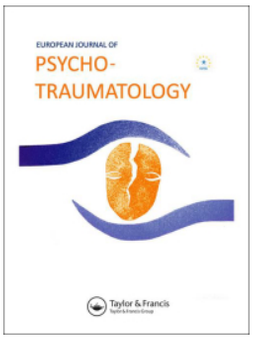

European Journal of Psychotraumatology

ISSN: 2000-8066 (Online) Journal homepage: www.tandfonline.com/journals/zept20

Spring PGD versus waiting list control in the treatment of prolonged grief disorder (PGD): protocol for a feasibility randomised controlled trial (RCT)

Catrin Lewis, Michelle Smalley, David M. Phillips, Gabriella Dattero Snell, Bronwen Thomas, Janice Wong Sing Yun & Jonathan I. Bisson

To cite this article: Catrin Lewis, Michelle Smalley, David M. Phillips, Gabriella Dattero Snell, Bronwen Thomas, Janice Wong Sing Yun & Jonathan I. Bisson (2025) *Spring PGD* versus waiting list control in the treatment of prolonged grief disorder (PGD): protocol for a feasibility randomised controlled trial (RCT), European Journal of Psychotraumatology, 16:1, 2554031, DOI: 10.1080/20008066.2025.2554031

To link to this article: https://doi.org/10.1080/20008066.2025.2554031

EUROPEAN JOURNAL OF PSYCHOTRAUMATOLOGY
2025, VOL. 16, NO. 1, 2554031
https://doi.org/10.1080/20008066.2025.2554031

STUDY PROTOCOL

OPEN ACCESS Check for updates

Spring PGD versus waiting list control in the treatment of prolonged grief disorder (PGD): protocol for a feasibility randomised controlled trial (RCT)

Catrin Lewis [a], Michelle Smalley[b], David M. Phillips[c], Gabriella Dattero Snell[a], Bronwen Thomas[a], Janice Wong Sing Yun[a] and Jonathan I. Bisson[a]

[a]National Centre for Mental Health, Cardiff University, Cardiff, UK; [b]Cwm Taf Morgannwg University Health Board, Royal Glamorgan Hospital, Ynysmaerdy, UK; [c]The Anna Phillips Foundation, Swansea, UK

ABSTRACT

Background: Prolonged Grief Disorder (PGD) is characterised by persistent longing or preoccupation with a deceased loved one, accompanied by intense emotional pain that lasts six-months or more and significantly impairs functioning. While Cognitive Behavioural Therapy (CBT) with a grief focus is effective, access is limited due to high costs and therapist shortages. Guided digital therapy, which delivers psychological support via an app or website with professional guidance, may offer a scalable solution. Building on the success of a guided digital intervention for post-traumatic stress disorder (PTSD), this study evaluates a similar intervention for PGD in a UK-based randomised controlled trial (RCT).

Objective: This study aims to assess the acceptability and feasibility of *Spring PGD*, a co-produced guided digital therapy for PGD, in preparation for a future definitive RCT.

Methods: This exploratory, randomised, parallel-group controlled trial will allocate 42 participants in a 1:1 ratio to either immediate access to *Spring PGD* or a waiting list control group. After 11 weeks, control participants will cross over to receive *Spring PGD*. The primary outcome measure is the Prolonged Grief 13 Revised (PG-13-R). A nested process evaluation will explore fidelity, adherence, and programme theory through interviews with purposively sampled participants and therapists.

Results: Findings will provide preliminary data on the acceptability, engagement, and feasibility of *Spring PGD*, informing the design of a future definitive RCT.

Conclusions: If *Spring PGD* shows promise, it could offer an accessible, scalable treatment for PGD, particularly in areas with limited access to specialised mental health services. The results will contribute to understanding the potential of guided digital therapy in addressing gaps in PGD treatment.

Spring TDP versus controles en lista de espera en el tratamiento de trastorno de duelo prolongado (TDP): protocolo de factibilidad de un ensayo controlado aleatorizado (ECA)

Antecedentes: El trastorno de Duelo Prolongado (TDP) se caracterizada por una añoranza o preocupación persistente por un ser querido fallecido, acompañado de un intenso dolor emocional que dura seis meses o más y afecta significativamente la funcionalidad. Si bien la Terapia Cognitiva Conductual (TCC) centrada en el duelo es efectiva, el acceso es limitado debido a altos costos y escasez de terapeutas. La terapia digital guiada, que brinda apoyo psicológico a través de una aplicación o página web con orientación profesional, podría ofrecer una solución escalable. Basándose en el éxito de una intervención digital guiada para el Trastorno de Estrés Postraumático (TEPT), este estudio evalúa una intervención similar para el TDP en un Ensayo Controlado Aleatorizado (ECA) realizado en el Reino Unido.

Objetivos: Este estudio tiene como objetivo evaluar la aceptabilidad y factibilidad de *Spring TDP*, una terapia digital guiada co-producida para el TDP, en preparación para un futuro ECA definitivo.

Métodos: Este ensayo exploratorio, aleatorizado y controlado de grupos paralelos asignará a 42 participantes en una proporción 1:1, ya sea al acceso inmediato a *Spring TDP* o a un grupo control en lista de espera. Después de 11 semanas, los participantes del grupo control van a recibir *Spring TDP*. La medida del resultado primario es el Duelo Prolongado 13 Revisado (PG-13-R). Una evaluación de procesos anidada explorará fidelidad, adherencia y la teoría del programa mediante entrevistas con participantes y terapeutas seleccionados intencionadamente.

Resultados: Los hallazgos proveerán datos preliminares sobre la aceptabilidad, la participación, y factibilidad del *Spring TDP*, lo que servirá de base para el diseño de un futuro ECA definitivo.

ARTICLE HISTORY
Received 12 February 2025
Revised 13 August 2025
Accepted 22 August 2025

KEYWORDS
Prolonged grief disorder (PGD); bereavement; digital; internet; app; guided; cognitive behavioural therapy (CBT)

PALABRAS CLAVE
Trastorno de Duelo Prolongado (TDP); duelo; digital; internet; aplicación; TCC

HIGHLIGHTS

- This study examines the feasibility of delivering a guided digital therapy for Prolonged Grief Disorder (PGD), a condition often lacking sufficient treatment options.
- It evaluates the acceptability, user engagement, and practical aspects of delivering a digital therapy with professional support, using both qualitative and quantitative methods.
- If *Spring PGD* shows promise, it could provide an accessible, scalable treatment for PGD, especially in areas with limited access to specialised therapies for PGD.

CONTACT Catrin Lewis lewisce7@cardiff.ac.uk National Centre for Mental Health Cardiff University Hadyn Ellis Building, Maindy Road, Cardiff CF24 4HQ, UK

Supplemental data for this article can be accessed online at https://doi.org/10.1080/20008066.2025.2554031

Conclusiones: Si el *Spring TDP* muestra potencial, podría ofrecer un tratamiento accesible, escalable para TDP, particularmente en áreas con acceso limitado a servicios de salud mental especializados. Los resultados contribuirán a comprender el potencial de la terapia digital guiada en abordar las brechas en el tratamiento de TDP.

1. Introduction

This study addresses the critical need for effective interventions for Prolonged Grief Disorder (PGD), a condition that has received increasing recognition since its formal inclusion in the International Classification of Diseases (ICD-11) in 2018 (World Health O, 2018). Previously referred to as Complicated or Traumatic Grief, PGD is characterised by a persistent preoccupation with a deceased loved one and enduring emotional distress that extends beyond six months, leading to significant functional impairment (World Health O, 2018). PGD affects an estimated 10% of bereaved individuals, resulting in a substantial number of new cases each year (Lundorff et al., 2017).

Despite the prevalence of PGD, routine access to evidence-based therapies remains limited across many regions, including the United Kingdom (Johannsen et al., 2019). The unaddressed and mounting problem of PGD has far-reaching implications, not only for affected individuals but also for society and the economy (Welsh Government, 2021). Our research aims to fill this gap by providing a scalable, effective intervention that could serve as a lifeline for individuals with PGD, while also delivering broader societal benefits.

Cognitive Behavioural Therapy (CBT) with a focus on grief has been shown to be effective for PGD (Bryant et al., 2014); however, its accessibility is limited by the high costs and extensive training requirements for therapists (Ochieng et al., 2019). A promising solution lies in guided digital therapy, a method that delivers psychological therapy through an app or website with professional guidance (Lewis et al., 2019). This approach offers a potentially cost-effective and scalable method of providing specialised therapy for PGD.

Thirteen studies have examined the efficacy of both guided and unguided digital therapies for grief-related mental health difficulties (Brodbeck et al., 2019; Dominguez-Rodriguez et al., 2023; Eisma et al., 2015; Kaiser et al., 2022; Kersting et al., 2011; Lenferink et al., 2023; Litz et al., 2014; Reitsma et al., 2023; Treml et al., 2021; Van der Houwen et al., 2010; Wagner et al., 2006; Wagner et al., 2022). A systematic review synthesised the findings of seven of these studies that specifically focused on CBT based interventions (Wagner et al., 2020). These trials, including 1,257 participants, revealed moderate to large effects on grief ($g = .54$) and traumatic stress symptoms ($g = .86$), with a smaller effect on depression ($g = .44$). Notably, these effects remained stable over time. Despite the promising results, the review noted the limited number of studies and insufficient statistical power for moderator analyses, underscoring the need for further research.

More recent randomised control trials have also demonstrated some promising outcomes. Dominguez-Rodriguez et al. (2023) reported on 114 participants using an unguided digital intervention based on CBT, mindfulness and positive psychology (Dominguez-Rodriguez et al., 2023). The intervention significantly reduced baseline clinical symptoms in the intervention group for all variables, including depression, hopelessness, grief, anxiety, and risk of suicide. However, the dropout rate was very high, with only 39.5% completing the intervention and 60.5% completing the waitlist period. Another RCT of unguided digital CBT conducted by Reitsma et al. (2023) with a sample size of 65 participants demonstrated significantly lower levels of disturbed grief, post-traumatic stress disorder (PTSD), and depression compared to waitlist controls (Reitsma et al., 2023). However, a high dropout rate (40.6%) was observed, with the lack of therapist assistance reported as the most common reason for withdrawal.

For therapist-supported interventions, Treml et al. (2021) evaluated an internet-based cognitive-behavioural grief therapy for individuals bereaved by suicide with 58 participants (Treml et al., 2021). Targeting this specific population, they found statistically significant improvement of grief symptoms for the intervention group compared to waiting list control group. Lenferink et al. (2023) included 40 participants in an RCT of internet delivered CBT for PGD after traumatic loss (Lenferink et al., 2023). They found a statistically significant reductions in symptoms of prolonged grief, traumatic stress, and depression relative to the waiting list condition at post-treatment and follow-up. In addition, Kaiser et al. (2022) enrolled 87 participants in a randomised waitlist-controlled trial for people experiencing bereavement due to cancer and found the intervention reduced symptoms of prolonged grief to a clinically significant extent (Kaiser et al., 2022). However, all three studies lacked diversity in participant demographics (e.g. more females, with high education), which restricts the generalisability of their findings to the broader bereaved population. Brodbeck et al. (2019) completed a larger RCT of 110 participants using a guided intervention for older adults after spousal bereavement or separation/divorce (Brodbeck et al., 2019). Although the intervention showed promise compared to a waitlist control

group, a high percentage were separated/divorced (77%) with only 23% of the participants widowed.

Despite these promising findings, several gaps in the existing literature highlight the critical need for further development and evaluation of guided digital interventions for PGD. Many of the existing interventions target specific subpopulations, such as older adults or individuals bereaved by a particular cause, for example cancer or suicide, limiting the generalisability of findings and their clinical applicability of the interventions to the broader bereaved population. Developing and evaluating new interventions offers a unique opportunity to address these limitations by enhancing accessibility and relevance for a more diverse range of users. Moreover, since all identified studies were conducted outside the UK, there is an urgent need for research within a UK context to better understand the effectiveness and applicability of digital CBT for PGD among UK bereaved individuals.

Building on our success in developing an evidence-based guided digital therapy for PTSD (Bisson et al., 2023; Lewis et al., 2017), we have developed an intervention based on similar principles for PGD. In a multi-site randomised controlled trial (RCT) conducted across Wales, England, and Scotland, our digital intervention for PTSD demonstrated non-inferiority to gold-standard face-to-face therapy and has been provisionally recommended by the National Institute for Health and Care Excellence (NICE) (Bisson et al., 2023; NICE, 2023). These achievements have facilitated the integration of the intervention within some regions of the National Health Service (NHS) in the UK, with plans underway to expand its implementation. This experience positions us to make a significant contribution to the growing field of digital interventions for PGD and further strengthen the evidence base for their effectiveness, relevance, and accessibility in supporting those experiencing PGD.

Despite growing interest in digital grief therapies, there remains a significant gap in high-quality evidence on the feasibility, acceptability, and preliminary outcomes of such interventions for PGD. A feasibility trial is therefore a necessary and appropriate first step to assess critical parameters such as recruitment and retention rates, adherence, safety, and user engagement. This study will provide essential data to determine whether progression to a fully powered effectiveness trial is warranted and to optimise the design of that future trial.

2. Method

2.1. Trial design

The study will be an exploratory, randomised, parallel-group controlled-trial. Participants will be allocated in a 1:1 ratio to either immediate *Spring PGD* or a waiting list control group using blocked randomisation. Randomisation will be conducted by a research team member who is independent of the intervention delivery, using an online true random number generator to ensure allocation concealment. To preserve blinding among trial staff involved in enrolment and assessment, specific operational details of the randomisation (e.g. block sizes) are not disclosed here. After a period of 11 weeks on the waiting list, participants in the control group will cross over to receive *Spring PGD*. Figure 1 shows planned participant flow.

2.2. Aim

To ascertain proof of concept for *Spring PGD* compared to a wait list control group and determine whether a definitive phase 3 trial is feasible.

2.3. Objectives

1. Evaluate the efficiency of participant recruitment. Data used: Recruitment logs detailing the number of participants approached, screened, consented,

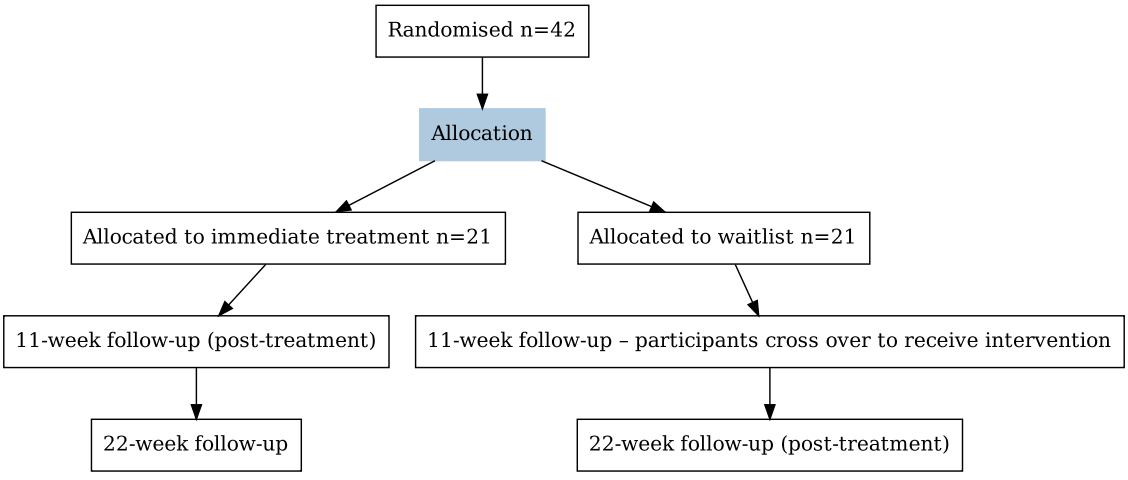

Figure 1. Participant flow.

and randomised, over time.
Track the rate of participant follow-up throughout the study.
Data used: Records showing the number of participants completing assessments at the planned time-points.

2. Calculate the necessary sample size for a future definitive trial.
Data used: Recruitment and retention data, drop-out data, and estimates of effect size.
3. Verify that the study sample is representative of the target service user population.
Data used: Demographic and baseline characteristics of participants compared to those of the target population.
4. Determine the acceptability of the intervention and trial procedures.
Data Used: Qualitative interview data from trial participants and therapists, survey data, adherence rates, drop-out rates, and reasons for drop-out.
5. Evaluate the risk of contamination between control and intervention groups.
Data used: Participant and therapist reports and qualitative interview data, reviews of adherence to the study protocol, records of any other treatment/input received during the trial as deviations from the protocol, and assessment of whether blinding was effectively maintained.
6. Record and monitor any adverse effects experienced by participants during the study.
Data Used: Adverse event logs, participant self-reports, responses to routinely asked questions in qualitative interviews and follow-up surveys, and clinical assessments throughout the study.

2.4. Ethics approval

Ethics and regulatory approvals have been secured for our trial from the Wales Research Ethics Committee 2 (IRAS ID: 287681) and participating NHS sites.

2.5. Sample size

A standard power calculation is not typically recommended for feasibility trials (Skivington et al., 2021). Instead, our proposed sample size of 42 participants is informed by a prior feasibility RCT of a guided digital intervention for PTSD conducted by our research team, with similar inclusion criteria (Lewis et al., 2017). This previous study successfully achieved objectives comparable to those of the current trial.

2.6. Study setting

The study will be conducted in primary and secondary care services within the NHS, as well as in charitable organisations that support individuals experiencing grief-related mental health problems.

2.7. Inclusion and exclusion criteria

To enhance the generalisability of our study, we have established broad eligibility criteria. Recognising the frequent co-occurrence of PGD with conditions such as PTSD, anxiety disorders, and depression, individuals with these comorbidities will be included if PGD is their primary diagnosis, and they meet the other eligibility criteria.

2.8. Inclusion criteria

1. Age 18 years or older
2. Primary diagnosis of PGD as defined by ICD-11
3. Access to the internet

2.9. Exclusion criteria

1. Limited proficiency in English
2. Inability to provide informed consent
3. Currently undergoing psychological therapy
4. Recent change in psychotropic medication (within the past four weeks)
5. Presence of current psychosis
6. Substance dependence
7. Active suicidal ideation or risk

2.10. Recruitment and consent

A fully trained member of the research team will contact potential participants and provide them with a copy of the relevant participant information sheet. Potential participants will be given a minimum of 24 hours to consider their involvement in the study. The study information sheet and consent form will be sent via post or email. A member of the research team will then follow up with a phone or video call to further explain the study and to answer any additional questions the participant may have. If they agree to participate, arrangements will be made for their enrolment in the study. The research team member responsible for obtaining consent will ensure that the participant has read and understood the information sheet and will address any questions or concerns.

To obtain informed consent, the researcher will read each of the consent statements verbatim and ask the participant to respond with a 'yes' or 'no' aloud. As the participant responds, the researcher will complete an electronic copy of the consent form. The conversation will be recorded using an encrypted device and later transcribed by a member of the research team. The audio recordings will be

securely destroyed immediately after transcription. A copy of the completed electronic consent form will be sent to the participant by post or email.

2.11. Intervention

Spring PGD is an eight-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. While grounded in CBT, *Spring PGD* also draws on Acceptance and Commitment Therapy (ACT), meaning-focused approaches, and a continuing bonds perspective. These influences are reflected in exercises that promote values-based living, connection with the deceased, and identity reconstruction following loss. Figure 2 gives an overview of the content.

Spring PGD will be administered by therapists who have experience of working with people with PGD. A

Step 1: Understanding PGD – This introduction to PGD features four characters, portrayed by actors, each sharing their unique experiences of PGD related to different types of bereavement.
Step 2: Looking after yourself - Participants learn about self-care with a focus on mindfulness, grounding techniques, and relaxation exercises.
Step 3. The story of your loss - This step focuses on gradually working through and reprocessing memories of the loss.
Step 4: Remembering the person you lost - Participants are guided through techniques to actively engage with positive memories of their loved one.
Step 5: Re-engaging with life - This step helps participants identify their values and gradually engage in pleasurable or meaningful activities.
Step 6: Thoughts and feelings - Cognitive techniques are introduced to help participants challenge and reframe unhelpful thoughts.
Step 7: Honouring the loss – This step helps participants identify unhelpful ways of honouring their loved one and explore meaningful alternatives, such as creating a memory jar or a memorial.
Step 8: The future – This final step consolidates lessons learned throughout the programme and provides strategies for managing grief in the future.

Figure 2. Overview of *Spring PGD*.

comprehensive therapist manual accompanies the intervention, providing detailed guidance and instructions for effective delivery.

2.12. Data collection

2.12.1. Quantitative data

Quantitative outcome measures have been selected based on expert consultations and literature reviews, while also considering the psychometric properties of the available options. The primary outcome will be symptoms of PGD, assessed using the Prolonged Grief 13 Revised (PG-13-R) scale (Prigerson et al., 2021). The PG-13-R is a validated 13-item instrument specifically designed to assess symptoms of PGD (Prigerson & Maciejewski, 2006).

The secondary outcome measures, all of which will be self-reported, include:

- **International Trauma Questionnaire (ITQ):** The ITQ is an 18-item scale that assesses self-reported symptoms of Post-Traumatic Stress Disorder (PTSD) and complex PTSD, as defined in the 11th edition of the International Classification of Diseases (ICD-11) (Cloitre et al., 2018). The ITQ is widely used and well-validated.
- **Generalised Anxiety Disorder-7 (GAD-7):** The GAD-7 is a brief, reliable, and well-validated self-report measure of anxiety, extensively used in both clinical and research settings (Spitzer et al., 2006).
- **Patient Health Questionnaire-9 (PHQ-9):** The PHQ-9 is a widely used, reliable, and well-validated self-report measure of depression, commonly employed in both clinical practice and research (Kroenke et al., 2001).
- **Insomnia Severity Index (ISI):** The ISI is a 7-item self-report questionnaire that assesses the nature, severity, and impact of insomnia. It has been shown to be a reliable and valid tool for detecting insomnia and measuring treatment response in clinical populations (Morin et al., 2011).
- **Goal-Based Outcomes (GBOs):** GBOs will assess progress towards self-identified goals, providing a personalised measure of treatment effectiveness (Law D, 2006).
- **Work and Social Adjustment Scale (WSAS):** The WSAS is a self-report measure that evaluates the impact of mental health difficulties on functioning across various domains, including work, home management, social leisure, private leisure activities, and personal or family relationships. The WSAS has demonstrated good reliability, validity, and sensitivity to change (Mundt et al., 2002).
- **EQ-5D-5L:** The EQ-5D-5L is a widely recognised instrument in health economic analysis and is endorsed by NICE as an appropriate measure of health-related quality of life (EuroQol, 1990).

Data will be collected electronically at baseline, post-treatment, and at a three-month follow-up using REDCap survey software. During the intervention, measures of grief, depression, and traumatic stress will be collected bi-weekly. The initial assessment will confirm that participants meet the inclusion criteria.

2.13. Qualitative data

Qualitative data will be gathered through one-to-one interviews using a topic guide developed with input from the Public Advisory Group (PAG). Participants will be interviewed before and after using the programme to discuss their experiences and expectations, with a focus on overall impressions, helpful aspects, and acceptability. Therapists will also be interviewed about their experiences with the programme in clinical practice. All interviews will be recorded and securely stored, with transcripts prepared for detailed analysis.

2.14. Data management

Data management will comply with General Data Protection Regulation (GDPR) principles and follow NHS Wales and Cardiff University policies on data protection and security. The Principal Investigator will oversee data management in line with National Centre for Mental Health Standard Operating Procedures. Participants will be assigned a unique identifier, and personal and clinical data will be stored separately and protected with passwords. Access to the data will be restricted to authorised personnel who have signed confidentiality agreements. Anonymised data will be retained for 15 years according to Cardiff University's record retention policy.

2.15. Data analysis

Quantitative Data: A CONSORT flow diagram will illustrate participant progression through the trial. Descriptive statistics, means and standard deviations for continuous variables, and frequencies and percentages for categorical variables, will be used to summarise baseline characteristics and key feasibility outcomes. Primary feasibility outcomes, including recruitment rates, retention rates, and data completeness, will be presented with 95% confidence intervals. Outcome data at each time point will be summarised descriptively and compared to baseline using group-wise means and mean changes, also with 95% confidence intervals. Any inferential analyses will be conducted solely for exploratory purposes and will be clearly identified as such. All analyses will be conducted using Stata software.

Qualitative Data: The qualitative data will be analysed using Inductive Thematic Analysis (Braun &

Clarke, 2006), with contributions from the Patient and Public Advisory Group (PAG) throughout the process. The analysis will follow these steps:

1. **Familiarisation**: A thorough reading of the transcripts will be conducted to gain an in-depth understanding of the participants' perspectives and the overall context of the data.
2. **Generating Codes**: Initial codes will be developed inductively, directly reflecting the content of the data. These codes will be refined through discussion within the research team and with the PAG, ensuring that they accurately capture participants' experiences. A proportion of transcripts (at least 10%) will be double-coded by a second researcher to ensure reliability and consistency in the coding process. Any discrepancies or differences in coding will be discussed within the team to reach consensus and improve coding accuracy.
3. **Searching for Themes**: The team will work together to identify overarching themes that encapsulate the key ideas and patterns emerging from the data, ensuring that they reflect the perspectives of the participants.
4. **Reviewing Themes**: The identified themes will be reviewed and refined in collaboration with the research team and the PAG, ensuring they are coherent, relevant, and accurately represent the data. This step will involve revisiting the data and checking that the themes adequately capture the richness and depth of participants' responses.
5. **Defining and Naming Themes**: Each theme will be carefully defined, with clear, descriptive labels assigned to reflect the essence of the theme. This process will involve ongoing discussion with the research team and PAG to ensure that the themes resonate with lived experiences.
6. **Writing Up**: Finally, the findings will be compiled into a comprehensive report, including illustrative quotations from the data that support and highlight the identified themes. This report will be developed in collaboration with the research team and PAG, ensuring that the final analysis is both accurate and meaningful.

Throughout the process, regular discussions with the research team and the PAG will ensure that the framework is applied consistently and refined as needed, enhancing the credibility and relevance of the findings.

2.16. Process evaluation

The process evaluation will follow Medical Research Council (MRC) guidelines, employing iterative programme theory and logic models to assess the implementation and effectiveness of *Spring PGD*. The evaluation will focus on clarifying the context, objectives, and mechanisms of the intervention, as well as the anticipated outcomes. The programme theory and logic models will be refined throughout the project to improve the understanding of trial results and inform potential larger-scale RCT.

2.17. Payment for study participants

To acknowledge their contributions, participants will receive £10 for completing post-treatment questionnaires, which typically take around 20 minutes. Additionally, participants who participate in qualitative interviews, lasting approximately 60 minutes, will be compensated £25 for their time.

2.18. Ethical considerations

Ethics and regulatory approvals have been secured for our trial from the Wales Research Ethics Committee (IRAS ID: 287681) and participating NHS sites. We are planning several measures to uphold ethical standards throughout the trial. Experienced Research Assistants will be employed under supervision and with clinical support. They will screen and consent participants and collect quantitative and qualitative data. Experienced therapists will oversee the digital intervention, ensuring participants receive regular supervision and ongoing therapist contact, with access to acute assistance if needed. Risk monitoring and safety protocols will adhere to established guidelines. Additionally, a comprehensive data management plan compliant with GDPR will be implemented. To ensure equitable access to the digital intervention, we will provide user-friendly navigation supported by a step-by-step paper guide. Should the intervention prove effective, we plan to develop a manual for face-to-face therapy to accommodate individuals who are unable to engage with the digital programme.

2.19. Public involvement

Public involvement is central to enhancing the quality and impact of our research. Public partners who contributed to the development of both the intervention and the design of the RCT will be invited to continue their involvement throughout the trial. Regular updates and feedback opportunities will be provided, with the option for participants to formalise their roles by joining the trial-specific PAG.

We aim to establish a diverse and representative PAG, including individuals who have experienced PGD under various circumstances, such as loss due to suicide or illness. To ensure inclusivity, we will promote participation widely, collaborating with relevant third-sector organisations to recruit members across different age groups, gender identities, and ethnic

backgrounds. The level of involvement will be flexible, accommodating the varying capacities of members.

An induction programme for the PAG will include a joint meeting with the Project Management Group (PMG) to emphasise the central role of public involvement and clarify roles and responsibilities. PAG members will be invited to participate in a study-specific public involvement support and learning programme, co-produced with the group and tailored to individual needs. This programme will likely include mentoring and training sessions. The PAG will set its own agenda, with the aim of collaboration across all aspects of the RCT. Based on our previous studies, we anticipate close collaboration in the following areas:

1. **Developing Recruitment Strategies:** Focusing on engaging groups typically underrepresented in grief research, such as men, older adults, and ethnic minorities.
2. **Enhancing the Trial Experience:** Devising strategies to improve participant experience and reduce burden, including continuous feedback on research procedures and participant-facing materials.
3. **Collaborating on Data Analysis:** Ensuring that the analysis is both scientifically rigorous and meaningful to people with PGD.
4. **Refining the Intervention:** Using trial results to ensure the acceptability and effectiveness of the intervention.
5. **Co-producing the Dissemination Strategy:** Making the research accessible and engaging to a broad audience, with PAG members having opportunities to co-author publications and present trial results at relevant events.

The PAG will be invited to monitor its own impact using the Public Involvement in Research Impact Toolkit (PIRIT) (Newman, 2023), and the UK Standards for Public Involvement (NIHR, 2018) will guide all our activities.

