

Randomised controlled trial of a complex intervention for persistently depressed women of Pakistani origin

Submission date
08/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
12/04/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
09/03/2011

Condition category
Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

0242003TAE006GATER

Study information

Scientific Title

Study objectives

For depressed Pakistani women:

1. The beneficial effects on severity of depression and social functioning of social group therapy including psycho-education exceed those of protocol guided antidepressant treatment
2. The beneficial effects of combined social therapy group with protocol guided antidepressant treatment exceed those of social group therapy alone

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval not yet received as of 12/04/06

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depressive disorder

Interventions

Participants will be randomly allocated to one of three intervention groups:

1. Social group and psycho-education
2. Protocol-guided antidepressant treatment
3. Combined social group, psycho-education and protocol-guided antidepressant treatment

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Severity of depression as measured by the Hamilton depression scale.

Key secondary outcome(s)

1. Social functioning measured by Bolton's social functioning questionnaire
2. Disability measured by the brief disability questionnaire and disability days
3. Service contacts measured by a modified version of the client service receipt inventory

Completion date

31/07/2006

Eligibility

Key inclusion criteria

Adult females, aged between 16 and 65, of Pakistani family origin who have a current depressive disorder.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Women who are pregnant or who are planning to become pregnant during the next six months
2. Women planning a trip away from Manchester for six weeks or more within the next six months (e.g. trip to Pakistan)

Date of first enrolment

01/08/2004

Date of final enrolment

31/07/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Rawnsley Building

Manchester

United Kingdom

M13 9WL

Sponsor information**Organisation**

University of Manchester (UK)

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) Trial Platform Grant TP192 (UK)

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	01/09/2010		Yes	No