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

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol		
28/09/2007				
Registration date	Overall study status	Statistical analysis plan		
28/09/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
27/09/2012	Mental and Behavioural Disorders			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number 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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

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

Funder(s)

Funder type

Government

Funder Name

Leeds Partnership Foundation NHS Trust (UK)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes