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# Therapist-assisted internet-based cognitive therapy for prolonged grief (iCT-PG): a feasibility randomised controlled trial

**Submission date**
27/02/2025

**Recruitment status**
Recruiting

**Registration date**
03/03/2025

**Overall study status**
Ongoing

**Last Edited**
03/03/2025

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Prolonged grief disorder (PGD) is a condition where intense and long-lasting grief disrupts everyday life. This study tests a new online treatment called Internet-based Cognitive Therapy for Prolonged Grief (iCT-PG). The aim is to find out if this digital therapy is practical to use (feasible), acceptable to patients, and has the potential to improve grief symptoms. The treatment is designed to help people manage distressing memories of loss, challenge negative thoughts, adopt healthier coping strategies, and reduce feelings of social isolation.

Who can participate?
The study is open to adults aged 18 years and over who at assessment meet criteria for PGD. Participants can be referred through NHS Adult Talking Therapies services, general practitioners, or may self-refer via the study's website (https://grief.web.ox.ac.uk/). All participants must have regular access to the internet and be comfortable using a digital device for therapy.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will begin the digital therapy immediately while the other group will join a waitlist and start the treatment after 14 weeks. The online therapy includes 12 sessions delivered over 14 weeks, with weekly support calls from a trained therapist. The therapy is tailored to each person’s needs through a series of interactive online modules and an integrated smartphone app that offers support in real-time. Participants will complete weekly questionnaires during treatment measuring grief, anxiety, depression, and daily functioning and at four times once weekly treatment has ended (monthly for 3 months), and at follow-up (around Week 39). An independent assessor, who does not know which group participants are in, will also conduct interviews to objectively evaluate their symptoms.

What are the possible benefits and risks of participating?
Participating in this study gives individuals the opportunity to try a new digital treatment that could help ease the pain of prolonged grief. The benefits include access to flexible, expert therapist-supported online therapy that can be used from home. Additionally, the study will

closely monitor how well the treatment works and how participants feel about it. However, it is not yet known whether the online therapies are more or less effective and acceptable to patients than face-to-face therapy. You should also be aware that some people may experience a temporary increase in distress as a result of remembering traumatic aspects of their loss during treatment, but this is usually short-lived.

Where is the study run from?
The study is managed by the University of Oxford, Department of Experimental Psychology, and is conducted in collaboration with NHS Adult Talking Therapies services (UK).

When is the study starting and how long is it expected to run?
February 2023 to February 2028

Who is funding the study?
The study is funded by the Medical Research Council, Oxford Health Biomedical Research Centre, and the Wellcome Trust. Their support ensures that the research is conducted to a high standard and that the findings can inform future, larger trials.

Who is the main contact?
Dr Kirsten Smith, kirsten.smith@psy.ox.ac.uk

# Contact information

### Type(s)
Scientific, Principal investigator


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# Additional identifiers

### Integrated Research Application System (IRAS)
311815

### Protocol serial number
CPMS 55621

# Study information

### Scientific Title
A digital approach to grief support and the treatment of post-loss mental health problems

### Acronym
iCT-PG

### Study objectives
The primary objective is to assess the feasibility and acceptability of an internet-based cognitive therapy programme for Prolonged Grief (iCT-PG) in bereaved adults in order to establish the key parameters for a definitive RCT. The secondary research objective is to gather data on clinical outcomes to provide a preliminary indication of the clinical efficacy of the intervention (iCT-PG) for adults with a diagnosis of Prolonged Grief Disorder (PGD).

The hypotheses related to clinical outcomes are:
1. Compared to waitlist, iCT-PG will reduce symptoms of PGD (post-treatment).
2. Compared to waitlist, iCT-PG will reduce symptoms of comorbid mental health problems (PTSD, depression, anxiety) and improve symptoms of social and occupational functioning (post-treatment).
3. Treatment effects will be maintained at follow-up.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 11/04/2023, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 23/YH/0061

### Study design
Randomized controlled trial

### Primary study design
Interventional

### Study type(s)

Treatment

## Health condition(s) or problem(s) studied
Prolonged grief disorder

## Interventions
Internet cognitive therapy for Prolonged Grief (iCT-PG)

Participants will be randomly assigned to one of two groups. The method of randomisation will be Sealed Envelopes. Stratification factors will be by severity of PGD symptoms (above and equal to or below the median score from the developmental case series) and type of loss (lost child versus other relationship) varying block sizes of 2 and 4 will be used to minimize imbalance of patients allocated to immediate start or delayed start (14 weeks)

One group will begin iCT-PG immediately while the other group will join a waitlist and start the treatment after 14 weeks. The online therapy includes 12 sessions delivered over 14 weeks, with weekly support calls from a trained therapist. The therapy is tailored to each person's needs through a series of interactive online modules and an integrated smartphone app that offers support in real time. Participants will complete weekly questionnaires during treatment measuring grief, anxiety, depression, and daily functioning and four times once weekly treatment has ended (monthly for 3 months), and at follow-up (around Week 39). An independent assessor, who does not know which group participants are in, will also conduct interviews to objectively evaluate their symptoms.

