

# Social intervention for depressed women: Pilot randomised controlled trial

<b>Submission date</b> 07/06/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/07/2008	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

**Study objectives**

There will be a reduction in depressive symptoms in a group of chronically depressed Pakistani women by attending a social group intervention at a local community centre.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved by the Ethical Research Committee of Pakistan Institute of Learning and Living (PILL).

Date of approval: 19/03/2008 (ref: PILL-080311)

### **Study design**

Randomised, rater-blind trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Depression

### **Interventions**

The 66 participants will be divided into 3 groups (22 participants each), and then they will be randomly allocated to the intervention and control sub-groups (therefore, each sub-group consists of 11 participants). The control group will be provided with antidepressants and another will be provided with a psychosocial intervention.

Psychosocial intervention: The group structure will be informal, active participation by the women will be encouraged at all times. The facilitators will motivate and encourage these women. The overall aim would be to provide social support, stimulation, education on mental and physical health needs, problem solving training and possibly giving these women a break from their distressing environment. This will provide an opportunity for them to initiate a process of getting acquainted with other women, even making friends. We hope that some of these relationships would be long lasting and would continue even when the group ends. Total number of sessions: 10. Duration of each session is 1 hour.

Total duration of interventions: 12 weeks.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

The following will be carried out before and after attendance at the social activities group for 10 sessions or taking antidepressants for 10 weeks:

1. Self Rating Questionnaire (SRQ)
2. Hamilton depression scale

**Key secondary outcome(s)**

Quality of life, assessed by EuroQol (EQ-5D) at 12 weeks.

**Completion date**

15/09/2008

**Eligibility****Key inclusion criteria**

Depressed women aged 16-55

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

Anyone leaving community within the next six months

**Date of first enrolment**

15/06/2008

**Date of final enrolment**

15/09/2008

**Locations****Countries of recruitment**

Pakistan

**Study participating centre**

11-C

Karachi

Pakistan

74500

**Sponsor information**

**Organisation**

Remedial Centre (Pakistan)

**ROR**

<https://ror.org/03wdref81>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Remedial Centre (Pakistan)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration