

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	<input type="checkbox"/> Prospectively registered
Registration date 08/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/08/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Atif Rahman

Contact details

Department of Psychological Medicine
Rawnsley Building
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M20 2AE
+44 (0)161 276 5331
atif.rahman@ntlworld.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/04/2005

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

Age group

Adult

Sex

Female

Target number of participants

900

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**

England

Pakistan

United Kingdom

Study participating centre

Manchester Royal Infirmary

Manchester

United Kingdom

M20 2AE

Sponsor information**Organisation**

University of Manchester (UK)

Sponsor details

Third Floor Finance Office

Rawnsley Building

Manchester Royal Infirmary

Oxford Road

Manchester

England

United Kingdom

M13 9WL

+44 (0)161 2765278

David.Walkden@manchester.ac.uk

Sponsor type

University/education

Website

<http://www.manchester.ac.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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