

# BMJ Open Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Adults with Prolonged Grief Disorder (PGD): A Study Protocol for a Randomized Feasibility Trial

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## ABSTRACT

**Introduction** Grief is an emotional reaction to the loss of a loved one with a natural recovery. Approximately 10% of people who lose a loved one develop prolonged grief disorder (PGD). Internet-based and computer-based interventions (ie, internet-delivered cognitive-behavioural therapy, iCBT) are a cost-effective alternative that makes it possible to reach more people with PGD. The main aim of this study is to assess the feasibility of a new iCBT—called GROw—for PGD. As a secondary objective, the potential effectiveness of GROw will be explored.

**Methods and analysis** This study is a two-arm feasibility randomised trial. A total of 48 adults with PGD who meet the eligibility criteria will be randomised to the experimental group (iCBT: GROw) or the active control group (face-to-face CBT treatment). The treatment is organised sequentially in eight modules in the iCBT format and 8–10 sessions in the face-to-face format, and both formats have the same therapeutic components. There will be five assessment points with qualitative and quantitative evaluations: screening, baseline, after the intervention, 3-month follow-up and 12-month follow-up. Consistent with the objectives, the measures are related to the feasibility outcomes for the main aim of the study (participant adherence, expectations and satisfaction with the treatment, preferences, alliance and utility) and psychological and mental health outcomes for secondary analyses (symptoms of grief, symptoms of depression, symptoms of anxiety, affectivity, quality of life, work and social adaptation, post-traumatic growth, purpose in life, mindfulness and compassion).

**Ethics and dissemination** The Ethics Committee of the Universitat Jaume I (Castellón, Spain) granted approval for the study (CD/002/2019). Dissemination will include publications and presentations at national and international conferences.

**Trial registration number** NCT04462146.

## INTRODUCTION

Grief is an emotional reaction to the loss of a loved one with gradual recovery. During the recovery process, intense feelings of regret and

## Strengths and limitations of this study

- Participants will be randomly assigned to the experimental group (internet-delivered cognitive-behavioural therapy (iCBT)) or active control group (face-to-face treatment).
- Both short-term and long-term follow-up periods (3 and 12 months) are planned.
- Due to the pandemic situation produced by COVID-19, adaptations in the treatment format in the face-to-face control condition could be made.
- Potential effectiveness of iCBT will be assessed by applying within-group changes, and comparisons between iCBT and face-to-face CBT will not be accomplished.

longing are considered natural and usually diminish over time.<sup>1</sup> Unfortunately, 9.8% of the adult non-psychiatric population who suffer a loss develop prolonged grief disorder (PGD).<sup>2</sup> PGD is described by the International Statistical Classification of Diseases and Related Health Problems<sup>3</sup> as a persistent and pervasive grief response characterised by longing for the deceased or persistent preoccupation with the deceased, accompanied by intense emotional pain. In addition, at least 6 months must have elapsed since the death of the loved one to make this diagnosis. Chronically disabling and distressing grieving symptoms are also formally recognised in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5<sup>4</sup>) as persistent complex bereavement disorder (PCBD) within the category of conditions for further study. PCBD is defined as a severe and persistent grief and mourning reaction.<sup>4</sup> The mourning period is not only associated with the risk of developing PGD or PCBD, but it is also associated with the development of



multiple psychological disorders and other physical and psychological symptoms (eg, panic disorder, physical health problems, sleep disturbances, increased use of medications, increased social and work interference).<sup>5–8</sup>

In the past decade, several studies have tested different interventions for grief symptoms and PGD: cognitive-behavioural therapies (CBTs),<sup>9–16</sup> expressive writing therapies,<sup>17–19</sup> group interventions (eg, see works<sup>20–22</sup>) and mindfulness and compassion-based interventions.<sup>23 24</sup> Results from a recent meta-analysis show that psychological interventions are effective for reducing grief symptoms in bereaved adults.<sup>25</sup>

However, most people in need of treatment do not receive any services.<sup>26</sup> The existence of effective psychological treatments does not ensure that these treatments reach the people who need them.<sup>27</sup> Different ways of administering treatments are needed to improve their dissemination and reach a larger number of underserved people.<sup>26 27</sup> Less than 50% of the people who need treatment receive it, even in high-income countries.<sup>28</sup> Therefore, internet-based and computer-based interventions are becoming increasingly popular. These interventions involve greater access to care and less stigma, compared with visiting mental health clinics.<sup>29 30</sup> They are cost-effective and often cheaper than face-to-face interventions.<sup>31</sup> Meta-analytic evidence has shown that internet-based interventions are effective, showing evidence of greater effects compared with control groups, and they are as effective as face-to-face psychotherapy (eg, see previous works<sup>30 32–36</sup>). Particularly, internet-delivered cognitive-behavioural therapy (iCBTs) belongs to the internet-based and computer-based intervention category. In iCBTs, patients log into a secure website to access, read and download online materials organised in a series of lessons or modules.<sup>37</sup> iCBTs are the most widely researched treatment models provided by the internet,<sup>38</sup> and more than 200 randomised controlled trials (RCTs) have been published about them.<sup>34</sup> iCBTs have been shown to be clinically effective compared with controls,<sup>39</sup> and they have a lower rate of negative symptom results than control conditions.<sup>40</sup>

In addition, COVID-19 has made PGD a major public health concern worldwide.<sup>41</sup> The pandemic has produced widespread implementation of social distancing and visitor restrictions in healthcare centres, thus complicating grief problems.<sup>42 43</sup> Recent evidence has pointed out that mental and physical health problems can emerge if the needs of people who experience the loss of a loved one are not addressed.<sup>44</sup> To our knowledge, evidence-based treatments delivered through internet for PGD are not widely available. Therefore, it is vital to promote the development and dissemination of internet-based PGD treatments,<sup>41</sup> and telecommunication-based alternatives are proposed as important components for supporting bereaved people.<sup>43</sup>

To date, there are several internet-based and computer-based interventions for the treatment and prevention of grief symptoms and PGD (eg, see previous works<sup>45–47</sup>),

with promising results in reducing symptoms associated with grief.<sup>48</sup> These studies have used treatment through email<sup>45 47 49</sup> or an online platform.<sup>46 50–52</sup> Despite this, few studies have tested iCBT for PGD. There are some studies on the feasibility, acceptance and usability of traditional face-to-face treatments (eg, see previous works<sup>53–56</sup>), but almost none focus on internet-based and computer-based interventions. Related to this, we found the study by Schladitz *et al*,<sup>57</sup> which evaluates the user acceptance of an internet-based self-help programme for grief and loss in elderly people, showing high user acceptance of the programme. As far as we know, none of these studies, whether feasibility studies or RCTs, has been tested in the Spanish population. For these reasons, an iCBT for PGD—called GROw—was originally developed for the Spanish-speaking population.

## Objectives

The main aim of this study is to investigate the feasibility of an iCBT for people with PGD—GROw—compared with a face-to-face intervention for PGD. Specifically, the objectives are (1) to explore patients views of GROw as a treatment for PGD; (2) to evaluate the expectations and preferences of the treatment in both formats, GROw and face-to-face; (3) to investigate patients' views of the materials and the study design; (4) to assess the satisfaction and acceptability of the treatment; (5) to assess if we can recruit the target population; (6) to explore whether the assessment is too burdensome; (7) to estimate the rate of recruitment and retention to inform the large-scale RCT. Additionally, as a secondary objective the potential effectiveness of GROw will be explored, this is defined as the intragroup changes of symptoms related to PGD from baseline to post-test and follow-ups, and with baseline-post-test being the main comparison.

## METHOD

### Study design and procedure

This study is a two-arm randomised trial testing the feasibility of an iCBT for PGD. The diagnosis of PGD will be based on an interview following the criteria of the ICD-11<sup>58</sup> and a score >25 on the 19-item inventory of CG (ICG).<sup>59 60</sup> Participants who meet the eligibility criteria will be randomly assigned to one of two groups: (1) experimental group (iCBT: GROw); and (2) active control group (face-to-face treatment applied by a therapist). The waiting list control group has already been used in several studies of internet interventions for PGD (eg, see previous works<sup>46 47 52</sup>). For this reason, and to increase the quality of this study, and based on feasibility questions to design future large studies, an active control group will be used. The informed consent form will be signed before randomisation. Five assessment points will be included: diagnosis and inclusion/exclusion criteria (screening), baseline (t1), immediately after the intervention (t2), 3-month follow-up (t3) and 12-month follow-up (t4). In order to promote participant retention in the

treatment and complete follow-up periods, reminders emails will be sent during treatment (eg, to enter the web platform or attend the face-to-face session) and follow-ups. The study was registered in the clinicaltrials.gov database (NCT04462146, 8 July 2020) and will be conducted following the extension of the Consolidated Standards of Reporting Trials (CONSORT) statement for pilot and feasibility studies,<sup>61</sup> the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth guidelines,<sup>62</sup> and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.<sup>63 64</sup>

