



Programa de Doctorado en Psicología
Escuela de Doctorado de la Universitat Jaume I

**GROw, an Internet-delivered Cognitive-Behavioral Therapy (iCBT)
for Adults with Prolonged Grief Disorder (PGD)**

**GROw, un Tratamiento Cognitivo Conductual (TCC) a Través de
Internet para Adultos con Trastorno por Duelo Prolongado (TDP)**

Memoria presentada por Cintia Tur Domenech para optar al grado de doctora por la
Universitat Jaume I

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PRESENTATION

The present doctoral thesis includes a general introduction, four publications and a general discussion of the main results obtained. Three of the publications included have already been published in an indexed journal. The last one publication is currently in preparation. The following table includes the complete reference of all publications included in this doctoral thesis.

Chapter 1	<p>Tur, C., Campos, D., & Quero, S. (2019). Tratamientos Psicológicos Basados en Internet para el Duelo: Revisión de la Literatura/ Internet-Based Psychological Treatments for Grief: Review of Literature. <i>Revista Argentina de Clínica Psicológica</i>, 884.</p> <p>Unique Identifier: 2020-35649-029</p> <p>Journal Impact Factor (JIF): 0.508</p> <p><i>Author contribution related to planning the study, conducting the study, and writing the study manuscript.</i></p>
Chapter 2	<p>Tur, C., Campos, D., Suso-Ribera, C., Kazlauskas, E., Castilla, D., Zaragoza, I., & Quero, S. (2022). An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in Adults: A Multiple-Baseline Single-case Experimental Design Study. <i>Internet Interventions</i>, 29, 100558.</p> <p>DOI: doi.org/10.1016/j.invent.2022.100558</p> <p>Journal Impact Factor (JIF): 4.144</p> <p><i>Author contribution related to planning the study, conducting the study, and writing the study manuscript.</i></p>
Chapter 3	<p>Tur, C., Campos, D., Herrero, R., Mor, S., López-Montoyo, A., Castilla, D., & Quero, S. (2021). Internet- delivered Cognitive- Behavioral Therapy (iCB) for Adults with Prolonged Grief Disorder (PGD): A Study Protocol for a Randomized Feasibility Trial. <i>BMJ Open</i>, 1–11.</p> <p>DOI: dx.doi.org/10.1136/bmjopen-2020-046477</p> <p>Journal Impact Factor (JIF): 2.86</p> <p><i>Author contribution related to planning the study, conducting the study, and writing the study manuscript.</i></p>
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This thesis has been accepted by the co-authors of the publications listed above that have waved the right to present them as a part of another PhD thesis.

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ABSTRACT

Losing a loved one is a painful process with physical, psychological, and social consequences characterized by feelings of longing and regret that usually diminish over time. However, between 9.8 and 21.5% of bereaved adults are at risk of developing Prolonged Grief Disorder (PGD), and the SARS-CoV-2 coronavirus (COVID-19) has made disturbed grief a major public health concern worldwide. There are effective treatments for PGD, but this does not ensure that the treatments reach the people who need them. Internet-delivered cognitive-behavioral therapies (iCBTs) make it possible to reach people who need therapy, and they are cost-effective and clinically effective.

The main aim of this thesis was to explore the feasibility of GROw, a novel iCBT developed in the Spanish language for adults with prolonged grief disorder (PGD). The secondary aim of this thesis was to explore the potential effectiveness of GROw in treating grief-related symptoms. Based on these aims, the present doctoral thesis is divided into four chapters:

Chapter one presents a literature review of all the published studies that have tested an Internet-based treatment for PGD using randomized clinical trial study designs. This chapter provides a synthesis of the characteristics and effects of each intervention, and it concludes that Internet-based treatments have promising results in improving grief-related symptomatology.

Chapter two presents a multiple-baseline single-case experimental study with six participants that explored the feasibility (usability and satisfaction) and potential effectiveness of GROw, concluding that participants reported high usability and satisfaction with GROw, which showed strong potential in treating grief-related symptomatology.

Chapters three and four present the study protocol and results of a randomized feasibility trial study that compared the GROw program and the same intervention delivered face-to-face through videoconference. The results showed that GROw was feasible and well-accepted in terms of adherence, preferences, expectations, satisfaction, and qualitative opinions about the usefulness of the intervention. In addition, GROw

showed strong potential in treating grief-related symptomatology, compared to the same intervention delivered face-to-face through videoconference.

The results obtained in both the multiple-baseline single-case experimental study and the randomized feasibility trial study recommend continuing to investigate GROw by scaling up the treatment with larger samples and more complex designs such as randomized controlled trials.

RESUMEN

La pérdida de un ser querido es un proceso doloroso con consecuencias físicas, psicológicas y sociales caracterizadas por sentimientos de anhelo y pesar que generalmente disminuyen con el tiempo. Aun así, entre un 9.8% y un 21.5% de los adultos en duelo tienen riesgo de desarrollar Trastorno por Duelo Prolongado (TDP) y el coronavirus SARS-CoV-2 (COVID-19) ha convertido el duelo prolongado en un importante problema de salud pública en todo el mundo.

Existen tratamientos eficaces para el TDP, pero esto no asegura que los tratamientos lleguen a las personas que los necesitan. Los tratamientos cognitivo-conductuales (TCC) a través de Internet (iCBT, por sus siglas en inglés) pueden llegar a personas que necesitan terapia, son rentables y clínicamente efectivos.

El principal objetivo de esta tesis doctoral fue explorar la viabilidad de GROw, una nueva terapia cognitivo-conductual (TCC) a través de Internet desarrollada en idioma español para adultos con Trastorno por Duelo Prolongado (TDP). El objetivo secundario de esta tesis doctoral fue explorar la efectividad potencial de GROw para el tratamiento de los síntomas relacionados con el duelo. De acuerdo con estos objetivos, la presente tesis doctoral contiene cuatro capítulos:

En el capítulo uno se realiza una revisión bibliográfica que recopila todos los estudios publicados que probaron tratamientos a través de Internet para el TDP mediante ensayos clínicos aleatorizados. Se proporciona una síntesis de las características y eficacia de cada intervención concluyendo que el tratamiento basado en Internet tiene resultados prometedores para mejorar la sintomatología relacionada con el duelo.

En el capítulo dos se presenta un estudio experimental de línea base múltiple con seis participantes en el que se exploró la viabilidad (usabilidad y satisfacción) y eficacia potencial de GROw. Se concluyó que los participantes reportaron alta usabilidad y satisfacción con GROw y demostró que el tratamiento obtuvo gran potencial para tratar sintomatología relacionada con el duelo.

En el capítulo tres y cuatro se presenta el protocolo y los resultados de un estudio aleatorizado de viabilidad que comparó el programa GROw con la misma intervención

administrada cara a cara a través de videoconferencia. Los resultados mostraron que GROw fue viable y aceptado en términos de adherencia, preferencias, expectativas, satisfacción y opinión cualitativa sobre la utilidad de la intervención. Además, GROw mostró un gran potencial para tratar sintomatología relacionada con el duelo en comparación con la misma intervención administrada cara a cara por videoconferencia.

Los resultados obtenidos tanto en el estudio experimental de línea base múltiple como en el estudio aleatorizado de viabilidad permiten continuar investigando GROw, utilizando muestras más grandes y diseños más complejos como ensayos clínicos aleatorizados.

GENERAL INTRODUCTION

Grieving the death of a loved one is a painful process that most people experience at some time during their lives. The process is unique for each individual, and there are no stages that occur in a specific order (Boelen & Smid, 2017; Stroebe et al., 2017), but commonalities have been recognized by clinicians (Shear, 2015a). Bereavement, the experience of losing a loved one to death, has physical, psychological, and social ramifications (Shear, 2015a). This process has been associated with the development of psychological disorders, such as panic disorder or depression, and physical and psychological symptoms, such as tiredness, sleep problems, hypersensitivity to noise, pain, increased use of medications, and work and social interference (Keyes et al., 2014; Lancel et al., 2020; Simon et al., 2007; Stroebe et al., 2007). Bereavement in the early period has also been associated with medical problems such as cardiac problems (in the subsequent days) (Martínez-Sellés, 2012; Mostofsky et al., 2012) and changes in the immune system (in the first six months of bereavement) (Buckley et al., 2012). However, intense feelings of regret and longing are considered natural and usually diminish over time with gradual recovery (Jordan & Litz, 2014; Shear et al., 2011) if the person can, among other things, accept the reality of the loss and the pain associated with the process (Worden, 2008).

Complicated Grief (CG), Prolonged Grief Disorder (PDG), and Persistent Complex Bereavement Disorder (PCBD)

Disturbing grief is recognized as an entity that is related to (but distinct from) other established mental health disorders (Doering & Eisma, 2016). In recent decades, different terms have been used to refer to severe, persistent, and disabling grief (Eisma et al., 2022). The three most widely used terms are: 1) “Complicated Grief (CG)”, proposed by Shear et al. (2011); 2) “Prolonged Grief Disorder (PGD)”, proposed by Prigerson et al. (2009) and Maercker et al. (2013) and included with some modifications in the eleventh edition of the International Classification of Diseases (ICD-11; World Health Organization [WHO], 2019); and 3) “Persistent Complex Bereavement Disorder (PCBD)”, which was included in the text revision of the Diagnostic and Statistical Manual of Mental Disorders 5 in 2022 (DSM-5-TR; Boelen et al., 2020; Prigerson et al., 2021). In the current scientific literature, the two most commonly used terms are PGD and PCBD. For the diagnosis of

PGD, according to the ICD-11, at least six months have to pass after the loss, whereas for a diagnosis of PCBD, according to the DSM-5-TR, at least 12 months have to pass after the loss. PCBD is defined as daily intense longing for the deceased person and/or preoccupation with thoughts or memories of the deceased person, as well as other symptoms such as identity disruption since the death, avoidance of reminders that the person is dead, feeling that life is meaningless as a result of the death, etc. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning, and the duration and severity of the reaction clearly exceed expected social, cultural, or religious norms for the individual's culture and context. PGD is defined as a disturbance in which, following the death of a partner, parent, child, or other person close to the bereaved, there is a persistent and pervasive grief response characterized by longing for the deceased or persistent preoccupation with the deceased accompanied by intense emotional pain (e.g. sadness, guilt, anger, denial, blame, difficulty accepting the death, feeling one has lost a part of one's self, an inability to experience positive mood, emotional numbness, difficulty in engaging with social or other activities). The grief response clearly exceeds expected social, cultural, or religious norms for the individual's culture and context and causes significant impairment. Concerns about the qualitative difference between PGD and PCBD have been raised. The existence of different sets of criteria affects the generalizability of the findings obtained in investigations. The overlap between the PCBD diagnosis and the PGD diagnosis is limited because the two diagnoses differ in content (criteria-sets) and diagnostic algorithms (cut-off point for each criterion), and so the findings obtained with instruments designed to assess PGD may not generalize to PCBD and vice versa (Eisma et al., 2022). The studies in this doctoral thesis were planned and executed following the PGD guidelines for differentiating between grief and severe, persistent, and disabling grief. For this reason, the term PGD will be used, and the findings related to this research cannot be generalized by using the terms PCBD and CG.

Prevalence of severe, persistent, and disabling grief

A percentage of people who experience the death of a loved one have long-term reactions that interfere with their daily lives (Lundorff et al., 2017). The reported prevalence rates of the range of severe, persistent, and disabling grief vary across samples, countries, and evaluation measures (Lundorff et al., 2017; Parro-Jiménez et al., 2021).

The systematic review by Parro-Jiménez et al. (2021) shows that studies that use diagnostic instruments (e.g., Prolonged Grief Disorder-13 [PG-13]; Prigerson et al., 2009), consensus criteria (e.g., criteria for the category of PGD; WHO, 2019), and expert evaluations find a prevalence of severe, persistent, and disabling grief of between 7.02%-22.7%. Studies using instruments that assess symptoms, specifically the Inventory of Complicated Grief (ICG) (Prigerson et al., 1995) and the Texas Grief Inventory (TRIG) (Faschingbauer et al., 1977), show a higher prevalence of between 19.1%-53.03%.

Another study by Lundorff et al. (2017) analyzed 14 epidemiological studies of individuals aged 18 or older who suffered the loss of a loved one through mainly non-violent deaths. The outcome variable was prolonged grief, assessed by a standardized, validated psychometric instrument (e.g., ICG). This meta-analysis revealed that one in ten bereaved adults is at risk for PGD worldwide.

Psychological treatments for severe, persistent, and disabling grief

Regarding the risk factors for specific bereavement-related mental health problems and the need for adapted treatments, recent studies show that a lack of emotion regulation strategies is associated with disturbing grief (Eisma & Stroebe, 2021). Emotion regulation is defined as "...the process by which individuals influence which emotions they have, when they have them, and how they experience them. Emotion regulation strategies may be automatic or controlled, conscious or unconscious, and may have their effects at one point or many points in the emotion generative process" (Gross, 1998). Experiential avoidance, behavioral avoidance, expressive suppression, rumination, and worry are associated with disturbing grief symptoms and posttraumatic stress disorder (PTSD) symptoms (Eisma & Stroebe, 2021; Williams et al., 2019). Putative adaptive emotion regulation strategies (e.g., problem solving, cognitive reappraisal, and mindfulness) are generally negatively associated with disturbing grief symptoms (Eisma & Stroebe, 2021). Other important elements such as preexisting mental disability, not believing in the survival of the soul after physical death, lack of preparation for death, poor physical/psychological health, and the idea that the deceased felt like a burden to others are associated with disturbing grief and symptoms of Major Depressive Disorder (MDD) (Aoyama et al., 2018).

In accordance with the cognitive-behavioral conceptualization of complicated grief (Boelen et al., 2006), three processes are crucial in the maintenance and development of Complicated Grief: 1) poor integration and elaboration of the loss into the personal

biography; 2) misinterpretations and negative beliefs related to grief; and 3) avoidance strategies. To these elements, considered the central processes, the characteristics of the event, individual vulnerability factors, and the sequelae of loss (see Image 1) can be added.

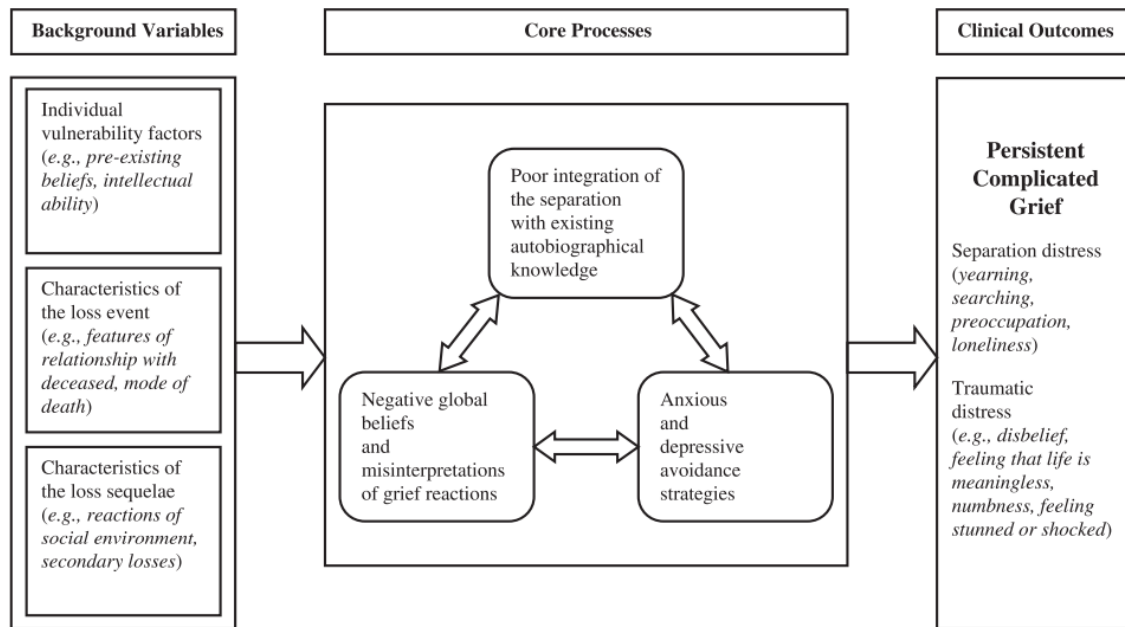


Fig 1. A cognitive-behavioral conceptualization of complicated grief (Boelen et al., 2006)

This model concludes that, in the treatment of Complicated Grief from a cognitive-behavioral perspective, the griever needs to achieve three goals: 1) The loss has to be integrated and conceptually processed with the existing autobiographical knowledge; 2) The problematic beliefs and interpretations have to be modified; and 3) Avoidance strategies have to be replaced by other strategies that facilitate adjustment. Exposure, psychoeducation, cognitive restructuring, and behavioral activation can be used to achieve these goals.

