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Internet-based relapse prevention for in-patients with anorexia nervosa

Submission date
05/06/2008

Recruitment status
No longer recruiting

Registration date
18/07/2008

Overall study status
Completed

Last Edited
12/09/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Relapse after in-patient treatment of anorexia nervosa (AN) is common, especially in the year following discharge. The aims of this study are to assess the feasibility of delivering a manual-based, e-mail-guided self-care relapse prevention programme for people with AN after discharge from in-patient treatment, added to usual care; and to get key information that would inform development of a large-scale study assessing the effectiveness, acceptability and cost-effectiveness of this intervention.

Who can participate?
In-patients with AN, aged 16 or above, in specialist eating disorders units in the UK.

What does the study involve?
Participants are randomly allocated to receive either manual-based email-guided self-care for 12 months combined with usual care, or usual care alone. The treatment manual used is based on the Maudsley Model of Anorexia Nervosa Treatment for Adults (MANTRA), a treatment approached tried and tested at the Maudsley Hospital. Email support is delivered weekly by experienced therapists. After 6 and 12 months, body mass index (assessed by patients weight and height) is measured and various questionnaires and research interviews are carried out to assess eating disorder symptoms, depression, anxiety, quality of life and service utilisation (in particular rehospitalisation).

What are the possible benefits and risks of participating?
The benefits of participating are a 50% chance of receiving additional after-care (added to usual care) following discharge from hospital and that this extra support and guidance from a clinician may be helpful in maintaining gains made in hospital and aid recovery. There is also the benefit of having contact with a trained researcher at 6 and 12 months and to use the research assessments as a way of reflecting on your situation and progress. Participants may also like the idea that they are contributing to helping other people by participating in clinical research that may lead to improved treatments. The risks are that the research assessments take time, may be exhausting (they take a couple of hours), and questions about eating disorder symptoms and feelings may be distressing to some people.

Where is the study run from?
Institute of Psychiatry, King's College London (UK)

When is the study starting and how long is it expected to run for?
July 2008 to June 2011

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Ulrike Schmidt
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Study website
http://www.iop.kcl.ac.uk/sites/edu/?id=126

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RP-PG-0606-1043

Study information

Scientific Title

A randomised controlled multi-centre trial of the efficacy and cost-effectiveness of an internet-based treatment in relapse prevention for patients with severe anorexia nervosa

Study objectives
The disease to be studied is anorexia nervosa (AN). This is a life-threatening illness with a mortality rate twice that of other psychiatric in-patients, and a suicide rate 200 times that of the general population. There are high levels of physical disability and psychological comorbidity and the median duration of AN is six years. There is evidence that the course of the AN has become more severe, as indicated by increasing admission rates and rising mortality. In adults with AN the response to treatment is poor with only about 30% in remission after one year of specialist treatment. Relapse following treatment is common. 30-50% of those who remit relapse, many within the first year of treatment. Relapse is a particular problem after in-patient treatment, which in the UK is reserved for the most severe cases. This group of AN patients continue to be high service users following weight restoration treatment, with a mean number of 85 treatment hours in the first 6 months of discharge.

Hypothesis:
Patients with AN who following successful completion of in-patient treatment will receive an internet-based relapse prevention programme in combination with treatment as usual (TAU) will have a longer time to relapse and lower relapse rates than those AN patients allocated to TAU alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint South London and Maudsley NHS Foundation Trust and Institute of Psychiatry ethics committee, 02/09/2010, ref: 08/H1208/33

Study design
Two-arm randomised controlled multi-centre 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Severe anorexia nervosa (AN)

Interventions
The participants will be randomly allocated to the intervention and control groups in equal numbers.

Experimental intervention: Internet-based relapse prevention. Participants allocated to this intervention will receive e-mail support for 12 months from a clinician from the Maudsley Eating Disorders Unit. The intervention will be over the first 6 months following discharge and then there will be a follow-up period during months 7-12. Patients will also have access to a moderated electronic bulletin board. In addition, they will be sent a workbook designed for relapse prevention in AN, focusing on nutritional and psychosocial aspects of recovery. The role of the therapist will be motivational and supportive, with the aim to guide patients in their use of the workbook by suggesting use of relevant modules, thereby tailoring the intervention to the assessment profile (relapse risk, neuropsychological and anxiety-trait profile) of the patient, e.g. with patients with rigid perfectionist traits, emphasis will be on promoting cognitive flexibility, whereas with highly anxious patients the emphasis will be on reducing intolerance of uncertainty and worry. Patients in this group will also receive treatment as usual (TAU) from their local Community Mental Health Team or Child and Adolescent Mental Health Team.

Control group: Patients in this group will receive only TAU from their local Community Mental Health Team or Child and Adolescent Mental Health Team, as deemed appropriate.

Total duration of interventions and follow-up: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Proportion of people who relapse, assessed at 6 and 12 months
2. Time to relapse, assessed at 6 and 12 months
3. Body mass index, measured monthly for 12 months
4. Global Eating Disorders Examination (EDE) scores at end of treatment (6 months) and follow-up (12 months)

Relapse will be defined as follows: Weight loss of >2 BMI points (or 6 kg) for 2 consecutive weeks or in-patient treatment due to weight loss or severe medical complications other than low weight resulting from the AN and requiring in-patient treatment (e.g., severe hypokalaemia) or severe psychiatric disorder (e.g., suicidality) requiring in-patient treatment.

Secondary outcome measures
1. Interview measures, carried out at baseline, 6 and 12 months:
1.1. EDE
1.2. Client Services Receipt Interview (CSRI)
2. Questionnaire measures for the assessment of anxiety-related processes, carried out at baseline, 1, 6 and 12 months:
2.1. Intolerance of uncertainty scale
2.2. Penn State Worry Questionnaire
2.3. Cognitive avoidance questionnaire (CAQ)
2.4. Meta-Cognitions Questionnaire (MCQ-30)

2.5. Negative problem orientation questionnaire (NPOQ)
3. Questionnaire measures for the assessment of other psychopathology, carried out at baseline, 1, 6 and 12 months:
3.1. Depression, Anxiety and Stress Scale (DASS) - Short Version (21 items)
3.2. World Health Organization Quality of Life brief
4. Biological measure: Salivary cortisol, measured at baseline, 1, 6 and 12 months

Overall study start date
01/07/2008

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Patients fulfilling criteria for the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) AN or atypical AN who have undergone a period of in-patient treatment in one of the participating Eating Disorders Services
2. Both males and females, aged 13 years or over
3. Patients who have reliable access to broadband internet
4. Available over the full duration of the study
5. Patients who have shown clinically significant weight gain during in-patient treatment (a minimum of approximately 6 kg or 2 body mass index [BMI] points)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
98

Key exclusion criteria
1. Unstable AN i.e. actively losing weight at the end of treatment
2. Insufficient knowledge of English or literacy levels insufficient to allow understanding of the manual and assessment
3. Psychosis
4. Acute suicidality
5. Substance dependence
6. Diabetes mellitus

Informed written consent will be sought from patients and for adolescents from their parents at initial assessment.

Date of first enrolment

01/07/2008

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
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SE5 8AF

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust (UK)

Sponsor details
1st Floor Admin Building
Maudsley Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.slam.nhs.uk/default.aspx

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) - Programme Grant for Applied Research (UK) (ref: RP-PG-0606-1043)

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	01/08/2017		Yes	No