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Responding to grief-related needs in older adults: protocol for a community-based matched-care trial (GriefDiff)

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Abstract

Background Prolonged grief disorder (PGD) affects a significant proportion of bereaved people and may be especially burdensome in later life, when cumulative losses, health problems, and reduced social resources can hinder adjustment. Grief support is often reactive, and many older adults do not access timely, appropriate care. GriefDiff will study a differentiated, community-based model that matches intervention intensity and format to individual risk and relational needs.

Methods GriefDiff is a mixed-methods (QUAN→QUAL) protocol. The quantitative component is a three-arm, tiered, parallel-group superiority randomised controlled trial delivered in community settings across Portugal, in collaboration with a national grief association. Eligible participants are Portuguese adults aged ≥60 years, bereaved 1–12 months, with a significant emotional bond to the deceased. After consent, participants complete a grief-risk tool and a mutuality-based relational-needs screener. Stratified block randomisation allocates participants to Information and Grief Literacy (IGLiteracy; one group session plus bi-weekly SMS reminders), an Individual Self-Help Program (ISelfHP; older-adult web app with optional offline materials and brief telephone guidance), or Moderated Self-Help Groups (MSHGroups; manualised weekly groups). Assessments occur at baseline, 3 months (post) and 6 months (follow-up). The primary outcome is prolonged grief symptoms; secondary outcomes are depression and anxiety. Target sample is N=324 (108/arm). Analyses will follow an intention-to-treat approach and will use mixed-effects models for repeated measures with fixed-sequence gatekeeping. Qualitative focus groups will compare matched versus non-matched allocations to clarify perceived fit, identify barriers, and inform future implementation strategies for differentiated grief care.

Discussion Developing scalable, differentiated community responses will help address a growing societal challenge while meeting the needs of older adults. By evaluating programme effectiveness and refining the screening procedure, this study aims to inform the development and implementation of needs-based grief care in community settings.

Trial registration ClinicalTrials.gov, NCT07433101; registered on 2026-02-25.

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Background

In most Western countries, advances in health and social welfare mean that increases in life expectancy will lead to a larger proportion of older adults. In Portugal, as in most European countries, by 2050, approximately one in three individuals will be over 65 years old [1]. Aside from the opportunities that arise from this evolution, several challenges are present, including vulnerabilities to chronic illness, physical frailty and cognitive decline. Beyond these physical effects, psychological and social issues such as grief and loss have received little attention. Although grief is a natural process, we as a society tend to address death as an uncomfortable issue, and adverse grief reactions are overlooked. While most people manage their grief process satisfactorily, it is estimated that 1 in 10 older adults develops prolonged grief disorder (PGD) [2–4]. Old age is a significant risk factor for PGD due to specific vulnerabilities associated with ageing, including poor social networks, economic impacts, and health-related issues [5–7]. This means that adverse grief reactions in older adults are a relevant societal challenge that will tend to worsen in the coming decades.

Most current responses to grief are delayed, focusing on dysfunction and prolonged grief reactions. Furthermore, a significant proportion of older adults never receive the support they need [8]. Considering the increase in life expectancy, the most suitable response should be both community-based – to proactively reach individuals in need – and differentiated to address individuals with relevant risk indicators and those who need broader preventive interventions [9]. This approach is consonant with the WHO's proposed organisation of mental health care [10] and the pyramid-like organisation of care for addressing grief reactions [11, 12]. In these proposals, low-intensity approaches (e.g., psychoeducation, self-care, self-managed interventions) focused on prevention or early intervention should be widely available. More intensive interventions should be reserved for individuals who show a more adverse grief reaction.

Despite clinical soundness, research on the differentiated organisation of care in grief remains scarce. Two models have been applied to grief care: (a) stepped care, in which the low-intensity interventions are provided universally, with more intensive interventions being provided subsequently when needed; and (b) matched care, in which lower and higher intensive or different types of interventions are provided according to a screening of the users (e.g., levels of symptom). A few studies have used a stepped-care approach [13, 14]. Kentish-Barnes and collaborators [14] showed the efficacy of a three-step program delivered throughout the grief process after a death in an intensive care unit. Steped care programs, like this, show promise comparable to individual interventions, with some indications of greater effectiveness. The second alternative – matched care approaches – seek to assess those in greater need and provide more intensive care initially.