## Intervention Type
Other

## Primary outcome(s)
Prolonged grief disorder symptoms measured with the International Prolonged Grief Disorder Scale (IPGDS) at baseline, 7, 15 weeks after random allocation (with follow-ups at 27, and 39), and weekly during treatment

## Key secondary outcome(s))
1. Assessor ratings of PGD symptoms, assessed with a structured clinical interview at 15 weeks after random allocation (with follow-up at 27 weeks).
2. Other symptom measures assessed at baseline, 7, 15 weeks after random allocation (with follow-ups at 27 and 39 weeks), and weekly during treatment:
2.1. Depression, assessed with the Patient Health Questionnaire (PHQ-9)
2.2. Anxiety, assessed with the Generalized Anxiety Disorder Scale 7-items (GAD-7)
2.3 Posttraumatic stress disorder with the PTSD checklist for DSM 5 (PCL-5)
2.4. Disability, assessed with the Work and Social Adjustment Scale (WSAS)
2.5. Sleep problems, assessed with the Insomnia Sleep Index (ISI)
2.6 Well-being, assessed with the Warwick Edinburgh Mental Wellbeing Scale (WEMBWS)
2.7 Alcohol use and dependence assessed with the Alcohol Use Disorders Identification Test (AUDIT)
3. Health economics measures (Euroqol EQ-5D-5L12, iMTA Productivity Cost Questionnaire (PCQ), Recovering Quality of Life (ReQoL-10), Client Service Receipt Inventory (CSRI), employment status and state benefits), assessed at baseline, 15, 27 and 39 weeks
4. Process measures assessed at baseline, 7, 15, 27, and 39 weeks after random allocation (and some weekly during treatment):
4.1. Excessively negative appraisals, assessed with the Oxford Grief Appraisals Scale (OG-A)

4.2. Memory characteristics, assessed with the Oxford Grief Memory Scale (OG-M)
4.3. Unhelpful strategies to deal with grief, assessed with the Oxford Grief Coping Strategies scale (OG-CS)
4.4 Social disconnection, assessed with the Oxford Grief Social Disconnection Scale (OG-SD)
4.5. Safety behaviours, assessed with the short version Safety Behaviours Questionnaire (SBQ)
4.6. Dissociation, assessed with the short version State-Trait Dissociation Questionnaire (TSDQ)

Other process measures:
1. Therapeutic alliance, assessed using the Working Alliance Inventory (WAI) at weeks 2 and 7
2. Patient satisfaction and comments on their experience with online therapy, assessed using Online Treatment Experience Interview and the Talking Therapies adult patient experience questionnaire at week 15

### Completion date
28/02/2028

## Eligibility

### Key inclusion criteria
1. Aged 18 years and above
2. Willing and able to provide informed consent
3. Meets diagnostic criteria for PGD using the ICD-11 criteria
4. Able to read and write in English
5. Regular, private access to internet-enabled device and reliable internet connection
6. Have enough time in their week to be able to log in and work on the programme regularly (i.e. at least 20 mins on 3-4 days each week)
7. Willing to be randomly allocated to psychological treatment or waitlist
8. If on medication for mood/anxiety, the participant agrees not to change medication during the study. This is routine practice within TTAD services. For those patients who are already taking medication at the start of the psychological therapy, participants are asked not to change their medication while they are learning psychological skills for overcoming PGD in order to avoid complicating the clinical picture.
9. If currently receiving psychological therapy, this treatment must have ended before randomisation

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria

1. History of psychosis
2. Current dependence on alcohol or substances
3. Current psychosis/bipolar affective disorder/emotionally unstable personality disorder (NB. These conditions are not typically treated within TTAD services)
4. Marked clinical risk based on the service's intake assessment or the eligibility assessment
5. Currently participating in another clinical research study

### Date of first enrolment
01/03/2025

### Date of final enrolment
30/09/2027

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**University of Oxford**
Centre for Anxiety Disorders and Trauma
Paradise Square
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### Study participating centre
**Oxford Health NHS Foundation Trust**
Oxford
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## Sponsor information

### Organisation
University of Oxford

### ROR
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Research council

**Funder Name**
Medical Research Council

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

**Funder Name**
Oxford Health Biomedical Research Centre

**Funder Name**
Wellcome Trust

# Results and Publications

**Individual participant data (IPD) sharing plan**
The Medical Research Council has a policy of data sharing. Therefore, only data that can be reliably anonymised (e.g. demographics, loss characteristics, and symptom outcomes as well as the engagement data (e.g. of time spent online, mobile app use, audiovisual downloads, online contact with therapist) will be available to other researchers via ORA-Data. ORA-Data is a searchable repository in the Oxford catalogue of research data https://ora.ox.ac.uk/. A webpage will be created on the Oxford Centre for Anxiety Disorders and Trauma (OxCADAT) website which will describe the available data and metadata. Participants will be made aware of the categories of anonymised data that will be stored for sharing purposes in the information sheet. Researchers wishing to access the data can submit a proposal to the study team via the ORA-Data site. Requests will be approved assuming that release does not (i) risk disclosure of participant identity; (ii) violate any ethico-legal or other stipulations that apply to the data; or (iii) run the risk of harming the study as a whole or any participants in it.

**IPD sharing plan summary**

Stored in non-publicly available repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |