A trial platform of guided self-help for mild /moderate depression in primary care

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
03/05/2005		☐ Protocol		
Registration date 11/08/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 07/10/2009	Condition category Mental and Behavioural Disorders	[] Individual participant data		
0111012009	Mental and benavioural Disorders			

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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G0401181

Study information

Scientific Title

Study objectives

To examine trial recruitment rates, protocol fidelity, treatment adherence, clinical outcome effect size, cost utility and acceptability of a standardised guided self help intervention within a pilot trial.

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)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Depression

Interventions

Guided self-help for depression versus usual care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Clinical response at three months
- 2. Cost and health resource utility
- 3. Trial process measures (recruitment rates: treatment fidelity, intervention effect size, acceptability)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2005

Completion date

31/08/2007

Eligibility

Key inclusion criteria

Mild/moderate depression presenting in primary care

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

- 1. Depression not as primary diagnosis
- 2. Risk to self or others

Date of first enrolment

01/09/2005

Date of final enrolment

31/08/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre School of Nursing, Midwifery & Social Work

Manchester United Kingdom M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

Oxford Road Manchester England United Kingdom M13 9PL

Sponsor type

University/education

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	24/11/2008		Yes	No