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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

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

Overall study start date
15/06/2008

Completion date
15/09/2008

Eligibility

Key inclusion criteria
Depressed women aged 16-55

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
66

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)

Sponsor details
D-9, Block I
North Nazimabad
Karachi
Pakistan
74500

Sponsor type
Hospital/treatment centre

Website
http://remedialcentre.com

ROR
https://ror.org/03wdref81

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Remedial Centre (Pakistan)

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