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A feasibility study to test the methods and recruitment procedures towards a future randomised trial of self-hypnosis versus antidepressant medication for the management of depression

Submission date	Recruitment status No longer recruiting	Prospectively registered	
02/12/2005		[_] Protocol	
Registration date	Overall study status	Statistical analysis plan	
24/01/2006	Completed	[X] Results	
Last Edited 20/01/2011	Condition category Mental and Behavioural Disorders	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers CZG/2/121

Study information

Scientific Title

Study objectives

The future aim of this work was to conduct a randomised trial of nurse-taught self-hypnosis versus antidepressant drug treatment in primary care. However, an initial feasibility study was proposed to determine the feasibility and acceptability of the study and its proposed methods.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Reviewed and approved by National Health Service Lothian Research Ethics Committee

Study design

Patient preference trial measuring the response to either nurse led antidepressants or selfhypnosis

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

A nurse led audio compact disc (CD) package on self-hypnosis versus GP prescribed antidepressant treatment (usual care).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Changes in scores on the Beck Depression Inventory

2. Brief Symptom Inventory

3. SF-36

Secondary outcome measures Not provided at time of registration

Overall study start date 31/05/2004

Completion date 12/12/2004

Eligibility

Key inclusion criteria

Eligible patients were all those aged 18-65 with a diagnosis of depression and receiving a new prescription for antidepressants from their general practitioner (GP)

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Upper age limit 65 Years

Sex Both

Target number of participants 100

Key exclusion criteria

Exceptions were those with bipolar depression, psychoses, alcohol and illicit drug use and active suicidal ideas.

Date of first enrolment 31/05/2004

Date of final enrolment

12/12/2004

Locations

Countries of recruitment Scotland

United Kingdom

Study participating centre Reader in Sociology Stirling United Kingdom FK9 4LA

Sponsor information

Organisation University of Edinburgh (UK)

Sponsor details Old College South Bridge

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Sponsor type University/education

Website http://www.ed.ac.uk

ROR https://ror.org/01nrxwf90

Funder(s)

Funder type Government

Funder Name

Chief Scientist Office of the Scottish Executive Health Division ref CZG/2/121 (UK)

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	01/07/2009		Yes	No