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Feasibility randomised controlled trial of Spring PGD, a digital guided therapy for prolonged grief disorder

Submission date
21/11/2024

Recruitment status
Recruiting

Registration date
28/02/2025

Overall study status
Ongoing

Last Edited
04/03/2025

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 happens when someone can't stop thinking about a loved one who has died, and it makes them feel very distressed for at least 6 months. Every year in Wales, about 18,250 new people experience prolonged grief disorder, but there aren't many good treatments available. One type of therapy called cognitive-behavioural therapy (CBT) focusing on grief seems to help, but there aren't enough therapists trained in it, and it takes a long time. Using an app or website for therapy, with about 3 hours of guidance from a health professional, might save time and money. With help from the Welsh Government, we created a guided therapy programme for prolonged grief disorder called Spring PGD, based on input from people who have experienced it. Now, we're getting ready to test it in a clinical trial.

Who can participate?
People aged 18 years or older with prolonged grief disorder

What does the study involve?
The researcher will discuss the details of the study with the participant, and the participant will be able to ask any questions they may have. The participant will be asked to give consent verbally by phone/video call. The conversation will be recorded, and the researcher will complete an electronic version of the consent form. The participant will be given a copy of the consent form to keep along with the information sheet.
If it is agreed that Spring PGD is right for the participant, they will be randomly placed into one of two groups. One group will receive Spring PGD straight away, and the other will receive Spring PGD after 11 weeks.
The participant will be asked to complete some questionnaires. The participant may also be invited to take part in an interview about their expectations of Spring PGD. This will take an additional 30-60 minutes.
When the participant starts Spring PGD, an appointment with a therapist will be arranged. At the first appointment, the therapist will talk to the participant about their symptoms and show them the Spring PGD programme. The participant will then have access to the programme, which they will use in their own time at home, with regular guidance from the therapist. The guidance will

be used to discuss the participant's progress and help them tackle any problems.
The participant will complete questionnaires about their symptoms at two more points during the study (11 and 22 weeks after joining). They may also be invited to take part in an interview about their experiences of using Spring PGD. Interviews will be recorded. Consent will be sought for these recordings, which will be stored anonymously. Direct quotations from these discussions may be published, but all quotations will be published anonymously.
The study will be conducted remotely. All meetings with the researcher will be conducted via telephone or video call.
The participant will receive a £10 shopping voucher or £10 via bank transfer, depending on their preference, as a token of appreciation for participating in the follow-up assessments of their symptoms. Additionally, if the participant is invited to take part in an interview, they will receive £25 for each completed interview.

What are the possible benefits and risks of participating?
Participants' input will contribute to the development of Spring PGD, with the aim of benefiting individuals with PGD in the future. It is hoped that participants may also experience an improvement in their own symptoms if Spring PGD proves to be effective.
It is acknowledged that some individuals may find it challenging or distressing to discuss mental health or engage in treatment. Additional support will be provided if the research causes any distress.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
June 2020 to September 2026

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Dr Catrin Lewis, LewisCE7@Cardiff.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
287681

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPON1830-20, CPMS 65849

Study information

Scientific Title
Digital guided self-help for Prolonged Grief Disorder (PGD)

Study objectives
To ascertain proof of concept for a co-produced guided digital therapy for PGD in comparison to wait list, to establish whether it is acceptable, and if findings appear to generalise to underserved groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/12/2020, Wales REC 2 (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)29 2078 5738; Wales.REC2@wales.nhs.uk), ref: 20/WA/0333

Study design
Exploratory single-blind randomized parallel group-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Prolonged Grief Disorder (PGD)

Interventions
Participants will be randomised in a 1:1 ratio to receive immediate guided self-help treatment (Spring PGD) or to a waiting list control group. After a period of 11 weeks on the waiting list, participants in the control group will cross over to receive Spring PGD.