A few studies have adopted this matched approach. Shear and colleagues [15] compared interventions based on symptom evaluation. The grief-specific intervention increased the effectiveness of the response, based on symptom profile. Kissane and collaborators [16] used a relational index to test the suitability of screening for a family-based intervention compared with an individual approach. This differentiation was useful for providing family-based approaches. While studies adopting matched care approaches remain scarce, they show promise in improving response effectiveness. One important issue is that the variables and are used for matching. While the severity of symptoms or other psychopathological aspects [15] remains central, other variables related to the grief process, like avoidance or coping [17–19] or relational dimensions, like attachment styles [20, 21], are being studied.

The main goal of this study is to evaluate a comprehensive, community-centred approach to addressing grief among older adults. It adopts a tiered, needs-based model designed to mitigate the negative effects of grief by providing tailored support at different levels. Three intervention levels are considered: Information and Grief Literacy (IGLiteracy), which serves as a control; Individual Self-Help Program (ISelfHP); and Moderated Self-Help Groups (MSHGroups). Each level builds on the previous one: ISelfHP includes informational support, while MSHGroups incorporates both self-help and informational resources. Older adults will receive targeted interventions based on a systematic assessment of their individual needs and risk.

Three specific aims are proposed. Firstly, it aims to evaluate the impact of the three interventions tailored to the individual needs and risk factors of older adults. We hypothesise that matching needs/risk to interventions will increase the effectiveness of care. Second, it aims to explore key factors - such as socioeconomic status, social support, and grief-related characteristics (e.g., nature of the loss, relationship to the deceased) - that influence engagement with these interventions. Thirdly, we aim to explore the personal experiences, needs, and challenges of older adults following the interventions through in-depth focus groups.

Methods

Study design

This mixed-methods study follows a QUAN → QUAL design. The quantitative stage employs a superiority randomised controlled trial (RCT) of a three-arm, tiered, parallel-group intervention to address grief in older adults. The model includes three intervention levels: Information and Grief Literacy (IGLiteracy), Individual Self-Help Program (ISelfHP), and Moderated Self-Help Groups (MSHGroups). IGLiteracy is considered a minimum intervention control condition for the two higher-intensity interventions. The absence of a non-intervention control is justified on ethical grounds, given the community context in which it is applied and considering the vulnerability of older adults in this context. Randomisation will test both efficacy and the matching hypothesis, whereby intervention intensity is aligned with participants' risk and relational needs profiles.

The qualitative component will consist of focus groups designed to extend and explain quantitative outcomes by exploring participants' experiences, perceived usefulness, unmet needs, barriers to engagement, and adherence factors. Focus groups will compare the experiences of participants whose allocation was matched versus non-matched to their risk/needs profile.

Recruitment and setting

The study will take place in a community setting across Portugal, through a partnership with InLuto, a national grief association. InLuto and its partner community entities will also serve as venues for participants to contact. The main sources of referral will be social organisations dedicated to supporting the community, including elderly associations, hospitals, primary care and other community-based services. Recruitment will be complemented by targeted social media outreach and participation in relevant forums to reach the required sample and engage participants. Considering existing community networks, participants are expected to be recruited from several Portuguese regions. Partner organisations will be asked to refer all eligible participants in their care. A standardised contact protocol will define when and how participants are contacted, and recruitment will be monitored against predefined milestones.

The trial sponsor is ISPA – Instituto Universitário, which also serves as the coordinating centre. The principal investigator is responsible for scientific leadership, protocol compliance, and oversight of trial delivery. A trial management group (principal investigator and co-investigators) will meet regularly to review recruitment, retention, adherence, and any safety concerns, and to manage operational decisions. Trained research staff will conduct screening, obtain informed consent, coordinate randomisation procedures, and support scheduling of assessments and intervention delivery.

Participants

Participants will be older Portuguese adults aged 60 or older who experienced the death of an individual with whom the participant had a significant emotional bond (e.g., spouse/partner, close family member, or highly meaningful relationship). The age interval reflects the typical Portuguese retirement age and accounts for the transition to old age. The death must have occurred between one month and one year before recruitment. This timeframe ensures the grieving process is still active and that the intervention may have preventive value for prolonged grief. Exclusion criteria are: (a) a self-reported diagnosis of a serious mental disorder within the past year; (b) significant cognitive impairment reported during screening; and (c) current engaged in psychological treatment or intention to initiate treatment during the study. Taking psychiatric medication will not be an exclusion criterion, but it will be monitored. Participants with relevant suicidal ideation and intention – assessed clinically at T0 - will be referred to a suitable service. Physical limitations that could hinder the use of digital means are not considered exclusion criteria, as offline modalities will be offered to those who need them. A specific effort will be made to gather participants who are usually underrepresented, namely, men and people of low socioeconomic status. This will be achieved through targeted messages and targeted outreach to community partners working directly with these populations.