Based on all these findings, different therapeutic components have been used to treat symptoms of grief: psychoeducation (e.g., García et al., 2013; Lund et al., 2010; McGuinness et al., 2015), behavioral activation (e.g., Acierno et al., 2021; Eisma et al., 2015; Litz et al., 2014), experiential exposure to stimuli avoided since the death of the loved one (e.g., Acierno et al., 2021; Boelen et al., 2007; Bryant et al., 2014), cognitive reappraisal (e.g., Boelen et al., 2007; Rosner et al., 2014; van der Houwen et al., 2010), writing assignments about emotional experiences and thoughts (e.g., Kalantari et al., 2012; Lichtenthal & Druess, 2010; Wagner et al., 2006), and compassion strategies

(Jahani et al., 2022; Johannsen et al., 2022). Several psychological interventions exist for the prevention and treatment of severe, persistent, and disabling grief, with both group (Maass et al., 2022) and individual formats (e.g., Boelen et al., 2007; Range et al., 2000; Shear et al., 2005; Shear et al., 2016). Systematic reviews and meta-analyses show that these interventions are effective in reducing disturbing grief symptoms in bereaved adults (Bergman et al., 2017; Johannsen et al., 2019; Wittouck et al., 2011).

One of the most studied treatments is the “Complicated Grief Treatment” (CGT) (Shear, 2015b). This treatment is a manualized and well-specified 16-session protocol. This protocol has shown its efficacy in several randomized controlled trials (RCT) comparing it with interpersonal psychotherapy (IPT), medication (i.e., citalopram), and placebos (Shear et al., 2005; Shear et al., 2014, 2016). Both CGT and IPT produced improvements in grief symptoms, but CGT obtained shorter response times and higher response rates (Shear et al., 2005; Shear et al., 2014). Adding antidepressant medication to CGT may not improve complicated bereavement outcomes, although medication is likely to improve concurrent depressive symptoms (Shear et al., 2016). As for the placebo group, results comparing CGT plus placebo vs. only placebo showed a greater response to the treatment in the CGT+placebo group (Shear et al., 2016). The CGT included resolving grief complications and facilitating natural mourning, supported by elements of cognitive-behavioral intervention and the dual-process model of coping with bereavement (Stroebe & Schut, 1999). Each session contained both loss-focused and restoration-focused components. According to the dual-process model, some coping strategies make it easier to accept the loss and avoid serious health consequences, whereas other coping strategies are detrimental to the person’s health. This model explains that the oscillation (as a dynamic back-and-forth process) between loss-focused and restoration-focused strategies involves adaptive coping with the death of a loved one, which consists of facing/avoiding loss and restoration stressors. Loss-focused refers to processing aspects of the loss experience itself with respect to the deceased person. This includes longing for the deceased (e.g., looking at old photos or crying over the death of a loved one). Restoration-focused refers to performing tasks that the deceased had undertaken (e.g., finances), doing new things, organizing one’s life without the loved one, and developing a new identity. It implies the need to take a break from the pain of grief and rebuild the environment itself. Avoidance strategies (i.e., avoiding external situations that are appraised as painful and achieving distance from emotions and other internal

experiences) must be used judiciously and in a fluid and dynamic way. Over-use of these strategies can hinder the grief process and lead to the development of severe, persistent, and disabling grief (Shear, 2010). The CGT (Shear, 2015b) contains elements such as psychoeducation, working with memories and pictures, and imaginal conversations with the deceased in four phases, from the review of the patient's history to the completion and consolidation of treatment aims. In Phase 1, therapists introduce a bereavement diary and review the patient's bereavement experience and history. In this phase, therapists also explain the characteristics of grief and complicated grief. In addition, they begin to work on aspirational goals and conduct a joint session with a loved one. Phase 2 includes exposure-based procedures (imaginary and situational). This phase works with memories and images while continuing to focus on personal goals. In Phase 3, a mid-therapy review is performed. Phase 4 includes an imaginary conversation with the deceased person and focuses on consolidation and the completion of the treatment. Another treatment for severe, persistent, and disabling grief is the "Meaning in Loss Protocol" (MIL) (Alves et al., 2018; Neimeyer & Thompson, 2014). This intervention is based on a constructivist narrative rationale. MIL proposes narrative techniques organized in sequential phases. The objective of this intervention is to promote a new and adaptive way to make sense of and integrate the experience of the loss and compassionately reconnect with the lost loved one. This intervention is organized in five phases and 12-14 sessions. In Phase 1 (reopening the story), the therapist encourages the patient to introduce their loved one, describing their death and relevant aspects of their lives. In the second phase (processing the event story of the loss), the therapist trains the patient to construct a loss timeline that includes turning points and life episodes and segments them into chapters of their lives with different titles. In Phase 3 (exploring sources of meaning), the therapist sifts through the emotions, memories, and themes that have emerged. To facilitate this, the therapist describes grief models such as the dual-process model of coping with bereavement (Stroebe & Schut, 1999). Phase 4 (accessing the back story of the relationship with the deceased) includes writing and other tasks (e.g., say "hello again" rather than say a final "goodbye", honor the imprint of the loved one) to provide resources to help the bereaved person reconstruct their life. In the last phase (consolidation), the therapist promotes the integration of the therapy by fostering a self-distancing perspective through tasks such as writing a short "make believe" story about topics related to loss or planning a remembrance ritual that honors their loved one.

“INTERAPY” is another widely studied treatment for severe, persistent, and disabling grief that has been especially used in interventions over the Internet. “INTERAPY” was created for posttraumatic stress disorder (Lange et al., 2003) and adapted to grief treatment (Hoffmann et al., 2018; Kersting et al., 2013; van der Houwen et al., 2010; Wagner et al., 2006). This treatment focuses on aspects such as helping the patient to remember the loved one in a more comforting way by creating a new life narrative that integrates the loss into the biography (Neimeyer & Levitt, 2001) and encouraging the development of rituals or activities to remember the deceased person and give them a place in one's life (Neimeyer et al., 2002). “INTERAPY” is composed of three modules: 1) Imaginal exposure to bereavement cues with the objective of develop skills for coping with distressing stimuli. In this module, patients are instructed to write about the circumstances of the death and express their fears and thoughts in the present tense and in the first person. 2) Cognitive reappraisal: restructuring dysfunctional thoughts using a specific writing task. Patients are instructed to write a supportive letter to a hypothetical friend who had also experienced the loss of a significant person and was facing the same difficulties. The aim is to develop a new perspective on the death, considering guilt feelings, dysfunctional automatic thoughts, behavior patterns, and unrealistic assumptions. 3) Integration and restoration: review the therapeutic progress, anticipate the future, and define new personal goals. Patients are instructed to write a letter to a significant person or to themselves about their most important memories related to the death, the therapeutic process, how the loss has changed them, and the future.

Finally, there are interventions that include other less-studied strategies. Mindfulness-based cognitive therapy (MBCT) (Williams et al., 2008) has been used for bereaved people, with promising results (Huang et al., 2021). This treatment has a duration of 8 weeks and consists of one meeting per week and daily home practice (45 min per day). The objective is to learn to interact with experiences such as feelings and thoughts using a “being mode of mind” and letting the feelings or thoughts stay in the mind without trying to avoid them. For this purpose, MBCT uses tasks such as specific guided meditations (e.g., raisin exercise, mindfulness of breathing, body scans). Compassion strategies have also been studied very little in relation to the treatment of disturbing grief, but recent studies have shown promising results (Jahani et al., 2022; Johannsen et al., 2022). Some findings suggest that bereaved people (specifically relatives of long-term missing persons) with more self-compassion experience less severe

psychopathology, partly because these people are less inclined to engage in ruminating thoughts related to the disappearance (Lenferink et al., 2017). Mindfulness and compassion interventions can help to cope with avoidance, rumination, and other strategies associated with disturbing grief, but more studies are needed.

Barriers to psychotherapy

Many evidence-based psychosocial treatments (EBTs) are available for clinical practice, but the existence of effective psychological treatments does not ensure that these treatments reach the people who need them (Kazdin, 2014). The majority (~70%) of individuals in need of treatment do not receive any services (Kessler et al., 2005), even in high-income countries (Chisholm et al., 2016). A key challenge is to disseminate EBTs, so that they can be used in clinical practice (Kazdin, 2016). Access to EBTs is limited for several reasons: lack of therapists, financial costs, waiting lists, and patients' reluctance to enter therapy, among others (Kaltenthaler et al., 2006). Moreover, geographical factors, such as distance, affect the use of mental health services. Apart from territorial aspects, there are other factors that are barriers to accessing medical care, such as the type of medical insurance, patient preferences, socio-economic factors, level of education, waiting lists, and the availability of medical care (López-Lara et al., 2012). A report by the European Union in the framework of the 3rd EU Health Programme (2014-2020) concluded that access to mental health care should be guaranteed for people who need it, regardless of their place of residence, social and economic circumstances, gender, race, or type of problem. In addition, the report concludes that the care provided should be of good quality, include evidence-based approaches, and consider the users' preferences (Barbato et al., 2016). Regarding opinions about mental health services, stigma also has a clear deterrent effect on help-seeking for mental health problems. Ethnic minorities, youth, men, and those in the military and health professions were the most deterred by stigma (Clement et al., 2015).

Impact and consequences of COVID-19 for severe, persistent, and disabling grief

The SARS-CoV-2 coronavirus (COVID-19) is an unprecedented global problem that has caused many deaths and psychological, psychiatric, relational, and economic consequences (Diolaiuti et al., 2021; Eisma & Tamminga, 2022; Giorli et al., 2020; Marazziti & Stahl, 2020; Pozza et al., 2020). Specifically, COVID-19 has made disturbed grief a major public health concern worldwide (Eisma et al., 2020). In this context, severe

forms of traumatic distress, guilt, somatization, regret, anger, and unspecific symptoms not yet included in prolonged grief disorder (PGD) criteria could emerge (Kokou-Kpolou et al., 2020).

There are (at least) two elements to consider in relation to severe, persistent, and disabling grief about losses during the pandemic and/or caused by COVID-19: 1) the circumstances surrounding the death of the deceased and 2) the consequences of living through the grieving process in quarantine. With regard to the circumstances surrounding the death, there are some factors that predispose vulnerable individuals to developing psychopathological conditions: prohibiting relatives from visiting at the hospital or healthcare center and depriving families of attending to their loved ones in their last days of life (Diolaiuti et al., 2021; Kokou-Kpolou et al., 2020; Neimeyer & Lee, 2022; Nyatanga, 2020; Ostadhashemi et al., 2022; Wallace et al., 2020)), problems performing funeral ceremonies (Kokou-Kpolou et al., 2020; Lazzerini & Putoto, 2020; Mitima-Verloop et al., 2022; Neimeyer & Lee, 2022), problems visiting cemeteries (Diolaiuti et al., 2021; Neimeyer & Lee, 2022), and unexpected, fast, and not properly reported deaths (Menichetti Delor et al., 2021; Neimeyer & Lee, 2022). All of these circumstances can produce emotions such as guilt in grievors related to COVID-19, and guilt has been found to be one of the main predictors of the severity of somatization after the loss (Kokou-Kpolou et al., 2018). Regarding the consequences of living through the grieving process under quarantine, Brooks et al. (2020) show a compilation of studies that analyze the psychological impact of quarantine. Longer quarantines were associated with poorer mental health due to fears about their own health and/or fears of infecting others, loss of their usual routine, reduced social and physical contact, isolation from the rest of the world, inadequate basic supplies (e.g., accommodation, clothes, food, water), stigma toward others, inadequate or poor information from public health authorities, and financial loss due to having to interrupt their professional activities without advanced planning.

PGD and PCBD occur in over one-third of COVID-19-related bereaved individuals (Tang & Xiang, 2021). Due to the COVID-19 pandemic, the need for novel approaches to psychotherapy that can be implemented in adverse conditions has increased. These approaches include, for example, Internet-based PGD treatments (Eisma et al., 2020) and telecommunication-based alternatives (Wallace et al., 2020). The use of these types of

treatments allows grievors to give meaning to the loss, express their emotions, say their last goodbyes, remember the victim, and solve practical issues (Menichetti et al., 2021).

To overcome the barriers to face-to-face interventions and those added by the SARS-CoV-2 coronavirus (COVID-19), Internet-based and computer-based interventions are becoming increasingly popular and can be a good alternative way to reach people who need treatment (Kazdin, 2014, 2016). These types of treatments allow people to work through the therapy material independently, with or without minimal assistance from a therapist or other mental health professional, and they are administered through a computer, tablet, or smartphone.

Internet- based and computer- based interventions

Internet- and computer-based psychotherapies can address many of the barriers to using traditional face-to-face psychotherapy. Internet interventions, particularly Internet-delivered cognitive behavioral therapy (iCBT), have existed for at least 20 years (Andersson et al., 2019), and the number of studies on Internet interventions exceeded 100 ten years ago (Hedman et al., 2012). This type of psychotherapy is cost-effective and often cheaper than face-to-face approaches, and it is a good way to reach people who need treatment (Donker et al., 2015; Musiat & TARRIER, 2014). Internet- based and computer-based interventions can overcome geographical barriers (e.g., reach rural people) and isolation problems (i.e., reach people living with an Alzheimer's sufferer who cannot travel) (Griffiths et al., 2006; Griffiths & Christensen, 2007). Internet interventions can also reach stigmatized groups (Griffiths et al., 2006), and they involve less stigma than visits to mental health clinics, in addition to having the ability to bypass specific obstacles to treatment (e.g., social anxiety) (Aboujaoude et al., 2015). iCBTs also have some issues that should be considered. Computer self-efficacy is associated with less computer anxiety and more interest in this type of treatment, and so creating a simple and intuitive iCBT interface is important to ensure satisfactory participant engagement. Furthermore, younger ages and the male gender have been associated with higher self-stigma, and for this reason, some authors conclude that there is a need for a targeted public policy that focuses on specific populations (Moskalenko et al., 2020). However, iCBTs can be successfully adapted to many different populations (e.g., children and adolescents) and psychological, psychiatric, and somatic conditions (Vigerland et al., 2016).

Regarding the effects of these treatments, more than 200 randomized controlled trials have been published (Carlbring et al., 2018) indicating that iCBTs are clinically

effective compared to controls (Andersson et al., 2017) and safer than no-treatment conditions (Karyotaki et al., 2018). Compared to active conditions, iCBTs and face-to-face treatments produced equivalent overall effects (Andersson et al., 2014; Carlbring et al., 2017). Furthermore, iCBTs showed short-term (Andersson & Cuijpers, 2009; Andrews et al., 2010; Cuijpers et al., 2008) and long-term effects compared to therapist-administrated therapy (Hedman et al., 2011). Finally, iCBTs also showed promising results in the treatment of depression and anxiety during the COVID-19 pandemic (Komariah et al., 2022).

