1. Have a diagnosed medical condition
2. Have a significant physical or learning disability
3. Have postpartum, or other forms of psychosis
4. Are currently under psychiatric care

Date of first enrolment
01/04/2005

Date of final enrolment
15/04/2006

Locations

Countries of recruitment
United Kingdom

England

Pakistan

Study participating centre
Manchester Royal Infirmary
Manchester
United Kingdom
M20 2AE

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

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?
Results article	results	13/09/2008		Yes	No
Results article	results	01/07/2015		Yes	No