Spring PGD is an 8-week intervention comprising audio-narrated content delivered in eight steps, featuring interactive elements allowing user input and control. The programme includes four characters with PGD following various bereavement experiences, with accompanying video content. A toolkit offers easy access to key programme components. Therapist guidance involves a one-hour meeting to establish rapport, provide log-in details, and demonstrate the programme. Subsequent fortnightly meetings, lasting 30 minutes, can be conducted face-to-face or remotely based on user and therapist preference. Additionally, users receive four brief contacts between sessions to discuss progress, address issues, and set new goals. Therapists can monitor patient progress via a clinician dashboard.
Spring PGD will be administered by skilled therapists who have experience of working with people with PGD. A comprehensive therapist manual accompanies the intervention, providing detailed guidance and instructions for effective implementation.

All participants will be assessed at baseline and at 11 and 22 weeks after randomisation.

Intervention Type
Behavioural

Primary outcome measure
Prolonged grief measured using Prolonged Grief 13 Revised (PG-13-R) at baseline and 11 and 22 weeks after randomisation

Secondary outcome measures
1. Traumatic stress symptoms measured using the International Trauma Questionnaire (ITQ) at baseline and 11 and 22 weeks after randomisation
2. Anxiety measured using the Generalised Anxiety Disorder 7 (GAD-7) at baseline and 11 and 22 weeks after randomisation
3. Symptoms of depression measured using Patient Health Questionnaire – 9 (PHQ-9) at baseline and 11 and 22 weeks after randomisation
4. Progress towards goals assessed using Goal Based Outcomes (GBOs) at baseline and 11 and 22 weeks after randomisation
5. Functional impairment measured using the Work and Social Adjustment Scale (WSAS) at baseline and 11 and 22 weeks after randomisation
6. Health-related quality of life measured using EQ5D-5L at baseline and 11 and 22 weeks after randomisation

Overall study start date
01/06/2020

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Aged 16 years or over with no upper age limit
2. Diagnosis of PGD
3. PGD is the primary diagnosis
4. Regular access to the internet to complete the digital programme
5. Ability to comply with the requirements of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Inability to understand spoken and/or written English
2. Inability to provide valid informed consent
3. Currently engaged in a course of psychological therapy
4. Change in psychotropic medication in the last 4 weeks
5. Current psychosis
6. Substance dependence
7. Active suicide risk

Date of first enrolment
10/01/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff and Vale University Health Board
Cardiff Joint Research Office
2nd Floor Lakeside Building
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Cwm Taf Morgannwg University Local Health Board
Royal Glamorgan Hospital
Ynysmaerdy
Llantrisant
United Kingdom
CF72 8XR

Sponsor information

Organisation
Cardiff University

Sponsor details
Cardiff Joint Research Office
2nd Floor Lakeside Building
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CF14 4XW
+44 (0)29208 79277
resgov@cardiff.ac.uk

Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The dissemination plan involves:
1. Collaborating with the Public Advisory Group to create a strategic plan for tailored outreach. The researchers will establish a dedicated project website and harness the expertise of the NCMH communications team to effectively promote the trial
and their findings through a range of approaches tailored to different audiences. They will produce a Podcast for the NCMH Piece of Mind series and consult the Public Advisory Group on a range of other approaches that have been by NCMH to
successfully promote research, such as webinars and public lectures (https://www.ncmh.info /videos-and-podcasts/).
2. Disseminating results to participants and the public, with the PAG selecting optimal methods like lay language reports, infographics, blog posts, animations, and public events for accessibility and engagement.
3. Sharing with the academic community by publishing the research protocol in an open-access journal. Post-trial, at least two academic papers will be published, with one presenting primary findings and the other detailing qualitative results.
The researchers will explore hypothesis-driven secondary analyses and present the findings at national and international conferences.
4. Engaging policymakers and stakeholders by preparing a briefing paper for the Welsh and UK Governments to influence future PGD service provision.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from ncmh-trials@Cardiff.ac.uk

IPD sharing plan summary

Available on request