2.20. Participant withdrawal

Participants will be informed through the participant information sheet that their involvement in this study is entirely voluntary. They will be free to withdraw from the study at any point, without the need to provide a reason, and their decision to withdraw will not impact their medical care or legal rights in any way.

If a participant chooses to withdraw, any data that has already been collected will be retained and used for research purposes, unless the participant specifically requests that their data be withdrawn. If such a request is made, all data associated with the participant will be securely destroyed.

2.21. Success criteria

In collaboration with the PAG and key stakeholders, the following criteria will guide our progression through the trial and inform the decision to advance to a definitive RCT. A 'stop' outcome would not necessarily indicate that all development of the intervention should cease. Rather, it would suggest that substantial modifications are required to the intervention and/or trial procedures, and that additional feasibility testing would be necessary before advancing to a full-scale trial.

1. **Participant Recruitment:**
   - *Proceed:* A recruitment rate of 3-4 participants per month, with consistent progress through all stages (approached, screened, consented, and randomised).
   - *Review:* A recruitment rate of 2-3 participants per month, suggesting the need for adjustments.
   - *Stop:* A recruitment rate of fewer than 2 participants per month, indicating significant recruitment challenges.
2. **Participant Follow-up:**
   - *Proceed:* A follow-up rate of 80% or more at each planned time point.
   - *Review:* A follow-up rate of 60-79%, indicating a need for review and potential improvements.
   - *Stop:* A follow-up rate of less than 60%, suggesting substantial issues with participant retention.
3. **Sample Size for a Future Trial:**
   - *Proceed:* Sample size calculations confirm that the required number of participants is feasible within the trial's scope and budget.
   - *Review:* Sample size calculations suggest challenges in achieving the required number within the trial's constraints.
   - *Stop:* Sample size calculations indicate that the required number of participants is not feasible within the scope and budget, raising concerns about the trial's viability.
4. **Representative Sample:**
   - *Proceed:* The demographic and baseline characteristics of participants closely match those of the target population.
   - *Review:* Notable discrepancies between the study sample and the target population require further investigation and adjustment.
   - *Stop:* Significant and unresolved differences between the study sample and the target population undermine the generalisability and validity of the findings, raising concerns about applicability to a larger trial.
5. **Acceptability:**
   - *Proceed:* The intervention and procedures are deemed highly acceptable, with 80% or more

of participants reporting satisfaction, high adherence rates, and drop-out rates below 20%.
- *Review:* Mixed acceptability, with 60-79% of participants reporting satisfaction, moderate adherence rates, and drop-out rates between 20% and 40%, highlighting areas needing refinement.
- *Stop:* Less than 60% of participants report satisfaction, drop-out rates exceed 40%, and there are significant concerns necessitating a major redesign of the intervention or procedures.

6. **Contamination Between Groups:**
   - *Proceed:* No significant contamination is detected.
   - *Review:* Potential contamination is identified, warranting closer monitoring.
   - *Stop:* Significant contamination is detected, compromising the study's integrity.
7. **Adverse Events:**
   - *Proceed:* Adverse events are minimal, affecting less than 5% of participants, with effective management and reporting mechanisms in place.
   - *Review:* Adverse effects are higher than expected, affecting 5-10% of participants, necessitating closer monitoring and possible protocol adjustments.
   - *Stop:* Adverse effects affect more than 10% of participants, with severe or frequent issues raising major safety concerns, potentially halting the study.

2.22. Dissemination, outputs, and anticipated impact

In collaboration with the PAG, we will create a tailored outreach plan. This will include establishing a dedicated project website and promoting the trial through various channels, including podcasts, leaflets, and webinars. Trial results will be communicated to participants and the public through accessible formats selected by the PAG, which may include lay language reports, infographics, blog posts, animations, and public events. For the academic community, we aim to publish the research in open-access journals, producing at least two academic papers, one on primary findings and one on qualitative results, along with presentations at national and international conferences.

3. Discussion

If *Spring PGD* shows promise, it would represent a significant advance in the treatment of PGD in the UK. The scalable nature of guided digital therapy offers the potential to reach a broader population than traditional face-to-face therapy, particularly in regions where access to specialised mental health services is limited. This is crucial given the substantial and growing demand for mental health support following bereavement, which has been exacerbated by recent global events such as the COVID-19 pandemic, and the increasing effects of climate change, which have led to widespread loss of life (Tang & Xiang, 2021).

The advantages of guided digital therapy, such as reduced costs and flexibility in delivery, mean that more individuals could receive timely support without the lengthy waiting times often associated mental health services. This is particularly pertinent in the context of the NHS in the UK, where mental health services are frequently under strain. Additionally, *Spring PGD* aligns well with current trends in mental health treatment that emphasise patient-centred care. The ability to tailor interventions to individual needs is likely to enhance engagement and adherence, leading to better outcomes.

3.1. Possible limitations

Several potential limitations must be considered. Firstly, the reliance on digital delivery may limit accessibility for certain groups. Individuals with limited internet access, low digital literacy, or those who are uncomfortable with technology might find it challenging to engage fully with *Spring PGD*. This could result in lower rates of participation among older adults or those from socioeconomically disadvantaged backgrounds, potentially impacting the generalisability of our findings.

Another limitation relates to the use of only self-reported outcome measures. While these measures are widely used and validated, they may be subject to biases such as social desirability or recall bias, particularly in a population affected by PGD. This could compromise the accuracy of data collected, leading to potential under- or over-reporting of symptoms.

The use of a waiting list control group also presents limitations. Participants in the control group may experience a natural decline in their PGD symptoms over time, which could complicate the interpretation of the results. Additionally, it might be preferable to include a more active control group, as this would allow for double blinding and provide a clearer comparison of treatment efficacy. However, it is important to acknowledge that there are currently limited options for active control groups in psychological therapy research, particularly for PGD.

Additionally, the ethical implications of delaying treatment for individuals in the control group must be considered. However, there are few therapeutic alternatives available for PGD, coupled with long waiting times for treatment within the NHS.

