RCT of self-help intervention - phase 2

[] Prospectively registered

[] Statistical analysis plan

[] Individual participant data

[] Protocol

[X] Results

Submission date 28/09/2007	Recruitment status No longer recruiting
Registration date 28/09/2007	Overall study status Completed
Last Edited 24/08/2012	Condition category Mental and Behavioural Disorders

Plain English summary of protocol Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Prof Mike Lucock

Contact details

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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 summary Not 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