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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

Registration date
16/05/2005

Overall study status
Completed

Last Edited
14/09/2009

Condition category
Mental and Behavioural Disorders

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

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

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
The Hospital Anxiety and Depression Scale (HADS) score

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

United Kingdom

England

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes