RCT of self-help intervention - phase 2

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/09/2007		☐ Protocol		
Registration date 28/09/2007	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 24/08/2012	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

Contact name

Prof Mike Lucock

Contact details

Adult Psychological Therapies Services Fieldhead Hospital Ouchthorpe Lane Wakefield United Kingdom WF1 3SP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0266184278

Study information

Scientific Title

Study objectives

Is there a difference in clinical outcomes between clients who receive a 1+ 1 model of facilitated self help intervention shortly after initial assessment compared to a waiting list control?

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)

Hospital

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

Mental and Behavioural Disorders: Anxiety disorders

Interventions

A randomised controlled trial of a self help intervention for anxiety patients waiting for psychological therapy phase 2. Quantitative & qualitative. Random allocation to:

- 1. Early facilitation group (EFG)
- 2. Delayed facilitation group (DFG)

EFG offered session > 2 weeks following screening; DFG standard waiting list.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2006

Completion date

01/09/2007

Eligibility

Key inclusion criteria

- 1. 2 groups of service users within Primary Care and Liaison Treatment Team (PLATT) team
- 2. Patients screened by a primary care mental health team who have mild to moderate anxiety and depression problems

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

205

Key exclusion criteria

- 1. Patients with severe depression
- 2. Personality disorders
- 3. Severe substance misuse and psychosis

Date of first enrolment

01/02/2006

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Adult Psychological Therapies Services

Wakefield United Kingdom WF1 3SP

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

South West Yorkshire Mental Health NHS Trust (UK), NHS R&D Support Funding

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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011		Yes	No