

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

<b>Submission date</b> 08/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/04/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/03/2011	<b>Condition category</b> 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 Richard Gater

### Contact details

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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  
University of Manchester  
Christie Building  
Oxford Road  
Manchester  
England  
United Kingdom  
M13 9PT

### **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?
<a href="#">Results article</a>	results	01/09/2010		Yes	No