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

Submission date	Recruitment status	[ ] Prospectively registered
08/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/04/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/03/2011	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Severity of depression as measured by the Hamilton depression scale.

Secondary outcome measures
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

Overall study start date
01/08/2004

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

Age group
Adult

Sex
Female

Target number of participants
120

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
England

United Kingdom

Study participating centre
Rawnsley Building
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Dr John Rogers
Head of the Research Office
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Sponsor type
University/education

Website
http://www.manchester.ac.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

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	01/09/2010		Yes	No