Internet and computer-based psychological interventions for grief

Some Internet and computer-based interventions have been created for the treatment and prevention of severe, persistent, and disabling grief and tested using randomized controlled designs. These treatments have shown promising results in reducing symptoms of grief and posttraumatic stress disorder (PTSD) (Tur et al., 2019; Wagner et al., 2020). Some of them included minimal therapeutic support (e.g., explanations about homework and minor logistical help) (Eisma et al., 2015; Litz et al., 2014; van der Houwen et al., 2010), and other studies involved individualized feedback from a therapist (Kersting et al., 2011, Kersting et al., 2013; Wagner et al., 2006; Wagner & Maercker, 2007). Regarding the format of the interventions and the technology used, some of them used communication by e-mail (Eisma et al., 2015; van der Houwen et al., 2010; Wagner et al., 2006), whereas others used modules or text-based sessions presented through a website platform (Brodbeck et al., 2017; Dominick et al., 2010; Hoffmann et al., 2018; Kersting et al., 2013; Litz et al., 2014). All of the interventions used an approach based on cognitive behavioral therapy (CBT), and many of the interventions used structured writing assignments (Kersting et al., 2011, 2013; van der Houwen et al., 2010; Wagner et al., 2006; Wagner & Maercker, 2007). Other therapeutic components have also been used (i.e., psychoeducation, exposure, cognitive reappraisal, and behavioral activation).

Regarding the type of loss, each study used different criteria: people who had experienced the death of a loved one (Wagner et al., 2006), death of a first-degree relative (Eisma et al., 2015; van der Houwen et al., 2010), death of an elderly relative (Dominick et al., 2010), caregivers of deceased persons (Litz et al., 2014), loss of a partner, separation or divorce (Brodbeck et al., 2017), loss of a relative due to hematological

cancer (Hoffmann et al., 2018), mothers after pregnancy loss (Kersting et al., 2011), and parents after pregnancy loss (Kersting et al., 2013).

Many of the studies did not use a time criterion related to the loss (Hoffmann et al., 2018; Kersting et al., 2013; van der Houwen et al., 2010), whereas other studies established a minimum period of six months after the loss (Brodbeck et al., 2017; Eisma et al., 2015; Wagner et al., 2006). Other studies required that no more than six months (Dominick et al., 2010) or 12 months (Litz et al., 2014) had passed after the loss.

These interventions have been created in several languages: German (Brodbeck et al., 2017; Hoffmann et al., 2018; Kersting et al., 2013; Wagner et al., 2006), English (Dominick et al., 2010; Litz et al., 2014; van der Houwen et al., 2010), and Dutch (Eisma et al., 2015). As far as we know, to date, no treatment has been created in Spanish and tested using a randomized controlled design or any other design.

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AIMS OF THE THESIS

General aims

The main aim of this doctoral thesis was to explore the feasibility of GROw, a novel Internet-delivered cognitive-behavioral therapy (iCBT) for adults with prolonged grief disorder (PGD). As a secondary aim, the potential effectiveness of GROw in treating grief-related symptoms was explored.

Specific aims

- I. To conduct a literature review that compiles all the published studies that have tested an Internet-based treatment for PGD using randomized clinical trial study designs, providing a synthesis of the characteristics and effects of each intervention.
- II. To develop GROw, an Internet-delivered cognitive-behavioral therapy (iCBT) for adults with PGD, in the Spanish language and accessible via a web platform (psicologiaytecnologia.labpsitec.es).
- III. To assess the feasibility (usability and satisfaction) of GROw using a multiple-baseline single-case experimental AB design, where A refers to the baseline phase and B corresponds to the treatment phase.
- IV. To assess the effect of GROw using a multiple-baseline single-case design with six participants that provides at least four replications of the effect.
- V. To assess the feasibility (adherence, preferences, expectations, satisfaction, and qualitative opinions about the usefulness of the intervention) of GROw compared to the same intervention delivered face-to-face through videoconferencing, using a randomized feasibility trial study design.
- VI. To explore the potential effect of GROw, compared to the face-to-face videoconferencing format, using a randomized feasibility trial study design.

HYPOTHESES OF THE THESIS

Main hypotheses

The main hypothesis of the present doctoral thesis is that GROw will be a feasible and well-accepted iCBT, and the information obtained from the studies will allow the treatment to be scaled up by using larger samples and more complex designs such as randomized controlled trials. The secondary hypothesis of the present doctoral thesis is that GROw will have potential clinical effectiveness in treating grief-related symptoms.

Specific hypothesis

- I. GROw will be well accepted by the participants in terms of usability and satisfaction in the multiple-baseline single-case design study.
- II. GROw will show promising results in reducing grief-related symptoms in the multiple-baseline single-case study.
- III. The randomized feasibility trial study will show that GROw is well accepted by the participants in terms of adherence, preferences, expectations, satisfaction, and qualitative opinions about the usefulness of the intervention.
- IV. GROw will show promising results in reducing grief-related symptoms, compared to the same intervention delivered face-to-face through videoconference, in the randomized feasibility trial study.
- V. GROw will be a feasible iCBT, and the results will support scaling up the treatment in studies with larger samples and more complex designs, such as randomized controlled trials.

CHAPTER 1

Internet-based Psychological Treatments for Grief: Review of Literature /
Tratamientos Psicológicos Basados en Internet para el Duelo: Revisión de
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Internet-based Psychological Treatments for Grief: Review of Literature / Tratamientos Psicológicos Basados en Internet para el Duelo: Revisión de la Literatura

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RESUMEN

Existen tratamientos cognitivo-conductuales eficaces para tratar el duelo prolongado, pero muchas personas no pueden acceder a ellos. Por su accesibilidad, el uso de Internet es una alternativa a este problema. El objetivo de este estudio fue revisar la literatura sobre las intervenciones psicológicas basadas en Internet para el duelo. Se realizó una búsqueda de palabras clave en tres bases de datos (PubMed, Web of Science y PubPsych) y se analizaron los estudios seleccionados. Los tratamientos online para el duelo arrojan resultados predominantemente positivos en cuanto a la reducción de síntomas de duelo y otros síntomas clínicos. Estos resultados son prometedores y ofrecen una primera aproximación sobre la eficacia de los tratamientos a través de Internet para el duelo.

Palabras clave: Trastorno de Duelo Prolongado, Duelo, Tratamientos Psicológicos, Internet, Revisión.

ABSTRACT

There are effective cognitive-behavioral treatments to treat prolonged grief, but many people cannot access them. Because of its accessibility, the use of internet is an alternative to this problem. The aim of this study was to review the literature of internet-based psychological interventions for grief. A search of keywords in three databases was carried out (PubMed, Web of Science y PubPsych) and the selected studies were analyzed. Online treatments for grief show predominantly positive results in terms of reducing grief symptoms and other clinical symptoms. These results are promising and offer a first approximation about the effectiveness of Internet-based treatments for grief.

Keywords: Prolonged Grief Disorder, Mourning, Psychological Treatments, Internet, Review.

1. INTRODUCCIÓN

El duelo es una reacción emocional que tiene lugar ante la pérdida de un ser querido. Se refiere a la transición entre la pérdida y la adaptación a la misma (Parkes, 1988). Durante este proceso, los sentimientos intensos de lamento y anhelo se consideran naturales y normalmente disminuyen con el tiempo (Jordan y Litz, 2014). Sin embargo, algunas personas tienen dificultad para adaptarse a la pérdida y desarrollan un duelo persistente.

La CIE-11 (*World Health Organization*, 2018) denomina Trastorno de Duelo Prolongado (TDP) a esta dificultad de adaptación relacionada con la pérdida. Propone el TDP como una nueva categoría dentro de los trastornos relacionados con estrés y trauma y lo define como un trastorno en el que, tras la muerte de una persona cercana, se sufre una respuesta intensamente dolorosa, incapacitante y anormalmente persistente (6 meses o más) que claramente excede las normas sociales, culturales o religiosas esperadas para la cultura y el contexto del individuo. Por su parte, el DSM-5 (*Association American Psychiatric*, 2013) lo denomina Trastorno de Duelo Complejo Persistente (TDCP). Lo define como anhelo persistente, pena, malestar emocional intenso o preocupación en relación a la persona fallecida o las circunstancias de la muerte que perdura durante más de 12 meses. Estos criterios propuestos en el DSM-5 se encuentran en el capítulo de afecciones que necesitan más estudio. Un estudio reciente realizado a 551 personas en duelo determinó que la prevalencia de participantes con alta probabilidad de ser diagnosticados de TDCP fue significativamente más baja (8,2%) que la prevalencia de participantes con alta probabilidad de ser diagnosticados de TDP (19,2%) (Boelen, Lenferink, y Smid, 2019). Aun así, esta reciente inclusión a los manuales diagnósticos es controvertida. En el DSM-IV-TR (*American Psychiatric Association*, 2002) y la CIE-10 (*World Health Organization*, 1992) no se contemplaba que el duelo pudiera llegar a ser patológico, y la distinción se realizaba entre el duelo normativo y el Trastorno Depresivo Mayor (TDM). Existen diversas opiniones en cuanto a la inclusión del TDP como una nueva categoría diagnóstica. Un estudio realizado a 2.088 profesionales de la salud mental determinó que solo el 42,2% de los encuestados consideraron que las ventajas de incluir el diagnóstico superaban las desventajas, frente a un 32,9 % que llegó a la conclusión de