## Participants

### Eligibility criteria

To participate in the study, participants will meet the following inclusion criteria: (1) age  $\geq 18$  years; (2) having a total score of  $>25$  on the 19-item inventory of CG (ICG)<sup>59 60</sup> and meeting diagnostic criteria for PGD according to the ICD-11; (3) ability to understand and read Spanish; (4) ability to use a computer and having access to the internet; (5) having an email address; and (6) signing an informed consent. Exclusion criteria are as follows: (1) presence of risk of suicide or self-destructive behaviours; (2) presence of another severe mental disorder (ie, substance abuse or dependence, psychotic disorder, dementia or bipolar disorder); (3) presence of severe personality disorder (eg, borderline personality disorder, obsessive-compulsive personality disorder); (4) presence of a medical condition whose severity or characteristics prevent participation in treatment; (5) receiving another psychological treatment during the study; (6) an increase and/or change in the medication during the study period. The medication is evaluated at baseline (t1), after the intervention (t2), at 3-month follow-up (t3) and at 12-month follow-up (t4). Any increase and/or change in the medication during the study period will imply the participant's exclusion from subsequent analyses.

### Sample size

Based on an estimated number of dropouts of 30%<sup>65-67</sup> and considering that the secondary objective is to explore the potential effectiveness defined as the pretest–post-test improvement of symptoms related to PGD, a minimum of 48 participants (24 per group) will be sufficient for the within-group t-test to detect a medium effect size (Cohen's  $d=0.50$ )<sup>68</sup> with a power of 0.80 and an alpha of 0.05. The effect size was defined as the pretest–post-test mean change divided by the SD of change scores. In a review of 50 meta-analyses on the effectiveness of psychological interventions,<sup>69</sup> integrated their average effect sizes, finding a median value of  $d=0.75$ . In place of using this estimate to determine the sample size, and with the purpose of obtaining a more demanding sample size, Cohen's recommendation for a medium effect size of  $d=0.50$  was assumed. G\*Power V.3 software was used to perform power analysis calculations.<sup>70</sup>

## Recruitment and screening

Recruitment will be conducted using professional social networks (ie, LinkedIn) and non-professional social networks (eg, Facebook and Instagram). The study will be announced on the Universitat Jaume I website and other media (eg, local newspapers and radio). Posters will be placed in different nearby places (Universitat Jaume I and Universitat de València). In addition, patients who attend the Emotional Disorders Clinic at Universitat Jaume I may be recruited.

People interested in the study may request participation via email or telephone directed to the specific account/number associated with the project, and an experienced therapist will conduct a telephone assessment to determine whether the inclusion and exclusion criteria are met. During this call, interested participants will also be informed of the study conditions (duration, specific characteristics, etc). After accepting the terms and signing the informed consent, the participants will be randomised, using EPIDAT V.4.2, to the experimental group or active control group by an independent researcher. Participants will be informed of the assigned treatment by phone call. All of them will complete the same evaluation (screening, t1, t2, t3 and t4) through a specific online platform (<https://psicologiaytecnologia.labpsitec.es/>) and phone call interviews. Participants will access the study voluntarily, and they will not receive financial compensation for participating.

## Intervention

### Therapeutic components

Both groups will receive the same therapeutic content, but applied in different formats. The treatment is organised sequentially in eight modules in the online format and 8–10 sessions in the face-to-face format (see table 1). The main therapeutic components are as follows: motivation for change, psychoeducation, behavioural activation, exposure, mindfulness and compassion strategies, integration and restoration of loss, cognitive reappraisal and relapse prevention. This is an adapted version of the original intervention protocol for complicated grief developed by Botella *et al.*<sup>71</sup> This protocol was based on Neimeyer's programme, which fosters meaning reconstruction in complicated grief (CG)<sup>72 73</sup> and includes elements of the Foa and Rothbaum<sup>74</sup> programme for treating trauma-like symptoms and Linehan's<sup>75</sup> guidelines for mindfulness strategies. In updating this treatment, elements of the intervention developed by Shear,<sup>76</sup> which has shown efficacy in different controlled studies,<sup>14-16</sup> have been included. This intervention is based on the dual-process model of coping with bereavement,<sup>77</sup> which identifies two types of stressors, loss-oriented and restoration-oriented, and proposes that adaptive coping is composed of confrontation-avoidance of loss and restoration stressors. Specific elements (ie, cognitive reappraisal) of other computerised psychological treatments for grief have also been included (eg, see previous works<sup>47 76 78</sup>). Lastly,

