

A pragmatic randomised controlled trial to assess the clinical effectiveness of 'guided self-help' versus 'waiting list control' in the management of anxiety and depression in primary care. Self-Help in Anxiety and DEpression (SHADE).

Submission date 11/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/05/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/09/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.npcrdc.man.ac.uk/ResearchDetail.cfm?ID=73>

Contact information

Type(s)

Scientific

Contact name

Dr Peter Bower

Contact details

National Primary Care Research and Development Centre (NPCRDC)
5th Floor
Williamson Building
University of Manchester
Oxford Road
Manchester
United Kingdom

M13 9PL
+44 (0)161 275 7638
peter.bower@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
SHADE

Study objectives

Provision of guided self-help will produce superior clinical outcomes to waiting list management at 3-month follow-up for patients with anxiety and depression

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Anxiety/depression

Interventions

Intervention group - use of a written self-help manual and up to 4 brief (15-30 minute) face-to-face facilitation sessions with a graduate assistant psychologist while on waiting list.

Waiting list control group - patients remain on waiting list, with routine support (as required) from primary care provider.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The Hospital Anxiety and Depression Scale (HADS) score

Secondary outcome measures

1. Beck Depression Inventory (BDI)
2. Social Adjustment Scale (SAS)
3. Clinical Outcomes in Routine Evaluation scale (CORE)
4. Patient satisfaction and other self-report measures of the treatment process

Overall study start date

01/01/2002

Completion date

31/01/2005

Eligibility**Key inclusion criteria**

Adult patients with anxiety/depression referred from primary care to one of three Greater Manchester psychological therapy services and currently with 3+ months remaining on the waiting list.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

114

Key exclusion criteria

1. Under 18 years of age
2. Baseline score <14 on the Beck Depression Inventory (BDI) and <11 on anxiety scale of the Hospital Anxiety and Depression Scale (HADS)
3. Referred for therapy from source other than primary care
4. Less than 3 months remaining on therapy service waiting list
5. Poor proficiency in English (i.e. inability to complete questionnaires or read the self-help manual)
6. Active suicidal thoughts
7. Current substance misuse
8. Organic brain disease
9. Current contact with specialist mental health services

Date of first enrolment

01/01/2002

Date of final enrolment

31/01/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

National Primary Care Research and Development Centre (NPCRDC)

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

National Primary Care Research and Development Centre (NPCRDC) (UK)

Sponsor details

5th Floor

Williamson Building

University of Manchester

Oxford Road

Manchester

England

United Kingdom

M13 9PL

Sponsor type

University/education

Funder(s)

Funder type

University/education

Funder Name

National Primary Care Research and Development Centre (NPCRDC) (UK) - via core funding from the Department of Health

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2005		Yes	No