optimizing the mentaL health and resiliencE of older Adults that haVe lost thEir spouSe via blended, online therapy

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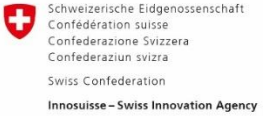

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Disclaimer

Abstract

This study aims to evaluate the clinical efficacy of LEAVES, an interactive self-help program, based on a conversational agent, to support the grief process of older adults who lost a spouse. Primary outcome of the clinical evaluation is grief symptomatology and secondary outcomes are depression and loneliness. Furthermore, this study will compare a standardised condition (modules are presented in a fixed order) with a self-tailored condition (user chooses the modules and the order of modules) and examine predictors, moderators, and mediators of LEAVES' effect, such as time since loss, age, adherence to the intervention, and the working alliance. The clinical evaluation will also consider the perceived benefits of LEAVES by secondary end-users, i.e., relatives of the mourners and healthcare professionals. As complementary research goals, this study aims to assess technology acceptance of the self-help intervention for grief in older population and to conduct a cost-effectiveness analysis of the use of LEAVES.

The study design for the clinical evaluation is a pragmatic two and three-arm randomized controlled trial with one or two active arms in Portugal and Switzerland with a waiting control condition of 10 weeks and a 20-weeks follow-up. In The Netherlands, a crossover pilot study will be conducted with an active arm and a waiting group focusing on technology acceptance of the LEAVES service including the developed tools for initial risk assessment and continuous monitoring. Participants will be asked to assess the usability of these tools and of the LEAVES service overall in focus groups. The designs have other small variations across the participating countries.

The sample is recruited from widows and widowers from the general population in Switzerland, The Netherlands and Portugal. In Portugal, participants will be recruited from a list of citizens registered and followed in their local primary care services ,hence, essentially a community-based sample. Based on power analyses, at least 205 mourners as primary end-users (40, 85, 80, in the Netherlands, Switzerland, and in Portugal, respectively) and 115 secondary end-users will be randomised.

Results will provide insights into the efficacy and acceptance of an online intervention among older adults suffering from grief symptoms, psychological distress, and adaptation problems in daily life after spousal bereavement. Findings will add to the existing knowledge by 1) evaluating an interactive dialogue-based online intervention specifically designed for spousal bereavement and its consequences; 2)

testing whether a personalised, self-tailored version is superior to a standardised version; 3) suggesting adaptations to improve the efficacy of the intervention, selective indication and adaptations for different needs; and 4) which mediators' and moderators' impact the success of the intervention. Strengths and limitations of the proposed program will be discussed considering the need for guidelines for self-help online interventions for an older population. Results of our cost-effectiveness analysis will be discussed to inform tailored business models and marketing strategies, ensuring the proposed product can effectively reach our target audience.

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1 Introduction

The death of a partner is frequently a very stressful and critical life event in later stages of life. Grief is a normal reaction to this loss, and, after a certain time, most individuals cope well with their new life without the partner. However, some develop a disturbed and prolonged grief reaction, which is often associated with mental health and/or physical health complications. Online self-help interventions have proved beneficial effects on a broad range of disorders including prolonged grief. Based on the task model by Worden (2009) and the dual process model of coping with bereavement by Stroebe & Schut (1999), the coordinators of the clinical team of LEAVES initially developed and evaluated a guided online self-help intervention called LIVIA, intended to support older adults who experienced the loss of a partner and were seeking help for coping with prolonged grief symptoms. Its content has been integrated into LEAVES, an online service designed to support older adults in dealing with grief and prevent prolonged grief, while using a user-centred, iterative, and agile approach. The development and implementation of the LEAVES online service requires a randomized control trial to 1) test the efficacy of the service compared to waiting list control group; 2) to examine whether a standardised version with a fixed order of the content modules or a self-tailored version of LEAVES leads to better user outcomes; and c) to investigate mediators for the outcomes. The randomized controls trial will test the fourth and final prototype of the service, which will be ready in M24.

Furthermore, a study on technology acceptance will focus on usability, the user experience, and the intention to use. Finally, a cost-effectiveness analysis complements the clinical evaluation.

This report describes the study protocol that will guide the procedures followed to conduct the real-life evaluation from M24 to M32. The study protocol includes the theoretical background that sustains the development of LEAVES, the methods used to test the service and the procedures underlying the statistical analysis of the data collected. It also describes the study on technology acceptance and the cost-effectiveness analysis.

T3.1 Development of the study protocol (M12-M22)

The design of the study protocol was developed and coordinated by SSW, while working in close collaboration with partners from the other two implementation countries (The Netherlands and Portugal). The study protocol is based in a core procedure to be implemented by the School of Social Work of the University of Applied Sciences and Arts Northwestern Switzerland and Department of Clinical Psychology and Psychotherapy of the University of Berne in Switzerland. This deliverable presents adaptations to the target population, the design, sample size and complementary research questions of the other countries. The study protocol follows the ethical principles of clinical research such as the Helsinki declaration, the Swiss Federal Act on Research involving Human Beings, and the General Data Protection Regulation (GDPR).

The development of the protocol for the clinical evaluation required six workshops with partners that would be involved in the design and implementation of the study in the three countries. To develop a protocol to assess the technology acceptance of LEAVES in The Netherlands, we conducted three internal meetings which resulted in a protocol for a qualitative study. The part of the evaluation that focuses on technology acceptance was the result of several discussions among the WP3 partners. Then, the Dutch partners RRD and NFE proposed a concept evaluation, which was discussed in terms of feasibility in the other countries. In the Netherlands, technology acceptance will be the main focus of the evaluation, while in Switzerland and Portugal, this will be a secondary outcome. In the latter countries, data collection and analysis on this topic will be trimmed down.

The following sections 2 and 3 describe the scoping and planning of the development work. Section 4 describes the core methods of the clinical study and the specific adaptations for each implementation country. Sections 5, 6 and 7 describe the expected analyses and results, present the ethics standards followed, and discuss its potential implications.

2 Objectives

This report aims to describe the clinical background for the LEAVES service and to present the design of the randomised controlled trial (RCT) for the clinical real-life

evaluation. The LEAVES Consortium will detail the rational for the two presentation conditions (standardised vs. self-tailored), the study hypotheses, the designs of the randomised controlled trial and procedures that will guide the study implementation. Furthermore, we will present the cross over pilot study for the technology acceptance evaluation and cost-effectiveness analysis.

This report does not intend to give an extensive description of the study procedures, but a summary of the core decisions and methods. An extensive protocol will be submitted to the ethics committee of each country.

3 Theoretical background

3.1 Theoretical introduction

3.1.1 Psychological and social consequences of the loss of a partner

The death of a partner is a frequent and very stressful critical life event in later life. It implies a dissolution of social and emotional ties. This deeply affects the attachment system, requires the acceptance of the loss as well as the formation of a new identity and a new perspective for the future. It involves the adaptation of daily routines which can be even more challenging when social, physical, and financial resources decline in later life (Znoj, et al., 2016). Grief and psychological distress after the loss of a spouse are normative reactions. For most people, grief intensity weakens to a manageable degree within several weeks or months. After the most intensive period, grief is still present, but the loss becomes gradually integrated and no longer hinders the way of ongoing life. However, some individuals are less able to cope with bereavement and show symptoms of disturbed or prolonged grief or adaptation problems (Aoun, at al., 2015; Shear, et al., 2013; Spahni, et al., 2015, Perrig-Chiello, et al., 2015). Some even develop a Persistent Complex Bereavement Disorder, which is characterised by separation distress, frequent or disabling cognitive, emotional, and behavioural symptoms such as avoidance of reminders of the loved one, difficulties moving on with life and functional impairment (Prigerson, et al., 2009; American Psychiatric Association, APA, 2013).

3.1.2 Coping with the loss of a partner

Several theoretical models describe factors which are crucial for an adaptive adjustment to bereavement. The task model identifies four tasks of mourning, namely accepting the reality of the loss, experiencing the pain of grief, adjusting to an environment without the deceased person, and withdrawing emotional energy and reinvesting it in another relationship (Worder, 2009). The dual-process model of coping with bereavement posits that a dynamic coping process oscillating between loss-oriented tasks such as grief work and restoration-oriented tasks such as attending to life changes is essential for adjustment (Stroebe, et al., 1999). Coping with loss-oriented tasks includes positive reappraisal versus rumination, revisions of personal goals, positive and negative event interpretation, and expressing emotions toward the deceased. Restoration-oriented coping is focused on attending to life changes, engaging in new activities, distracting from grief, and finding new roles and identities.

3.1.3 Interventions for coping with grief

The dual process model for coping with bereavement (1999) and the task model by Worden (2009) provide a theoretical background for interventions ranging from self-help groups, pastoral care to psychotherapy. Cognitive-behavioural interventions for complicated grief are often based on three components: 1) Exposure, e.g., confrontational technique of ‘revisiting’ the deceased person or telling the story of the loss; 2) cognitive reappraisal or restructuring of individual dysfunctional thoughts (e.g., guilt, anger) associated with the loss; and 3) integration and restoration (Shear et al., 2005; Boelen et al., 2007).

More and more, online interventions complement grief counselling or therapy (Eisma, et al., 2014; Litz, et al., 2014; van der Houwen, et al., 2010; Wagner, et al, 2013). Online interventions have advantages compared to face-to-face therapy. Benefits of internet-based approaches are low threshold accessibility, flexible usage independent of time and place, usage at a self-determined pace, a high level of autonomy and privacy, and lower costs (Schröder, et al., 2016). These factors may be especially relevant for older adults. However, challenges of online interventions include

technological problems and lower computer literacy or unease using computers, which may be more prevalent in old age.

In a meta-analysis, online interventions for prolonged grief have proved to be as effective as face-to-face therapy for depressive symptoms, social anxiety disorder and other psychological or somatic disorders (Anderson, et al., 2014). A recent meta-analysis summarized the evidence for online interventions for bereaved people and found that all the interventions, based on CBT, showed moderate effects (g = .54) for symptoms of grief large effects (g = .86) to posttraumatic stress disorder (PTSD), with effects being stable over time (Wagner et al., 2020). Most internet interventions combine the presentation of a web-based self-help program with minimal but regular therapist contact Despite the effect for depression was small (g = .44), more individual feedback increased effects for depression.

Components of online interventions for grief: Exposure, cognitive reappraisal, and integration and restoration as treatment components have been implemented and evaluated in two randomised controlled trials of online self-help interventions for complicated grief after bereavement (van der Houwen, et al., 2010; Wagner, et al, 2013). In contrast to these two studies, Litz and colleagues evaluated an online intervention focusing on self-care, social reengagement, and goal-focused activities (Litz, et al, 2014). No formal exposure or cognitive reappraisal was included. Finally, a recent study compared an online exposure and behavioural activation treatment (Eisma et al., 2015). Both interventions reduced complicated grief, posttraumatic stress, and grief rumination, but only exposure showed an effect on depression and brooding levels relative to the control group.

LIVIA, as the basis of LEAVES, included exposure, cognitive reappraisal, integration, and restoration as well as self-care and social reengagement treatment components (refs, see below for details). It was based on the task model by Worden (2009) and the dual process model of coping with bereavement by Stroebe & Schut (1999). The target groups were mourning older adults who had lost their spouse in the previous six or more months, and still suffered from grief symptoms or were seeking help for their emotional adaptation to the loss. Additionally, LIVIA addressed separated/divorced older adults who were suffering from prolonged grief or adaptation problems after the loss. The intervention was developed and evaluated by a team of

psychologists at the University of Bern (Brodbeck, et al., 2017, Brodbeck, et al., 2019) who are now part of the clinical LEAVES team.

3.1.4 Rationale for the present LEAVES study

Clinical evaluation

LIVIA as text-based online intervention, without sophisticated interaction with users, proved its efficacy for mourning older adults from a general population sample with a mean age of 59 years, who had lost their spouse in the previous six (or more) months. It confirmed that the intervention is also efficacious for milder grief symptoms and thus may prevent grief-related disorders. The loss occurred, on average, in the previous two years. Compared to the control group, the intervention resulted in significant reductions in grief (d = 0.81), depression (d = 0.59), psychopathological distress (d = 0.39) (primary outcomes), embitterment (d = 0.37), loneliness (d = 0.37) and an increase in life satisfaction (d = −0.41) (secondary outcomes). These gains were maintained over three months. Improvements were similar among participants with low, medium, or high levels of grief at baseline. LIVIA left open some questions, such as whether the intervention would also be effective for bereaved older adults whose loss took place within the previous six months and whether the effects of intervention would be superior under a self-tailored format.

Therefore, LIVIA provides a promising basis for the development of a more sophisticated and attractive intervention with a more inclusive target group, e.g., mourners who lost their spouse within the previous six months, while still seeking help for coping with the loss. Apart from extending the target population of the intervention, LEAVES also aims to examine whether the efficacy of LIVIA can be increased by providing a self-tailored version, in which the users can chose the content which is relevant for them and which best fits their current needs. This is in line with concurrent developments in face-to-face and online interventions (Karyotaki, et al., 2017), which explore the effects of personalising interventions to the specific needs of clients.

The need to adapt treatment planning to each client has been guiding research in face-to-face CBT interventions (e.g., Persons, et al, 2006). These efforts resulted in studies testing modular, vs. standardized, intervention which showed robust results on the efficacy of modular approaches (e.g., Chorpita et al., 2005). While in standardized

formats, therapists are expected to deliver therapies based in a predefined and fixed sequence of techniques; in flexible modular formats, therapists are expected to implement the therapy in modules according to clients' specific symptoms and/or specific needs at different times (e.g., Chorpita et al., 2005). Despite modular formats can correspond to a fixed content, they are designed to allow a flexible implementation of that content depending on ongoing decisions. Thus, modular formats do not correspond to an unguided approach but are based on a system of rules or algorithms that allow flexibility, ensuring fidelity and preventing clinical bias (see e.g., Boustani, et al., 2020). Furthermore, modular formats allow to integrate clients' therapeutic goals and their perceptions about their own needs. Following this principle, self-guided online CBT interventions (iCBT) may lead to promising results, as modular face-to-face approaches. A study, addressing comorbidity in depression, compared self-guided iCBT with standardized (non-tailored) iCBT and revealed that both conditions improved measures of depression, anxiety and quality of life. This study also revealed that the self-tailored treatment was more effective than the standardized treatment among participants with more severe symptoms at baseline and more comorbidity (Johansson et al., 2012). However, research tends to overlook the comparison between fixed standardized vs flexible modular, or neglects to test the specific impact of users' therapeutic decisions in iCBT interventions. Most research tend to compare online interventions (regardless they are self-tailored or standardized) with other therapeutic formats, such treatment as usual or discussion groups (Karyotaki, et al., 2017). To fill this gap in the literature, we propose to compare LEAVES in two delivery conditions, standardised/fixed and self-tailored.

The role of technology acceptance

Technology acceptance among primary and secondary end users is crucial for the successful implementation of an online service such as LEAVES in a real-life setting. For primary end-users, a caring technology like LEAVES should instil trust, should be engaging, and should provide a solid level of usability. For secondary end-users (like healthcare professionals) the technology should be perceived as useful and should fit in with their working routines. In order to optimize the implementation of LEAVES after the project phase, a focus will be placed on understanding technology acceptance in the Dutch branch of the evaluation.

The cost effectiveness analysis

In order to determine if the LEAVES tool is worth adopting by end users, but also to inform the business models and market strategies for each country, a cost-effectiveness analysis will also take place. This analysis is commonly used to decide whether choosing a certain intervention is an efficient use of existing resources. In practice, the cost effectiveness-analysis is calculated by dividing the difference in total costs (between the intervention and control) by the difference in the chosen measure of health outcome or effect (between the intervention and control).

3.2 Research goals

The real-life evaluation of LEAVES aims to meet three main research goals, to conduct a clinical evaluation of the program, to understand the acceptance of the proposed technology among older adults and to conduct a cost-effectiveness analysis that will later contribute to inform the LEAVES business model.

The objectives of the study are as follows:

A) Clinical evaluation (Portugal and Switzerland)

(1)

To evaluate the effects of the guided dialogue-based online self-help programme compared to the waiting control condition (CH) or care as usual (PT) on the outcome measures

- Grief symptoms (primary outcome)
- Depression, loneliness (secondary outcomes)

(2)

To compare the efficacy of a standardised versus a self-tailored version of the programme on the outcomes measures, adherence, working alliance, session outcomes, and user satisfaction (CH)

(3)

a) To analyse mediators for the efficacy of the programme (CH), i.e.,

- The working alliance and the matching of expectations of the user to the programme

- Session outcomes, i.e., the module's perceived usefulness, gains in insight, coping experiences, and self-esteem.

b) To analyse moderators for the efficacy of the programme (CH, PT), i.e.:

- Duration since the loss
- Severity of grief symptoms at baseline

(4)

Inclusion of secondary end-user as complimentary clinical goals

a) To include informant reports of close ones to the mourners on the perceived effects of LEAVES

b) To include evaluation by healthcare professionals on the general effects of LEAVES. In Switzerland and The Netherlands, pastoral carers will be included as secondary end-users.

B) Technology acceptance (The Netherlands)

To assess LEAVES' technology acceptance from the perspective of primary end-users and secondary end-users (with a focus on older people). For primary end users, the study will include three measurement moments (t0 = baseline, t0.5 = halfway use, t1 = post treatment) and the following assessments:

- Expectations of using the technology (t0)
- Use and appreciation of the LEAVES monitoring and escalation functions (t0,5)
- Usability (t0,5 and t1)
- User experience (t0,5 and t1)
- Critical incidents (t0,5)
- Acceptance (t1)
- Willingness to pay (t1)

At the end of the trial period, focus group sessions with care professionals and with mourners will be conducted. This will allow to identify arguments for (not) using LEAVES, and ultimately to triangulate the qualitative results with the quantitative findings.

C) Cost-effectiveness analysis

To estimate the cost-effectiveness of the LEAVES online service for providers, to support the business models and marketing strategies for each country.

In sum, this study adds to the existing knowledge by 1) evaluating a dialogue-based online intervention specifically designed for spousal bereavement and its consequences; 2) testing whether a self-tailored (personalised) version is superior to a standardised version; 3) testing whether the intervention is also efficacious for mourners whose loss was less than six months before; 4) suggesting adaptations in order to improve the efficacy of the intervention, selective indication and adaptations for different needs by evaluating mediators and moderators of the intervention effect.

As complementary research goals, this study is intended to 1) bring new insights to the technology acceptance of self-help online CBT interventions on grief for an older population, their informal caregivers and the main clinical stakeholders, namely the General Practitioner and community nurse (The Netherlands) and 2) bring new insights about the cost-effectiveness of LEAVES, as well as the development of tailored business models and marketing strategies for the eHealth market pertaining community dwelling older adults (Portugal). Moreover, the study implemented in Portugal will also include a qualitative study on barriers and facilitators to use LEAVES.

3.3 Research hypotheses

A) Clinical evaluation (Switzerland and Portugal)

Efficacy of LEAVES

1) Primary outcome: We hypothesize that LEAVES will decrease grief symptoms significantly compared to the waitlist control (CH) or usual care group (PT).

2) Secondary outcomes: We hypothesize that LEAVES will decrease depressive symptoms and perceived loneliness significantly compared to the waitlist control (CH) or usual care group (PT).

Comparison of the two active arms (Switzerland)

The self-tailored condition provides participants the opportunity to meet their specific needs every time they use LEAVES. We hypothesize that by giving end-users the opportunity to decide what is best for them, LEAVES will allow the development of greater trust in the intervention, hence better working alliance.

3) When assessing the presentation format of LEAVES, we hypothesize that the self-tailored condition will lead to a significantly higher decrease in grief, depressive symptoms and loneliness than the standardised condition. (CH)

Mediators: Session outcomes and working alliance (Switzerland)

4) We hypothesize that session outcomes, i.e., the overall helpfulness of the modules, gains in mastery experiences, self-esteem, insights, the matching of the needs of the user and a better working alliance mediate the effect of the treatment.

5) Comparison of the two active arms: We hypothesize that self-tailored condition will lead to higher perceived session outcomes and higher working alliance.

Moderated mediation:

6) We hypothesize that the self-tailored condition will lead to higher perceived session outcomes and better higher working alliance, thus leading to lower levels of grief symptoms, depressive symptoms and loneliness compared to the standardised condition.

Moderators: Time since the loss; severity of grief symptoms at baseline (Portugal and Switzerland)

Exploratory analyses will test whether age, time passed since the loss and the severity of grief symptoms are moderators for treatment outcome.

B) Technology acceptance (The Netherlands)

Technology acceptance studies are not so much concerned about hypotheses, as they are about explaining (non) use. Exploratory analysis will focus on the understanding of the end-users' experience of using LEAVES in order to inform implementation in real life. As a secondary aim, the Dutch branch of the evaluation will assess potential health effects, in which it is hypothesized that LEAVES will decrease grief symptoms significantly compared to the waitlist control group.

C) Cost effectiveness analysis

The cost-effectiveness analysis follows and exploratory paradigm, where no *a priori* hypotheses are defined.

4 Methods

4.1 Study paradigms and design of the RCTs for the clinical evaluation

The real-life evaluation of LEAVES will be conducted in three countries, Portugal, Switzerland, and The Netherlands, corresponding to three different studies, each with specific research questions. The study conducted in Portugal will recruit participants from a list of citizens registered in the local primary care services located in an essentially rural region of Portugal. The study in Switzerland will focus on further clinical evaluation, comparing the two delivery formats of LEAVES (standardized and self-tailored) and exploring clinical mediators and moderators of the effect of the service. The study in The Netherlands will focus on assessing the acceptance of LEAVES technology. A country specific cost-effectiveness analysis of each study will be conducted by UNL using the information collected in all countries.

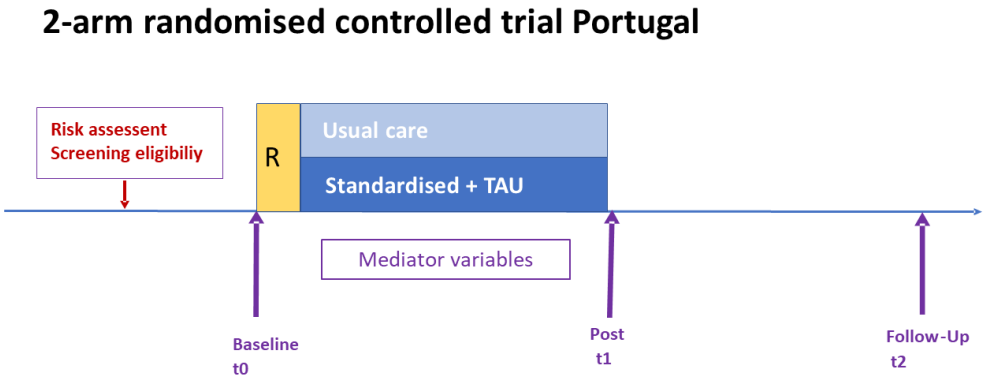

Figure 1.Overview of the design of study conducted in Portugal

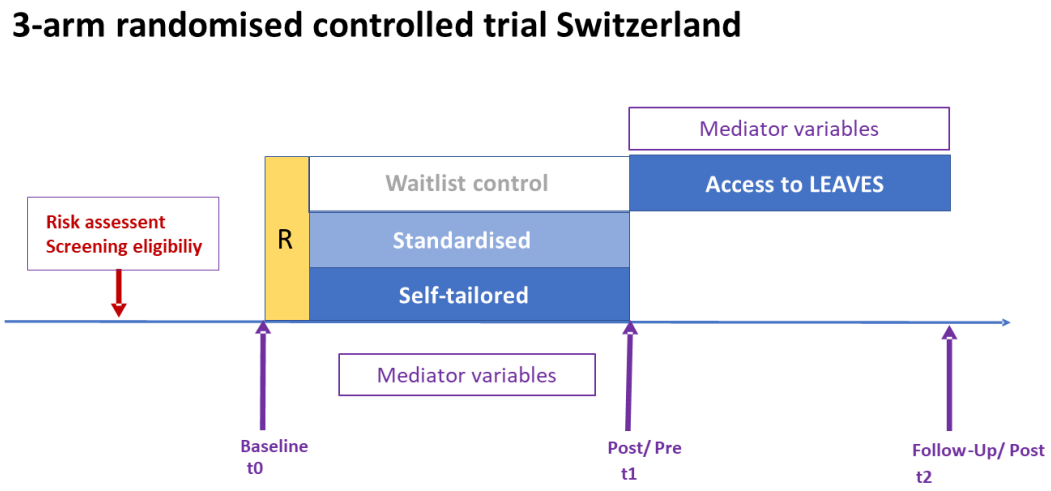

Figure 2.Overview of the design of study conducted in Switzerland

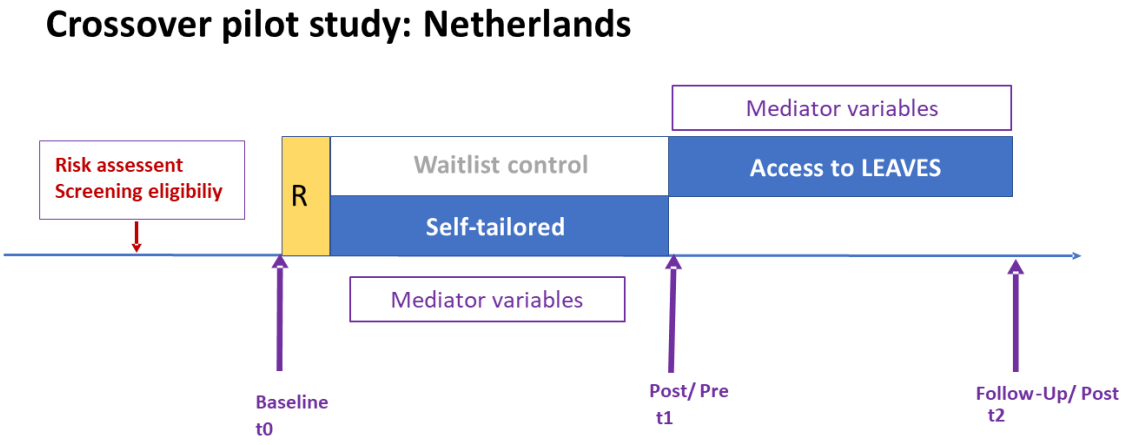

Figure 3.Overview of the design of study conducted in The Netherlands

Figures 1, 2, 3: Describe the experimental conditions, types of variables, measurement points and timeline of study in each implementation country, according to the specific design of each study.

To meet the different research goals, the methods of the studies conducted in each country will adapt the main research paradigm to each country, see Figures 1-3. In Portugal, the study will be conducted using a list-based sample and will follow a two-

arms design, comparing the standardised LEAVES program vs. usual care treatment. This study will be led by ULSBA.

In Switzerland, the study main paradigm consists of a three-arm randomized controlled trial with two active arms (standardised vs. self-tailored) and a waiting list control condition using a general population sample. This study will be conducted by the LEAVES clinical coordinator team (SSW and UoB).

In The Netherlands, a crossover pilot study led by NFE and RRD will be conducted with a two-arms design, comparing the self-tailored LEAVES to the waiting condition. This study setup will be implemented with assessment of technology-accepted parameters, as represented in Figure 4. An additional qualitative focus group study will focus on technology acceptance among healthcare professionals to better understand their user experience and bring new insights to the quantitative findings.

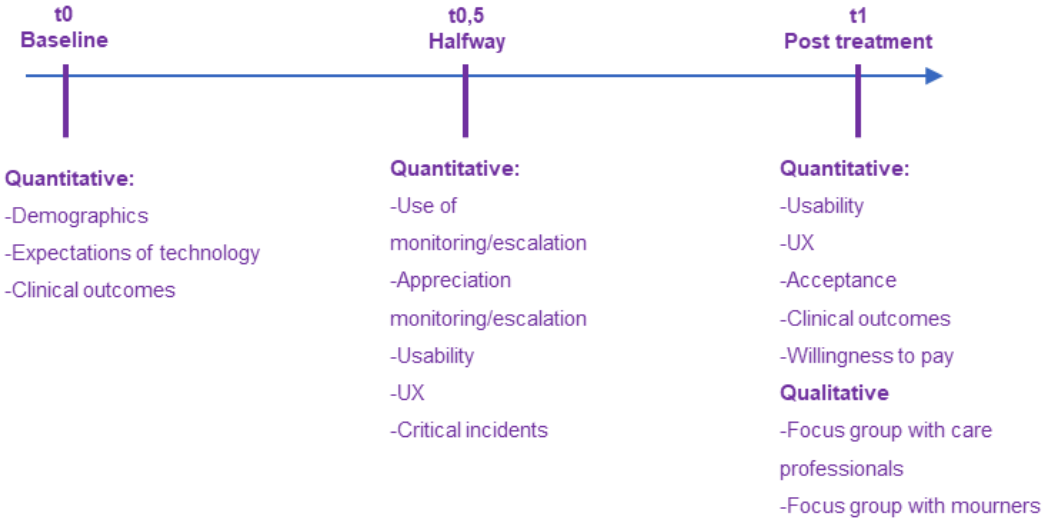

Figure 4.Overview of the technology acceptance measures

Randomisation: An external block randomisation using computer generated random numbers will be provided by RRD. Participants will receive a code that will link them to the assigned study condition. Apart from Portugal, participants in the waiting control condition will get access to the intervention 10 weeks after the baseline measurement moment.

Table 1.Summary of study design in each implementation country

Country	Study design	Main research goals
Switzerland	Quantitative study: 3 arms study (standardised x self-tailored x waiting list control)	- Clinical efficacy - Comparison of standardised vs. self-tailored version - Analysis of clinical mediators
The Netherlands	Quantitative study: cross over pilot study Qualitative study	- Technology acceptance
Portugal	Quantitative study: 2 arms study (Standardised x care as usual) Qualitative study	- Clinical efficacy - Country-specific cost-effectiveness analysis conducted by UNL

4.2 Sample

Primary end-users: The main target group for the primary end-users are older adults who experienced loss of the spouse and seek help for their grief process or (in Portugal) are willing to accept help to cope with grief, psychological distress, and/or the psychosocial adaptation to a life without their partner. Considering that age will be tested as a moderator variable of the effect of LEAVES, we will not impose an age limit to the sample. Increasing the age range will allow us to have the necessary variance in age to conduct the moderation analysis.

Secondary end-users: Secondary end-users include close ones to the mourners, either family members or close friends, that may provide their impression on the well-being of primary end-users and the perceived benefits of LEAVES.

Professional informants as further secondary end-users: A group of professionals healthcare or pastoral care (CH, NL) will be included to provide their professional impression on the benefits of using LEAVES.

4.2.1 Sample size

We specified the sample size needed for the different analyses conducting a power analysis based on a probability level of .05 and a power of 0.80 with G*Power (Faul et al., 2017) which is based on the results of the evaluation of LIVIA (Brodbeck et al. 2019). For the efficacy of the intervention compared to the control condition, we found a large effect of *d* = .81 for reduction in grief symptoms as primary outcome. Figures 2 and 3 present the power analyses for a repeated measures ANOVA with a within-between interaction for two and three groups as basic analyses. We anticipate a dropout rate of 15% and will accordingly recruit more end-users than indicated by the power analysis. The sample sizes will be determined per country. Later in the evaluation, data will be pooled to examine moderator and mediator analyses with a larger sample size.

For the comparison of LEAVES and a waitlist condition, we expect a large effect size of d > .80. We expect small to moderate effects (d = 0.30 and d = 0 .50) for the comparison of LEAVES and usual care in Portugal. For the comparison of the standardised and the self-tailored version in Switzerland, we expect a small to moderate effect (d = 0.30) in favour of the self-tailored version.

In Portugal, we aim to include 80 participants in the trial. Among Portuguese older adults (55 years and over) we expect the LEAVES intervention to have a small to medium effect on grief (d > 0.30) (as measured by TRIG) vs usual care (control arm). To find a significant difference between intervention and control at 80% power and with an α of 0.05, and assuming a correlation of 0.65 among repeated measurements we would need a total of 52 participants using ANOVA. We anticipate 20% attrition between recruitment and the start of the intervention and an extra dropout of 30% over the study duration to the follow-up (20 weeks). In view of the sample size calculation, we aim to include at least 80 participants in the trial where at least 40 participants will be allocated for each arm.

For the two-arm crossover pilot study in The Netherlands, we will include 40 participants. For the most basic analyses, 20 participants will be sufficient. Forty participants will suffice for assessing the metrics on technology acceptance. For the focus groups at the end of the runtime, we will target a sample of 10 participants.

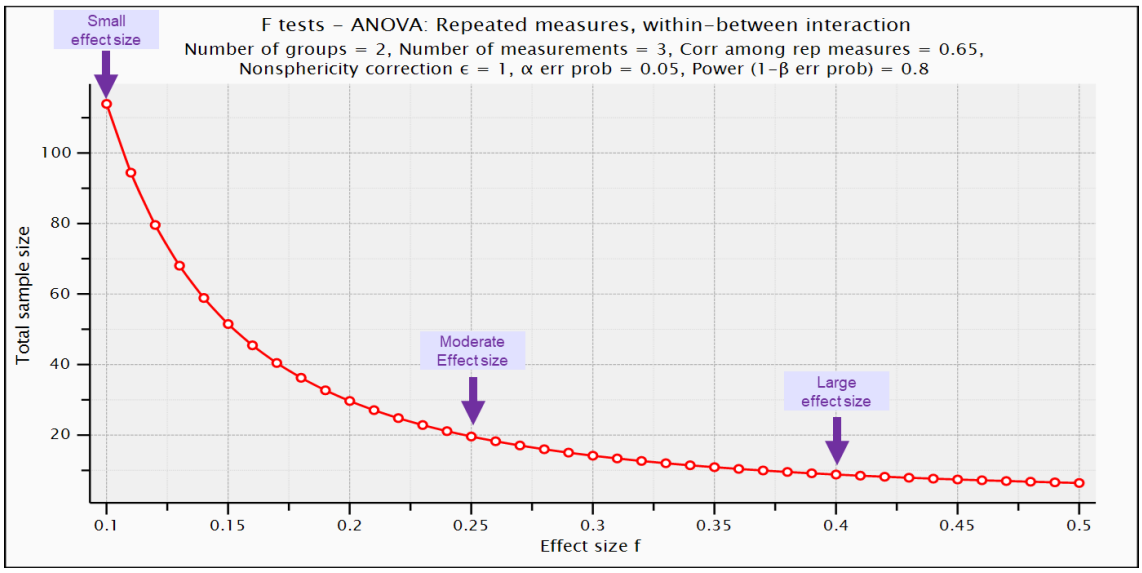

Figure 5.Power analyses for two-arm design (The Netherlands & Portugal*)

*Small effect size *f* =.1; moderate effect size *f* =.25; and large effect size *f* =.4.

For the three-arm design in Switzerland, we expect a large effect for the comparison with the waitlist control group and small to moderate effects for the comparison of the two active conditions. We will include at least 85 participants with an allocation ratio of 40:40:20 for the two active conditions and the waitlist group.

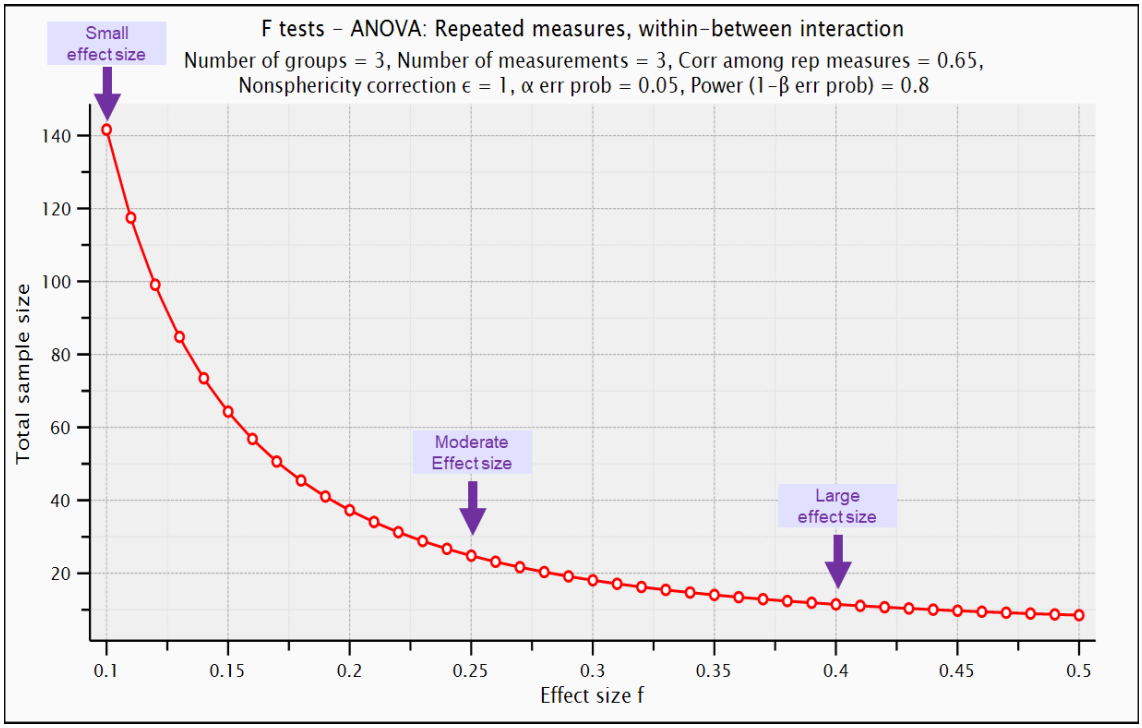

Figure 6.Power analyses for three-arm design in Switzerland*

*Small effect size *f* =.1; moderate effect size *f* =.25; and large effect size *f* =.4

Table 2.Overview of the number of participants included in the studies in each country

Country	Sample size
The Netherlands	Primary end-users: 40
	Secondary end-users: 20
	Professional informants: 10
Switzerland	Primary end-users: 85
	Secondary end-users: 40
	Professional informants: 10
Portugal	Primary end-users: 80
	Secondary end-users: 40
	Professional informants: 10

4.2.2 Dropout and non-compliance definition

Dropout will consist of participants who withdraw actively from the study after randomisation. Additionally, for the clinical evaluation, study dropout is defined as not filling out the post measurement questionnaires in spite of two reminders. Adherence will be assessed with the number of modules completed, the numbers of filling out the monitoring questions and the self-reflection items.

For technology acceptance, non-compliance is defined as not filling out the monitoring questionnaires (bi-weekly mental check-ups) despite two reminders. We also define non-compliant participants as those that, despite not actively quitting from the study, do not complete the two mandatory study modules (Modules 1 and 2) within 10 weeks (between t0 and t1). Nevertheless, these participants are a part of the intent-to-treat sample as they have been randomised. For this reason, these participants will be included in the correspondent analyses.

4.3 Recruitment

Recruitment will vary across implementation countries to ensure a recruitment method is adjusted to the specific study design of each country, sample characteristics, and country culture.

Table 3.Description of recruitment strategy per implementation country

Country	Recruitment
The Netherlands	Primary end-users: Recruitment will be based on the network of NFE. NFE has several services in which older adults participate. Through our intensive contact with volunteers, who lead these services, we will recruit participants based on the inclusion criteria. In addition, DELA will recruit participants within their customer database and DELA Panel via targeted emails. Also, healthcare professionals and churches will be contacted to further recruit eligible participants. Finally, newspaper articles and internet forums may be used to disseminate our research and recruit participants.
	Secondary end-users: After the recruitment of primary end-users, NFE (including NFE volunteers) and DELA consultants will discuss which participants can be asked to include their family members. Contacts with these participants will be made to invite them to invite sending an invitation email to a family member or close friend.
	Professional informants: Through the means of NFE's professional network of healthcare professionals, care institutions, volunteers of NFE and churches, professional informants will be recruited. Professional secondary end-users will receive an invitation email to participate in the study.
Switzerland	Primary end-users: Recruitment will be based on newspaper articles, internet forums, healthcare professionals and churches.
	Secondary end-users: Primary end-users will be invited to send an invitation email to a family member or close friend. Secondary end-users will be invited to participate in the study by completing a short online survey anonymously.

	Professional informants: Healthcare providers will receive an invitation email to participate in the study.
Portugal	Primary end-users: Trained mental healthcare staff will be given access to a list of older adults with a widowed civil status registered in the primary care services of ULSBA and will contact them via telephone, screening their eligibility and willingness to participate.
	Secondary end-users: Trained mental healthcare staff will recruit secondary end-users (relatives or close friends) during primary end-users' initial assessment (t0), preferably no more than one relative per participant.
	Professional informants: Trained mental healthcare staff will recruit other healthcare professionals involved in assisting the participants via direct invitation.

4.3.1 Recruitment contingency plan

Initial recruitment phase will occur from November 2021 to January 2022 before participants start using LEAVES (t0). An assessment of the recruitment strategy will be conducted in March 2022. In Portugal, individuals registered at ULSBA's primary care services will be screened for eligibility and willingness to take part in the trial via a telephone call. For each implementation country, if the required number of recruited participants is not met, and the number of recruited participants is less than half of the needed sample size in The Netherlands, Switzerland, and Portugal the lead country will activate the recruitment strategy contingency plan.

Table 4.Description of recruitment strategy per implementation country

Country	Recruitment contingency plan
The Netherlands	Extend the initial recruitment strategy to the Volunteer network of NFE, where a great number of volunteers meet the inclusion criteria for the study. Furthermore, we will use our (social) media channels to further enhance our recruitment, for instance newsletters.

Switzerland	Extend the initial recruitment strategy to other German speaking European countries (Germany and Austria). Distribute brochures with information about the study in day care centres.
Portugal	Extend the recruitment strategy to in-person recruitment in day care centres and other places of interest and/or extension to other regions of Portugal.

4.3.2 Eligibility criteria

All interested participants are required to complete a telephone interview to assess eligibility prior to randomisation. For recruitment strategies that are list-based, and where participants' eligibility is known *a priori*, the telephone interview will assess participants' motivation to participate in the study and if they meet the eligibility criteria.

General inclusion criteria are:

1. Experience of spousal bereavement
2. Seeking help or willingness to accept help to cope with grief symptoms, psychological distress, or the psychosocial adaptation to a life without the partner.
4. Access to an internet connection, adequate equipment.
5. Mastery of the country's first language (Dutch, German, and Portuguese).
6. An informed consent by the participant.

General exclusion criteria for the studies are the following:

1. Loss in the previous month (at the start of the intervention, t0)
2. Severe psychological or somatic disorders which need immediate treatment (CH and PT)
3. Acute suicidality (CH and PT)
4. No emergency plan: In the telephone interview, an emergency plan will be developed which specifies a healthcare professional who participants can turn to if they find themselves in crisis. If no such person or health care service can be found, individuals are excluded from the study. This won't be the case in Portugal since there is permanent General and Psychiatric Emergency Services at disposal in ULSBA.

5. Inability to follow the procedures of the study, e.g., due to comprehension problems, dementia, among others.

6. Inability to follow the procedures of the study due to physical impairment, e.g., visual impairment, lack of sufficient motor skills.

Table 5.Overview of eligibility criteria per implementation country

Country	Eligibility criteria
The Netherlands	Follows general inclusion and exclusion criteria, with the exception of point 3 of exclusion criteria (see support and guidance section).
Switzerland	Follows general inclusion and exclusion criteria
Portugal	Follows general inclusion and exclusion criteria Additional inclusion criterion: Lives in the area of coverage of ULSBA

4.3.3 Timeline for recruitment and data analysis

- Initial recruitment phase will occur from November 2021 to January 2022.
- MVP (Minimum Viable Product) will be available in February 2022
- Enrolment of the first participant in February 2022
- Enrolment of last participant will occur no later than July 2022
- Data analysis, results, and interpretation will occur from July to December 2022
- Final report: January 23

4.4 Description of the intervention

LEAVES content was designed to follow the content structure of LIVIA. Each session/module includes Readings describing scientific knowledge about grief related topics (e.g., how to positively influence thoughts, emotions, and behaviours) and Exercises to encourage mourners to actively reflect on what was learned in the Readings and apply their new knowledge into their grief journey and coping strategies (e.g., how to change attentional focus). Each module is divided in several submodules

that include Readings and Exercises. This content structure has been complemented with dialogues involving the virtual agent, who introduces the modules, leads the user through them and, lastly, wraps up the modules.

LIVIA also proposes end-users to engage in specific activities that encourage mourners to try new daily tasks or routines aimed at promoting mental and physical well-being. While LIVIA's activities were adapted to the LEAVES service, a few others were developed. Descriptions of the Activities were also further developed and added to provide clarify to those activities (e.g., Guided imagery, Journey though the body). Activities in LEAVES were categorized according to end-users' main needs (e.g., activities with/for others; activities for finding comfort, etc.).

LEAVES is designed to be a guided 10-week online self-help programme. In certain conditions, users can use LEAVES as a compliment to other therapy formats. In this intervention, users are asked to complete grief related modules, which include Readings – grief and coping related evidence-based texts – and Exercises – questions to help participants reflect on their new knowledge and how to apply it to their daily life. The 10 modules are described in detail in Table 6. Participants are encouraged to work through one module a week and to complete the assignments. One submodule takes between 15 and 20 minutes. The first two study modules include general information about 1) the impact of the loss of a partner and grief reactions and 2) an assessment of the current personal situation. Sessions 3 – 5 focus on resources and restoration-oriented interventions for fostering positive thoughts and emotions as well as self-care. Sessions 6 and 7 consist of loss-oriented interventions for accepting memories and pain and address unfinished business. Sessions 8 and 9 include again restoration-oriented interventions focusing on creating a new life without the partner and social relationships. The last module addresses the redefinition of the relationship to the lost person.

Table 6.Outline of the 10 self-help sessions of the online intervention

1. Psychoeducation about grief	Information about the self-help intervention, grief reactions, reactions to separation, predictors, and treatment of complicated grief.
2. Assessment of current situation	Information about and assessment of emotions in the context of the interpersonal loss, changes in life since the loss and obstacles for a positive adaptation.
3. Fostering positive thoughts and emotions	Information about emotion regulation and cognitive-behavioural strategies to promote positive thoughts and emotions. Procedures for practising these strategies in daily life.
4. Finding comfort	Suggestions for self-soothing strategies and exercises to promote positive feelings (e.g., diary for positive experiences).
5. Self-care	Checklists for current physical, emotional, and practical self-care, formulation of self-care goals and suggestions for implementing self-care behaviour in daily life.
6. Accepting memories and pain	Writing tasks to integrate painful memories of the loss into the autobiographical memory and to be able to tell the story of the loss.
7. Unfinished business	Identification of unfinished business and regrets, writing tasks to formulate unfinished business and to find ways how to put issues at rest.
8. Creating a new life without the partner	Identifying changes in daily life since the loss and sources of support and strengths before and after the loss. Information about posttraumatic growth. Identifying and activating resources in daily life.
9. Social relationships	Clarifying current relationships using a sociogram. Defining goals related to social relationships, e.g., changing relationships, building up new social contacts, and suggestions how to promote social well-being.
10. Redefinition of the relationship to the lost partner	Writing a farewell letter to the lost partner: Saying good-bye and telling the lost partner about the future importance of the loss and how the participant will continue life without the lost partner.

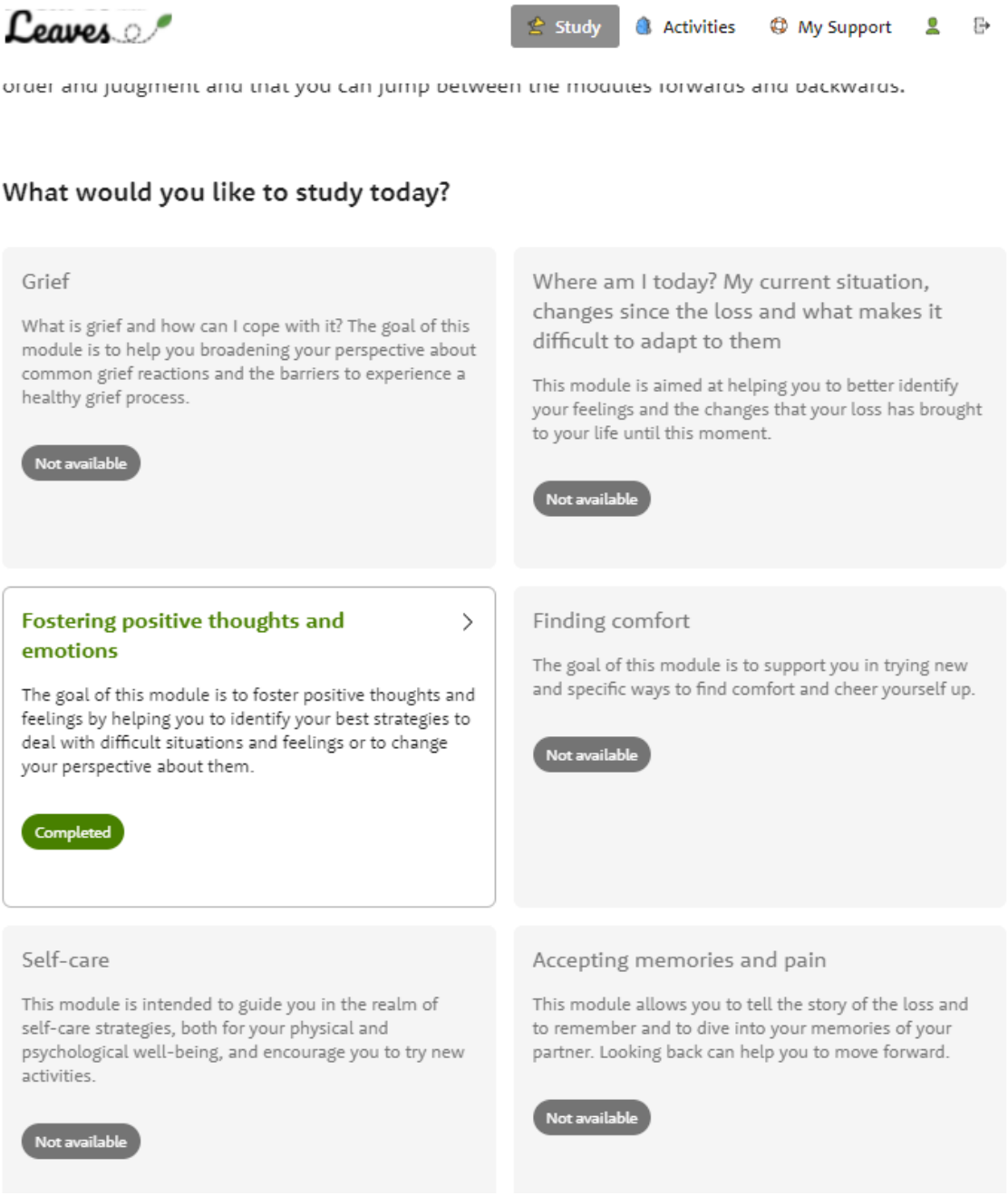

Figure 7.Study modules presentation in LEAVES platform

4.4.1 Participants support and guidance

During the 10 weeks of the study, while using LEAVES and completing the text-based sessions, users will receive weekly monitoring and support from the LEAVES contact persons. The format of the support will vary across countries to ensure adaptation to each study design and sample characteristics. This weekly support

acknowledges and motivates participants for their work with the self-help programme and provide a weekly structure and support for technical problems. This support is also intended to create a safe space for users to ask for further help if they experience intense suffering while using LEAVES, ensuring participants safety while participating in the study. In Portugal, this support and guidance will be performed mainly based on technical and troubleshooting support, considering that the treatment as usual arm of the study will not include regular telephonic check-ups.

Table 7.Overview of support and monitoring per country

Country	Participation support and monitoring
The Netherlands	Participants receive e-mail support by a team member specialized in social support to older people from NFE. Participants can contact their supporter anytime by sending an e-mail made available at the beginning of the study. Participants will also be given the contact details of the support line 'Luisterlijn' which is available 24 hours a day.
Switzerland	Participants receive e-mail support by a psychologist of the Department of Clinical Psychology and Psychotherapy of the University of Berne. Participants can contact their supporter anytime with questions via e-mail. The e-mail supporter will be supervised by a fully trained psychotherapist.
Portugal	Participants will receive only technical and troubleshooting support via telephone by an appointed technician. Participants are free to contact their GP, community nurse, psychologist, or other healthcare worker from which they usually receive care.

4.5 Measurement times

All self-report questionnaires will be completed online. Baseline measurements for the clinical evaluation will take place at t0; post-measurement (t1), 10 weeks after the start of the programme; and follow-up (t2), 20 weeks after the start of the programme

(t0). In Switzerland and the Netherlands, the waitlist group will receive access to the intervention at t1, while t2 will be the post measurement and t3 will be the follow-up 30 weeks after the baseline evaluation.

4.6 Measures

4.6.1 LEAVES tools for Risk Assessment & Monitoring

Initial LEAVES risk assessment

After screening for the general eligibility criteria and informed consent procedures, participants will receive the access code for the LEAVES program. Afterwards, during the onboarding, participants will fill out the LEAVES service risk assessment tool.

One of the purposes of the initial risk assessment is to assess whether the user meets the inclusion criterion for using LEAVES. In this study, this step will correspond to the confirmation that participants meet eligibility criteria since they were previously screened during the recruitment phase. In this study, the initial risk assessment will correspond to the baseline (t0) of the monitoring measurements in each implementation country.

Continuous LEAVES monitoring

LEAVES was designed to identify users' crisis during their grief journey in LEAVES if they occur. These crises are conceptualized as states of high emotional distress and psychological suffering that require additional support from specialist healthcare professionals. Participants will be asked to complete bi-weekly the LEAVES monitoring tool, a questionnaire including that assess perceived crisis (lack of control and need of support associated to emotional distress); hopelessness (key depression symptom); grief symptoms, suicidality; and social isolation and therapeutic progress.

The bi-weekly check-up questionnaire serves the purpose to identify different levels of psychological suffering (according to the key variables measured), which will guide subsequent recommendations tailored to different urgency levels. These recommendations consist of recommending additional support if needed. To achieve this goal, this tool required the development of an algorithm (under development). The implementation of this tool during the clinical study will vary in the different countries. In The Netherlands and in Portugal, monitoring survey and clinical recommendations

will be provided by the LEAVES service (supported by the algorithm). In Switzerland, the results of the risk assessment and the monitoring survey will be made available to the psychologist providing the e-mail support who will give clinical recommendations if needed. Monitoring will be conducted bi-weekly in all countries.

Risk Assessment and Monitoring Questionnaires

The *risk assessment* and *bi-weekly monitoring* items were designed based on the set of user clinical parameters for monitoring that emerged from the Delphi study and that were selected by the consortium partners based on commonly agreed upon decision criteria in the monitoring decision-making workshop in M13 (please see deliverable D2.1.3 for more details). Among the clinical parameters selected, it is important to note that the decision of assessing *Hopelessness* is linked to the assessment of *Suicidality,* key parameters to monitor the emergence of a crisis in LEAVES (see e.g., Beck et al., 1979; Brown, 2001; Kroenke & Spitzer, 2002). The set of five monitoring items that emerged from the monitoring decision-making workshop was extended with *Time since loss, Violent loss*, and *History of recent inpatient treatment* for both, the risk assessment and the bi-weekly check-up, and with *Technical skills* for the risk assessment and *Therapeutic progress* for the bi-weekly check-up. *Time since loss, Violent loss*, and *History of recent inpatient treatment* have important implications for determining how urgent the user may need professional offline support. *Therapeutic progress* complements the otherwise pathology-focused monitoring parameters, since it is a commonly assessed parameter as input for face-to-face therapeutic sessions. The LEAVES risk assessment and monitoring tools were described in detail in D2.1.3 (see section 6 of D2.1.3).

Table 8.Summary of risk assessment and monitoring parameters

Monitoring key parameters	Definition
Time since loss (RA)	Must be greater than 1 month.
Violent loss (RA)	Higher risk to develop complicated grief if loss was violent (e.g., murder, suicide, accident).
History of recent inpatient treatment (RA)	Previous psychological problems that required intensive inpatient treatment indicates higher vulnerability.
Technical skills/digital literacy (RA)	Poor digital literacy and/or technical skills increases the risk of non-adherence as intended.
Crisis detection (RA &M)	Perceived experienced crisis in the past two weeks, current support may be insufficient.
Depressive symptom: Hopelessness (RA & M)	Depressive dimension expected to be sensitive to change and impair daily life.
Grief symptoms (RA & M)	Grief dimensions expected to be sensitive to change and impair daily functioning.
Suicidality (RA & M)	Concrete plans for committing suicide.
Social isolation (RA & M)	Dimensions expected to be sensitive to change: perceived burdensomeness and withdrawal behaviour
Perceived therapeutic progress (M)	Assesses the user's perceive progress in processing their loss.

4.6.2 Clinical evaluation measures

Grief symptoms

Grief symptoms are the primary outcome measure in Portugal and Switzerland and the secondary outcome measure in The Netherlands. In the three implementation countries, grief symptoms are assessed with the Texas Revised Inventory of Grief (Znoj, 2008). The TRIG is a widely used measure to assess the severity of grief

symptoms. A recent factor analyses identified three factors for Emotional Response, Thoughts, and Non-Acceptance regarding loss (Futterman, et al., 2008). The German and the (soon to be available) European Portuguese versions of TRIG consist of a 16-item measure that assesses the severity of grief symptoms, ranging each item from 1 (= completely true) to 5 (= completely false). Since there was no validated TRIG version in European Portuguese, either the English or Brazilian Portuguese version will be adapted to European Portuguese. Similarly, the TRIG will be translated into Dutch. All scales can be found in Appendix.

The Grief Risk Assessment Instrument (GRAI), a checklist for prolonged grief risk factors and PG-13 will also be used in Portugal, seeing that they constitute standard procedure and are part of the usual care, as recommended by a national clinical guideline (NOC 003/2019). Both participants of standardised LEAVES and usual care arms will receive usual care. This usual care ranges from giving out information on grief and some basic support (universal intervention) to referring participants to grief-unspecialized support (selective intervention) or even to specialized grief appointments (indicative intervention) when necessary. Said referral will be based on the GRAI score (≥10 points) at t0 (when the intervention starts). In addition to the GRAI, a flyer, developed by the national health system, will be offered to participants. Moreover, a Prolonged Grief Disorder Risk Factors Checklist, along with the PG-13 measure, will also be used.

Table 9.Primary clinical outcomes

Country	Measure	Measurement time
	Grief symptoms	
The Netherlands	TRIG	t0, t1, t2
Switzerland	TRIG	t0, t1, t2
Portugal	TRIG	t0, t1, t2
	GRAI + PGD Checklist	t0
	PG-13	t0, t1, t2

Depression and loneliness

The secondary outcome measures consist of measures for depression and loneliness. Depression will be assessed with the PHQ-9.

Loneliness will be assessed with the De Jong Gierveld short scale for emotional and social loneliness or the UCLA Loneliness scale (ULS).

Table 10.Secondary clinical outcome measures

Country	Measure	Measurement time
	Depression symptoms	
The Netherlands	PHQ-9	t0, t1, t2
Switzerland		
Portugal		
	Loneliness	
The Netherlands	De Jong Gierveld short scale for emotional and social loneliness	t0, t1, t2
Switzerland		
Portugal	UCLA Loneliness scale (Original)	t0, t1, t2

Mediators and Moderators and Other Variables

Mediators, moderators, and context variables are described in the following tables. Mediators will be mainly assessed in Switzerland. Adherence, completion as well as data on the duration and the intensity of the use of the self-help intervention are collected within the LEAVES platform.

Table 11.Mediators for clinical evaluation

Country	Measure	Measurement time
Switzerland	**Session Outcomes**	
	LEAVES self-reflection items	Between t0 and t1 After each submodule and module.
	Working alliance	
	WAI (Task and Goals dimension)	Between t0 and t1 W2, W5, W8, W10
	Adherence measures	
	Completion of modules of submodules	Between t0 and t1 All data collected
	Date of visited page,	Between t0 and t1 All data collected
	Number of logins	Between t0 and t1 All data collected

Table 12.Moderators and other variables

Country	Measure	Measurement time
	Demographics	
The Netherlands **Switzerland** **Portugal**	Age Gender Education	t0
	Loss details	
The Netherlands **Switzerland** **Portugal**	Time since loss	t0
	Health Variables	
Portugal	Overall self-rated health	t0, t1, t2

4.6.3 Technology acceptance and cost effectiveness measures

Measures for the technology acceptance study – The Netherlands

In the Netherlands, where the primary focus of the evaluation will be on technology acceptance, it will be used (in addition to the demographic questions and primary and secondary outcomes) measurement scales for the following factors.

- Perceived usefulness (self-devised) at t0
- Effort expectancy (based on de Veer, et al., 2015) at t0
- Usability (based on Holden, 2020]) at t0,5 and t1
- User experience, using the Attrakdiff instrument (Papachristos, E., 2019) at t0,5 and t1
- Acceptance (self-devised at t1)
- Effort (based on de Veer, et al., 2015) at t1

Additionally, at T1, we will add open questions to assess the following:

- Use and appreciation of monitoring and escalation in LEAVES
- Critical incidents

Finally, at T2, we will conduct focus groups with end-users and care professionals with the following goals:

- Understand how end users/care professionals have perceived the use of the tool during the last 10 weeks. Focusing on the following topics:
  - o Usability
  - o Technical acceptance
- Understand which elements of the tool need improvement
- Understand how end users/care professionals perceive a potential use of LEAVES in their working routines tool during their daily life

Measures of technology acceptance – Switzerland, Portugal

In Switzerland and in Portugal, technology acceptance will be assessed by the variable Satisfaction with the self-help programme with measure ZUF-8, at t1.

4.6.4 Cost-effectiveness measure

Table 13.Overview of the measurement for the cost effectiveness analysis

Country	Measure	Measurement time
	Willingness to pay	
The Netherlands	How much would you be willing to pay for a service like LEAVES? 5-10€, 11-30€ or 31-60€ per month	t1
Switzerland		
Portugal		

4.6.5 Qualitative study on barriers and facilitators to use LEAVES (Portugal)

In Portugal, an additional qualitative study will be conducted to assess the barriers and facilitators to implementation, adoption, and engagement with the LEAVES online intervention. This study will be conducted separately with primary and secondary end-users (health care professionals). Topic guided interviews will be developed using the COM-B Model (Michie et al, 2013) approach to assess barriers and facilitators in relation to aspects of Competence, Opportunity, and Motivation to use the LEAVES online intervention. Thematic saturation will be used to determine the sample sizes, with a minimum of 10 interviews planned with each sample.

5 Data collection, data management and analyses

Data will be assessed using online questionnaires programmed in REDCap or Qualtrics (Qualtrics, Provo, UT). Data integrity is enforced through a variety of mechanisms, i.e., referential data rules, valid values, range checks, and consistency checks. The option to choose a value from a list of valid codes and a description of what each code means will be available where applicable. Checks are applied at the time of data entry into a specific field. In addition, data on the use of the self-help sessions are collected within the platform. All data will be saved in an anonymous

manner, only identified by a code which is not related to the participant's identity. Data will be divided over three databases, one anonymized database containing data entered by the user into the platform (e.g., exercises), one anonymized database containing usage data logs, and one database that contains personal identifiers and the link to the internal anonymized identifier. After the end of the study, the last database will be deleted so that the complete data set is anonymous. The platform and all data will be stored at ISO 27001 certified servers and will make use of secured connections. In Switzerland, the informed consent and the case report form will be stored in REDCap. All involved researchers at RRD are certified at Good Clinical Practice. All data will be treated according to the guidelines of Dutch law and good clinical practices of the Swiss Federal Act on Research involving Human Beings. Only the researchers directly involved in the study will have access to the data.

5.1 Statistical analyses

Analyses will be conducted according to the intention-to-treat paradigm. Firstly, we will analyse the extent of missing data, explore the missing data patterns, and determine the type of missing data (Missing Completely at Random, Missing at Random, Not Missing at Random). If the missing mechanism is Missing at Random, we will use multilevel mixed-effects regression analyses which allow a different number of measurement points per participants and are thus less sensitive to missing data.

Multilevel mixed-effects models with repeated measures data will be conducted in SPSS to evaluate the efficacy of the intervention and the stability of the effects. Restricted maximum likelihood (REML) estimation will be used, which is recommended for small group samples and yields asymptotically efficient estimators for balanced and unbalanced designs. Mixed-effects model have several advantages. They take into account the dependency of the data and account for the correlation of the repeated measures within individuals. Furthermore, mixed-effects models use all available data of each participant and estimates parameter of missing values. Single models for each outcome variable will be computed. The pre-post comparisons of all outcome measures will include time as a within-group variable, the condition as a between-group variable and an interaction term time by group for cross-level interactions. To test the stability of the effects from post-treatment to follow-up, only time will be included as within-group factor in the mixed-effects models. Cohens *d* will be

calculated as effect size for all observed outcome variables. Furthermore, a Reliable Change Index will be computed as measure of clinical change. To analyse the longitudinal interplay of predictor variables and test the mediation analyses, we will conduct structural equation models. Analyses will be conducted in SPSS and Mplus.

With respect to the technology acceptance data, all rating scales will be checked for reliability (Cronbach's alpha) and multicollinearity (correlation analysis). Results will be reported on scale averages, as well as multiple two-way correlations. In order to explain acceptance, backward regression analysis will be conducted. All qualitative data will be analysed thematically, following the guidelines by Braun and Clarke (Braun & Clark, 2006, while reporting will be done according to the Coreq standards (Tong, et al., 2007).

5.2 Cost-effectiveness analysis

We will estimate the incremental cost-effectiveness ratio (ICER) of the intervention, in terms of cost per point-improvement in the grief scale. We will also look at depression and loneliness (secondary outcomes) and estimate ICERs using improvements in the depression or loneliness scales in the denominator.

$$ICER = \frac{Cost\ of\ delivering\ the\ intervention}{Total\ improvements\ in\ grief\ symptoms}$$

We will adopt a provider perspective, taking into account, in the numerator, the costs borne by the provider of the intervention. We will also consider both technological (equipment costs, cost of using the platform) and human costs (training, time spent by staff delivering the intervention) associated with providing the intervention. The analyses described in the previous section will provide the necessary inputs for the ICER denominators (i.e., effect of the intervention in terms of grief improvements). These analyses will be conducted separately by country, as the costs involved differ. Results from these analyses will also inform the business models.

6 Ethics

The study protocol for Switzerland will be submitted to the Cantonal Ethics Committee of Northwestern and Central Switzerland. In the Netherlands, the study protocol will be submitted to the Medical Ethical Committee Arnhem-Nijmegen. In Portugal, the study protocol will be submitted to ULSBA's medical ethical committee to assess the scientific content and compliance with applicable research on human subjects' regulations. These ethics committees will also be informed if important protocol modifications occur.

Informed consent to participate in the study as primary end-users will be provided by the mourners. Additionally, informed consent to complete the measures focused on the informant reports will be provided by secondary end-users, if it is possible to link relatives or close friends to the respective primary end-users.

Informed consent will be given by the study participants after the study has been explained. LEAVES study will be conducted, in each implementation country, in line with the Declaration of Helsinki and no participants will be randomised unless a written informed consent is available for that participant. Participants can withdraw from the trial at any time and will be informed and assured of such right. This study follows the principles of data protection and management described in the EU's General Data Protection Regulation (GDPR).

7 Discussion

The results of this study will provide insights into the acceptability and efficacy of online self-help interventions directed at older adults who are suffering from grief symptoms, psychological distress, or adjustment problems in daily life after spousal bereavement, as well as insights into prevention of prologued grief. Specifically, findings will add to the existing knowledge by 1) evaluating an interactive dialogue-based online intervention specifically designed for spousal bereavement and its consequences; 2) testing whether a personalised, self-tailored version leads to better clinical outcomes then a standardised version; 3) suggesting adaptations to improve the efficacy of the intervention, selective indication and adaptations for different needs; and 4) which mediators' and moderators' impact the success of the intervention. Strengths and limitations of the proposed program will be discussed considering the

need for guidelines for self-help online interventions for an older population. Results of our cost-effectiveness analysis will be examined to inform tailored business models and marketing strategies, ensuring the proposed product can effectively reach our target audience.

Comparisons across implementation countries will provide higher insights on the efficacy of LEAVES in different contexts, enable specific analysis on the acceptability of the proposed technology, and provide further knowledge about the potential generalization of LEAVES to a broader audience. The analysis of other moderator variables may further aid future selective indication and adaptations for different needs. Results will also be analysed under a health economics perspective.

Limitations of this study include the self-selectivity of the sample. It may be possible that older adults who are willing to take part in an online self-help intervention have more cognitive resources and a higher education level. Although this may compromise the generalization of the results to a broad population of older adults, the focus groups included in technology acceptance study conducted in The Netherlands will provide important insights on users' skills and difficulties while using LEAVES, ultimately, contributing to overcome this potential limitation,

Results of the study will be presented in scientific journal articles and conferences and will be disseminated to the general population using the project's website and other media channels, such as the project's twitter account and online newsletters.

8 Declarations

8.1 Competing interests

ULSBA, UNL, SSW, UoB, DELA and NFE have no conflicting interests to declare. RRD is a commercial company and one of the developers of the LEAVES service. It has the aim to bring LEAVES to the market.

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Symbols, abbreviations and acronyms

AAL	Active Assisted Living
D	Deliverable
DELA	DELA Natura- en levensverzekering N.V.
EC	European Commission
M	Month
NFE	National Foundation for the Elderly
NTH	Nothing AG
RRD	Roessingh Research and Development
SFT	Sensing Future Technologies
SSW	School of Social Work, University of Applied Sciences and Arts, Olten
T	Task
ULSBA	Local Health Unit of Baixo Alentejo, chiefly its Psychiatric Service.
UNL	NOVA University of Lisbon
UoB	University of Bern
WP	Work Package
GDPR	General Data Protection Regulation
RA	Risk assessment
M	Monitoring
DSM	Diagnostic and Statistical Manual of mental disorders
TRIG	Texas Revised Inventory of Grief
CBT	Cognitive Behavioural Therapy
iCBT	Internet-based Cognitive Behavioural Therapy
ULS	UCLA Loneliness Scale
ZUF-8	Questionnaire to evaluate patient satisfaction

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A. Risk Assessment (RA) & Monitoring (M) (NL, CH, PT)

B. Clinical outcomes

Primary outcome – Grief symptoms (ND, CH, PT)

Texas revised inventory of grief (TRIG)

Past feelings

	Completely False	Mostly False	True and False	Mostly True	Completely True
1. After this person died I found it hard to get along with certain people	1	2	3	4	5
2. I found it hard to work well after this person died	1	2	3	4	5
3. After this person's death I lost interest in my family, friends, and outside activities.	1	2	3	4	5
4. I felt a need to do things that the deceased had wanted to do.	1	2	3	4	5
5. I was unusually irritable after this person	1	2	3	4	5
6. I couldn't keep up with my normal activities for the first 3 months after this person died.	1	2	3	4	5
7. I was angry that the person who died left me.	1	2	3	4	5
8. I found it hard to sleep after this person died	1	2	3	4	5

Present feelings

	Completely False	Mostly False	True and False	Mostly True	Completely True
1. I still cry when I think of the person	1	2	3	4	5
who died.	1	2	3	4	5
2. I still get upset when I think about the person who died.	1	2	3	4	5
3. I cannot accept this person's death.	1	2	3	4	5
4. Sometimes I very much miss the person who died.	1	2	3	4	5
5. Even now it's painful to recall memories of the person who died.	1	2	3	4	5
6. I am preoccupied with thoughts (often think) about the person who died.	1	2	3	4	5
7. I hide my tears when I think about the person who died.	1	2	3	4	5
8. No one will ever take the place in my life of the person who died.	1	2	3	4	5
9. I can't avoid thinking about the person who died.	1	2	3	4	5
10. I feel it's unfair that this person died.	1	2	3	4	5
11. Things and people around me still remind me of the person who died.	1	2	3	4	5
12. I am unable to accept the death of the person who died.	1	2	3	4	5
13. At times I still feel the need to cry for the person who died.	1	2	3	4	5

Secondary Outcome – Depression Symptoms

Patient Health Questionnaire-9 (PHQ-9) (NL, CH)

Over the last 2 weeks, how often have you been bothered by any of the following problems?

(Use "✔" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all __

Somewhat difficult __

Very difficult __

Extremely difficult __

Secondary outcomes – Loneliness

De Jong Gierveld Loneliness Scale - Short Version (NL, CH)

	None of the time	Rarely	Some of the time	Often	All of the time
1 I experience a general sense of emptiness	1	2	3	4	5
2 I often feel rejected	1	2	3	4	5
3 I miss having people around	1	2	3	4	5
4 There are plenty of people I can rely on when I have a problem	1	2	3	4	5
5 There are many people I can trust completely	1	2	3	4	5
6 There are enough people I feel close to	1	2	3	4	5

UCLA Loneliness Scale – Short (6 items for cross cultural comparison) (ULS-6) (P)

	Never	Rarely	Sometimes	Always
1 I felt in tune with the people around me	1	2	3	4
2 I lacked companionship	1	2	3	4
3 I felt left out	1	2	3	4
4 I could find companionship when I wanted it	1	2	3	4
5 There were people who really understood me	1	2	3	4
6 People were around me but not with me	1	2	3	4

Loneliness - UCLA Loneliness Scale (ULS) – Long version (20 items) (PT)

	Never	Rarely	Sometimes	Always
1 I felt in tune with the people around me	1	2	3	4
2 I lacked companionship	1	2	3	4
3 There was no one I can turn to	1	2	3	4
4 I did not feel alone	1	2	3	4
5 I felt part of a group of friends	1	2	3	4

6 I had a lot in common with the people around me	1	2	3	4
7 I was no longer close to anyone	1	2	3	4
8 My interests and ideas were not shared by those around me	1	2	3	4
9 I was an outgoing person	1	2	3	4
10 There were people I feel close to	1	2	3	4
11 I felt left out	1	2	3	4
12 My social relationships were superficial	1	2	3	4
13 No one really knew me well	1	2	3	4
14 I felt isolated from others	1	2	3	4
15 I could find companionship when I wanted it	1	2	3	4
16 There were people who really understood me	1	2	3	4
17 I was unhappy being so withdrawn	1	2	3	4
18 People were around me but not with me	1	2	3	4
19 There were people I could talk to	1	2	3	4
20 There were people I could turn to	1	2	3	4

C. Mediators of clinical evaluation

Session Outcomes (NL, CH, PT)

	Not at all	No	Rather not	Neither	Rather yes	Yes	Yes, exactly
1. Overall, this was helpful.							
2. I can better feel my strengths now.							
3. Now, I am able to cope with situation I was not able to cope before.							
4. I understand myself and my problems better now.							
5. This content matched my current needs.							

Working alliance (CH)

WAI-I items (Task & Goals dimension)

1. With LEAVES, it has become clearer to me how I can change.

2. What I am doing with LEAVES gives me new ways of looking at my problems.

3. I knew what to expect as a result of using LEAVES.

4. The goals of LEAVES are in line with my goals.

5. The goals of LEAVES are important goals for me.

6. I feel that what I am doing in LEAVES will help me to accomplish the changes that I want.

7. Working with LEAVES helps to establish a good understanding of the kind of changes that would be good for me.

8. I believe the way LEAVES is working with my problem is correct.

Satisfaction with treatment

ZUF-8 Questionnaire to evaluate patient satisfaction

How would you rate the quality of the treatment you received? excellent (1)
Excellent (1)
Good (2)
Not so good (3)
Poor (4)

Did you receive the kind of treatment you wished for?
Not at all (1)
Not really (2)
Mostly yes (3)
Absolutely yes (4)

How much did our hospital meet your individual needs?
It met almost all my needs (1)
It met most of my needs (2)
It met only some of my needs (3)
It didn´t meet my needs (4)

Would you recommend our hospital to your friends if they would require similar help?
Not at all (1)
I don´t think so (2)
Maybe I would (3)
Yes, absolutely (4)

How satisfied have you been with the extend of help you received?
Reasonably unsatisfied (1)

Slightly unsatisfied/fairly satisfied (2)
Mainly satisfied (3)
Completely satisfied (4)

Did the treatment you received help you improve your coping strategies?
Yes, a lot (1)
Yes, a little (2)
No, not really (3)
It made things even more complicated (4)

How satisfied have you been in general with the treatment you received?
Very satisfied (1)
Mostly satisfied (2)
Fairly satisfied/moderately unsatisfied (3)
Unsatisfied (4)

Would you return to our hospital, should you need help again?
Not at all (1)
I don´t think so (2)
Maybe I would (3)
Yes, absolutely (4)

D. Other clinical measures (Portugal)

GRAI

	Risk factor	Indications	Score
1	Anger	None Mild irritation Moderate (occasional outbursts) Severe (spoiling relationships) Extreme (always bitter)	1 2 3 4 5
2	Blame/guilt, feeling bad and or responsible for something	None Mild (vague and general) Moderate (some clear thoughts of blame, etc) Severe (preoccupied with self blame) Extreme (major problem)	1 2 3 4 5
3	Current relationships	Close, intimate relationship with another Warm, supportive family Family supportive but lives at a distance Doubtful (person uncertain whether others will be supportive) Unsupportive	1 2 3 4 5
4	How will the key person cope?	Well (normal grief and recovery without help) Fair (probably get by without specialist help) Doubtful (may need specialist help) Badly (requires specialist help) Very badly (requires urgent help)	1 2 3 4 5
Complete a separate form for each person at risk			**Total:**
A = ABSENT Low risk (score less then 7)		**Provide local brochure/information as available**	
C = CAUTION Moderate risk (score 7–9)		**Give a copy of your bereavement brochure and suggest contacting one of the local support agencies (see over)**	
E = EXTRA HELP FROM SPECIALIST SUPPORT RECOMMENDED High risk (score 10 or more)		**Encourage the person to contact a specialist health care professional eg, GP, counsellor or hospice bereavement service Give a copy of your bereavement brochure**	

Prolonged Grief Disorder Risk Factors Checklist

(https://www.dgs.pt/directrizes-da-dgs/normas-e-circulares-normativas/norma-n-0032019-de-23042019-pdf.aspx)

	Yes/No	Remarks
Personal Factors		
Female Gender		
Young age of deceased		
Old age of bereaved person		
Psychiatric background		
Previous suicide attempts and/or suicidal ideation		
Substance use		
Unresolved past bereavements		
Insecure attachment style		
Persistent denial/avoidant coping/rumination		
Intense guilt/anger manifestations		
Inability to make sense of the loss		
Neuroticism		
Interpersonal Factors		
Loss of children/spouse		
Highly dependent relationship		
Conflicted relationship		
Conflicted/ambivalent relationship		
Lack of socio-familial support		
Unresolved family crises		
Unfinished projects/pending affairs		
Inability to carry out religious/spiritual rituals		
Circumstantial Factors		
Sudden death		
Violent death /suicide, homicide, or accident)		
Multiple loss		
Subjective feeling of unpreparedness for the passing		
Primary carer for the patient		
Lack of symptom control		
Dysfunctional relationships with healthcare workers		
Perceived deterioration and disfigurement of the patient		
Caregiver burnout		
Minors present in the family		
Economic issues		

PG-13

(https://endoflife.weill.cornell.edu/sites/default/files/pg-13.pdf)

PART I INSTRUCTIONS: FOR EACH ITEM, PLACE A CHECK MARK TO INDICATE YOUR ANSWER.

1. In the past month, how often have you felt yourself longing or yearning for the person you lost?

_____ 1= Not at all
_____ 2 = At least once
_____ 3 = At least once a week
_____ 4 = At least once a day
_____ 5 = Several times a day

2. In the past month, how often have you had intense feelings of emotional pain, sorrow, or pangs of grief related to the lost relationship?

_____ 1= Not at all
_____ 2 = At least once
_____ 3 = At least once a week
_____ 4 = At least once a day
_____ 5 = Several times a day

3. For questions 1 or 2 above, have you experienced either of these symptoms at least daily and after 6 months have elapsed since the loss?

_____ No
_____ Yes

4. In the past month, how often have you tried to avoid reminders that the person you lost is gone?

_____ 1= Not at all
_____ 2 = At least once
_____ 3 = At least once a week
_____ 4 = At least once a day
_____ 5 = Several times a day

5. In the past month, how often have you felt stunned, shocked, or dazed by your loss?

_____ 1= Not at all
_____ 2 = At least once
_____ 3 = At least once a week
_____ 4 = At least once a day
_____ 5 = Several times a day

Overall self-rated health

In general, how would you rate your health?

1. Excellent
2. Very Good
3. Good
4. Fair
5. Poor

E. Technology Acceptance

T0 (NL)

Expectations of technology

Perceived usefulness (5-point Likert scale from 1 (totally disagree) to 5 (totally agree)):

1. Using LEAVES will be beneficial to me
2. LEAVES will help me during my grieving period
3. LEAVES will help me to process the loss of my partner
4. LEAVES will be the guide in my grieving process

Effort expectancy[1] (5-point Likert scale from 1 (totally disagree) to 5 (totally agree)):

Using LEAVES will:

1. Be easy to learn
2. Fit easily into my daily routine
3. Be easy to do

T1 (NL)

Use/appreciation of monitoring and escalation

1. Did you make use of the option to monitor how you are doing?

Yes / No (if no, skip remaining questions and go to Usability)

2. How often did you complete the monitoring questions?

Once, 1-3 times, 3 -10 times, >10 times

3. Did LEAVES give you the advice to contact a care professional or relative or friend?

Yes / No (if no, skip remaining questions and go to next survey)

4. Did you follow this advice?

Yes / No / Sometimes

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[1] Scale based on: de Veer, A.J.E., Peeters, J.M., Brabers, A.E. *et al.* Determinants of the intention to use e-Health by community dwelling older people. *BMC Health Serv Res* **15,** 103 (2015). https://doi.org/10.1186/s12913-015-0765-8

5. Why?

[open answering field]

6. Did you feel comfortable with LEAVES assessing whether you need additional help from a professional?

Yes / No / Somewhat

7. Why?

[open answering field]

8. Did you think that the monitoring function of LEAVES infringed upon your privacy?

Yes / No / Somewhat

9. Why?

[open answering field]

Usability2

(5-point Likert scale from 1 (totally disagree) to 5 (totally agree))

1. I would use LEAVES frequently
2. LEAVES is too complex for me
3. LEAVES was easy to use
4. I really need help from someone to use LEAVES
5. The various parts of LEAVES were well integrated
6. LEAVES was confusing for me
7. Learning to use LEAVES was quick for me
8. LEAVES was hard to use
9. I felt confident using LEAVES
10. I will need to learn a lot before using LEAVES

[2] Scale based on: Holden, R. J. (2020, September). A simplified system usability scale (SUS) for cognitively impaired and older adults. In Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care (Vol. 9, No. 1, pp. 180-182). Sage CA: Los Angeles, CA: SAGE Publications.

UX

Attrakdiff short user experience scale[3]

5 point semantic scale.

Pragmatic Quality

PQ1: confusing – structured

PQ2: impractical – practical

PQ3: unpredictable – predictable

PQ4: complicated – simple

Hedonic Quality

HQ1: dull – captivating

HQ2: tacky – stylish

HQ3: cheap – premium

HQ4: unimaginative – creative

Critical incidents

1. If you look back to the past time in which you have been using LEAVES, can you describe the moments at which you found LEAVES particularly helpful?
2. If you look back to the past time in which you have been using LEAVES, can you describe the moments at which you found LEAVES particularly unhelpful?

T2 (NL)

Usability

(5-point Likert scale from 1 (totally disagree) to 5 (totally agree))

1. I would use LEAVES frequently
2. LEAVES is too complex for me
3. LEAVES was easy to use
4. I really need help from someone to use LEAVES
5. The various parts of LEAVES were well integrated
6. LEAVES was confusing for me
7. Learning to use LEAVES was quick for me

[3] Based on: Papachristos, E. (2019). Assessing the performance of short multi-item questionnaires in aesthetic evaluation of websites. Behaviour & Information Technology, 38(5), 469-485.

8. LEAVES was hard to use
9. I felt confident using LEAVES
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UX

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HQ4: unimaginative – creative

Acceptance

Perceived usefulness (5-point Likert scale from 1 (totally disagree) to 5 (totally agree)):

1. Using LEAVES will be beneficial to me
2. LEAVES will help me during my grieving period
3. LEAVES will help me to process the loss of my partner
4. LEAVES will be the guide in my grieving process

Effort (5-point Likert scale from 1 (totally disagree) to 5 (totally agree)):

Using LEAVES:

1. Was easy to learn
2. Fitted easily into my daily routine
3. Was easy to do

Focus group with care professionals

General instructions for the focus group moderator

(Create a save atmosphere and introduce some ground rules)

- Explain about the project and the end product we want to develop;
- Explain that we want to learn more about the process people go through when using the tool, we want to get insight into the user experience in order to further improve the service;
- Explain why they are an interesting participant for the focus group;
- Explain that the focus group will be recorded to be able to listen to it again for clarification;
- Explain that the focus group results are confidential and responses will be anonymized;
- There are no wrong or right answers, we just want to get insight into your user experiences;
- Are there any further questions? Okay we will start now;

Interview techniques for the moderator

The research questions you find here serve as a guide. You do not literally need to ask each question in a static manner and go on to the next. The most important thing is that the topics have been covered. The focus group should be a fluid and dynamic group conversation in which participants share their experiences and are given space to respond to each other and exchange those experiences.

If you find some interesting topics, taken the time to ask about it in more detail, also when a topic is brought of that you did not think of in advance. Make sure to have the flexibility to dive into it, when it provides you with interesting insights in the user experience. Try to go into dept. Question that can help to dive deeper into the subject are the*: Why, When, Where, How, How often* - questions. This is how you get more detailed and precise information on the topic. Also asking sequential 'why' questions can help you to find out the intrinsic motivations and reasons behind participants actions. For example: *And why did/(n't) you do that? Why is that important for you?* Ask open ended questions and avoid being suggestive.

<u>Concerning all questions, ask follow up in-dept questions like:</u>

- *How was this for the others?*
- *Did you have a similar of different experience?*
- *Is there anybody who would like to add something on this topic/ comment on this?*
- *Have we covered everything?*

For the process it can be useful to have one moderator, the person who solely focused on guiding the conversation, bringing the research questions into the conversation and the (group) process. It can be valuable to have a second moderator supporting the process by keeping an eye on the timelines, handing out materials, preparing coffee and tea etc.

	Activity	Questions	Materials	Time
1	Welcome		Preparation: - Check the audio settings of your audio recorders and	1

			test them. - Check whether you have all materials - Make sure there is someone to receive the participants - Coffee/tea	
2	Obtaining permission for audio recording		- Try to explain the informed consent during the kick-off meeting to save time during this focus group. - Informed consent form - Pen	1
3	Turn on audio/video recorders		2x Audio recorder (if you use 1, you will always see batteries run out, it doesn't record correctly) or an audio recorder and video recorder	1
4	**Project presentation**	Welcome and thank the participants for joining the session. 1. Explain LEAVES and mention the practical information 2. Mention that we want to learn from them and understand how they feel about using the tool of Leaves Explain that this is a confidential environment where their views, thoughts and feelings are valued. Nothing that will be said in this focus group will be shared with others (without being anonymized).		2

5	**Explain the goal of the focusgroup**	**Goals**
		- Find out how care professionals have perceived the use of the tool during the last 10 weeks. Focussing on the following topics :
		  ○ **Usability**
		  ○ **Technical acceptance**
		- Find out which elements of the tool need improvement
		- Find out if care professionals are positive on the tool
		- Find out if they feel the tool can be blended with their treatment
				5

6	**Warming-up & introduction**	Let people get to know each other by using one of these tools / questions : • Could you introduce yourself? • Could you also tell which module of Leaves you found most interesting / helpful ?		10
7	**General impression**	You have now used Leaves for over 10 weeks: 1. Can you give us your general impression of the tool? 2. What do you like / what don't you like? 3. Did you experience any problems/barriers?	**Open discussion** – make sure everyone is heard	15
8	**Usability**	1. How easy/difficult did you find using LEAVES? 2. Do you think your clients would need help using the tool? Additional questions if these elements are not yet answered by the first three questions : - Could you elaborate on how logical or cumbersome the tool seemed to you?	**Open discussion** – make sure everyone is heard	10
9	**(TAM) Enjoyment**	1. Do you find using the tool pleasant / interesting ? Why/why not?	**Open discussion** – make sure everyone is heard	5

10	**(TAM) Online vs Offline**	1. Did you miss the connection with a real person? 2. Do you think that this tool can be used as a stand alone tool?		5
11	**(TAM) Control & trust**	*Control* 1. Do you think your clients would be able to feel in control when using the tool? 2. Would your clients prefer self-tailored or guided/sequential? 3. Did you like that you could choose which module to work on? *Trust* 1. Do you feel that the tool creates a safe space? Why/why not? 2. Do you think your clients would trust this tool?	**Open discussion** – make sure everyone is heard	10
12	**(TAM) Perceived Usefulness**	1. Do you think that the tool meets the needs of your clients? 2. In what way does the tool supports/improves the needs of your clients during this time of grief?	**Open discussion** – make sure everyone is heard	5
13	**Blended treatment**	1. Do you think that LEAVES is a contribution to your service? Why? 2. Do you think that LEAVES can be added to your service? How?		10
14	**Intention to use**	1. Would you recommend this tool to others? 2. Would you refer your clients to this tool?	**Open discussion** – make sure everyone is heard	5
15	**Closure** Thank the participants and ask them one last question.	From what you all said and heard, what do you think is the greatest benefit of the Leaves tool during a grieving process?		5

		This is the end of the focus group and with that, also the end of this pilot study. Do you have any other comments or questions? Is there something you believe we have not addressed that we should discuss? I want to thank you so much for taking the time and effort to partake in this study! Give gift (cake/present/etc.)		
16	**Total**			90

Focus groups with mourners

General instructions for the focus group moderator

(Create a save atmosphere and introduce some ground rules)

- Explain about the project and the end product we want to develop;
- Explain that we want to learn more about the process people go through when using the tool, we want to get insight into the user experience in order to further improve the service;
- Explain why they are an interesting participant for the focus group;
- Explain that the focus group will be recorded to be able to listen to it again for clarification;
- Explain that the focus group results are confidential and responses will be anonymized;
- There are no wrong or right answers, we just want to get insight into your user experiences;
- Are there any further questions? Okay we will start now;

Interview techniques for the moderator

The research questions you find here serve as a guide. You do not literally need to ask each question in a static manner and go on to the next. The most important thing is that the topics have been covered. The focus group should be a fluid and dynamic group conversation in which participants share their experiences and are given space to respond to each other and exchange those experiences.

If you find some interesting topics, taken the time to ask about it in more detail, also when a topic is brought of that you did not think of in advance. Make sure to have the flexibility to dive into it, when it provides you with interesting insights in the user experience. Try to go into dept.

Question that can help to dive deeper into the subject are the*: Why, When, Where, How, How often* - questions. This is how you get more detailed and precise information on the topic. Also asking sequential 'why' questions can help you to find out the intrinsic motivations and reasons behind participants actions. For example: *And why did/(n't) you do that? Why is that important for you?* Ask open ended questions and avoid being suggestive.

Concerning all questions, ask follow up in-dept questions like:

- *How was this for the others?*
- *Did you have a similar of different experience?*
- *Is there anybody who would like to add something on this topic/ comment on this?*
- *Have we covered everything?*

For the process it can be useful to have one moderator, the person who solely focused on guiding the conversation, bringing the research questions into the conversation and the (group) process. It can be valuable to have a second moderator supporting the process by keeping an eye on the timelines, handing out materials, preparing coffee and tea etc.

	Activity	Questions	Materials	Time
1	Welcome		Preparation: - Check the audio settings of your audio recorders and test them. - Check whether you have all materials - Make sure there is someone to receive the participants - Coffee/tea	1
3	Obtaining permission for audio recording		- Try to explain the informed consent during the kick-off meeting to save time during this focus group. - Informed consent form - Pen	1

4	Turn on audio/video recorders		2x Audio recorder (if you use 1, you will always see batteries run out, it doesn't record correctly) or an audio recorder and video recorder	1
5	**Project presentation**	Welcome and thank the participants for joining the session. 3. Explain LEAVES and mention the practical information 4. Mention that we want to learn from them and understand how they feel about using the tool of Leaves Explain that this is a confidential environment where their views, thoughts and feelings are valued. Nothing that will be said in this focus group will be shared with others (without being anonymized).		2
6	**Explain the goal of the focusgroup**	**Goals** - Find out how end users have perceived the use of the tool during the last 10 weeks. Focussing on the following topics : o **Usability** o **Technical acceptance** - Find out which elements of the tool need improvement - Find out if end users are positive on using the tool during their daily life		5
7	**Warming-up & introduction**	Let people get to know each other by using one of these tools / questions : • Could you introduce yourself. Name, where you from *and who you lost* ? • Could you also tell which module of Leaves you found most interesting / helpful ?		10

8	**General impression**	You have now used Leaves for over 10 weeks: 4. Can you give us your general impression of the tool? 5. What do you like / what don't you like? 6. Did you experience any problems/barriers?	**Open discussion** – make sure everyone is heard	15
9	**Usability**	3. How easy/difficult did you find using LEAVES? 4. Could you describe how you got yourself familiar with how to use the platform? Additional questions if these elements are not yet answered by the first three questions : - Did you feel you needed support or could you master it on your own? - Could you elaborate on how logical or cumbersome the tool seemed to you?	**Open discussion** – make sure everyone is heard	10
10	**(TAM) Enjoyment**	2. Do you find using the tool pleasant / interesting ? Why/why not?	**Open discussion** – make sure everyone is heard	5
11	**(TAM) Online vs Offline**	3. Did you miss the connection with a real person?		5
12	**(TAM) Control & trust**	*Control* 4. Did you feel in control when using the tool? Why/why not? 5. Did you like that you could choose which module to work on? 6. Would you prefer that the tool guides you through the modules? *Trust* 3. Do you feel that the tool creates a safe space? Why/why not?	**Open discussion** – make sure everyone is heard	10

13	**(TAM) Perceived Usefulness**	3. Does the tool meet your needs in this time of grief? 4. In what way does the tool supports/improves your needs during this time of grief?	**Open discussion** – make sure everyone is heard	10
14	**Intention to use**	3. Would you recommend this tool to others? 4. What would you be willing to pay?	**Open discussion** – make sure everyone is heard	10
15	**Closure** Thank the participants and ask them one last question.	From what you all said and heard, what do you think is the greatest benefit of the Leaves tool during a grieving process? This is the end of the focus group and with that, also the end of this pilot study. Do you have any other comments or questions? Is there something you believe we have not addressed that we should discuss? I want to thank you so much for taking the time and effort to partake in this study! Give gift (cake/present/etc.)		5
16	**Total**			90

F. Cost-effectiveness analysis

Willingness to pay (NL, CH, PT)

How much would you be willing to pay for a service like LEAVES? 5-10€, 11-30€ or 31-60€ per month