Social intervention for depressed women: Pilot randomised controlled trial

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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DHA

Phase 5

Karachi

Pakistan

74500

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.

Phychosocial 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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes