

Social intervention for depressed women: Pilot randomised controlled trial

Submission date 07/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/07/2008	Condition category 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

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