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Stages, progression, and recovery of eating disorders in youth

Submission date
15/08/2023

Recruitment status
Recruiting

Registration date
29/08/2023

Overall study status
Ongoing

Last Edited
02/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Eating disorders (EDs, including anorexia nervosa [AN], bulimia nervosa [BN], binge eating disorder [BED], amongst others) are serious and disabling mental illness that most commonly onset during adulthood and can affect anyone regardless of gender, ethnicity, sexuality, and life circumstances. There is more and more evidence suggesting that EDs are progressive disorders, yet the understanding of how symptom profiles differ between earlier- and later-stage presentations, and how symptoms may change over time, is limited. In addition, though recovery from EDs is always possible, our understanding of the factors that help or hinder the process is also underdeveloped.
This study involves repeated online assessments (i.e. questionnaires) and continuous data collection via a smartphone and (optionally) a wearable device. By following individuals with different EDs and illness durations for the duration of the study, the study aims to investigate how symptom profiles differ across different stages of illness and the factors that help or hinder progression within and recovery from EDs in young people. Ultimately, a greater understanding of illness stages, progression, and recovery in EDs is an important step in developing more personalised and effective interventions.

Who can participate?
Individuals aged between 16 and 25 years who have an eating disorder diagnosis or suspect that they have one, or individuals aged 16-25 years with no history of an eating disorder or any other mental disorder.

What does the study involve?
Being a participant involves completing several assessment measures at different time points over the course of 2 years. When a participant joins the study, they will complete a series of online questionnaires about different aspects of their life, including their mental health and well-being and their social environment. These questionnaires are then repeated at 6-, 12-, and 24-month follow-up points. Participants will also download two apps onto their smartphone (or onto a smartphone given to them by the study team if they do not have an Android smartphone). These apps will continuously collect data throughout the study, both in the background and more frequent, short questionnaires.
Participants can also choose to come to King's College London or the University of Edinburgh (if

they live locally) to complete some psychological tasks in person and/or have a brain scan. These take place at the start of the study and at 12- and 24-months follow-ups. Additionally, participants can choose to wear a smart ring for the duration of the study which will measure things such as heart rate and sleep quality. All data will be anonymised and participants will not be able to access any of the feedback.

What are the possible benefits and risks of participating?
This is an observational study and does not involve any clinical intervention and therefore will not benefit or detract from the participant's treatment (if they are currently receiving treatment). There may be some discomfort associated with completing questionnaires, although all the questionnaires given are very widely used and usually do not cause distress.
Participants can receive up to £175 if they complete all components of the study. Participants can also keep the study smartphone after the study ends, if received. This study should allow for a better understanding of how eating disorders progress and how people recover from eating disorders to be gained which in turn will aid the development of more personalised treatment in the future. Participating in the study will help other people in the future who experience similar symptoms - which can be experienced as enriching.

Where is the study run from?
King's College London and the University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
July 2022 to August 2025

Who is funding the study?
UK Research and Innovation (UKRI)

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

Study website
https://edifyresearch.co.uk

Contact information

Type(s)
Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
325803

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 325803, CPMS 58055

Study information

Scientific Title
Characterising illness stages, progression, and recovery trajectories of eating disorders in young people

Acronym
STORY

Study objectives
The first main aim (objectives 1-3 below) is to understand the details of the recovery process from Eating Disorders (EDs) by unobtrusively measuring behaviour, physiology, and daily experiences of young people (YP) in real-time via smartphone apps and inbuilt sensors in smartphones and wearable devices.

The second main aim (objectives 4-6 below) is to investigate how biopsychosocial symptom profiles, behavioural and brain responses differ between earlier- and later-stage EDs and what factors predict outcome.

Objective 1: Using biological and psychological Remote Measurement Technology (RMT) measures to compare young people (YP) presenting with a 1st ED episode with healthy control YP.
Objective 2: Assessing differences in recovery trajectories within and across ED groups.
Objective 3: Identifying early RMT predictors of ED recovery or lack of recovery at 12 months.
Objective 4: Using a multi-modal assessment protocol to cross-sectionally and longitudinally compare YP with early and later illness stages in terms of their biopsychosocial profiles and how these change over time. This will be done within and across ED diagnostic groups.
Objective 5: Identifying baseline biopsychosocial predictors of outcome at 6 and 12 months within and across ED diagnostic groups and illness duration groups.
Objective 6: Using cognitive tasks with illness-relevant stimuli to compare YP with early and later stage illness in terms of their cognitive profiles and changes in these over time within and across ED diagnostic groups and illness duration groups.

The STORY study is exploratory in nature and therefore will not use directional hypotheses.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/10/2023, London – Bloomsbury (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207104828, (0)207 104 8256, (0)207 104 8276; bloomsbury.rec@hra.nhs.uk), ref: 23/PR/0927

Study design
STORY is a prospective cohort non-randomised non-interventional study using wearable technology and smartphone sensors.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home, Internet/virtual, University/medical school/dental school

Study type(s)
Other

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
Eating disorders (including but not limited to anorexia nervosa, bulimia nervosa, binge eating disorder, avoidant restrictive food intake disorder, other specified feeding and eating disorder)

Interventions
STORY is an observational study, involving no intervention or change to a participant's usual standard of care.

Being a participant in STORY involves completing several assessment measures at different timepoints over the course of 2 years. When a participant joins the study, they will complete a series of online questionnaires about different aspects of their life, including their mental health and well-being and their social environment. These questionnaires are then repeated at 6-, 12-, and 24-month follow-up points. Participants will also download two apps onto their smartphone (or onto a smartphone given to them by the study team if they do not have an Android smartphone). These apps will continuously collect data throughout the study, both in the background and more frequent, short questionnaires.

Participants can also choose to come to King's College London or the University of Edinburgh (if they live locally) to complete some psychological tasks in person and/or have a brain scan. These take place at the start of the study and at 12- and 24-months follow-ups. Additionally, participants can choose to wear a smart ring for the duration of the study which will measure things such as heart rate and sleep quality. All data will be anonymised and participants will not be able to access any of the feedback.

Intervention Type
Other

Primary outcome measure
Eating disorder symptoms are measured using the Eating Disorder Examination Questionnaire (EDE-Q) global score at baseline, 3, 6, 12 and 24 months

Secondary outcome measures
1. Eating disorder symptom changes and related clinical outcomes are measured using brief clinical symptom questionnaires and visual analogue scales (VAS) every 2 weeks for 1 year, and at 24-month follow-up
2. Other related psychological, social, and functional outcomes are measured using scores on validated questionnaires and VAS at baseline, 6-, 12- and 24-month follow-up

3. Speech prosody is measured using a speech task every month for 1 year
4. Real-time experiences, mood changes and stressors in daily life are measured using an Experience Sampling Methodology (ESM) protocol every 12 weeks, for 6 consecutive days, at 6 times per day, for 1 year
5. Digital biomarkers of ED symptom changes are measured using ongoing remote monitoring via purpose-built smartphone applications and wearable devices for 1 year
6. Neurocognitive functioning is measured using performance on tasks involving food-related attentional bias, decision making, impulse control, temporal discounting, and emotion regulation at baseline, 12- and 24-month follow-up

Overall study start date
01/07/2022

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Aged 16-25 years – all genders, all ethnicities
2. Ability to give informed consent
3. Access and ability to complete the self-reported assessments via smartphone and/or computer
4. Willingness to use either their own Android smartphone or a provided Android study smartphone as their only smartphone during the data collection period of 12 months
5. Willingness and ability to install a RADAR Passive App and RADAR Active App on the study smartphone provided, during the data collection period of 12 months

Participant type(s)
Healthy volunteer, Patient, Population, Service user, Other

Age group
Mixed

Lower age limit
16 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
840

Key exclusion criteria
1. Insufficient knowledge of English to complete study assessments
2. Severe learning disabilities

3. Any other major medical condition which might impact the patient’s ability to participate in normal daily activities (e.g., due to hospitalisations)
4. Residing outside the UK

Date of first enrolment
20/11/2023

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
University of Edinburgh
School of Health in Social Science
Teviot Place
Edinburgh
United Kingdom
EH8 9AG

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
Trust Headquarters Block B2
St Ann's Hospital
St Ann's Road
London
United Kingdom
N15 3TH

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

Study participating centre
Bradford District Care NHS Foundation Trust
New Mill
Victoria Road
Saltaire
Shipley
United Kingdom
BD18 3LD

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE

London
United Kingdom
NW1 3AX

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Derbyshire Healthcare NHS Foundation Trust
Trust Headquarters
Kingsway Hospital
Kingsway Derby
United Kingdom
DE22 3LZ

Sponsor information

Organisation
King's College London

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Sponsor type
University/education

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

ROR
https://ror.org/0220mzb33

Organisation
South London and Maudsley NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is planned the the results of STORY, as well as a study protocol, will be disseminated primarily via publications in peer-reviewed high-impact journals.

Intention to publish date
01/09/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available on request from Prof. Ulrike Schmidt (ulrike.schmidt@kcl.ac.uk) or Dr Başak İnce Çağlar (basak.ince@kcl.ac.uk).

The anonymised data created in STORY will be fully suitable for sharing and all participants will be asked for consent to this. Timely and fair data sharing will be offered after a 2-year period of exclusive use of data by the investigators, to allow publication of main findings and key secondary findings. External users of data will be required to sign data sharing agreements providing assurances about ethical and lawful storage and processing of data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/05/2024	28/10/2024	Yes	No