Another challenge could arise from variability in therapist adherence to the delivery of *Spring PGD*. While efforts will be made to standardise the delivery of *Spring PGD* through comprehensive training and supervision and a detailed therapist manual, individual differences in therapist experience, interpretation of the manual, and engagement with participants could introduce inconsistencies that affect the outcomes.

Furthermore, the relatively small sample size, typical of feasibility trials, may limit the statistical power to detect significant effects. While the primary aim is to assess feasibility and acceptability, the small sample will preclude definitive conclusions about efficacy. This limitation highlights the importance of interpreting the findings with caution and considering them as preliminary data that will inform larger, more definitive trials.

4. Conclusion

If *Spring PGD* is successfully implemented in the future, it could lead to significant reductions in the functional impairment associated with PGD, improving the overall quality of life for affected individuals. It also has the potential to contribute to broader public health goals, including reducing the economic burden associated with untreated mental health conditions.

The potential for translation and adaptation of *Spring PGD* to different cultural contexts and languages further underscores its potential for global impact. As digital health interventions become increasingly prevalent, the lessons learned from this study could inform the development of similar programmes for other mental health conditions, thereby expanding the reach and impact of evidence-based psychological therapies worldwide.

Author contributions

CL, JIB, and MS conceived the study, designed the trial, secured grant funding, and will oversee the management of the trial. DP is the lead for public involvement. GDS, BT, and JWSY will screen participants, obtain informed consent, and collect data. All authors contributed to the manuscript. The corresponding author confirms that all listed authors meet the criteria for authorship and that no eligible authors have been omitted.

Disclosure statement

Spring PGD was developed by and is owned by Cardiff University and, if commercialised, Cardiff University would benefit, as would authors CL, JIB, ad MS. The remaining authors have no competing interests.

Funding

This project is funded by Health and Care Research Wales (HCRW; 01-TC-00032). Sponsor: Cardiff University.

Ethics approval and consent to participate

Ethics and regulatory approvals have been secured for our trial from the Wales Research Ethics Committee 2 (IRAS ID: 287681) and participating NHS sites. All participants will provide informed consent.

Availability of data and materials

Data will be available upon reasonable request from the corresponding author.

ORCID


Catrin Lewis http://orcid.org/0000-0002-3818-9377

References

Bisson, J. I., Ariti, C., Cullen, K., Kitchiner, N., Lewis, C., Roberts, N. P., Simon, N., Smallman, K., Addison, K., Bell, V., Brookes-Howell, L., Cosgrove, S., Ehlers, A., Fitzsimmons, D., Foscarini-Craggs, P., Harris, S. R. S., Kelson, M., Lovell, K., McKenna, M., … Williams-Thomas, R. (2023). Pragmatic randomised controlled trial of guided self-help versus individual cognitive behavioural therapy with a trauma focus for post-traumatic stress disorder (RAPID). *Health Technology Assessment*, *27*(26), 1–70.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. doi:10.1191/1478088706qp063oa

Brodbeck, J., Berger, T., Biesold, N., Rockstroh, F., & Znoj, H. J. (2019). Evaluation of a guided internet-based self-help intervention for older adults after spousal bereavement or separation/divorce: A randomised controlled trial. *Journal of Affective Disorders*, *252*, 440–449. doi:10.1016/j.jad.2019.04.008

Bryant, R. A., Kenny, L., Joscelyne, A., Rawson, N., Maccallum, F., Cahill, C., Hopwood, S., Aderka, I., & Nickerson, A. (2014). Treating prolonged grief disorder: A randomized clinical trial. *JAMA Psychiatry*, *71*(12), 1332–1339. doi:10.1001/jamapsychiatry.2014.1600

Cloitre, M., Shevlin, M., Brewin, C. R., Bisson, J. I., Roberts, N. P., Maercker, A., Karatzias, T., & Hyland, P. (2018). The international trauma questionnaire: Development of a self-report measure of ICD-11 PTSD and complex PTSD. *Acta Psychiatrica Scandinavica*, *138*(6), 536–546. doi:10.1111/acps.12956

Dominguez-Rodriguez, A., Sanz-Gomez, S., González Ramírez, L. P., Herdoiza-Arroyo, P. E., Trevino Garcia, L. E., de la Rosa-Gómez, A., González-Cantero, J. O., Macias-Aguinaga, V., & Miaja, M. (2023). The efficacy and usability of an unguided web-based grief intervention for adults who lost a loved one during the COVID-19 pandemic: Randomized controlled trial. *Journal of Medical Internet Research*, *25*, e43839. doi:10.2196/43839

Eisma, M. C., Boelen, P. A., van den Bout, J., Stroebe, W., Schut, H. A. W., Lancee, J., & Stroebe, M. S. (2015). Internet-based exposure and behavioral activation for complicated grief and rumination: A randomized controlled trial. *Behavior Therapy*, *46*(6), 729–748. doi:10.1016/j.beth.2015.05.007

EuroQol. (1990). EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy*, *16*(3), 199–208. doi:10.1016/0168-8510(90)90421-9

Johannsen, M., Damholdt, M. F., Zachariae, R., Lundorff, M., Farver-Vestergaard, I., & O'Connor, M. (2019). Psychological interventions for grief in adults: A systematic review and meta-analysis of randomized controlled trials. *Journal of Affective Disorders*, *253*, 69–86. doi:10.1016/j.jad.2019.04.065

Kaiser, J., Nagl, M., Hoffmann, R., Linde, K., & Kersting, A. (2022). Therapist-assisted web-based intervention for prolonged grief disorder after cancer bereavement: Randomized controlled trial. *JMIR Mental Health*, *9*(2), e27642. doi:10.2196/27642

Kersting, A., Kroker, K., Schlicht, S., Baust, K., & Wagner, B. (2011). Efficacy of cognitive behavioral internet-based therapy in parents after the loss of a child during pregnancy: Pilot data from a randomized controlled trial. *Archives of Women's Mental Health*, *14*(6), 465–477. doi:10.1007/s00737-011-0240-4

Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine*, *16*(9), 606–613. doi:10.1046/j.1525-1497.2001.016009606.x

Law D. (2006). *Goal based outcomes (GBOs): some useful information*. Internal CORC Publication.

Lenferink, L. I., Eisma, M. C., Buiter, M., de Keijser, J., & Boelen, P. A. (2023). Online cognitive behavioral therapy for prolonged grief after traumatic loss: A randomized waitlist-controlled trial. *Cognitive Behaviour Therapy*, *52*(5), 508–522. doi:10.1080/16506073.2023.2225744

Lewis, C. E., Farewell, D., Groves, V., Kitchiner, N. J., Roberts, N. P., Vick, T., & Bisson, J. I. (2017). Internet-based guided self-help for posttraumatic stress disorder (PTSD): randomized controlled trial. *Depression and Anxiety*, *34*(6), 555–565. doi:10.1002/da.22645

Lewis, C., Roberts, N., Simon, N., Bethell, A., & Bisson, J. (2019). Internet-delivered cognitive behavioural therapy for post-traumatic stress disorder: Systematic review and meta-analysis. *Acta Psychiatrica Scandinavica*, *140*(6), 508–521. doi:10.1111/acps.13079

Litz, B. T., Schorr, Y., Delaney, E., Au, T., Papa, A., Fox, A. B., Morris, S., Nickerson, A., Block, S., & Prigerson, H. G. (2014). A randomized controlled trial of an internet-based therapist-assisted indicated preventive intervention for prolonged grief disorder. *Behaviour Research and Therapy*, *61*, 23–34. doi:10.1016/j.brat.2014.07.005

Lundorff, M., Holmgren, H., Zachariae, R., Farver-Vestergaard, I., & O'Connor, M. (2017). Prevalence of prolonged grief disorder in adult bereavement: A systematic review and meta-analysis. *Journal of Affective Disorders*, *212*, 138–149. doi:10.1016/j.jad.2017.01.030

Morin, C. M., Belleville, G., Bélanger, L., & Ivers, H. (2011). The insomnia severity index: Psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep*, *34*(5), 601–608. doi:10.1093/sleep/34.5.601

Mundt, J. C., Marks, I. M., Shear, M. K., & Greist, J. M. (2002). The work and social adjustment scale: A simple measure of impairment in functioning. *The British Journal of Psychiatry*, *180*(5), 461–464. doi:10.1192/bjp.180.5.461

Newman, A. (2023). Public Involvement in Research Impact Toolkit (PIRIT).

NICE. (2023). NICE recommends 8 digitally enabled therapies to treat depression and anxiety 2023. https://www.nice.org.uk/news/articles/nice-recommends-8-digitally-enabled-therapies-to-treat-depression-and-anxiety.

NIHR. (2018). *National standards for public involvement*. INVOLVE.

Ochieng, C. A., Harrop, E., Evans, A., Newman, A., Seddon, K., Nelson, A., & Byrne, A. (2019). *A scoping survey of bereavement services in Wales- end of study report*. The Welsh Government.

Prigerson, H. G., Boelen, P. A., Xu, J., Smith, K. V., & Maciejewski, P. K. (2021). Validation of the new DSM-5-TR criteria for prolonged grief disorder and the PG-13-revised (PG-13-R) scale. *World Psychiatry*, *20*(1), 96–106. doi:10.1002/wps.20823

Prigerson, H. G., & Maciejewski, P. K. (2006). *Prolonged grief disorder (PG-13)*. Dana-Farber Cancer Institute.

Reitsma, L., Boelen, P. A., de Keijser, J., & Lenferink, L. (2023). Self-guided online treatment of disturbed grief, posttraumatic stress, and depression in adults bereaved during the COVID-19 pandemic: A randomized controlled trial. *Behaviour Research and Therapy*, *163*, 104286. doi:10.1016/j.brat.2023.104286

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K. A., Craig, N., French, D. P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M., & Moore, L. (2021). Framework for the development and evaluation of complex interventions: Gap analysis, workshop and consultation-informed update. . *Health Technology Assessment (Winchester, England)*, *25*(57), 1–132. doi:10.3310/hta25570

Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine*, *166*(10), 1092–1097. doi:10.1001/archinte.166.10.1092

Tang, S., & Xiang, Z. (2021). Who suffered most after deaths due to COVID-19? Prevalence and correlates of prolonged grief disorder in COVID-19 related bereaved adults. *Globalization and Health*, *17*(1), 1–9. doi:10.1186/s12992-021-00669-5

Treml, J., Nagl, M., Linde, K., Kündiger, C., Peterhänsel, C., & Kersting, A. (2021). Efficacy of an internet-based cognitive-behavioural grief therapy for people bereaved by suicide: A randomized controlled trial. *European Journal of Psychotraumatology*, *12*(1), 1926650. doi:10.1080/20008198.2021.1926650

Van der Houwen, K., Schut, H., van den Bout, J., Stroebe, M., & Stroebe, W. (2010). The efficacy of a brief internet-based self-help intervention for the bereaved. *Behaviour Research and Therapy*, *48*(5), 359–367. doi:10.1016/j.brat.2009.12.009

Wagner, B., Hofmann, L., & Maaß, U. (2022). A therapist-supported internet-based intervention for bereaved siblings: A randomized controlled trial. *Palliative Medicine*, *36*(10), 1532–1543. doi:10.1177/02692163221122344

Wagner, B., Knaevelsrud, C., & Maercker, A. (2006). Internet-based cognitive-behavioral therapy for complicated grief: A randomized controlled trial. *Death Studies*, *30*(5), 429–453. doi:10.1080/07481180600614385

Wagner, B., Rosenberg, N., Hofmann, L., & Maass, U. (2020). Web-based bereavement care: A systematic review and meta-analysis. *Frontiers in Psychiatry*, *11*, 525. doi:10.3389/fpsyt.2020.00525

Welsh Government. (2021, October 28). National framework for the delivery of bereavement care. https://www.gov.wales/national-framework-delivery-bereavement-care-html

World Health O. (2018). *International classification of diseases for mortality and morbidity statistics (ICD-11)*. World Health Organization.