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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 28/09/2007 | No longer recruiting | [ ] Protocol |
| **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

**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 |