

# 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

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<b>Registration date</b> 27/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/07/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### ORCID ID

<https://orcid.org/0000-0002-7840-4158>

### Contact details

King's College London

Department of Psychological Medicine

Institute of Psychiatry, Psychology & Neuroscience (IoPPN)

16 De Crespigny Park

Denmark Hill

London

United Kingdom

SE5 8QF

+44 (0)20 7848 0160

Julian.Baudinet@kcl.ac.uk

**Type(s)**  
Scientific

**Contact name**  
Dr Julian Baudinet

**ORCID ID**  
<https://orcid.org/0000-0002-7840-4158>

**Contact details**  
King's College London  
Department of Psychological Medicine  
Institute of Psychiatry, Psychology & Neuroscience (IoPPN)  
16 De Crespigny Park  
Denmark Hill  
London  
United Kingdom  
SE5 8QF  
+44 (0)20 7848 0160  
[Julian.Baudinet@kcl.ac.uk](mailto:Julian.Baudinet@kcl.ac.uk)

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
234354

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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)

### **Key secondary outcome(s)**

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

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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

### **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

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

### Participant type(s)

Mixed

### Healthy volunteers allowed

No

### Age group

Mixed

### Sex

All

### **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**

United Kingdom

England

### **Study participating centre**

**Maudsley Centre for Child and Adolescent Eating Disorders**

De Crespigny Park

Denmark Hill

London

United Kingdom

SE5 8AZ

## **Sponsor information**

### **Organisation**

King's College London

### **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

### 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?
<a href="#">Protocol article</a>	Participant information sheet	16/06/2021	18/06/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes