ISRCTN10166784 https://doi.org/10.1186/ISRCTN10166784

Comparing the clinical effectiveness, acceptability and cost-effectiveness of a ‘stepping into day treatment’ approach versus inpatient treatment as usual for anorexia nervosa

Submission date
17/02/2020

Recruitment status
No longer recruiting

Registration date
28/02/2020

Overall study status
Completed

Last Edited
20/02/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Anorexia nervosa is a disabling and deadly disorder. About 20-30% of patients with anorexia nervosa need intensive treatment (day patient or inpatient treatment or both) to help them improve or recover. It is not known whether either of these two intensive treatment approaches has advantages/disadvantages for patients, families, the NHS and wider society. The aim of this study is to assess the effectiveness and acceptability of these two intensive treatment approaches: (a) specialist inpatient treatment as usual, and (b) specialist day patient treatment (either immediately or, if needed, after brief inpatient treatment to medically stabilise the patient), called ‘stepped care’, and to see whether they provide value for money.

Who can participate?
People aged 17 and above with severe anorexia nervosa or a related disorder (e.g., avoidant /restrictive food intake disorder) and a body mass index (BMI) of 16kg/m2 or below, who are are in need of intensive treatment (e.g., due to illness severity, medical risk, or lack of response to outpatient psychological therapy)

What does the study involve?
After providing informed consent, participants will complete questionnaires and a clinical interview to assess eating disorder symptoms, comorbid symptoms (e.g., mood), psychosocial adjustment, quality of life, and treatment motivation and expectations. Participants will then be randomly allocated to one of the two intensive treatment approaches: inpatient treatment-as-usual or the stepped care day-patient treatment approach. Participants’ eating disorder symptoms will be monitored monthly from the first assessment to 12 months after random allocation. Participants will be asked to complete follow-up assessments (identical to the baseline assessment) at 6, 12 and 24 months after random allocation. If agreed by the patient, the researchers will also invite their main carer to complete two brief questionnaires at the start

of the study and 6, 12 and 24 months later. Following the 6-month assessment (updated 12/08 /2021, previously 12-month assessment), a sample of patients (20 per treatment group) and family carers (20 per treatment group) will be invited to complete a short audio-recorded qualitative interview with one of the researchers about their experiences of treatment within the study.

What are the possible benefits and risks of participating?
Both treatment approaches are effective, safe and routinely used in the NHS. The researchers expect participants to benefit in terms of improvement in eating disorder and related psychological and physical symptoms, quality of life, general well-being and relationships with close others. Additionally, many people enjoy being part of a large study such as this one, which helps answer important questions about the treatment and care given to patients in the NHS. Research assessment meetings with members of the research team (face-to-face or by phone) and the opportunity to think about their situation, progress and experiences of treatment often is also experienced as enriching by participants. This research will also enhance the evidence base on the treatment of people with severe anorexia nervosa. There may be some discomfort associated with completing questionnaires evaluating the outcome of treatment, although all the questionnaires given are very widely used and usually do not cause distress.

Where is the study run from?
King's College London and Specialist Eating Disorder Services across the UK

When is the study starting and how long is it expected to run for?
December 2019 to August 2022

Who is funding the study?
National Institute of Health Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
Başak İnce Çağlar, basak.ince@kcl.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Başak İnce Çağlar

ORCID ID
https://orcid.org/0000-0003-1177-3490

Contact details
Trial Coordinator
PO59 Section of Eating Disorders
Institute of Psychiatry, Psychology & Neuroscience
King's College London
De Crespigny Park
London
United Kingdom

SE5 8AF
+44 (0)207 848 5608
basak.ince@kcl.ac.uk

Type(s)
Scientific

Contact name
Prof Ulrike Schmidt

ORCID ID
https://orcid.org/0000-0003-1335-1937

Contact details
Principal Investigator
PO59 Section of Eating Disorders
Institute of Psychiatry, Psychology & Neuroscience
King's College London
De Crespigny Park
London
United Kingdom
SE5 8AF
-
ulrike.schmidt@kcl.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
272903

Central Portfolio Management System (CPMS)
43945

Study information

Scientific Title
A randomised controlled multi-centre open-label parallel-group non-inferiority trial of the clinical effectiveness, acceptability and cost-effectiveness of a 'stepping into day treatment' approach versus inpatient treatment as usual for anorexia nervosa in adult specialist eating disorder services

Acronym
DAISIES

Study objectives
This study aims to compare the clinical effectiveness, acceptability and cost-effectiveness of two intensive treatment approaches in routine NHS practice: specialist inpatient treatment as usual (IP-TAU) and a stepped care day treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 14/04/2020, Wales Research Ethics Committee 5 (Health and Care Research Wales Castlebridge 4 15-19 Cowbridge Road East Cardiff, CF11 9AB, UK; +44 (0)7970 422139; Wales.REC5@wales.nhs.uk) ref: 20/WA/0072

Primary study design
Interventional

Study design
Randomized; Both; Design type: Treatment, Process of Care, Psychological & Behavioural, Complex Intervention, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Current intervention as of 23/10/2020:
The researchers will start by assessing their ability to recruit participants (internal pilot trial; aiming to recruit 62 patients over 4 months). If this goes well, they will then progress to the full study, which will include 386 adults (including the pilot participants) with severe AN, who are deemed to need intensive treatment. Participants will be recruited from specialist eating disorder services across the UK. After completion of a baseline assessment, patients will be allocated by chance to either stepped care day treatment or IP-TAU.

Inpatient treatment-as-usual (IP-TAU)
IP-TAU uses the current standard patient care pathway. In this care pathway, patients admitted to a specialist eating disorder inpatient unit are treated until they reach a body mass index (BMI) of 18.5 kg/m2 and normalise their eating, or get as close to this point as possible (e.g., a pre-defined BMI goal for patients with severe enduring AN). Patients admitted to IP-TAU are treated by a multidisciplinary team (including psychiatrists, psychologists, dieticians, nurses and others) and receive expert refeeding, therapeutic programmes and supervised meals and snacks. A proportion may also have day patient treatment at the end, at the discretion of the treating team.

Stepped care day patient treatment approach
This stepped care day patient treatment approach combines intensive day patient treatment with the option of inpatient treatment for medical stabilisation and progression to day patient treatment at the earliest opportunity. Regular risk assessments will be conducted with clear decision rules around patients' suitability for stepping down into multi-disciplinary specialist day patient treatment. Day patient treatment will involve 4-5 days a week with 2-3 meals per day, multi-disciplinary support (including psychiatrists, psychologists, dieticians, nurses and others) and high-quality evidence-based psychological interventions for patients and their carers. Patients will return home for weekends and evenings. Due to COVID-19, day patient treatment may be delivered using a blended approach of remote and physical attendance. Patients who are allocated to the stepped care intervention can either start day patient treatment immediately or be stepped down to day patient treatment after a period of inpatient treatment. The main aim

of the day patient treatment will be to treat patients until they reach a healthy weight and normalise their eating, or get as close to this point as possible.

The most important clinical outcome will be body mass index (BMI) at 12 months after randomisation. The researchers will test whether stepped care is no worse than inpatient treatment (a 'non-inferiority' study design). They will also assess a number of secondary outcomes, including eating disorder symptoms, comorbid symptoms, social functioning, quality of life, any relapses or re-admissions to hospital, as well as outcomes for carers. Additionally, they will evaluate treatment acceptability and participants' treatment experience (using both qualitative [interviews] and quantitative methods [questionnaires]). Finally, they will look at the cost of the two different treatment approaches and explore whether day patient treatment is better value for money than inpatient treatment to the NHS.

———

Previous intervention:
The researchers will start by assessing their ability to recruit participants (internal pilot trial; aiming to recruit 62 patients over 4 months). If this goes well, they will then progress to the full study, which will include 386 adults (including the pilot participants) with severe AN, who are deemed to need intensive treatment. Participants will be recruited from specialist eating disorder services across the UK. After completion of a baseline assessment, patients will be allocated by chance to either stepped care day treatment or IP-TAU.

Inpatient treatment-as-usual (IP-TAU)
IP-TAU uses the current standard patient care pathway. In this care pathway, patients admitted to a specialist eating disorder inpatient unit are treated until they reach a body mass index (BMI) of 18.5 kg/m2 and normalise their eating, or get as close to this point as possible (e.g., a pre-defined BMI goal for patients with severe enduring AN). Patients admitted to IP-TAU are treated by a multidisciplinary team (including psychiatrists, psychologists, dieticians, nurses and others) and receive expert refeeding, therapeutic programmes and supervised meals and snacks. A proportion may also have day patient treatment at the end, at the discretion of the treating team.

Stepped care day patient treatment approach
This stepped care day patient treatment approach combines intensive day patient treatment with the option of inpatient treatment for medical stabilisation and progression to day patient treatment at the earliest opportunity. Regular risk assessments will be conducted with clear decision rules around patients' suitability for stepping down into multi-disciplinary specialist day patient treatment. Day patient treatment will involve 4-5 days a week with 2-3 meals per day, multi-disciplinary support (including psychiatrists, psychologists, dieticians, nurses and others) and high-quality evidence-based psychological interventions for patients and their carers. Patients will return home for weekends and evenings. Patients who are allocated to the stepped care intervention can either start day patient treatment immediately or be stepped down to day patient treatment after a period of inpatient treatment. The main aim of the day patient treatment will be to treat patients until they reach a healthy weight and normalise their eating, or get as close to this point as possible.

The most important clinical outcome will be body mass index (BMI) at 12 months after randomisation. The researchers will test whether stepped care is no worse than inpatient treatment (a 'non-inferiority' study design). They will also assess a number of secondary outcomes, including eating disorder symptoms, comorbid symptoms, social functioning, quality of life, any relapses or re-admissions to hospital, as well as outcomes for carers. Additionally,

they will evaluate treatment acceptability and participants' treatment experience (using both qualitative [interviews] and quantitative methods [questionnaires]). Finally, they will look at the cost of the two different treatment approaches and explore whether day patient treatment is better value for money than inpatient treatment to the NHS.

Intervention Type
Mixed

Primary outcome(s)
Body mass index (BMI) measured at 12 months post-randomisation

Key secondary outcome(s)
Current secondary outcome measures as of 09/08/2021:

1. Body mass index (kg/m2) measured at baseline, 6- and 24-months post-randomisation and on a monthly basis from baseline to 12-months post-randomisation
2. Eating disorder symptomology measured using the Eating Disorder Examination (EDE) Interview at baseline, 6-, and 12-months post-randomisation, the Eating Disorder Examination Questionnaire – short form (EDE-QS) at baseline, 6-, and 12-months post-randomisation and on a monthly basis from baseline to 12-months post-randomisation, and the Eating Disorder Examination Questionnaire (EDE-Q) at 24-months post-randomisation
3. Comorbid symptomology measured using the Depression, Anxiety and Stress Scales – version 21 (DASS-21) and Obsessive Compulsive Inventory-Revised (OCI-R) at baseline and 6-, 12- and 24-months post-randomisation
4. Psychosocial adjustment measured using the Clinical Impairment Assessment (CIA), the Multidimensional Scale of Perceived Social Support (MSPSS), the Work and Social Adjustment Scale (WSAS) and the UCLA Loneliness Scale - Version 3 at baseline and 6-, 12- and 24-months post-randomisation
5. Treatment motivation measured using Motivational Rulers (willingness and readiness to change) at baseline and 6-, 12- and 24-months post-randomisation
6. Treatment acceptability measured using Visual Analogue Scales of treatment acceptability at baseline and 6-, 12- and 24-months post-randomisation
7. Cost and cost-effectiveness measured using the Health-related Quality of Life (EQ-5D-5L) at 6-, 12- and 24-months post-randomisation

Additional measures:
1. Autistic traits measured using the Autism Spectrum Quotient (AQ-10) at baseline
2. Treatment expectations measured using Visual Analogue Scales of treatment expectations at baseline
3. Service utilisation measured using the Adult Service Use Schedule (AD-SUS) modified for AN at baseline and 6-, 12- and 24-months post-randomisation and Hospital Episode Statistics (HES) will also be requested from NHS Digital (for participants from England) and Information Services Division (for participants from Scotland) to assess the number of hospital admission days (e.g., to A&E, specialist eating disorder units, and general psychiatric inpatient wards) in the year prior to participation in the study and 2-years post-randomisation
4. Treatment experience measured using the Therapeutic Environment Scale (TESS) at 3-months post-randomisation, and the Perceived Coercion Scale (PCS) at baseline and 6-months postrandomisation
5. COVID-19 diagnosis and symptoms measured using a purposely designed checklist at baseline and 6-, 12- and 24-months post-randomisation

6. Carer burden measured using the Depression, Anxiety and Stress Scales – version 21 (DASS21) and the Eating Disorders Symptom Impact Scale (EDSIS) at baseline and 6-, 12- and 24-months post-randomisation

---

Previous secondary outcome measures as of 23/10/2020:
1. Body mass index (kg/m2) measured at baseline, 6 and 24months post-randomisation and on a monthly basis from baseline to 12 months post-randomisation
2. Eating disorder symptomology measured using the Eating Disorder Examination (EDE) Interview at baseline, 6, and 12 months post-randomisation, the Eating Disorder Examination Questionnaire – short form (EDE-QS) at baseline, 6, and 12 months post-randomisation and on a monthly basis from baseline to 12 months post-randomisation, and the Eating Disorder Examination Questionnaire (EDE-Q) at 24 months post-randomisation
3. Comorbid symptomology measured using the Depression, Anxiety and Stress Scales – version 21 (DASS-21) and Obsessive Compulsive Inventory-Revised (OCI-R) at baseline and 6, 12 and 24 months post-randomisation
4. Psychosocial adjustment measured using the Clinical Impairment Assessment (CIA), the Multidimensional Scale of Perceived Social Support (MSPSS), the Work and Social Adjustment Scale (WSAS) and the UCLA Loneliness Scale - Version 3 at baseline and 6, 12 and 24 months post-randomisation
5. Treatment motivation measured using Motivational Rulers (willingness and readiness to change) at baseline and 6, 12 and 24 months post-randomisation
6. Treatment experience measured using Visual Analogue Scales of treatment acceptability at baseline and 6, 12 and 24 months post-randomisation, the Therapeutic Environment Scale (TESS) at 3-months post-randomisation, the Perceived Coercion Scale (PCS) at baseline and 6 months post-randomisation, and the proportion of patients who self-discharge at 6 and 12 months post randomisation
7. Cost and cost-effectiveness measured using the Health-related Quality of Life (EQ-5D-5L) at baseline and 6, 12 and 24 months post-randomisation
8. Service utilisation measured using the Adult Service Use Schedule (AD-SUS) modified for AN at baseline and 6, 12 and 24 months post-randomisation and Hospital Episode Statistics (HES) will also be requested from NHS Digital (for participants from England) and Information Services Division (for participants from Scotland) to assess the number of hospital admission days (e.g., to A&E, specialist eating disorder units, and general psychiatric inpatient wards) in the year prior to participation in the study and 2 years post-randomisation
9. Carer burden measured using the Depression, Anxiety and Stress Scales – version 21 (DASS-21) and the Eating Disorders Symptom Impact Scale (EDSIS) at baseline and 6, 12 and 24 months post-randomisation

Moderators:
1. Autistic traits measured using the Autism Spectrum Quotient (AQ-10) at baseline
2. Treatment expectations measured using Visual Analogue Scales of treatment expectations at baseline
3. COVID-19 diagnosis and symptoms measured using a purposely designed checklist at baseline

Mediators:
1. COVID-19 diagnosis and symptoms measured using a purposely designed checklist at 6 and 12 months

---

Previous secondary outcome measures:
1. Body mass index (kg/m2) measured at baseline, 6 and 24months post-randomisation and on a monthly basis from baseline to 12 months post-randomisation
2. Eating disorder symptomology measured using the Eating Disorder Examination (EDE) Interview at baseline, 6, 12, and 24 months post-randomisation and the Eating Disorder Examination Questionnaire – short form (EDE-QS) at baseline, 6, 12, and 24 months post-randomisation and on a monthly basis from baseline to 12 months post-randomisation
3. Comorbid symptomology measured using the Depression, Anxiety and Stress Scales – version 21 (DASS-21) and Obsessive Compulsive Inventory-Revised (OCI-R) at baseline and 6, 12 and 24 months post-randomisation
4. Psychosocial adjustment measured using the Clinical Impairment Assessment (CIA), the Significant Others Scale (SOS), the Work and Social Adjustment Scale (WSAS) and the Revised UCLA Loneliness Scale at baseline and 6, 12 and 24 months post-randomisation
5. Treatment motivation measured using Motivational Rulers (willingness and readiness to change) at baseline and 6, 12 and 24 months post-randomisation
6. Treatment expectations measured using Visual Analogue Scales at baseline
7. Treatment experience measured using Visual Analogue Scales of treatment acceptability at baseline and 6, 12 and 24 months post-randomisation, the Therapeutic Environment Scale (TESS) at 3-months post-randomisation, and the Perceived Coercion Scale (PCS) at baseline and 6 months post-randomisation
8. Cost and cost-effectiveness measured using the Health-related Quality of Life (EQ-5D-5L) and the Adult Service Use Schedule (AD-SUS) modified for AN at baseline and 6, 12 and 24 months post-randomisation
9. Hospital Episode Statistics (HES) will also be requested from NHS Digital (for participants from England) and Information Services Division (for participants from Scotland) to assess the number of hospital admission days (e.g., to A&E, specialist eating disorder units, and general psychiatric inpatient wards) in the year prior to participation in the study and 2 years post-randomisation
10. Carer burden measured using the Depression, Anxiety and Stress Scales – version 21 (DASS-21) and the Eating Disorders Symptom Impact Scale (EDSIS) at baseline and 6, 12 and 24 months post-randomisation

Completion date
24/08/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 04/09/2020:
1. Adults aged 17 years and above
2. Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 diagnosis of severe anorexia nervosa (AN) or related disorder (e.g., avoidant/restrictive food intake disorder [ARFID; where food restriction and weight loss occur in the absence of concerns about shape and weight])
3. Body mass index (BMI) equal to or less than 16 kg/m²
4. In need for intensive treatment because of either rapid weight loss, and/or evidence of system /organ failure/medical instability and/or unsuccessful outpatient treatment
5. Have mental capacity to give informed consent to participate in the study

Previous inclusion criteria:
1. Male and female adults
2. Aged 17 years and above
3. Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 diagnosis of severe anorexia

nervosa (AN) or related disorder (e.g., avoidant/restrictive food intake disorder [ARFID; where food restriction and weight loss occur in the absence of concerns about shape and weight])
4. Body mass index (BMI) of less than 16 kg/m²
5. In need for intensive treatment because of either rapid weight loss, and/or evidence of system /organ failure/medical instability and/or unsuccessful outpatient treatment
6. Have mental capacity to give informed consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 Years

Sex
All

Total final enrolment
15

Key exclusion criteria
Current exclusion criteria as of 04/09/2020:
1. Insufficient knowledge of English to complete study assessments or understand treatment
2. Severe learning disability
3. Severe medical or psychiatric (co)morbidity (e.g. psychosis, substance dependence) needing treatment in its own right
4. Those living too far away from day-patient treatment (and where no alternative arrangements for regular attendance at day-patient treatment can be made).

Previous exclusion criteria:
1. Insufficient knowledge of English to complete study assessments or understand treatment
2. Severe learning disability
3. Severe medical or psychiatric (co)morbidity (e.g. psychosis, substance dependence) needing treatment in its own right
4. Those living too far away from day-patient treatment (and where no alternative arrangements for regular attendance at day-patient treatment can be made).
5. Those who are involved in current research or have recently been involved in any research prior to recruitment

Date of first enrolment
16/11/2020

Date of final enrolment
25/03/2022

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
South London and Maudsley NHS Foundation Trust
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Central and North West London NHS Foundation Trust
Stephenson House
75 Hampstead Road
London
United Kingdom
NW1 2PL

Study participating centre
Leicestershire Partnership NHS Trust
Riverside House
Bridge Park Plaza
Bridge Park Road
Leicester
United Kingdom
LE4 8PQ

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre
South West London St George's Mental Health NHS Trust
Springfield Hospital
61 Glenburnie Road
London
United Kingdom
SW17 7DJ

Study participating centre
Surrey And Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
Leatherhead
United Kingdom
KT22 7AD

Study participating centre
NHS Dumfries and Galloway
Grierson House
The Crichton
Bankend Road
Dumfries
United Kingdom
DG1 4ZG

Study participating centre
King's College London
P059 Psychological Medicine
De Crespigny Park
London
United Kingdom
SE5 8AF

Study participating centre
Dorset Healthcare University NHS Foundation Trust
Sentinel House
4-6 Nuffield Road
Nuffield Industrial Estate
Poole
United Kingdom
BH17 0RB

Study participating centre
2gether NHS Foundation Trust
Rikenel
Montpellier
Gloucester
United Kingdom
GL1 1LY

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
Unit 1, B1 50 Summerhill Road
Ladywood
Birmingham
United Kingdom
B1 3RB

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name

National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 14/03/2023:
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Ulrike Schmidt (Principal Investigator, ulrike.schmidt@kcl.ac.uk) or Dr Başak İnce Çağlar (Trial Coordinator, basak.ince@kcl.ac.uk).

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Ulrike Schmidt (Principal Investigator, ulrike.schmidt@kcl.ac.uk) or Dr Bethan Dalton (Trial Coordinator, bethan.dalton@kcl.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/03/2023	20/02/2024	Yes	No
Results article		18/12/2023	20/02/2024	Yes	No
Protocol article		16/06/2022	17/06/2022	Yes	No
HRA research summary			28/06/2023	No	No