**Table 1** Specific objectives and therapeutic contents of the intervention

Module/Session	Objective	Content
1. Welcome module: Starting the programme	Present the treatment Increase motivation and adherence Introduce strategy to manage stress and anxiety	General explanation of treatment Presentation of grief cases as an example Motivation for change Slow breathing technique
2. Understanding reactions to loss	Information about the grieving process and PGD Increase adaptive activities Become aware of grief	Psychoeducation Behavioural activation Grief self-monitoring diary
3. Coping with loss	Recognise and accept emotional experiences Exposure to loss-related objects and situations	Mindfulness Exposure hierarchy
4. Loss integration and restoration: First steps	Integration and restoration of loss by writing	Giving a metaphorical meaning to loss Loss diary: Chapter 1, life before loss
5. Deepening integration and restoration of loss	Integration and restoration of loss by writing Contemplating the death from a different perspective Develop a realistic and complete picture of the deceased	Loss diary: Chapter 2, reaction to the death Cognitive reappraisal Questions about positive and negative aspects and memories of the deceased
6. Consolidating loss integration and restoration	Integration and restoration of loss by writing	Loss diary: Chapter 3, life after loss Imaginary conversations with the deceased
7. Self-care, guilt and forgiveness in the grieving process	Working on compassion in grief Working on the emotion of guilt Working on forgiveness	Psychoeducation about compassion The compassionate gesture and phrases Compassionate coping with difficulties Psychoeducation and strategies about guilt Psychoeducation and exercise for forgiveness (optional)
8. Evaluating progress and looking to the future	Achievements review Anticipate future problems Reflect on the coping process	Review of the therapeutic achievements Action plan for high-risk situations Action plan to face difficult dates Letter of projection towards the future

PGD, prolonged grief disorder.

the treatment contains new mindfulness activities and compassion and self-compassion strategies.<sup>79–84</sup>

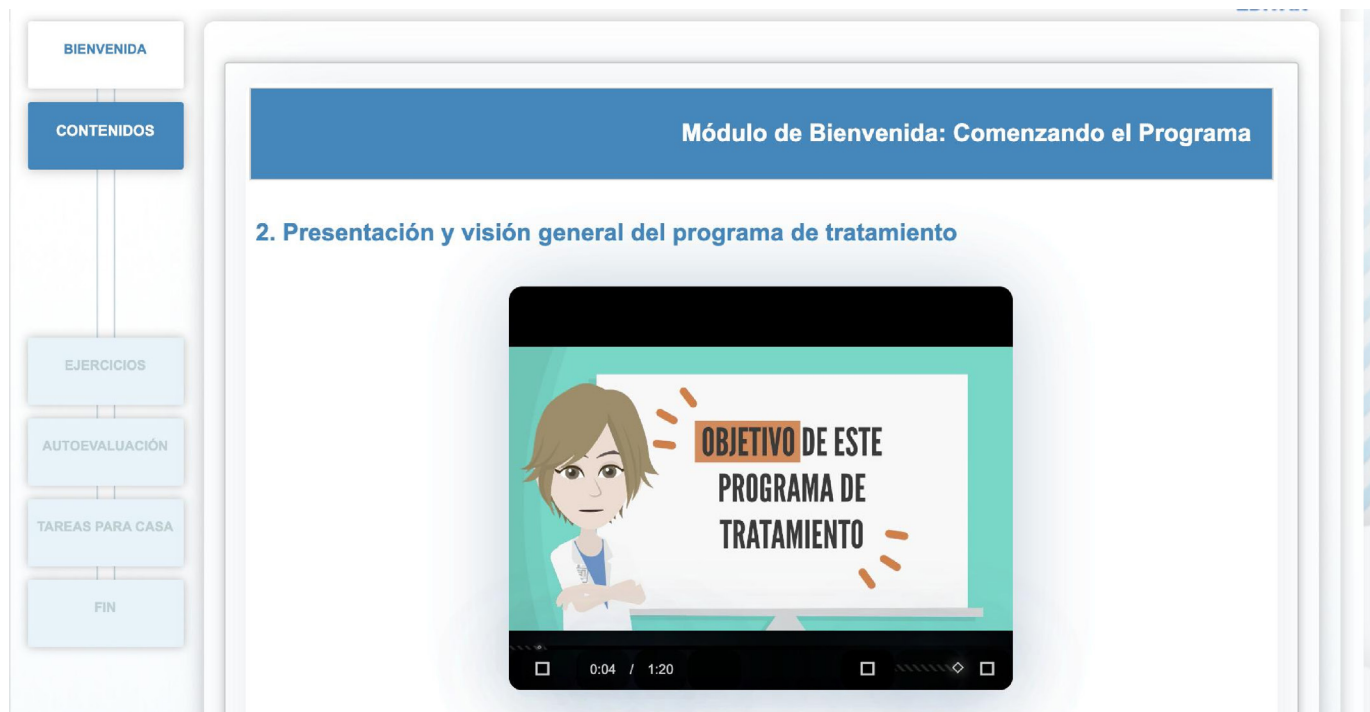
#### iCBT for PGD (GROW)

This individual self-applied programme is accessible online via <https://psicologiaytecnologia.labpsitec.es>, a website designed by Labpsitec (Laboratory of Psychology and Technology, Universitat Jaume I, and Universitat de València). Participants will receive a username and password sent to their email address, and they will have access to one 60-minute module per week, although modules 4–6 may take 2 weeks due to their difficulty. The treatment will last 8–10 weeks. The programme contains texts, videos, photos, diagrams, interactive exercises, and downloadable pdfs and audios (see [figure 1](#)). Participants can also log in at any time to review content, see the calendar where the session record appears and view their progress through visual graphs (ie, measures of grief, anxiety, depression, and positive and negative affect). A weekly support call from a trained clinician will be made (maximum 10 min) in order to (1) review and reinforce

participants' effort and achievements, (2) motivate them to continue to work on the programme content, and (3) clarify any doubts about the use and functioning of GROW. Patients will receive up to 10 phone calls over a period of 8–10 weeks, and so they will have a maximum of 100 min of therapeutic support. No additional clinical content will be released during the phone calls.

#### Individual face-to-face treatment for PGD

This treatment will be carried out face-to-face by a trained clinician with a master's degree in clinical psychology and specific training in the treatment of grief. The participant will receive materials about meditation audios and annexes with records and templates to complete the exercises. The sessions will take place at the Emotional Disorders Clinic at Universitat Jaume I in Castellón and Valencia (Spain) or in nearby centres and associations (eg, Valencia or Alicante). Each session will last approximately 60 min. There will be weekly individual sessions, and the content from 4 to 6 sessions could require 2 weeks



**Figure 1** 'Screenshot' of the 'Psicología y Tecnología' (Psychology and Technology) web platform.

due to its difficulty. The treatment lasts up to 8–10 weeks. No weekly support call will be provided.

### Outcome measures

A clinical team of mental health professionals with extensive experience in diagnosing and treating stress-related disorders will oversee all the cases. Some questionnaires will be self-administered online through the virtual platform used in the intervention (<https://psicologiaytecnologia.labpsitec.es>), and other questionnaires/interviews will be administered by phone. Participants in both groups (GROw and face-to-face) will have the same evaluation format. Participants and researchers will receive email reminders of each assessment. Table 2 provides an overview of the measurements used, each timepoint, administration type and group.

### Demographics, screening and diagnostic measures

Demographics will include age, sex, educational level, occupation, civil status, place of residence and influence of situations stemming from the health crisis caused by COVID-19 (confinements, care situations, nearby infections, related deaths, etc), if applicable.

A semistructured interview developed for this study will be used to assess some inclusion/exclusion criteria (eg, internet access, email, etc).

For the diagnosis, two specific PGD assessment instruments will be used: The Inventory of Complicated Grief (ICG), which rates current feelings of grief and differentiates between normal and pathological grief. A total score of >25 is needed because this score indicates complicated grief.<sup>59 60</sup> The Structured Clinical Interview for Complicated Grief (SCI-CG)<sup>85</sup> evaluates symptoms of prolonged

grief in people who lost a loved one 6 months ago or more, and it has been adapted specifically for this study by translating it into the Spanish language following a back-translation procedure. The clinical team may consider using the Structured Clinical Interview for DSM-IV (SCID-I)<sup>86</sup> in some cases in order to make the differential diagnosis and ensure that the inclusion/exclusion criteria are met. At the end of the interview, the clinician will assess the level of distress-interference in functioning (from 0 'Absent' to 8 'Very severely disturbing/disabling') using the ADIS (Anxiety Disorders Interview Schedule) clinician's severity rating scale.<sup>87</sup> A clinical team of mental health professionals with extensive experience in diagnosing and treating stress-related disorders will oversee all cases.

### Primary outcomes: measures of feasibility

Participant adherence (ie, attrition and dropout percentages) will be assessed in both groups. Moreover, the number of sessions/modules completed will be counted. In addition, the iCBT format (GROw) will record how many times participants enter the modules, how much time they spend on each one and whether they review the content of the modules.

Participants' acceptance will be assessed with *Expectations and Satisfaction Questionnaires* adapted from Borkovec and Nau,<sup>88</sup> usability with the *Usability and Acceptance Questionnaire*<sup>89 90</sup> and alliance with the *Working Alliance Inventory (WAI)*, adapted from Horvath and Greenberg<sup>91</sup> for online self-administered treatments.

Finally, a semistructured opinion interview with quantitative and qualitative questions was specifically developed

**Table 2** Measures, time of assessment, source of measurement and group

Measures	Assessment point	Assessment source	Group
Sociodemographic data	Screening	Phone interview	GROw Face-to-face
Semistructured interview about inclusion/ exclusion criteria	Screening	Phone interview	GROw Face-to-face
SCI-GC	Screening, t2, t3, t4	Phone interview	GROw Face-to-face
SCID-I	Screening	Web	GROw Face-to-face
ADIS clinician's severity rating scale	screening, t2, t3, t4	Web	GROw Face-to-face
ICG	Screening, t1, t2, t3, t4	Web	GROw Face-to-face
BDI-II	t1, t2, t3, t4	Web	GROw Face-to-face
TBQ	t1, t2, t3, t4	Web	GROw Face-to-face
OASIS	t1, POSTm/s, t2, t3, t4	Web	GROw Face-to-face
ODSIS	t1, POSTm/s, t2, t3, t4	Web	GROw Face-to-face
PANAS	t1, POSTm/s, t2, t3, t4	Web	GROw Face-to-face
QLI	t1, t2, t3, t4	Web	GROw Face-to-face
WSAS	t1, t2, t3, t4	Web	GROw Face-to-face
PTGI	t1, t2, t3, t4	Web	GROw Face-to-face
PIL-10	t1, t2, t3, t4	Web	GROw Face-to-face
FFMQ-15	t1, t2, t3, t4	Web	GROw Face-to-face
SCS-SF	t1, t2, t3, t4	Web	GROw Face-to-face
<i>Expectations and Satisfaction Questionnaires</i>	t1, t2	Phone interview	GROw Face-to-face
<i>Usability and Acceptance Questionnaire</i>	t2	Web	GROw
WAI	t2	Web	GROw
Semistructured opinion interview			
▶ Preferences	t1, t2	Phone interview	GROw Face-to-face
▶ Usefulness of content	t1, t2	Phone interview	GROw Face-to-face
▶ Usefulness of each element of the web	t2	Phone interview	GROw

ADIS, Anxiety Disorders Interview Schedule; BDI-II, Beck Depression Inventory—Second Edition; FFMQ-15, Five-Facet Mindfulness Questionnaire; GROw, Grief-Online, internet-based self-applied treatment for PGD; ICG, Inventory of Complicated Grief; OASIS, Overall Anxiety Severity and Impairment Scale; ODSIS, Overall Depression Severity and Impairment Scale; PANAS, Positive and Negative Affect Schedule; PIL-10, Purpose-In-Life Test; POSTm/s, post module/session; PTGI, Post-traumatic Growth Inventory; QLI, Quality of Life Index; SCID-I, Structured Clinical Interview for DSM-IV; SCI-GC, Structured Clinical Interview for Complicated Grief; SCS-SF, Self-Compassion Scale Short Form; t1, baseline; t2, immediately after the intervention; t3, 3-month follow-up; t4, 12-month follow-up; WSAS, Work and Social Adjustment Scale.

for this study. It includes (1) a 5-point questionnaire that assesses treatment preferences (GROW vs face-to-face) and opinions about which treatment is the most useful, logical, aversive and recommended; (2) a list of 14 points (eg, motivation to change, mindfulness, exposure) about the usefulness of each content (assessed from 0; not at all useful to 10; maximum usefulness); (3) a list of 4 points (text, video, audio and images) about the usefulness of each part of the iCBT format (from 0; not useful at all to 10; maximum usefulness); (4) three semistructured questions on satisfaction, usefulness and adherence on a scale from 0 (not at all) to 10 (very much), with an open question about the reason for the score; (5) an open question about adverse or unexpected effects in the iCBT group; (6) an open question about adverse or unexpected effects due to the health crisis produced by COVID-19; and (7) two semistructured questions about the acceptance of the evaluation procedure and the materials used (from 0; not burdensome at all to 10; extremely burdensome).

### Psychological and mental health outcomes

Grief symptoms will be assessed using the *Inventory of Complicated Grief (ICG)*,<sup>59 92</sup> and depression symptoms will be assessed using the *Beck Depression Inventory—Second Edition (BDI-II)*.<sup>93 94</sup> To assess the maladaptive thinking common in people with complicated grief, the *Typical Beliefs Questionnaire (TBQ)*<sup>95</sup> will be used. The *Overall Anxiety Severity and Impairment Scale (OASIS)*<sup>96 97</sup> and the *Overall Depression Severity and Impairment Scale (ODSIS)*<sup>98 99</sup> will be used to assess the frequency and severity of anxiety and depression, respectively. Two independent dimensions of affectivity (PA: positive affect; NA: negative affect) will be assessed using the *Positive and Negative Affect Schedule (PANAS)*.<sup>100 101</sup> To assess health-rated quality of life, the *Quality of Life Index (QLI)*<sup>102</sup> will be used. The *Work and Social Adjustment Scale (WSAS)*<sup>103 104</sup> will be used to assess psychosocial functional impairment. Post-trauma growth and self-improvement will be assessed using the *Posttraumatic Growth Inventory (PTGI)*.<sup>105 106</sup> The *Purpose-In-Life Test (PIL- 10)*<sup>107</sup> will be used to assess the personal experience of meaning in life. The *Five-Facet Mindfulness Questionnaire (FFMQ-15)*<sup>108</sup> and the *Self-Compassion Scale-Short Form (SCS-SF)*<sup>109 110</sup> will be used to assess the ability to be aware in experiencing the moment and the capacity for self-compassion, respectively.

### Statistical analysis plan

As the main aim of this study is related to the feasibility, the main data will be reported narratively illustrated with descriptive statistics using the CONSORT 2010 statement<sup>61</sup> to guide for reporting this information. Attrition and dropout rates will be calculated using the missing data. In the experimental group, the number of times each patient uses the programme will be used as the measure of adherence. In the active control group, the number of times each patient attends a face-to-face treatment session will be used as the measure of adherence. The summary of the data will be presented as a mean (DS) or

frequency (%). As a secondary objective, potential effectiveness of iCBT will be assessed by applying within-group t-tests between the baseline and post-test and follow-ups. In addition, effect sizes and their respective 95% CI for intragroup changes will be reported. Comparisons between iCBT and face-to-face CBT will not be accomplished. These statistical analyses will be conducted for completers and intent-to-treat data. Statistical analyses will be accomplished with the program SPSS V.25.0.

### Patient and public involvement statement

There was no involvement in the design and development of the study by patients or the public. The results will be communicated to the patients involved through an end-of-study report by email. The public will participate in the dissemination of the research.

### ETHICS AND DISSEMINATION

The protocol for this study was approved by the Ethical Committee of the Universitat Jaume I (Castellón, Spain) (06 March 2019) (file number CD/002/2019). The informed consent of each participant will be explained and required in the initial phone call. Before giving their informed consent, the researchers will inform participants about the study and the possibility of leaving at any stage. Written consent will be obtained before starting the intervention. The study will be conducted in compliance with the Declaration of Helsinki and good clinical practice and current EU and Spanish legislation on privacy and data protection (Spanish Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights). Most of the questionnaires will be administered from the web <https://psicologiaytecnologiaabpsiteces>. Each participant will have a unique username-password combination to access the site. All data will be protected according to AES (Advanced Encryption Standard) polynomial  $m(x) = x^8 + x^4 + x^3 + x + 1$  and stored on secure servers at the Universitat Jaume I separately from personal information, using codes. To protect the participants' privacy, all participant identification information will be replaced by a randomly assigned code. An isolated list will link the numerical codes with the names of the participants. This list and the information obtained from the phone calls will be stored in a locked file cabinet located inside a room with an electronic lock that records access (person, day and time). Only researchers directly involved in the current study will have access to these data. Dissemination will include publications in open access journals with impact factor indexed in Journal Citation Reports (JCR) and presentations at national and international conferences. An end-of-study report of the results of this study will be developed and sent to all participants by mail.

### DISCUSSION

The main aim of this study is to investigate the feasibility of an iCBT for people with PGD—GROW—compared with a face-to-face intervention for PGD. Specifically, we want to investigate the opinion of the participants about the



treatment, the study design, the materials used and the evaluation process, and also to assess dropout rates and evaluate if we can recruit the target population to carry out a large-scale RCT in the future. In contrast to other psychological disorders, few studies have evaluated the acceptability and feasibility of this type of treatment and there are few studies focused on the efficacy of internet-based and computer-based interventions for PGD (eg, see previous works<sup>45–47</sup>), and almost none of them have focused on iCBT.<sup>46 50–52</sup>

The current situation, due to the COVID-19 pandemic, has made PGD a major public health problem worldwide.<sup>41</sup> Increased PGD rates are expected<sup>41</sup> due to different factors, such as (1) the inability to perform proper grief rituals that can have significant positive outcomes for people experiencing a loss (such as attending a funeral)<sup>111</sup>; (2) the possible feeling that the loved one's death was distressing and not peaceful<sup>112</sup>; (3) widespread implementation of social distancing and visitor restrictions in health centres<sup>42 43</sup>; and (4) the fact that disasters with many victims produce higher levels of grief symptoms.<sup>41</sup>

Therefore, psychological treatments for PGD are necessary, but the existence of these treatments does not ensure that they reach the people who need them.<sup>27</sup> The current situation states a new challenge, the restrictions in terms of mobility, access to the traditional healthcare system is at least more difficult than usual, given the overburden of the system due to the pandemic situation, and the potential increased risk of exposure for attending to the healthcare system. Moreover, the challenges that society will face concerning the pandemic in the near future is at least unknown, but not very promising. Therefore, internet interventions could be a potential solution to overcome the current situation and to reach more people in need. In addition to that, it is well stated that internet provides greater access to care, less stigma compared with visiting mental health clinics, and the ability to avoid specific obstacles to diagnosis or treatment, such as when social anxiety keeps the patient from leaving home.<sup>29</sup> In addition, there is no need for a therapy room, a lesson/module can be repeated,<sup>113</sup> and they are cost-effective<sup>114</sup> and often cheaper than face-to-face interventions.<sup>31</sup>

As far as we know, GROw is the first iCBT for PGD created in the Spanish language, and it could reach many Spanish-speaking countries as a psychological treatment to care for people with PGD, who represent about 10% of people who have suffered a loss of a loved one<sup>2</sup> and is becoming a major public health concern worldwide due to the COVID-19.<sup>41</sup>

GROw has been developed based on larger and more recent studies on the treatment of PGD (eg, see previous works<sup>15 16 47</sup>). It includes both evidence-based traditional therapeutic components for PGD and more innovative ones, such as mindfulness and compassion strategies. In addition, delivery will be guided, including a weekly phone call from a trained therapist, which has been shown to be more effective than unguided iCBTs.<sup>115 116</sup>

We expect that iCBT—GROw—will be feasible in order to carry out a large-scale RCT to determine the efficacy and effectiveness of GROw as a treatment for adult patients with PGD.

### Trial limitations

First, due to the pandemic situation caused by COVID-19 and related to the mobility restrictions, it is possible that the participants assigned to the face-to-face group will not be able to attend the sessions in person. For this reason, changes and adaptations could be made in the control group treatment application format (eg, conduct video-conferencing sessions). These adaptations would be taken into consideration for the future large-scale RCT. Second, high dropout rates are expected (30%) according to the literature.<sup>65–67</sup> For this reason, dropout rates have been taken into account in the sample size considerations. Finally, for the secondary aim of this feasibility randomised trial, conclusions will be limited to exploring its potential effectiveness in terms of intragroup changes (changes from baseline to post-intervention and follow-ups), with baseline–post-test being the main comparison, without considering between-group comparisons.

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