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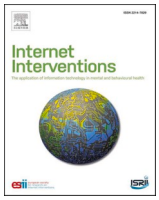

Loss and bereavement in late life (60+): Study protocol for a randomized controlled trial regarding an internet-based self-help intervention

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ABSTRACT

Background: The death of a close person is a highly stressful, yet common life event in later life. While most individuals seem to cope well with bereavement, a substantial proportion of older individuals suffer from prolonged grief symptoms. E-mental health interventions have been shown to be efficient for a variety of psychological illnesses. Yet, there is a large research gap of studies with a special focus on older adults. This study protocol describes a randomized controlled trial for an internet-based self-help intervention addressing bereavement and loss in adults aged 60 years and over. The self-management intervention is based on techniques of cognitive behavioral therapy and consists of 8 modules. The objective of the AgE-health study is to evaluate the effectiveness and acceptability of this intervention in comparison to a bibliotherapy control group.

Methods: The AgE-health study aims at implementing a randomized controlled trial. Eligible participants aged 60+ years will be randomly allocated to an intervention group (access to the intervention) or to an active control group (access to bibliotherapy). Primary outcome is the reduction in grief symptoms (13-item Prolonged Grief Inventory); secondary outcomes are depression, social activity and network, quality of life, self-efficacy, satisfaction with the intervention/bibliotherapy, loneliness, acceptability, up-take and adherence. Assessments will take place before the intervention (baseline) as well as 4 months (follow-up 1) after the intervention.

Discussion: This study addresses an under-recognized and understudied mental health burden in later life and may add valuable insight into our knowledge about the effectiveness of eHealth interventions for loss and bereavement in late life. To our knowledge, the AgE-health study will be the first randomized controlled trial to evaluate the effectiveness of an internet-based intervention targeting prolonged grief in adults aged 60 years and over.

Trial registration: The study has been registered at the German Clinical Trials Register (Identifier: DRKS00020595, Registered 30th July 2020, https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00020595).

1. Introduction

Loss experiences such as the death of a significant person like a spouse, a relative or a close friend are highly stressful, but very common life events in later life (Förster et al., 2018; Stein et al., 2019; Williams et al., 2007). The death of a close relative has been found to have major impact on well-being, health and role functioning (Shear et al., 2013) and has been associated with increased risk for mortality (Shear et al., 2013; Mostofsky et al., 2012; Shah et al., 2012; Shah et al., 2013), as well as for developing physical (e.g. headaches, hypertension, sleep impairment etc.) (Stroebe et al., 2007) and mental health problems, as for instance depressive symptoms, anxiety, or posttraumatic stress

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disorder (Boelen and van den Bout, 2005; Keyes et al., 2014; Sikorski et al., 2014). Loss experiences are frequently accompanied by the loss of social and emotional bonds, a disruption of daily routines and necessitate a change in the individual's perspective of the future (Brodbeck et al., 2017). While most individuals seem to cope well with bereavement, approximately 10 to 20% develop a prolonged grief disorder (PGD) (Kersting et al., 2011; Shear et al., 2011). Prolonged grief disorder is characterized by continued existence of cognitive, emotional and behavioral symptoms, including intense longing and persistent yearning for the deceased, intrusive thoughts, emotional pain or numbness, feelings of anger, and bitterness or guilt related to the loss (Shear et al., 2013; Jordan and Litz, 2014; Prigerson et al., 2009). Suffering from prolonged grief disorder has been shown to predict symptoms of posttraumatic stress disorder (Djelantik et al., 2018) and has been associated with increased levels of depression (Ott et al., 2007). This may be particularly problematic in older adulthood, as prolonged grief may facilitate the development of late-life depression; a disorder that is often unrecognized, untreated or undertreated (Morichi et al., 2015; Sanglier et al., 2015; Stein et al., 2016; van Damme et al., 2018).

New, innovative and efficient ways in the field of prevention, treatment and aftercare of mental health problems include internet-based self-help interventions built on elements of cognitive behavioral therapy. Internet-based interventions provide a convenient way of educational training and counselling and come with the advantage of low threshold support. Several authors have highlighted the benefits of internet-based interventions, e.g. flexibility and anonymity, a faster attainability, as well as the ability to overcome barriers in help seeking (e.g. stigma, limited mobility and/or physical disability), which may be specifically relevant for older adults (Brodbeck et al., 2017; Musiat and Tarrier, 2014; Rochlen et al., 2004; Schroeder et al., 2016). There is evidence of a rapid increase of internet users among older adults, both international (Hart et al., 2008; Wagner et al., 2010; Edwards et al., 2015) and in Germany (Frees and Koch, n.d.). Recently, the percentage of people aged 65 years or older using the internet is estimated at about 63% for Germany (Statistisches Bundesamt, 2018), with the highest increase in daily internet use among this age group (Frees and Koch, n.d.).

With regard to the acceptability of internet-based interventions in later life, previous research has emphasized a positive attitude of older adults being open to consider the usage of internet-based interventions in case of mental health problems (Crabb et al., 2012; Dorow et al., 2018).

So far, numerous studies have demonstrated the effectiveness of internet-based interventions for a wide range of mental illnesses including eHealth as treatment support for anxiety disorders, depression, posttraumatic stress disorder and obsessive-compulsive disorder (Andersson et al., 2014; Arnberg et al., 2014; Richards and Richardson, 2012; Stein et al., 2018). In addition, it has been shown that internet-delivered cognitive behavior therapy (iCBT) interventions may significantly reduce symptoms of anxiety and depression in older adults (Jones et al., 2016; Spek et al., 2007; Titov et al., 2015; Titov et al., 2016). Similarly, internet-based interventions have been shown to mitigate possible negative health-related implications associated with bereavement and loss (Litz et al., 2014). So far, few studies have examined the efficacy of internet-based interventions focusing on prolonged grief disorder and found significant reductions of depression, grief, anxiety and posttraumatic stress (Dominick et al., 2009; Eisma et al., 2015; Kersting et al., 2013; van der Houwen et al., 2010; Wagner and Maercker, 2007). While those studies point to a potentially promising road for effective mental health care, there appears to be a lack of internet-based interventions specifically aimed to improve mental health in later life. Previous research on internet-based interventions for grief and loss experiences has either focused on specific kinds of loss experiences (e.g. child loss during pregnancy, marital bereavement or separation, loss of a first-degree relative) (Dominick et al., 2009; Eisma et al., 2015; Kersting et al., 2013; van der Houwen et al., 2010; Hoffmann et al., 2018) or consisted of samples of young to middle-aged individuals (Litz et al., 2014; Wagner and Maercker, 2007). In late life, however, various kinds of loss experiences may significantly impact mental and physical health of older adults due to diminished social networks, less social support and a higher probability for chronic diseases (Förster et al., 2018; Stein et al., 2019; Williams et al., 2007). At the same time, this age group appears to be underserved with regard to mental health care and unrecognized among innovative research on internet-based interventions.

Aside from a few studies and projects (Brodbeck et al., 2017; Litz et al., 2014; Preschl et al., 2011) randomized controlled trials for internet-based interventions including aging citizens are still lacking. To our knowledge, no internet-based intervention specifically focusing on loss and bereavement in older adults (60+ years) has been evaluated in Germany to date.

1.1. Objectives

The objective of the AgE-health study is to evaluate the effectiveness of the internet-based self-management intervention “trauer@ktiv” focusing on older adults (60+ years) with loss experience. The eHealth intervention has been developed under participation of the target group and aims at reducing symptoms associated with prolonged grief. Therefore, the present study closes a research gap and if proven effective may further close a supply gap for mental health in later life.

2. Methods

2.1. Study design

The AgE-health-study will implement a randomized controlled trial using a parallel arm design with allocation of adults aged 60+ years to either a control group (CG) receiving bibliotherapy or an intervention group (IG) with access to the internet-based self-management intervention “trauer@ktiv”. After screening for eligibility, data will be collected from participants at baseline (BL) and after 4 months (FU1). A detailed description of the study procedure is described below.

2.2. Recruitment practices

Participants will be recruited through cooperating health care providers, grief support groups, newspaper advertisements, advertisements on grief websites, internet forums and advertisements in public places (e.g. in public transportation, flyer in hospitals). The Institute of Social Medicine, Occupational Health and Public Health (ISAP) of the University of Leipzig has established a network that consists of cooperating general practitioners (GP), psychiatrists and psychotherapists. Medical and mental health care practitioners of the ISAP network will be contacted and invited to hand out information flyers to suitable patients or recruit eligible patients. Additionally, information about the study will be published on suitable websites, internet forums and using social media. Further, local self-help networks for older people will be contacted and introduced to the AgE-health-study either through telephone contacts, personal presentation or information flyer. Apart from that, advertisements in the local media and in appropriate public places will be used to recruit participants.

2.2.1. Informed consent

Interested participants will be contacted, will receive a detailed information sheet on the study and will be asked to sign a consent form. Participants will be informed about the requirement to include contact information on their general practitioner, who could be informed in case of an emergency. The research team will be available to answer questions at any time during the study.

2.2.2. Screening assessment

Individuals applying for study participation and who gave informed consent will be screened with regard to prolonged grief symptoms using the Brief Grief Questionnaire (BGQ) (Shear et al., 2006). Individuals will further be screened according to predefined inclusion and exclusion criteria. Screening will be administered using a short screening questionnaire sent by postal mail or delivered through participating GPs. Individuals who meet eligibility criteria will be enrolled as study participants and randomized to either IG or CG.

2.2.3. Baseline assessment

Baseline assessments will be conducted using written questionnaires sent to participants before the intervention (BL).

2.2.4. Access to intervention

After completion of baseline assessments participants of the IG will be sent a personal login to the internet-based self-management program in a sealed envelope. Participants of the CG will receive a detailed bibliotherapy.

2.2.5. Follow-up assessment

Follow-up assessments (FU) will be scheduled four months after the baseline assessment. Data will be collected using postal questionnaires. An overview of the recruitment and study timeline is shown in Fig. 1.

2.3. Inclusion and exclusion criteria

Participants will be included based on the following inclusion criteria: (a) experience of the death of a close person, (b) a time period of six months or longer since loss, (c) feelings of grief (a score of 2 or more on the BGQ (Shear et al., 2006)), (d) age 60+ years, (e) Internet access, and (f) sufficient proficiency in the German language. Participants will be excluded if (a) they suffer from suicidal tendencies, (b) they have no contact person (GP, medical specialist) in case of a crisis situation, (c) they are currently in psychotherapy, (d) they currently have an unstable psychopharmacological treatment with changes within the last six weeks, (e) they have had medical treatment due to a severe mental disorder not related to bereavement within the last year.

Individuals not eligible for study participation according to the inclusion and exclusion criteria will receive general information on grief symptoms, treatment options, emergency hotlines and information on professional help.

2.4. Randomization and blinding

Eligible persons who consented to participate will be randomly assigned to either IG or CG. A block-randomization algorithm with a targeted assignment ratio of 1:1 for participants in IG or CG will be used, stratified by sex and grief severity. This ensures balance between study arms in both sample size and basic demographic variables and bereavement severity. Stratified randomization will be achieved by

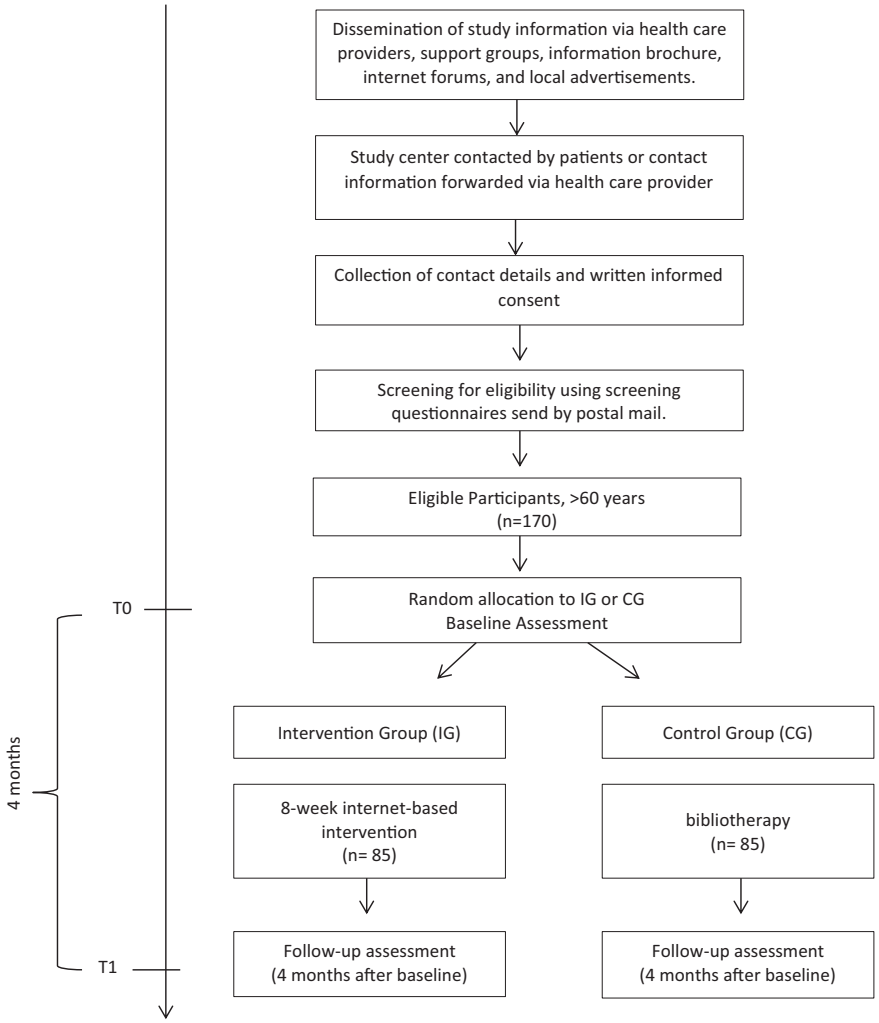

Fig. 1. Overview of the recruitment and study timeline.

using a separate randomization procedure within each of the strata. Randomization will be done by an external, independent statistician, generating randomization block lists with respective statistics software (e.g., R or Stata). The randomization lists (one for each stratum) will be concealed to the study coordinator and recruiting staff members with regard to the lists' strata identity.

Cooperating medical and mental health care providers, who recruit eligible participants, will remain blind to the group allocation. Participants of both IG and CG will not be blinded to the intervention they receive, because blinding is per se not possible when conducting an eHealth intervention. However, the statistician analyzing the data and staff members evaluating the results will remain blind to the group allocation.

2.5. Intervention

Intervention: Trauer@ktiv is an internet-based self-management intervention focusing on loss and bereavement in older adults (60+ years). The intervention is based on established cognitive and behavioral therapy techniques (Rosner et al., 2015) and has been developed by mental health professionals (e.g. psychologists, psychotherapists, psychiatrists) at the University of Leipzig and under participation of older adults with previous loss experiences. Trauer@ktiv is a fully unguided intervention. According to a regulatory feedback model (Rosner et al., 2015; Rosner et al., 2011), prolonged grief symptoms emerge as a result of continuing negative reinforcement of the initial grief symptoms due to dysfunctional coping processes of severe avoidance or intense occupation with the deceased or the death. While such coping mechanisms may result in short term symptom reductions, impairments in emotional and functional abilities follow in long term as everyday situations can trigger memories of the deceased or the circumstances of the death. The intervention consists of eight knowledge sections combined with practical exercises. An overview of the intervention modules is provided in Table 1. In addition, the intervention includes information on grief rituals, how to cope with anniversaries, support for relatives of the bereaved, and spirituality in the context of loss and bereavement. Furthermore, the intervention provides information and support in case of emergency. The development of the intervention took age-specific technical features into account, such as enlarging the text (“zoom function”) and a “read-aloud function” (audios of the texts). Additionally, the intervention takes age-specific contents into account by implementing illustrations of three example characters (aged 60+). These example persons present development tasks of older ages with regard to grief and loss.

Intervention group (IG): Participants allocated to the IG will get access to the intervention after the baseline assessment took place. Participants will be asked to complete the eight modules sequentially within eight weeks (one program module per week); however, participants are generally free to use the program in a flexible manner according to their needs.

Control group (CG): Participants of the CG will get bibliotherapy. The bibliotherapy consists of an information brochure and was specifically developed for participants of the control group by mental health professionals. The brochure comprises 15 pages and eight chapters providing general information on grief, prolonged grief symptoms and coping strategies. In comparison to the intervention trauer@ktiv the information brochure is non-interactive (e.g. does not include exercises or the possibility to track one's mood), and provides relevant information on grief in an abbreviated version. An overview of the contents of the bibliotherapy is provided in Table 2. Participants will receive the bibliotherapy after baseline assessment by postal mail.

Table 1
Content overview of the intervention “trauer@ktiv”.

Module	Content
Farewell and grief	Information on grief and prolonged grief; Preparation of a personal emergency kit.
Room for memories	Describing the personal grief situation and exploring changes with regard to roles and tasks after the loss.
Thinking and feeling	Information on the link between thoughts, emotions and behavior; coping strategies for dealing with rumination; differentiating functional and dysfunctional thinking patterns.
Developing helpful thoughts	Developing helpful thoughts and coping strategies with regard to burdensome feelings of grief (longing, guilt, anger).
Daily help	Information on coping strategies to improve self-care (e.g. relaxation techniques, coping with sleeping problems, activity management, making contacts).
Grief and avoidance	Information on avoidance and strategies for dealing with avoidance in the context of grief.
Reshaping the relationship	Redesigning the relationship with the deceased person.
Farewell and future	Summarizing the module contents and the personal progress, saying goodbye and setting goals for the future.
Additional information	- Information and support for anniversaries - Grief rituals - Information for relatives - Information on belief and spirituality in the context of grief

2.6. Outcomes and measures

Enrolled participants will be assessed at baseline and at 4 months follow-up (FU) by questionnaires sent per postal mail. An overview of all screening variables, outcomes and other measures that will be implemented is shown in Table 3.

2.6.1. Screening measures

Besides the assessment of inclusion and exclusion criteria, as well as socio-demographic variables, screening measures will include the assessment of suicidal tendencies and ongoing grief symptoms. Suicidal tendencies will be assessed using the suicide item of the Beck Depression Inventory (BDI-II, score > 1) (Hautzinger et al., 2006; Beck et al., 1996). Grief symptoms will be screened with the Brief Grief Questionnaire (BGQ) (Shear et al., 2006). The BGQ consists of 5 Items scored on a 3-point Likert scale ranging from 0 (=not at all) to 2 (=a lot). Individuals with a score ≥ 2 on the BGQ will be eligible for study participation.

2.6.2. Primary outcome

In line with previous studies in this field the reduction of prolonged grief symptoms will be the primary outcome (Litz et al., 2014; He et al., 2014), which is assessed by using the 13-item Prolonged Grief Inventory (PG-13) (Prigerson et al., 2009; Pfoh and Rosner, 2015). The PG-13 is a self-report questionnaire including 11 items assessing specific symptoms associated with grief (e.g. yearning, intense feelings of emotional pain or

Table 2
Content overview of the bibliotherapy.

Chapter	Content
Grief and bereavement	Information on grief, individual pathways of grief and grief rituals.
When grief remains	Information on prolonged grief and associated symptoms.
Taking care of yourself	General information on coping strategies to improve self-care (e.g. coping with sleeping problems, activity management).
Maintaining social contacts	Information on the importance of maintaining social contacts.
Find relaxation	General information on relaxation and relaxation techniques.
Handling anniversaries	Information and support for anniversaries.
Information for relatives	Information for relatives of people suffering from prolonged grief.
Finding help	Information on further support options (e.g. counselling services, psychotherapy)

Table 3
Overview of collected data.

Measures	Psychometric validation	Screening	Baseline	Follow-up
		T-1	T0	T1
Primary outcome				
Prolonged Grief (PG-13[a])	Cronbach's alpha: r = 0.94, test-retest-reliability: r = 0.80, convergent validity: r = 0.80 (Prigerson et al., 2008)		x	x
Secondary outcomes				
Grief symptoms (WÜTI[b])	Cronbach's alpha: r = 0.67 to r = 0.93 for 5 subscales (Wittkowski, 2013)		x	x
Depression (BDI-II[c])	Cronbach's alpha: r = 0.90, retest-reliability: r = 0.78 (Hautzinger et al., 2006)		x	x
Social activity (SASS[d])	Cronbach's alpha: r = 0.89, criterion validity: correlation with Self Rating Depression Scale: r = 0.70 (Duschek et al., 2003; Bosc et al., 1997)		x	x
Social network (LSNS-6[e])	Cronbach's alpha: r = 0.83 (Lubben et al., 2006)		x	x
Quality of life (SF-12[f])	Cronbach's alpha: r = 0.89 (Wirtz et al., 2018)		x	x
Loneliness (DJGLS[g])	Cronbach's alpha: r = 0.76 (Gierveld and van Tilburg, 2006)		x	x
Self-efficacy (6 item Hope and self-efficacy subscale from the EPAS[h])	Cronbach's alpha: r = 0.94 (Kilian et al., 2012)		x	x
Satisfaction with intervention/ bibliotherapy				x
Acceptability (SUS[i], IG only)	Cronbach's alpha: r = 0.911 (Bangor et al., 2008)			x
Uptake and adherence with intervention/ bibliotherapy				x
Other measures				
Sociodemographics				
Sex		x	x	x
Age		x	x	x
Marital status			x	x
Living status			x	x
Education			x	x
Height			x	x
Weight			x	x
Religious belief			x	x
Loss-related information				
Type of loss			x	
Time since loss		x	x	
Utilization of health care				
Utilization of health care		x	x	x
Use of antidepressant drugs		x	x	x
Internet-specific information				
Access to Internet		x	x	
Familiarity with Internet use			x	
Familiarity with eHealth			x	
Suicidal tendencies				
Suicide item of the BDI-II[c]		x	x	x
Grief (BGQ[j])	Cronbach's alpha: r = 0.82 (Shear et al., 2006)	x		
Personality (BFI-10[k])	Correlations with corresponding dimensions on the NEO-PI-R r = 0.40 to r = 0.57, retest-reliability: r = 0.58 to r = 0.84 for 5 subscales (Rammstedt and John, 2007)		x	

IG Intervention Group.
[a] *PG-13* Prolonged Grief-13 (Prigerson et al., 2009; Pfoh and Rosner, 2015).
[b] *WÜTI* Würzburger Trauerinventar (Wittkowski, 2013).
[c] *BDI-II* Beck Depression Inventory (Hautzinger et al., 2006; Beck et al., 1996).
[d] *SASS* Social Adaptation Self-evaluation Scale (Duschek et al., 2003; Bosc et al., 1997).
[e] *LSNS-6* abbreviated version of the Lubben Social Network scale (Lubben et al., 2006).
[f] *SF-12* Short-Form Health Survey (Ware et al., 1996).
[g] *DJGLS* De Jong Gierveld Loneliness Scale (de Jong-Gierveld and Kamphuls, 1985; van Tillburg and Jong Gierveld, 1999; Gierveld and van Tilburg, 2006).
[h] *EPAS* Empowerment im Prozess der psychiatrischen Behandlung von Patienten mit Affektiven und Schizophrenen Störungen (Kilian et al., 2012).
[i] *SUS* System Usability Scale (Brooke, 1996).
[j] *BGQ* Brief Grief Questionnaire (Shear et al., 2006).
[k] *BFI-10* Big-Five-Inventory short form (Rammstedt and John, 2007).

