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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
08/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/04/2006	Completed	[X] Results		
<b>Last Edited</b> 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

Dr Richard Gater

#### Contact details

Rawnsley Building Manchester Royal Infirmary Oxford Road Manchester United Kingdom M13 9WL

## 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

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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