Screening and randomisation

Individuals referred by community partners will be assessed for eligibility. Eligible participants will be informed about the study and asked to sign the informed consent form. Participants will then be asked to complete the two screening tools: the Prolonged Grief Screening Tool (PGST) [22] and the Mutuality subscale of the Relational Needs in Grief Scale (RNGS) [23]. Final cut-offs are defined a priori (e.g., low, moderate, and high risk), based on available validation data. Participants will be classified according to risk level based on the PGST score. low (≤ 12), moderate (≥ 13 and ≤ 14) and high (≥ 15). Participants will be classified into relational needs categories based on the relational needs mutuality subscale score: low (≤ 6) or high (≥ 7). These cut-offs are based on median data from the adaptation studies, except for high risk, which is based on the predictive value of a PGD score on the PG-13-R [22, 24].

Effective matching is hypothesised to be: (a) low-risk participants - IGLiteracy; b) moderate/high risk & low relational needs - ISelfHP – ?; and (c) moderate/high risk & high relational needs - MSHGroups. Randomisation

is stratified in two tiers: (1) low- and moderate-risk participants are randomised either to IGLiteracy or to one of the higher-intensity interventions (ISelfHP or MSHGroups); and (2) within the moderate/high-risk strata, participants are further stratified by relational needs (low and high) and randomised between ISelfHP and MSHGroups. Participants classified as high risk will not be randomised to IGLiteracy. This is done for ethical reasons to avoid offering the low-intensity intervention to high-need participants. Randomisation follows a 1:1:1 schedule, within predefined risk × needs strata, based on the screening assessment. Within each stratum, block randomisation (block sizes of 6) will be used to ensure balanced group sizes.

The allocation sequence will be generated by an independent member of the research team who is not involved in participant enrolment or outcome assessment, using a computer-generated randomisation schedule. The allocation sequence will be implemented using a centralised, password-protected electronic randomisation file. Group assignments will remain concealed from enrolment staff until a participant has completed the screening and has been irreversibly entered into the randomisation system. While participants will not be blinded to the assigned intervention, concealment will be maintained regarding the matching status (matched vs. non-matched) for the participant and the researcher accompanying the interventions. Following randomisation, participants enter the intervention stage. For all three interventions, participants first attend an initial group meeting, where the details of the specific intervention are presented, and the baseline assessment is conducted.

Interventions and participation timeline

Three interventions will be included over three months: Information and Grief Literacy (IGLiteracy), Individual Self-Help Program (ISelfHP), and Moderated Self-Help Groups (MSHGroups). The interventions will focus on promoting the grief process and preventing Prolonged Grief Disorder. While IGLiteracy could be considered a universal intervention, both ISelfHP and MSHGroups are designed as selective psychological interventions and will follow existing guidelines for developing and implementing psychological interventions [25]. ISelfHP and MSHGroups follow the integrative model of grief intervention [26, 27].

1) Information and Grief Literacy (IGLiteracy). IGLiteracy focuses on enhancing participants' understanding of bereavement by providing information on common and uncommon grief responses, as well as resources for seeking help. It is centred on a single group session that introduces fundamental concepts and materials. Following this session, participants who consent will receive bi-weekly text reminders (via SMS) to reinforce key concepts and resources presented in the initial session.

2) Individual Self-Help Program (ISelfHP). This digital psychological intervention will be implemented in a web-based application specifically designed for older adults. The intervention aims to promote personal well-being and foster the grief process. It emphasises self-care, emotional regulation, grief elaboration, and the acceptance of emotions, while offering guidance to encourage adherence. The intervention involves: (a) psychoeducation; (b) emotional regulation and well-being promotion; and (c) grief elaboration and acceptance. To respond to different needs and ways of grieving, no specific set of modules or minimum dose is set. Participants will be encouraged to complete at least one exercise per week. Engagement with the digital intervention (e.g., log-ins, time spent, modules completed) will be monitored and considered in the analysis. The intervention is designed to include reminders and prompts that respond to usage (e.g., reduced usage, negative intermediate assessments). Participants allocated to ISelfHP will be contacted by phone during the program to encourage engagement, clarify doubts, and provide motivational support, ensuring minimal but meaningful guidance. Personalisation is based on users' preferences, and usage is monitored. A non-digital alternative (i.e., a book with the same contents) will be offered for participants with low digital literacy.

3) Moderated Self-Help Groups (MSHGroups). MSHGroups is a manualised self-help group facilitated by a trained professional. It is a semi-structured and flexible intervention to foster peer support and shared understanding. The intervention is structured around specific topics, including grief process, emotional regulation, acceptance, guilt, and grief elaboration. It provides a safe and compassionate environment to share experiences, normalise feelings, and learn practical coping strategies from peers. The sessions are weekly, and the group sessions are scheduled to last 3 h. The group ends with a closing session focused on relapse prevention and promotion of continuous elaboration. MSHGroups will use attendance records and post-session participant feedback to monitor adherence and perceived usefulness. The moderator of this group will be a psychologist with specific training in this intervention. To ensure adherence to procedures, the moderator will maintain a detailed record of each session and will be supervised.

Public involvement contributed to intervention planning through collaboration with the community partner (inLuto), and consultation focused on acceptability, accessibility, and participant burden. The community partners also support recruitment procedures and will assist with dissemination through a plain-language summary of findings. All materials used in the different interventions are culturally adapted in collaboration with

community partners. Assessments occur at baseline, post-intervention (3 months), and follow-up (3 months). The overall flow of participants through the trial is depicted in Fig. 1 (CONSORT flow diagram).

Outcomes and other measurements

A sociodemographic and death-related questionnaire will assess: (a) social and demographic characteristics; (b) death-related characteristics (e.g., type of death, relationship with the deceased, previous care status); and (c) post-death impacts (e.g., living status, relationship status change). Engagement and completion of the intervention tasks will also be quantitatively assessed. All self-report measures will be administered via Qualtrics, with a researcher available to assist with the assessment.

The initial screening will be based on two instruments. First, the Relational Needs in Grief Scale (RNGS), developed by Coelho and colleagues [23]. It is a 11 item self-report measure based on Erskine's [28] Relational Needs Theory, assessing perceived relational support needs in grief across different components (e.g., security, validation, appreciation). The RNGS comprises two subscales: Need for Protection and Validation (9 items) and Need for Mutuality (3 items). Items are rated on a 5-point Likert scale (1 = "nothing" to 5 = "extremely"), yielding subscale and total scores; higher scores indicate stronger perceived relational needs in the context of grief. The RNGS showed a stable two-factor structure, excellent internal consistency ($\alpha \approx 0.81–0.94$; $\omega \approx 0.81–0.95$) and good convergent, discriminant, and incremental validity in a sample of 354 bereaved adults.

The Prolonged Grief Screening Tool (PGST) [22] is a brief 5-item self-report checklist developed to identify bereaved adults at elevated risk of developing Prolonged Grief Disorder. Items assess loss-related anger and guilt, perceived closeness to the deceased, concurrent stressful life events, and perceived ability to cope with the loss, rated on 5-point Likert scales and summed to yield a total score (5–25), with higher scores indicating greater risk. A preliminary validation study in a community sample supported its predictive validity for grief severity.

Primary outcome measures

The primary outcome will be grief symptoms, measured with the Prolonged Grief Disorder – 13 Revised (PG-13-R) [24]. The PG-13-R is a 13-item self-report questionnaire assessing DSM-5-TR prolonged grief disorder symptoms in bereaved adults. Ten items are rated on a 5-point Likert scale (1 = "not at all" to 5 = "overwhelmingly") to signal frequency/severity of grief symptoms. Three items assess the occurrence of a significant loss, time since the death, and associated functional

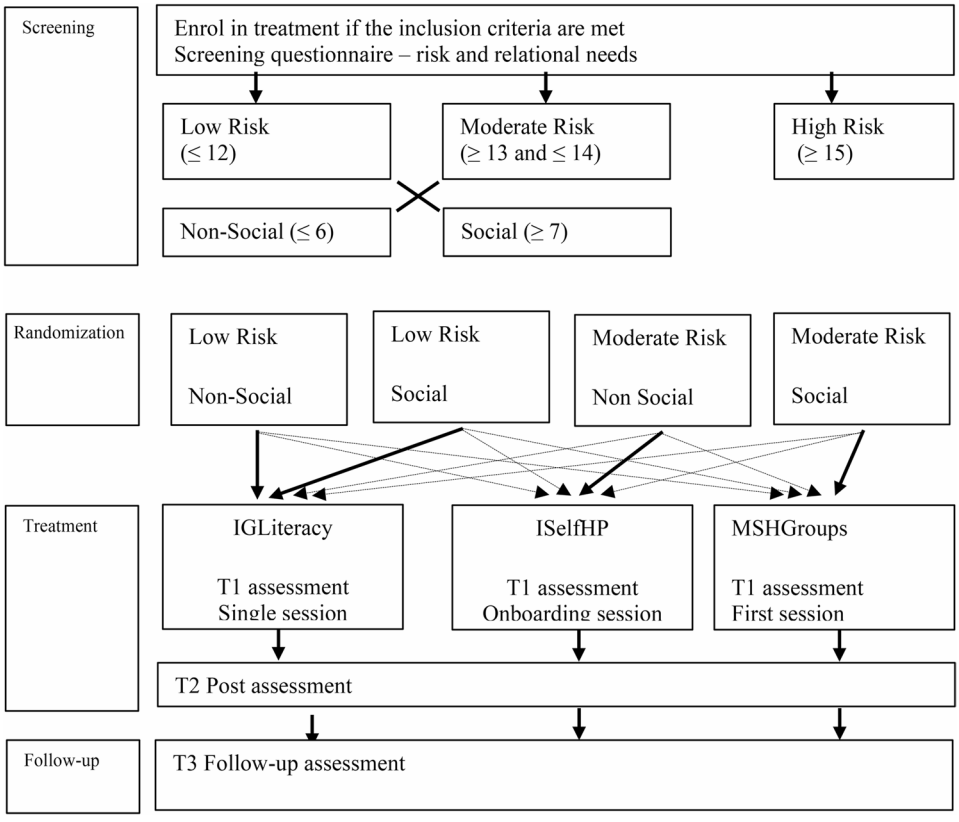

Fig. 1 CONSORT Flow Diagram — Matched Three-Intervention Trial (GriefDiff)

Table 1 Schedule of enrolment, interventions, and assessments

SPIRIT item	Enrolment and Allocation	T0 baseline / Initial session	Intervention period (0–3 mo)	T1 3 mo (post)	T2 6 mo (follow-up)
Eligibility screen	X				
Informed consent	X				
RNGS Mutuality Subscale, Prolonged Grief Screening Tool	X				
RandomisationAllocation disclosed	X				
Initial group meeting		X§			
Baseline assessments: (e.g., Sociodemographic, death-related, post-death impacts)		X			
Primary outcome — PG-13-R		X		X	X
Secondary outcomes - Anxiety & depression (DASS-21)		X		X	X
Posttraumatic stress (IES-R-6)		X		X	
Attachment (ECR-RS)		X		X	
Perceived social support (MSPSS)		X		X	
Engagement/Adherence: IGLiteracy — message engagement + brief survey			Prompts (0–3 mo)	X	
Engagement/Adherence: ISelfHP — website analytics (usage, module completion)			Usage analytics (0–3 mo)	X	
Engagement/Adherence: MSHGroups — attendance logs + post-session feedback			Weekly sessions (0–3 mo)	X	
Qualitative focus groups (sub-sample)					X
Access to intervention materials after 3 months (IGLiteracy/ISelfHP resources)				Access continues	Access continues

impairment, yielding a symptom severity score typically ranging from 10 to 50. The PG-13-R has shown a unidimensional structure, good internal consistency ($\alpha \approx 0.83–0.93$) and strong convergent, discriminant, and predictive validity across several international samples.

Secondary outcome

The secondary outcome considered will be depression and anxiety, measured by the Depression, Anxiety and Stress Scales – Short Form (DASS-21) [29]. The DASS-21 is a 21-item self-report questionnaire that assesses symptoms over the previous week. It comprises three 7-item subscales: Depression (low mood, anhedonia, hopelessness), Anxiety (physiological arousal, fear, panic) and Stress (tension, irritability, difficulty relaxing). Items are rated on a 4-point Likert scale (0–3), and subscale scores are summed (often doubled) to yield severity indices for each domain.

Predictors

Three variables (i.e., traumatic stress, attachment, and social support) will be measured to conduct explanatory analyses to inform future refinements of the matching procedure by exploring the moderating effect of the interventions' outcomes. The following three instruments will be used for this effect. The Impact of Event Scale IES-R-6 [30, 31] is a brief 6-item self-report measure of posttraumatic stress symptoms related to a specific event, covering intrusion, avoidance and hyperarousal. Items are rated on a 5-point Likert scale and summed to yield a total severity score. The Experiences in Close Relationships – Relationship Structures (ECR-RS) [32] is a 9-item self-report measure of adult attachment that assesses attachment-related anxiety and avoidance in emotionally close relationships. Nine items rated on a 7-point Likert scale are combined into two subscales - Avoidance (6 items) and Anxiety (3 items) - with higher scores reflecting more avoidant or anxious attachment. The Multidimensional Scale of Perceived Social Support (MSPSS) [29, 30] is a 12-item self-report questionnaire that assesses perceived adequacy of social support from three sources: Family, Friends, and a Significant Other. Items are rated on a 7-point Likert scale and averaged to yield subscale and total scores, with higher values indicating greater perceived support.

Instruments will be filled on the screening, T0, T1 and follow-up as described in Table 1.

Data management and dissemination

Data will be collected electronically (Qualtrics) and stored on a secure, access-controlled ISPA – Instituto Universitário server. Participants will be assigned unique study codes; the identification key will be stored separately and restricted to authorised personnel. Only authorised research staff will access password-protected datasets. Data quality will be ensured via predefined coding rules and routine completeness, range, and

consistency checks, with all cleaning decisions documented prior to analysis.

Data management responsibilities (including database setup, access control, audit trails/record keeping, routine data quality checks, and preparation of the analysis dataset) will be undertaken by the ISPA research team. Given the low-risk psychosocial nature of the interventions, no independent data monitoring committee is planned, and no interim efficacy analyses are scheduled. There will be no endpoint adjudication committee; outcomes will be assessed using standardised self-report measures and analysed according to a pre-specified analysis plan. Trial conduct (recruitment, adherence, data completeness, and safety signals) will be reviewed regularly by the study team, and the principal investigator may pause or stop the trial in consultation with the ethics committee if unexpected safety concerns arise.

Findings will be disseminated through peer-reviewed publications and presentations at scientific conferences. A plain-language summary will be shared with participants and community partners, and the trial registration record will be updated in line with registry requirements (including summary results, where applicable).

Statistical analysis

Analyses will follow the intention-to-treat principle. The primary endpoint is grief severity (PG-13-R), defined as the adjusted mean difference between arms averaged across post-treatment and 3-month follow-up. We will fit a linear mixed-effects model for repeated measures (MMRM) with baseline PG-13-R as a covariate. Fixed terms are Treatment (IGLiteracy, ISelfHP, MSHGroups), Time (post, 3-month follow-up), Treatment×Time, and the stratification factors Risk (Low/Moderate), Needs (High/Low relational needs), and Risk×Needs; a participant random intercept will model within-person correlation. If delivery in MSHGroups induces clustering, we will include a group-level random effect or use cluster-robust SEs. Results will be reported as least-squares mean differences with 95% CIs and standardised effects.

Family-wise error will be controlled by a fixed-sequence gatekeeping procedure: we first test MSHGroups vs. IGLiteracy at two-sided $\alpha = 0.05$; ISelfHP vs. IGLiteracy will be tested at $\alpha = 0.05$ only if the primary contrast is significant. ISelfHP vs. MSHGroups will be presented as exploratory. Secondary outcomes (i.e., DASS-21: depression and anxiety) will be analysed with the same MMRM structure, emphasising effect sizes and precision rather than formal multiplicity control.

Missing data will be handled under a MAR assumption by the MMRM; sensitivity analyses will include multiple imputation with auxiliary predictors and pattern-mixture/tipping-point checks for MNAR. We will assess model fit via residual diagnostics and compare covariance structures (e.g., unstructured vs. heterogeneous compound symmetry); if assumptions are doubtful, robust (sandwich) SEs will be reported. A per-protocol sensitivity analysis will exclude pre-specified major deviations.

To contextualise matching (exploratory), within the Moderate-risk stratum, we will add Needs and Treatment×Needs×Time and present subgroup contrasts aligned with the matching logic (MSHGroups vs. IGLiteracy in Moderate×Social; ISelfHP vs. IGLiteracy in Moderate×Non-social). We will also probe a pre-specified moderator set (attachment dimensions, perceived social support, traumatic-stress severity) via Treatment×Moderator×Time terms, summarising effects with CIs; any further subgroups (e.g., sex, age, SES, time-since-loss) will be clearly labelled hypothesis-generating.

Sample size and power calculation

The sample size targets the detection of a small between-group difference for the primary comparison (MSHGroups vs. IGLiteracy) while preserving strong control of the family-wise error rate when gatekeeping to ISelfHP vs. IGLiteracy. We plan three arms with equal allocation (1:1:1) within each randomised stratum. The primary endpoint is defined as the adjusted average treatment effect over the post-treatment period and the 3-month follow-up, adjusted for baseline.

Power calculation assumed a small effect (Cohen's $d = 0.30$) at two-sided $\alpha = 0.05$ and 80% power. Because the primary analysis adjusts for baseline and averages two post-baseline assessments, we used an effective standardised difference: assuming a baseline–follow-up correlation $r = .60$ and a post–3-month correlation $\rho = 0.50$, this yields $d\_eff \approx 0.43$ (ANCOVA $f \approx 0.216$). In G*Power (F tests → ANCOVA, fixed effects; 2 groups, 1 covariate), this requires ≈ 170 participants in total (≈ 85 per group) for the two-arm primary test. Allowing 20% attrition and 1:1:1 allocation across three arms, the randomised target is $N = 324$ (108 per arm; 27 per arm per stratum).

We will randomise $N = 324$ (108 per arm; 27 per arm per stratum), yielding ≈ 86–88 analysed per arm at 3 months. This meets the power target for the MSHGroups vs. IGLiteracy primary test; the gatekept ISelfHP vs. IGLiteracy comparison uses the same dataset at $\alpha = 0.05$. If attrition exceeds 20%, the target N will be increased proportionally. Potential clustering in MSHGroups will be handled analytically (random-group effects or cluster-robust SEs), so no a priori inflation is applied; a design-effect adjustment would be considered only if pilot data indicate a sizable ICC.

Focus Groups and qualitative analysis

Focus groups will be conducted with trial participants to (1) explore their experience of receiving the interventions in relation to perceived needs and (2) contrast

the perspectives of participants whose allocation was matched versus non-matched to their risk/needs profile. Participants who complete the post-intervention assessment and consent to contact further will be classified, using trial data, as matched or non-matched, and invited to separate focus groups by matching status (approximately 4–8 participants per group) and intervention type, seeking variation in age, gender, and risk level.

A semi-structured topic guide, common to all groups, will explore the perceived fit between the intervention's content and intensity and participants' relational needs; helpful and unhelpful elements; perceived usefulness and impact; unmet needs; barriers and facilitators to engagement; and suggestions for improving tiered grief care. Groups will be audio-recorded, transcribed verbatim, anonymised and analysed using reflexive thematic analysis, supported by MAXQDA. An initial coding frame will combine deductive codes (derived from research questions and existing literature on grief interventions and treatment fit) with inductive codes emerging from the data. Themes will first be developed across the full dataset and then examined comparatively between matched and non-matched groups, highlighting convergences and divergences in perceived fit, usefulness, unmet needs, and barriers. In this way, the qualitative findings will help explain quantitative results, illuminate potential mechanisms of change, and inform the refinement of differentiated grief care for older adults.

Ethical considerations

The study was approved by the Ethical Council of Ispa – Instituto Universitário (I-001-01-26). Several considerations were taken into account. To protect participant confidentiality, data will be collected anonymously from the onset. Each participant will generate a unique code to facilitate data pairing across study phases.

Prior evidence suggests that psychoeducation/grief literacy, guided self-help (including digital formats), and moderated group interventions may reduce grief-related distress and improve coping and support. Across these approaches, serious harms are not expected; the main potential risks relate to transient emotional distress when engaging with loss-related content, frustration or non-fit with self-guided formats, and discomfort or emotional activation in group settings. Accordingly, the trial includes procedures to identify and respond to clinically significant deterioration or emergent risk during participation.

A safety protocol is established to address worsening of symptoms or distress. This protocol includes systematic risk assessment and, when indicated, a supported referral to appropriate health or mental health services. Because we are working with a vulnerable population, several actions are planned: (A) participants assessed at higher risk are not allocated to the low-intensity treatment; (B) if a participant requests a more intensive intervention or a research assistant identifies a case of concern, they will be offered a step-up in intervention and monitored throughout participation; (C) if a participant wishes to withdraw or a clinician identifies the need for an alternative intervention, they will be offered a traditional intervention and will drop out of the study; (D) to avoid digital exclusion, non-digital/offline alternatives (e.g., written materials, recordings) will be provided to participants with lower digital literacy.

Any important protocol modifications will be submitted for approval to the ISPA – Instituto Universitário ethics committee and communicated to relevant parties, including updating the trial registry entry and reporting amendments in subsequent publications.

Discussion

GriefDiff was developed to help address a social challenge. Although most bereaved older adults adapt over time, a meaningful minority develop prolonged grief symptoms, and many never receive timely, appropriate support. At a community level, the goal is to organise grief-related interventions so that support is both accessible and proportionate to need. GriefDiff seeks to study a matched-care approach within a three-tier model: (i) information and grief literacy support, (ii) an individual self-help program, based on a digital intervention, and (iii) moderated self-help groups. These interventions are progressive and seek to respond to differentiated needs.

The trial is designed to examine whether aligning intervention intensity and format with participants' risk and relational-needs profiles improves grief outcomes and engagement. Furthermore, it seeks to constitute a community response that can be easily delivered through community partners. The study is conceptually aligned with matched care-care approaches in which treatment intensity is determined by clinical need. The potential of this approach lies in maximising efficiency and reach under real-world resource constraints.

Several challenges should be considered when interpreting findings. First, because participants cannot be blinded to the intervention they receive, expectancy effects are possible. However, concealment of matched versus non-matched allocation status is intended to reduce bias related to the matching hypothesis. Second, the absence of a non-intervention control condition may limit causal interpretation relative to natural recovery. However, it is justified on ethical grounds given the vulnerability of the target group and the community context. Third, engagement and attrition - particularly in the digital arm - may affect effectiveness estimates. To mitigate this, GriefDiff includes reminders, brief motivational

phone contacts, usage monitoring, and an offline alternative to reduce digital exclusion.

If effective, GriefDiff will offer a scalable model for proactive grief support for older adults, tailored to risk and relational needs and supported by a clinical protocol. It will further contribute to the discussion on matched care for grief, validating the proposed pyramid-like guidelines and refining screening procedures. By choosing a matched approach, it is possible to reach more individuals more sensitively.

Abbreviations

ANCOVA	Analysis of covariance
CI	Confidence interval
CONSORT	Consolidated Standards of Reporting Trials
DASS	21-Depression Anxiety Stress Scales-21
DSM	5-TR-Diagnostic and Statistical Manual of Mental Disorders, 5th edition, text revision
ECR	RS-Experiences in Close Relationships-Relationship Structures
ICC	Intraclass correlation coefficient
ICU	Intensive care unit
IES	R-6-Impact of Event Scale-Revised (6-item version)
MAR	Missing at random
MAXQDA	MAXQDA (qualitative data analysis software)
MMRM	Mixed model for repeated measures
MNAR	Missing not at random
MSPSS	Multidimensional Scale of Perceived Social Support
PG	13-R-Prolonged Grief Disorder-13 Revised
PGD	Prolonged grief disorder
QUAL	Qualitative
QUAN	Quantitative
PGST	Prolonged Grief Screening Tool
RCT	Randomised controlled trial
RNGS	Relational Needs in Grief Scale
SE	Standard error
SES	Socioeconomic status
SMS	Short message service
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
WHO	World Health Organization

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Authors' contributions
DDN conceived the study. DDN, AC, MB, and SA contributed to the study design. DDN drafted the manuscript. AC, MB, and SA critically revised the manuscript for conceptual and methodological content. All authors read and approved the final manuscript.

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The funder had no role in the study design and will have no role in data collection, analysis, interpretation, or manuscript preparation.

Data availability
No datasets were generated or analysed for this study protocol. Following study completion and publication of the primary outcomes, de-identified data will be made publicly available via Zenodo, together with a data dictionary and relevant metadata. Where necessary to minimise any residual risk of re-identification, access will be restricted and managed through a controlled-access request procedure, subject to ethical approval and applicable data protection regulations.

Declarations

Ethics approval and consent to participate
The study was approved by the Ethical Council of ISPA – Instituto Universitário (I-001-01-26). The study will be conducted in accordance with the Declaration of Helsinki and its later amendments, and in compliance with applicable Portuguese regulations and the General Data Protection Regulation (EU) 2016/679. Written informed consent will be obtained from all participants prior to enrolment.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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