sorrow with regard to the loss, having trouble accepting the death) scored on a 5-point Likert scale ranging from 1 (=never) to 5 (=always or several times daily). Two further items assess the presence of social or occupational dysfunction and a duration criterion (>6 months present) for the two most specific grief symptoms (yearning, intense feelings of emotional pain or sorrow). A sum score of the PG-13 will be calculated by summing up the scores of items 1, 2, and 4 to 12 (Vogel et al., 2016). Symptom scores can range from 11 to 55. In addition, the PG-13 allows identifying clinical levels of prolonged grief according to the diagnostic criteria established by Prigerson et al. (2009).

2.6.3. Secondary outcomes

Severity of grief symptoms will be assessed using the Würzburger Trauerinventar (Wüti) which includes 24 items scored on a 4-point Likert scale from 1 (=not true) to 4 (=very true) (Wittkowski, 2013). The Wüti covers symptoms of grief on the five subscales impairment, growth, feelings of guilt, empathy, and closeness to the deceased person. Depression will be assessed with the Beck Depression Inventory (BDI-II) (Hautzinger et al., 2006; Beck et al., 1996). The BDI-II consists of 21 Items and can be used to assess the severity of symptoms of depression. Higher scores indicate more severe perceived depressive symptoms. The degree of social integration will be assessed using the German version of the Social Adaptation Self-evaluation Scale (SASS) (Duschek et al., 2003; Bosc et al., 1997). This instrument covers 20 items assessing the degree of social activity. Higher scores on the total sum score of the SASS indicate a higher degree of social integration. Information on the extent of the social network will be assessed using the short version of the Lubben Social Network Scale (LSNS-6) (Lubben et al., 2006). The LSNS-

6 comprises 6 Items scored on a scale of 0 to 30. A cut-off-score < 12 indicates a risk for social isolation (Lubben et al., 2006). Health-related quality of life will be evaluated using the Short-Form Health Survey (SF-12) (Ware et al., 1996). The SF-12 is a short version of the SF-36 (Ware et al., 1993), and assesses quality of life on the eight dimensions physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health with 12 items. Furthermore, loneliness will be assessed with the De Jong Gierveld loneliness scale (DJGLS) (de Jong-Gierveld and Kamphuls, 1985; van Tillburg and Jong Gierveld, 1999; Gierveld and van Tilburg, 2006). The scale comprises 6 items on a 5-point Likert scale from 1 (=none of the time) to 5 (=all of the time). The scale assesses both emotional loneliness and social loneliness. A total loneliness score can be calculated and categorized into four loneliness categories (not lonely, moderate lonely, severe lonely, very severe lonely). Self-efficacy will be assessed using the 6-item Hope and Self-efficacy subscale from the questionnaire for the assessment of empowerment in patients with affective and schizophrenic disorders (EPAS) (Kilian et al., 2012). Participants will further be asked about their satisfaction with the intervention, or bibliotherapy respectively. Acceptability of the intervention will be assessed using the 10-item System Usability Scale (SUS) (Brooke, 1996). Higher scores indicate a higher perceived acceptability. In addition uptake and adherence of the intervention will be investigated via pseudonymised login-data of the intervention program.

2.6.4. Other measures and covariates

In addition to demographic characteristics (sex, age, marital status, living status, education, height, weight), other measures will include information on religious belief, loss-related characteristics (type of loss, time since loss), the utilization of health care (utilization of health care, use of antidepressant drugs), access to the internet, familiarity with the internet use and eHealth programs, as well as suicidal tendencies using the suicide item of the BDI-II (score > 1) (Hautzinger et al., 2006; Beck et al., 1996). Personality traits will be assessed with the 10-item Big Five Inventory (BFI-10) (Rammstedt and John, 2007). The BFI-10 is a short version of the original BFI-44 and assesses each of the five personality dimensions on two items scored on a 5-point Likert scale ranging from 1 (=disagree strongly) to 5 (=agree strongly).

2.7. Sample size

Sample size calculations are based on the primary outcome measure PG13 (Prigerson et al., 2009; Pfoh and Rosner, 2015). Based on previous studies reporting large effect sizes in grief reduction when comparing grief interventions to wait-list conditions (Litz et al., 2014; Brodbeck et al., 2019) and still moderate improvements of grief specific interventions over other support control groups (Eisma et al., 2015; Boelen et al., 2007) we assumed a moderate effect size of Cohen's d = 0.5 as a feasible between-group effect. To detect a moderate between-group effect at 4 months (Cohen's d = 0.5), considering a significance level of $\alpha = 0.05$ (two-sided) and a statistical power of $1 - \beta = 0.80$, a target sample of $n = 128$ participants ($n = 64$ per group) is estimated. Anticipating a drop-out rate of 25%, based on experiences with previous clinical research projects, the total sample size would have to comprise $n = 170$ individuals.

2.8. Data collection and data management

Data will be collected through standardized questionnaires sent by postal mail at all assessment points. To ensure high follow-up rates, prepaid return envelopes will be provided as well as monetary incentives. For each included participant, GPs will be receiving an expense allowance of €50. Participants will be compensated with €30 for their study participation. Further, gentle reminders will be sent up to three times in case of missing returns. Meta-data on uptake, adherence and program feedback for the Internet-based intervention will be collected through log-files that store pseudonymised information.

Collected data will be entered in a database using a statistical package and stored locally and password protected. To ensure completeness and accuracy of data entry, a double entry check will be performed. Each participant will receive a pseudonym. This allows entering and analyzing the collected data in a strictly pseudonymous form. Further, to ensure data protection with regard to the usage of the Internet-based intervention and the transfer of meta-data anonymous log-files will be secured through SSL-technology.

2.9. Data analysis

All data will be examined with regard to potential inconsistencies and missing values. Missing information in variables at baseline will be inspected and addressed by using multiple imputation methods (van Buuren, 2012), if appropriate. In order to check for systematic differences between completers and non-completers we will perform a dropout analysis.

Analyses on primary and secondary outcomes will be performed as intention-to-treat. Changes in outcomes will be described using mean scores and standard deviations. Treatment effects on primary and secondary outcomes at FU will be tested using linear mixed effects models using relevant covariates and baseline outcome measures. Acceptability, uptake and adherence with regard to the intervention will be evaluated using descriptive statistics from pseudonymised computer log-files. For all analyses the level of statistical significance will be set to $p < .05$. The results of the study will be reported according to the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) statement (Schulz et al., 2010).

2.10. Monitoring

2.10.1. Data monitoring

The current study will implement an independent external data monitoring committee (DMC). The DMC will monitor the study by periodic inspections including the establishment of periodic protocols during the course of the trial to ensure the study is performed in accordance with the Guidelines for Good Clinical Practice (ICH-GCP) and the Declaration of Helsinki. In case of severe or urgent adverse events the DMC will be contacted immediately. The DMC will be responsible for monitoring the study progress, protocol adherence, and study safety. Recommendations by the DMC regarding the need to modify or discontinue the trial will be provided to the principal investigator.

2.10.2. Harms

The risk for the occurrence of adverse events through study participation is estimated to be minimal. However, for safety concerns, the study will only enroll participants who can provide a medical health care professional in case of a crisis situation. Further, individuals with acute suicidal ideation will be excluded from study participation. Additionally, a standardized protocol on handling the contact with participants with suicidal ideation will be implemented for all staff members entrusted with recruitment or participant assessments.

The occurrence of adverse events (AE, e.g. increase in frequency or intensity of symptoms) and severe adverse events (SAE, e.g. suicidality, severe depressive symptoms, hospitalization) will be monitored and documented at each assessment. In case of any [AEs and] SAEs the principal investigator and the DMC will be immediately informed through a standardized case-report form. Subsequently a shared decision will be made between the study center and the DMC with regard to appropriate actions in response to the negative events. Attending GPs will be contacted in case of an emergency. Participants will be informed about the requirement to include contact information of their GP. Documented AEs and SAEs will be analyzed and reported in terms of study outcomes.

Information on emergency hotlines and professional help will be made available to participants of both groups (IG and CG). Participants of the IG will have access to information about emergencies through the online emergency kit embedded in the intervention. Participants of the CG will be provided with the same information on emergency help as part of the reading material that will be sent to them after the baseline assessment.

2.10.3. Auditing

Data auditing will be administered in form of reviews of the data collection across BL and FU. Auditing will be performed by a commissioned, external statistician independently from investigators and staff members entrusted with the AgE-health-study. Auditing will comprise the inspection of 5% of the questionnaires at each assessment wave. Questionnaires will be randomly drawn and checked with respect to their degree of matching with database input.

2.11. Dissemination

The AgE-health study will provide results and materials that will be disseminated nationally and internationally. First, study results will be published in peer-reviewed journals and presented at relevant national and international conferences. Second, the Internet-based self-management intervention will be made accessible for anonymous use after its successful evaluation. To disseminate the intervention among the target group of older adults with prolonged grief national and local health care providers will be approached. Additionally, the intervention will be promoted among relevant media targeting adults aged 60+ years.

2.12. Ethical considerations

The AgE-health study will be performed according to the Guidelines for Good Clinical Practice (ICH-GCP), the Declaration of Helsinki and international and local laws. The ethics committee of the University of Leipzig has approved the AgE-health study (ID: 052/20-ek). Informed consent will be obtained from all participants ahead of study participation.

3. Discussion

The present study protocol describes the aim of the AgE-health study to test and evaluate an eHealth intervention focusing on loss and bereavement in adults aged 60+ years. The interactive self-management intervention was developed based on cognitive and behavioral therapy techniques (Rosner et al., 2015) and has been developed under participation of older adults with previous loss experiences. The intervention takes age-specific contents into account by implementing three "example characters" (aged 60+). These examples include development tasks of older ages as well as possible physical impairments. Additionally, age-specific aspects of the intervention have been taken into account through technical features (e.g. the possibility to enlarge the text, a read-aloud function).

We assume that the usage of "trauer@ktiv" will reduce symptoms of prolonged grief and associated mental health problems (e.g. depressive symptoms, social isolation) to a greater extent compared to the bibliotherapy handed to the participants of the CG. The intervention further aims to prevent the development of late-life depression in the course of loss experiences.

In advanced age there may be an increasing vulnerability with regard to mental health problems due to diminished social networks, less social support, a higher probability for chronic diseases and immobility as well as negative life events, such as bereavement and loss experiences (Förster et al., 2018; Stein et al., 2019; Williams et al., 2007). Previous studies have shown the various negative effects bereavement can have on the physical and mental health of older adults (e.g. depressive symptoms, anxiety) (Stroebe et al., 2007; Boelen and van den Bout, 2005; Keyes et al., 2014; Sikorski et al., 2014). While mental health problems create a serious burden in later life, they appear to be under-recognized and undertreated in older adults within the current health care system (Morichi et al., 2015; Sanglier et al., 2015; Stein et al., 2016; van Damme et al., 2018).

However, there seems to be an increasing openness and acceptance of older people regarding the use of mental health support as well as the use of new technologies as a medium for health support (Crabb et al., 2012; Dorow et al., 2018). In a preliminary qualitative study to the AgE-health study two focus groups ((a) $N = 12$ older people with loss experiences, (b) $N = 8$ experts of the medical care system) were implemented to assess acceptability towards a web-based intervention regarding loss experience among older people, possible access paths as well as barriers for the implementation of such an intervention (Schladitz et al., 2020). Results of the patient focus group show that the majority of individuals aged 60+ years use the Internet on a regular basis. Furthermore, a web-based self-management intervention was perceived as a possible alternative besides the support through family and self-help groups for coping with prolonged grief. According to older adults with previous loss experience an Internet-based intervention should include ideas for improving self-respect and activities in everyday life as well as information for relatives, information on beliefs and spirituality and coping strategies for negative emotions. Experts of the medical care system supported the idea of a web-based intervention focusing on bereavement and loss in older individuals (Schladitz et al., 2020).

With regard to eHealth interventions there is a fast growing market of various health care apps and self-management programs. However, the vast majority of such eHealth interventions has not been adequately validated.

3.1. Strengths

To our knowledge, the AgE-health study is the first RCT-study to evaluate the effectiveness of an Internet-based intervention targeting prolonged grief in adults aged 60 years and over. Therefore, the AgE-health study may add valuable insight into our knowledge about the effectiveness of interventions for loss and bereavement in advanced age. The strength of this study is its specific focus on older adults as they seem to be under-recognized with regard to customized treatment of mental health problems and eHealth interventions. A further strength of this study is its method of randomization. Using a block-randomization will ensure balanced sample sizes across both groups (IG, CG) and avoid imbalance between the two groups with regard to covariates.

4. Conclusion

The AgE-health study addresses an under-recognized and under-studied mental health burden in later life. By integrating evidence-based cognitive and behavioral therapy techniques, age-specific features and development tasks as well as the possibility for a flexible usage, the intervention is expected to improve life quality and mental health of older adults with prolonged grief symptoms. The results of this study may further enhance our knowledge with regard to the effectiveness of Internet-based self-management interventions for prolonged grief in late life. If proven to be effective, the intervention will be made available to the general public and disseminated Germany-wide.

Declarations

Consent for publication

Not applicable.

Availability of data and material

After publication of the final AgE-health trial results, electronic

research data will be made accessible to interested researchers upon reasonable request after signing a non-disclosure agreement.

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CRediT authorship contribution statement

JS conceptualized and designed the study and was supported by MLö, ML, AP, FW and SRH. This included the research questions, the selection of assessments, sampling and randomization procedures. JS attained the project funding and is principal investigator of the project. MLö, ML, FW, JQ, were involved in the development of the intervention trauer@ktiv. MLö, FW, and SRH will monitor the implementation of the study as well as data collection and management. AP will provide methodological and statistical expertise. FW, Mlö, AP, JQ and SRH drafted and revised the manuscript. All authors contributed to the manuscript and have revised it critically for intellectual content. All authors have read and approved of the final version of the manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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