

Guided self-help for eating disorders: A randomised controlled trial

Submission date
28/09/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
28/09/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
27/09/2012

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
Ms Gemma Traviss

Contact details
University of Leeds
Leeds Institute of Health Sciences
Charles Thackrah Building
101 Clarendon Road
Leeds
United Kingdom
LS2 9LJ
+44
umgt@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0626191789

Study information

Scientific Title

Study objectives

This study aims to evaluate the effectiveness of this GSH (Guided Self Help) pack in both primary and secondary care as delivered by trained, supervised mental health professionals.

Until 15/05/08:

- the title was: Guided self-help for eating disorders in primary care
- the end date was 31/12/07

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 15/05/08:

Leeds (East) Research Ethics Committee 06/Q1206/51

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

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: Eating disorder

Interventions

A mail shot of GPs able to refer the trained guides will inform GPs of the research project and help them to identify appropriate patients/participants. Once referred to the guide the participant will undergo that guide's service routine screening or assessment process. If the participant meets the inclusion criteria, the project is explained to them verbally and in writing. The participant is also asked to make an appointment with their GP to obtain any relevant blood tests and get their BMI. If a participant is not suitable to participate or does not wish to, they receive the treatment as usual from the service. After consent is given the guide contacts the

researcher sending her the consent form. Participants details are anonymised and a code is used. The research randomises the participant to GSH or waiting list control. People randomised to the waiting list control group will remain on the service's waiting list for the amount of time they would usually have done if they were not taking part in the research. The researcher will also contact the participants GP to inform them of the participants involvement in the project.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

It would evaluate the outcome of using the pack as compared to a group of people on the waiting list (in terms of mental health, and eating disordered behaviour and psychopathology), the effect of the therapeutic alliance on the GSH and the adherence to and usefulness of the pack as rated by users.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/2006

Completion date

31/08/2009

Eligibility

Key inclusion criteria

Participants for the research will be recruited from people accessing primary or secondary mental health care.

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Added 15/05/08: 70

Key exclusion criteria

Added 15/05/08:

1. BMI<16 or rapid weight loss
2. <16 years of age
3. If primary difficulty is not an eating disorder

4. High risk of self-harm or suicide
5. Abusing drugs or alcohol
6. Severe depression
7. Major co-morbid physical disorder

Date of first enrolment

01/07/2006

Date of final enrolment

31/08/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9LJ

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

Leeds Partnership Foundation NHS Trust (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	01/01/2011		Yes	No