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A MultiCentre randomised Trial of the outcome, acceptability and cost-effectiveness of family therapy and multi-family day treatment compared with inpatient care and outpatient family therapy for Adolescent Anorexia Nervosa

Submission date	Recruitment status	[ ] Prospectively registered
05/04/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/11/2023	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
1206/1287

Study information

Scientific Title
A MultiCentre randomised Trial of the outcome, acceptability and cost-effectiveness of family therapy and multi-family day treatment compared with inpatient care and outpatient family therapy for Adolescent Anorexia Nervosa

Acronym
MCTAAN

Study objectives
The following main research hypotheses will be tested:
1. In severely ill patients Multi-Family Day Treatment (MFDT) will be equally effective as inpatient treatment in returning patients to a normal nutritional state by the three month assessment.
2. The overall cost-effectiveness of MFDT will be significantly higher than inpatient treatment and will compare favourably with outpatient family therapy.
3. In less severely ill patients MFDT will lead to a more rapid nutritional recovery than outpatient family therapy.
4. MFDT will lead to the highest levels of client and family satisfaction of the three treatments.

A subsidiary hypothesis is that MFDT will lead to the greatest reduction of distress and difficulties experienced by other family members.

Independent research assessors will evaluate the outcome, costs and client acceptability before the start of treatment, at three months, 12 months (end of treatment) and 18 months (six month follow-up).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institute of Psychiatry Ethics Approval, 10/10/2002, ref: 234/02
2. London MREC approval, 25/08/2004, ref: 04/MREC/022

Primary study design
Interventional

Study design
Multi-centre randomised treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anorexia Nervosa (in adolescents)

Interventions
Group one:
Inpatient treatment is based around a carefully structured nursing regimen, the main aims of

which are:
1. To form a therapeutic alliance
2. To achieve weight restoration
Other members of the multidisciplinary team provide additional therapeutic input depending on the needs of individual patients. Patients allocated to inpatient treatment will be admitted to a specialist Eating Disorder Unit for approximately 12 weeks. The actual length of inpatient stay will be determined by the time needed for each individual patient to reach a healthy weight. The study design, however, will limit the length of time from reaching a healthy weight to discharge from hospital to two weeks. Following discharge from hospital they will receive regular follow-up treatment for six months for themselves and their families. We are currently developing a modification of the outpatient family therapy treatment manual so that it can be used for patients entering family therapy at a point when their weight is normal. To ensure continuity of treatment the therapist responsible for the follow-up treatment will engage the patient and her family during the last two weeks of the inpatient stay. The overall length of treatment (i.e. inpatient plus follow-up) will be 12 months.

Group two:
Outpatient family therapy for adolescent anorexia nervosa has been the focus of our previous treatment trials and a treatment manual has been developed to guide the therapists' interventions. Patients are seen for a number of sessions over a period of 12 months. These are mainly conjoint family meetings although some individual sessions are included where appropriate (particularly with older adolescents at later stages of the treatment). Therapy begins with an emphasis on the parents taking control of re-nutrition, with a gradual move towards conversations exploring more general implications of adolescence for children and parents as soon as the nutrition level is safe. The aim is to help the family to disentangle individual psychological issues (e.g. self esteem, individuation, psychosocial functioning) and family relationship issues from the eating disorder behaviour and the interactional patterns that have developed around it.

Group three:
MFDT is a new treatment programme that has been developed over the past three years at the Maudsley Hospital and at the Eating Disorder Service in Dresden. The treatment provides a more intensive form of family intervention than the usual outpatient family therapy but is conceptually very similar. In common with our outpatient family therapy, MFDT aims to help families rediscover their own resources by emphasising ways in which parents can take control of re-nutrition. At the same time the families are encouraged to use the group setting to explore how the eating disorder and the interactional patterns in the family have become entangled, making it difficult for the family to follow the normal developmental course of the family life-cycle. The sharing of experiences and the dynamics of the multiple family group are important components of the treatment. The treatment starts with an intensive one week multiple family day programme for up to six families and is followed by a further four to five one day meetings at four to eight week intervals. Individual family meetings are scheduled in the intervals between group meetings as needed, with the overall length of treatment for each family being 12 months. A wide range of intervention techniques is used (including group, family, psycho-educational and creative techniques) with multiple family, parent or adolescent groups as well as individual family meetings. There is also practical input around managing mealtimes and food.

Intervention Type
Behavioural

Primary outcome(s)

1. Symptomatic change:
1.1. Body Mass Index (kg/m^2)
1.2. SEverity of Eating Disorder (SEED) symptomatology
1.3. Eating Disorder Examination (EDE)
1.4. Children's Eating Disorder Examination (C-EDE)
2. Health economic costs:
2.1. Client service receipt inventory

Key secondary outcome(s)
1. Client/family satisfaction questionnaire
2. Experience of caregiving

Completion date
30/06/2008

Eligibility

Key inclusion criteria
Patients referred to five eating disorder services (South London and Maudsley NHS Trust, St Georges and South West London NHS Trust , Blackwater Valley Primary Health Care Trust, Central & Northwest London Trust, The Child and Adolescent Eating Disorder Service of the Royal Free Hampstead Trust), who meet Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for anorexia nervosa or eating disorders not otherwise specified and who are aged between 13 and 20 years.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 Years

Upper age limit
20 Years

Sex
All

Key exclusion criteria
1. Patients in care
2. Patients with learning disabilities, psychosis or alcohol/substance dependence
3. Patients with medical condition that may lead to significant weight loss (e.g. Crohn's disease)

Date of first enrolment
01/07/2003

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Psychiatry
London
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Sponsor information

Organisation
The Health Foundation (UK)

ROR
https://ror.org/02bzj4420

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (UK) (ref. 1206/1287)

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	24/11/2016		Yes	No
Other publications	Moderators of treatment effect	27/11/2023	28/11/2023	Yes	No