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The BEAM trial: feasibility and acceptability of adding a 5-day multi-family therapy group to the early stages of family therapy for adolescent anorexia nervosa

Submission date
27/11/2020

Recruitment status
Suspended

Registration date
27/01/2021

Overall study status
Completed

Last Edited
11/07/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An eating disorder is when you have an unhealthy attitude to food, which can take over your life and make you ill. Family therapy (FT-AN) and multi-family therapy (MFT) are both recommended treatments for adolescent eating disorders in the UK. MFT is a group-based treatment that is typically offered in addition to FT-AN. During MFT up to eight families work together with a clinical team over 10 full days of treatment spread across 6 months.
MFT is associated with improved outcomes compared to FT-AN alone. However, relatively little is known about how the treatment works, for whom it is most appropriate, and what is the most effective dose of treatment. In the field of eating disorders, it is now well established that early behaviour change is associated with improved outcomes at the end of treatment. The format of MFT means it is well placed to offer increased, intensive support at this early stage, meaning a brief, intensive version offered early in treatment may be sufficient to improve outcomes.
This study aims to assess whether it is feasible to randomly allocate adolescents and their families to a 5-day intensive version of MFT delivered within the first 2 months of FT-AN treatment. The secondary aims of this study are to explore changes in weight, eating disorder symptoms, and family functioning in both FT-AN and MFT. The results will inform a larger-scale study.

Who can participate?
Patients aged 10-18 attending the Maudsley Centre for Child and Adolescent Eating Disorders with anorexia nervosa or atypical anorexia nervosa (with rapid weight loss over the past 3 months)

What does the study involve?
There are four parts to participating in this study for those who consent:
1. All adolescents complete a diagnostic interview and questionnaire pack focused on the participant's current concerns at the beginning of the study.
2. All participants then receive 6 months of family therapy (FT-AN) from a specialist eating

disorder clinician. Half of the people in this study will also come to a 5-day multi-family group that will happen in the first 8 weeks of treatment. People are randomly allocated to get this or not. Participants repeat the questionnaire pack at 2 months.
3. At the end of treatment everyone will be asked to complete the questionnaire pack again. Everyone will also be invited to participate in an optional in-depth interview about their experience of the treatment.
4. After treatment has finished participants will be asked to complete questionnaires 6 months and 12 months after the treatment has ended to see if any changes that are made during treatment are still present.

What are the possible benefits and risks of participating?
By taking part, participants have the chance to receive a new treatment as well as the first-line recommended treatment available. One of these treatments is not being offered anywhere else in the world currently. Participants will also be helping to contribute to eating disorders research and the development of new treatments.

Where is the study run from?
Maudsley Centre for Child and Adolescent Eating Disorders (UK)

When is the study starting and how long is it expected to run for?
June 2019 to January 2024

Who is funding the study?
Maudsley Centre for Child and Adolescent Eating Disorders (UK)

Who is the main contact?
Dr Julian Baudinet
Julian.Baudinet@kcl.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Julian Baudinet

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
234354

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20/LO/0839, IRAS 234354, Version 7

Study information

Scientific Title
Brief early adolescent multi-family (BEAM) therapy trial for anorexia nervosa: a feasibility randomized controlled trial

Acronym
BEAM

Study objectives
1. Intensive 5-day multi-family therapy will be a feasible new treatment approach for adolescents with restrictive eating disorders and their families.
2. Intensive 5-day multi-family therapy will be an acceptable treatment approach for adolescents with restrictive eating disorders and their families.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2020, London Stanmore Research Ethics Committee (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2561; stanmore.rec@hra.nhs.uk), REC ref: 20/LO/0839

Study design
Single-center feasibility randomized controlled 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 participant information sheet

Health condition(s) or problem(s) studied
Adolescent anorexia nervosa or atypical anorexia nervosa with rapid weight loss

Interventions
Randomization:
Block randomization will be performed by the King's Clinical Trials Unit who is not involved in data collection or analysis on this study. This will ensure blinding of the CI when collecting analyzing data to reduce bias. No demographic or baseline characteristics will inform the randomization process. Block randomization, with random block sizes, will be used to ensure both arms of the RCT are equal.

Interventions:
1. Family therapy for Anorexia Nervosa (FT-AN)
All participants (in both the control and experimental arms) will receive family therapy for anorexia nervosa (FT-AN; Eisler, et al., 2016). FT-AN is the NICE (2017) recommended treatment for adolescent eating disorders and has good outcomes. FT-AN is typically offered for 6 months. Young people and their families are seen weekly as a whole family initially, which becomes less frequent as the treatment progresses. Treatment initially focuses on engagement and managing eating disorder symptoms. Once the young person is managing food more effectively and are more stable medically treatment shifts to developmental and lifecycle needs. FT-AN is delivered by one qualified clinician.
2. Multi-Family Therapy for Anorexia Nervosa (MFT-AN)
Adolescents and families randomized to the experimental arm will receive FT-AN plus a 5-day

intensive multi-family therapy group (MFT-AN; Simimc, et al., in press) within the first 8 weeks of treatment. MFT is also NICE (2017) recommended and entails up to eight whole families working together with a clinical team over the course of a week to build skills, promote engagement and increase understanding around the illness and family dynamics. MFT is offered as five full consecutive days (10 am-4 pm) over one week (Monday to Friday). MFT is delivered by 2-3 clinicians.

Intervention Type
Behavioural

Primary outcome measure
Feasibility and acceptability measured in five domains:
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study during the study period (18 months) reported as a percentage
2. Feasibility of measurement tools recorded as:
2.1. The mean time taken to complete questionnaires in minutes
2.2. Amount of missing data per questionnaires reported as a percentage per measure
2.3. The number of participants who complete the questionnaire at 2 months, end of treatment (6 months), 6-month follow up and 12-month follow up, reported as a percentage of the total sample
3. Prospective acceptability recorded as:
3.1. Free text responses for why individuals did not take part or discontinued the trial
3.2. Mean responses to the Expectation of Improvement and Suitability of Treatment (EIST)
4. Acceptability of intervention for participants recorded as:
4.1. The total number of sessions attended recorded at the end of treatment (6 months)
4.2. The total number of sessions cancelled with reason recorded at the end of treatment (6 months)
4.3. The total number of sessions participants did not attend without provided notice recorded at the end of treatment (6 months)
5. Participant satisfaction measured using interview responses during qualitative interviews at the end of treatment (6 months)

Secondary outcome measures
Current secondary outcome measures as of 05/02/2021:
Measured at assessment, 2 months, end of treatment (6 months), follow up 1 (12 months), follow up 2 (18 months):
1. Weight: percentage median body mass index (%mBMI)
2. Psychiatric symptoms measured using EDE-A; RCADS
3. General functioning measured using WSAS-Y
4. Emotion regulation measured using DERS
5. Reflective functioning/mentalising measured using RFQ
5. Therapeutic alliance measured using SOFTA
6. Parental difficulties measured using HADS
7. Family functioning (criticism, warmth and emotional overinvolvement) measured using BDSEE, FQ, FMSS

Previous secondary outcome measures:
Measured at assessment, 2 months, end of treatment (6 months), follow up 1 (12 months), follow up 2 (18 months):

1. Weight: percentage median body mass index (%mBMI)
2. Psychiatric symptoms measured using EDE-A; RCADS
3. General functioning measured using WSAS-Y
4. Emotion regulation measured using DERS
5. Reflective functioning/mentalising measured using RFQ
5. Therapeutic alliance measured using SOFTA; MFT-GQ
6. Parental difficulties measured using HADS
7. Family functioning (criticism, warmth and emotional overinvolvement) measured using BDSEE, FQ, FMSS

Overall study start date
01/06/2019

Completion date
01/01/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/02/2021:
Patient criteria:
1. Patient aged 10-17 years (inclusive) living with their parent/s or carer/s for at least the past 3 months
2. Diagnosis of anorexia nervosa in the child at clinical assessment using DSM-V criteria (APA, 2013) or atypical anorexia nervosa paired with rapid weight loss (< 15% mBMI over 3 months)
3. Assessed as medically and psychiatrically fit for outpatient treatment
4. Adequate level of English, i.e. sufficient to understand study information sheets and consent forms

Parent/carer criteria:
1. Parent/carer of a child meeting inclusion criteria as above
2. Parent/carer will be involved in attending family therapy and multi-family therapy treatment sessions
3. Adequate level of English, i.e. sufficient to understand study information sheets and consent forms

_____

Previous inclusion criteria:
Patient criteria:
1. Patient age 10 – 18 years (inclusive) living with their parent/s or carer/s for at least the past 3 months
2. Diagnosis of anorexia nervosa in the child at clinical assessment using DSM-V criteria (APA, 2013) or atypical anorexia nervosa paired with rapid weight loss (< 15% mBMI over 3 months)
3. Assessed as medically and psychiatrically fit for outpatient treatment
4. Adequate level of English, i.e. sufficient to understand study information sheets and consent forms

Parent/carer criteria:
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2. Parent/carer will be involved in attending family therapy and multi-family therapy treatment

sessions
3. Adequate level of English, i.e. sufficient to understand study information sheets and consent forms

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
70

Key exclusion criteria
Patient criteria:
1. Active psychotic disorder
2. Current physical and/or sexual abuse occurring in the household between any members of the family

Date of first enrolment
01/07/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Maudsley Centre for Child and Adolescent Eating Disorders
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maudsley Centre for Child and Adolescent Eating Disorders

Results and Publications

Publication and dissemination plan
1. The protocol is currently being written up for publication, to be submitted in early 2021
2. Planned publication of the results in a high-impact peer-reviewed journal in 2024

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Anonymised data will be available upon request to Julian Baudinet (Julian.Baudinet@kcl.ac.uk). Only data that has been consented to being shared anonymously will be made available. All data is stored in the Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King’s College London, UK.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/06/2021	18/06/2021	Yes	No
HRA research summary			28/06/2023	No	No