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Social intervention for depressed women: Pilot randomised controlled trial

Submission date
07/06/2008

Registration date
24/06/2008

Last Edited
11/07/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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)

Primary study design
Interventional

Study design
Randomised, rater-blind trial

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