que incluir el diagnóstico generaba más desventajas, y un 24,7% que consideraba que existían ventajas y desventajas de manera equilibrada (Dietl, Wagner, y Fydrich, 2018). Uno de los motivos por los que no se considera el duelo como un trastorno mental es debido a que se trata de algo temporal, normal y que se da en respuesta a un evento y, por tanto, incluirlo en los manuales de diagnóstico podría conducir a la medicalización y el estigma de esta condición (Fallis, 2013). Sin embargo, existe una amplia evidencia que determina que los síntomas relacionados con el duelo no prolongado son distintos a los que se producen en el duelo prolongado o complejo persistente. En el duelo prolongado aparece, por ejemplo, problemas para aceptar el fallecimiento, desesperanza respecto al futuro o enfado relacionado con la pérdida. Además, se produce un aumento tanto de la intensidad de los síntomas como en su duración, así como malestar significativo e interferencia que va más allá de lo esperado en relación al evento (Boelen y van den Bout, 2008; Dillen, Fontaine, y Verhofstadt-Denève, 2008; Holland, Neimeyer, Boelen, y Prigerson, 2009; Prigerson et al., 1995) Además, un estudio realizado por Lichtenthal et al. (2018) analizó el impacto de proporcionar información sobre el diagnóstico de TDP a distintos profesionales de salud mental y concluyeron que aquellos que recibieron información sobre TDP no tenían más probabilidades de patologizar el duelo normativo que aquellos que no recibieron esta información. Por otro lado, un conjunto sustancial de investigaciones ha demostrado que el TDP, debido a características como su etiología, curso y respuesta al tratamiento, constituye un trastorno distinto al TDM (Prigerson et al., 2009).

En cuanto a su prevalencia, un meta-análisis reciente refleja una tasa de prevalencia agrupada de TDP del 9,8% en población adulta no psiquiátrica que ha sufrido una pérdida (Lundorff et al., 2017). Aun así, el período de duelo no se asocia únicamente con riesgo de desarrollar TDP, se relaciona también con riesgo elevado de aparición de múltiples trastornos psicológicos, entre los que destacan el trastorno de pánico, TDM y el trastorno de estrés postraumático (TEPT) (Keyes et al., 2014). Además, el duelo está relacionado con el incremento de riesgo de mortalidad debido a distintas causas, incluido el suicidio, y personas en duelo tienen más probabilidades de tener problemas de salud física, mayores tasas de discapacidad, mayor uso de medicamentos y hospitalización (Stroebe, Schut, y Stroebe, 2007), así como una mayor interferencia social y laboral (Simon et al., 2007).

Varios ensayos controlados aleatorizados han demostrado que existen tratamientos cognitivo-conductuales (TCC) eficaces para el TDP, tanto en formato tradicional cara a cara (Acierno et al., 2012; Boelen, de Keijser, van den Hout, y van den Bout, 2007; Bryant et al., 2014; Shear, Frank, Houck, y Reynolds, 2005; Shear et al., 2014) como en formato de tratamiento a través de internet (p.ej., Kersting et al., 2013; Litz et al., 2014; Wagner, Knaevelsrud, y Maercker, 2006). Hasta la fecha, el enfoque de tratamiento tradicional más estudiado es el propuesto por Shear, Frank, Houck, y Reynolds (2005), denominado Tratamiento de Duelo Complicado. Su objetivo es identificar y resolver las complicaciones del duelo, así como facilitar la adaptación a la pérdida. En el Tratamiento de Duelo Complicado aparecen componentes de confrontación con la pérdida adaptados de las técnicas de exposición utilizadas en el tratamiento del TEPT (Foa, y Rothbaum, 1998; Hembree, Foa, Dorfan, Street, y Kowalski, 2003). Esta intervención ha demostrado ser un tratamiento mejorado en comparación con la psicoterapia interpersonal (Weissman y Markowitz, 2000) ya que, a pesar de que ambas han demostrado ser eficaces, el Tratamiento de Duelo Complicado muestra tasas de respuesta más altas y un tiempo de respuesta más rápido. Tomados juntos, todos los ensayos sugieren que las intervenciones que incluyen estrategias para reducir la evitación, tanto de pensamientos como de experiencias o lugares relacionados con la pérdida, son más eficaces que aquellos tratamientos que no incluyen estas técnicas (Shear, 2015). En relación a otro tipo de intervenciones, Huang et al. (2019) demostraron que una terapia cognitiva basada en *mindfulness* para individuos en duelo de 8 semanas de duración mejoró significativamente la regulación emocional y el control ejecutivo de los participantes.

Sin embargo, que existan tratamientos psicológicos eficaces no asegura que las personas que los requieren accedan a los mismos. Se necesitan diferentes formas de administrar los tratamientos para mejorar su diseminación y que puedan llegar a un mayor número de personas desatendidas (Kazdin, 2015). En esta línea, el acceso a intervenciones mediante el uso de ordenadores o internet es cada vez más popular. Este tipo de tratamiento permite que las personas trabajen en base a material de terapia de forma independiente, con o sin asistencia mínima de un terapeuta u otro profesional de salud mental. El formato de tratamiento a través de internet se puede aplicar mediante ordenador, *Tablet* o móvil inteligente (*Smartphone*). Estas intervenciones incluyen un mayor acceso a la atención, menor estigma en comparación con la visita a clínicas de salud mental y permiten eludir obstáculos específicos del diagnóstico o tratamiento, como

cuando la ansiedad social impide al paciente salir de casa (Aboujaoude, Salame, y Naim, 2015). Además, son rentables y a menudo más baratas en comparación con las intervenciones cara a cara (Musiat y Tarrier, 2014). En cuanto a su eficacia, diferentes estudios de meta-análisis indican que tamaños del efecto de intervenciones basadas en internet fueron comparables con intervenciones cara a cara tradicionales (Andersson, Cuijpers, Carlbring, Riper, y Hedman, 2014; Andrews et al., 2018; Andrews, Newby, y Williams, 2014; Sijbrandij, Kunovski, y Cuijpers, 2016).

A pesar de las pruebas sustanciales que demuestran los beneficios de intervenciones basadas en internet para una gran variedad de trastornos psicológicos en general, la evidencia de estos tratamientos para el duelo todavía no se ha establecido. Así pues, se han desarrollado programas de tratamiento basados en internet para el duelo pero, que sepamos, los resultados de estos estudios no se han revisado hasta la fecha. Por tanto, el objetivo de este trabajo es llevar a cabo una primera revisión de la literatura acerca del uso este tipo de intervenciones para el tratamiento del duelo mediante la identificación y síntesis de los hallazgos publicados.

2. MÉTODO

2.1 Estrategia de búsqueda

Para recopilar las publicaciones más relevantes se realizó una búsqueda sistematizada el 16 de abril de 2019 en las bases de datos PubMed, Web of Science y PubPsych. Se utilizó la siguiente secuencia de palabras clave: [(grief OR bereaved) AND (“psychological treatments” OR intervention OR therapy) AND (internet OR online OR ICTs OR “Information and Communication Technologies”)]. El TDP ha sido recientemente incluido como categoría diagnóstica en la CIE-11 (WHO, 2018), por tanto, no se ha utilizado como palabra clave debido a que, en muchos de los estudios publicados hasta el momento, todavía no se incluye específicamente este concepto. No se utilizó un intervalo de tiempo específico en la búsqueda.

2.2 Proceso y criterios de selección

Los títulos y resúmenes de los artículos se examinaron para determinar su inclusión en la fase de lectura de texto completo tras eliminar los registros duplicados. Los criterios de inclusión fueron (a) que la intervención estuviera enfocada hacia personas en duelo, (b) que los participantes fueran mayores de 18 años de edad, (c) que el programa de intervención fuera diseñado para prevenir o mejorar problemas de salud mental

relacionados con la pérdida, (d) que la intervención fuera administrada a través de internet, (e) que el diseño experimental del estudio fuera un ensayo controlado aleatorizado (ECA). Fueron excluidos estudios que (a) su intervención no estaba dirigida exclusivamente a personas en duelo, (b) los participantes tenían menos de 18 años de edad y (c) eran estudios cualitativos, estudios de caso, revisiones o protocolos de estudio que ya contaban con resultados posteriores de eficacia. Todos los documentos que, tras leer el título y resumen, parecían ajustarse a los criterios de inclusión/exclusión fueron recuperados para la lectura de su texto completo. Tras ello, se evaluó la elegibilidad de cada uno y se tomó nota de las razones de exclusión. Cualquier cuestión relacionada con la elegibilidad de un artículo fue resuelta a través de discusiones de equipo. La figura 1 muestra el diagrama de flujo de la selección de los estudios desde la selección inicial hasta la muestra incluida en la revisión.

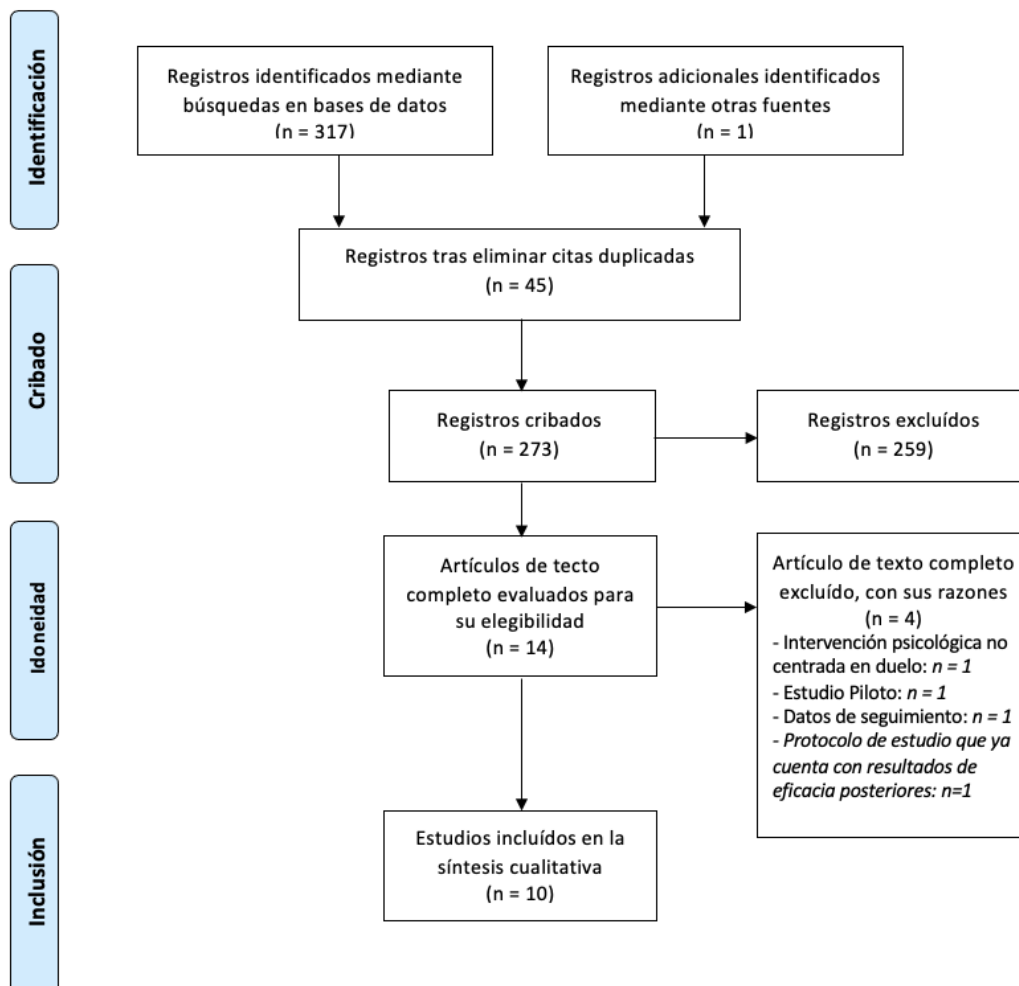


Fig 1. Flujo de información de las diferentes fases de una revisión sistemática. Adaptación al español de PRISMA 2009 Flow Diagram

3. RESULTADOS

A continuación, se describen las características más importantes de los 10 artículos seleccionados. Una síntesis de esta información se puede consultar en la tabla 1.

3.1 Metodología empleada y tipo de estudio

La mayoría de los ensayos controlados aleatorizados (ECAs) utilizados en los estudios encontrados incluyó un grupo de lista de espera como condición de grupo control (9/10). La duración de la espera varió desde 5 a 12 semanas, a excepción de dos de los estudios (2/10; Eisma et al., 2015; van der Houwen, Schut, van den Bout, Stroebe, y Stroebe, 2010), en los que los participantes accedieron al tratamiento inmediatamente después de responder el último set de cuestionarios. En todos los casos se dio la posibilidad a los participantes de realizar los tratamientos en línea o un tratamiento en persona tras completar la participación. Por su parte, Dominick et al., (2010) utilizaron el tratamiento habitual como intervención para el grupo control. En cuanto al grupo experimental, la mayoría de los estudios (9/10) emplearon un solo protocolo de tratamiento, mientras que Eisma et al. (2015) aplicaron dos condiciones de tratamiento (exposición y activación comportamental) y, por tanto, incluyeron dos grupos en la condición experimental.

3.2 Características de la muestra

El número de integrantes de los estudios varió en cada caso, con un mínimo de 47 participantes y un máximo de 757, a excepción de Hoffmann et al. (2018), cuyo estudio todavía está en marcha, aunque se prevé una muestra mayor o igual a 128 participantes.

En cuanto al tipo de pérdida, cada investigación estableció un perfil distinto: personas que habían sufrido la muerte de un ser querido (1/10; Wagner, Knaevelsrud, y Maercker, 2006), muerte de un familiar de primer grado (2/10; Eisma et al., 2015; van der Houwen et al., 2010), muerte de un pariente mayor (1/10; Dominick et al., 2010), cuidadores de personas fallecidas (1/10; Litz et al., 2014), pérdida de pareja, separación o divorcio (1/10; Brodbeck et al., 2019), pérdida de un familiar por cáncer hematológico (1/10; Hoffmann et al., 2018) y pérdida de un hijo durante el embarazo (3/10; Kersting et al., 2013; Kersting, Dölemeyer, Wagner, y Linde, 2017; Klinitzke, Dölemeyer, Steinig, Wagner, y Kersting, 2013). Cabe destacar que no existen tres investigaciones distintas que hayan evaluado una muestra de madres y padres tras la muerte de un hijo durante el

embarazo, sino que se trata de una sola intervención cuyas diferentes medidas de resultado han sido publicadas en diferentes revistas científicas.

Por otro lado, el tiempo transcurrido tras la pérdida varía en cada estudio: más de 6 meses antes de comenzar la intervención (3/10; Brodbeck et al., 2019; Eisma et al., 2015; Wagner et al., 2006), como máximo 12 meses antes de la intervención (1/10; Litz et al., 2014) y entre 1-6 meses antes de la intervención (1/10; Dominick et al., 2010). El resto de estudios no establecieron un criterio temporal concreto tras la pérdida (5/10; Hoffmann et al., 2018; Kersting et al., 2013, 2017; Klinitzke et al., 2013; van der Houwen et al., 2010).

3.3 Evaluación del duelo

Cada estudio evaluó los síntomas de duelo de forma distinta mediante ítems específicos creados a partir de la literatura, escalas adaptadas, partes seleccionadas de escalas u otros cuestionarios no creados específicamente para sintomatología de duelo. Algunos utilizaron también escalas de duelo, siendo el inventario de duelo complicado (IGC; Prigerson et al., 1995) el más utilizado (3/10; Eisma et al., 2015; Hoffmann et al., 2018; Kersting et al., 2013).

3.4 Intervención

En los 10 artículos revisados fueron identificados 5 programas de intervención distintos. Más de la mitad utilizaron una intervención basada en la escritura denominada “INTERAPY” (6/10; Hoffmann et al., 2018; Kersting et al., 2013, 2017; Klinitzke et al., 2013; van der Houwen et al., 2010; Wagner et al., 2006). Esta fue desarrollada en primer lugar por Lange et. al. (2003) para el tratamiento del TEPT. Está compuesta por tres módulos: (1) Exposición a estímulos relacionados con la pérdida, (2) reestructuración cognitiva e (3) integración y restauración. El resto de programas incluyen otros elementos como psicoeducación del duelo, manejo del estrés, activación comportamental, objetivos personales, autocuidado y psicología positiva, entre otros.

La duración de las intervenciones osciló entre 5 y 10 semanas: 5 semanas (5/10; Hoffmann et al., 2018; Kersting et al., 2013, 2017; Klinitzke et al., 2013; Wagner et al., 2006), 6 semanas (1/10; Litz et al., 2014), 6-8 semanas (1/10; Eisma et al., 2015), 7 semanas (1/10; van der Houwen et al., 2010), 10 semanas (1/10; Brodbeck et al., 2019); o bien seguían el tratamiento sin un número de semanas específico (1/10; Dominick et al., 2010).

En cuanto a su formato, algunos de los tratamientos fueron aplicados a través de internet mediante correo electrónico (3/10; Eisma et al., 2015; van der Houwen et al., 2010; Wagner et al., 2006) y la mayoría a través de una plataforma web (7/10; Brodbeck et al., 2019; Dominick et al., 2010; Hoffmann et al., 2018; Kersting et al., 2013, 2017; Klinitzke et al., 2013; Litz et al., 2014).

Las intervenciones se originaron en diferentes países y, por tanto, están disponibles en distintos idiomas: alemán (6/10; Brodbeck et al., 2019; Hoffmann et al., 2018; Kersting et al., 2013, 2017; Klinitzke et al., 2013; Wagner et al., 2006), inglés (3/10; Dominick et al., 2010; Litz et al., 2014; van der Houwen et al., 2010) y holandés (1/10; Eisma et al., 2015).

El apoyo por parte de un terapeuta se dio en todos los casos excepto en el estudio de van der Houwen et al. (2010). Las intervenciones del terapeuta incluyeron supervisiones con comentarios e instrucciones de las tareas, adaptación de las mismas a cada caso y/o asistencia extra si el paciente lo requería o puntuaba alto en ciertas medidas de resultado.

3.5. Reducción de síntomas

Uno de los estudios revisados no cuenta todavía con resultados de eficacia (1/10; Hoffmann et al. 2018). La eficacia del resto de intervenciones se calculó en base a sus tamaños del efecto. Para ello, utilizaron la d de Cohen y Eta cuadrada (η^2). Según los criterios de Cohen (1988), los valores Eta cuadrada (η^2) de .01 a .04 se consideran pequeños, de .04 a .14 moderados y mayores de .14 grandes. Por su parte, en la d de Cohen, los valores menores de .50 se consideran pequeños, entre .50 y .70 moderados, y valores iguales o mayores que .80 se consideran tamaños del efecto grandes.

Los estudios que incluyeron evaluación específica de síntomas de duelo utilizaron la d de Cohen. Todos ellos establecieron un tamaño del efecto grande y significativo al comparar los resultados previos y posteriores a la intervención en el grupo experimental (con un mínimo de .80 y un máximo de 1.52) (5/10; Brodbeck et al., 2019; Eisma et al., 2015; Klinitzke et al., 2013; Litz et al., 2014; Wagner et al., 2006). Para el grupo control, el tamaño del efecto pre-post tratamiento resultó no significativo, a excepción del estudio de Wagner et al. (2006), en el que el tamaño del efecto varió con un mínimo de .009 y un máximo de .56 en el grupo control, y el estudio de Litz et al. (2014) en el que no se especifican estos resultados concretos.

Además de síntomas de duelo, se evaluaron distintas medidas clínicas de salud mental. En cuanto a síntomas depresivos, los tamaños del efecto pre-post tratamiento del grupo experimental medidos a partir de la d de Cohen dieron como resultado una reducción significativa de síntomas en todos los estudios que valoraron esta variable, con un tamaño del efecto grande (con un mínimo de .45 y un máximo de 1.47) (5/10; Brodbeck et al., 2019; Eisma et al., 2015; Klinitzke et al., 2013; Litz et al., 2014; Wagner et al., 2006). Cabe destacar que en el estudio de Eisma et al. (2015) se produjo reducción de síntomas depresivos solamente en la condición de tratamiento que incluyó exposición, frente a la condición que incluía activación comportamental, en la que estos síntomas no se redujeron de forma significativa.

Por otro lado, la mitad de los estudios (5/10; Dominick et al., 2010; Eisma et al., 2015; Klinitzke et al., 2013; Litz et al., 2014; Wagner et al., 2006) evaluaron síntomas de ansiedad. En todos ellos se produjo una reducción de la ansiedad de manera significativa en el grupo experimental, con tamaños del efecto moderados y grandes (d cohen desde .51 a 1.74; η^2 de .083), excepto en el caso del estudio de Eisma et al. (2015), en el que la reducción de síntomas de ansiedad no fue significativa para ninguna de las intervenciones utilizadas (exposición y activación comportamental).

En la tabla 1 se presenta un resumen de la información de los resultados del resto de medidas de síntomas clínicos: salud mental y física, soledad emocional, afecto positivo y negativo, actitud, autoeficacia, apoyo percibido, búsqueda de apoyo, necesidad de ayuda, síntomas de TEPT, luto, miedo a la pérdida, culpabilidad, tristeza, ira y búsqueda de significado.

Tabla 1. Características de los estudios incluidos

Estudio	N	Tipo de estudio	Tipo de duelo	Evaluación de la sintomatología	Tratamiento	Apoyo de terapeuta	Resultados	Tamaño del efecto
								d Cohen (Pre x Post)
							Duelo	
							Intrusión GE	1.52 (p<0.1)
							Intrusión GC	.56
							Evitación GE	1.25 (p<.0001)
							Evitación GC	.09
							Adaptación GE	1.47 (p<.01)
							Adaptación GC	.31
							BSI (depresión) GE	1.47 (p<.01)
							BSI (depresión) GC	.45
							BSI (ansiedad) GE	1.74 (p<.01)
							BSI (ansiedad) GC	.07
							SF-12 (salud mental) GE	.98 (p=.09)
							SF-12 (salud mental)GC	-.38
							SF-12 (salud física) GE	.02 (p=.97)
							SF- 12 (salud física) GC	-.03
								d Cohen (Pre x Post)
van der Houwen, Schut, van den Bout, Stroebe, y Stroebe. (2010)	757	ECA GE: 460 GC (LE NE nº semanas): 297	Muerte de un familiar de primer grado	Organización del apego: ECR-R Rumiación general y rumiación sobre el duelo: 8 ítems creados a partir de la literatura en general. Interpretación de duelo como amenaza: 2 ítems del cuestionario GCQ Evitación: 13 ítems creados a partir de la literatura general	Tareas de escritura basadas en Lange et al. (2003): 1. Exposición a estímulos relacionados con la pérdida 2. Reestructuración cognitiva 3. Integración y restauración • Administración mediante	Sin intervención de un terapeuta	Soledad emocional GE Soledad emocional GC PANAS GE PANAS GC	.19 NE .30 NE

			Reacciones de duelo: 9 ítems formulados a partir de Prigerson, Vanderwerker, y Maciejewski, 2008 Otras medidas de estado de ánimo (PANAS) y soledad emocional	<ul style="list-style-type: none"> correo electrónico 7 semanas 		Apego, rumiación, interpretación del duelo como amenaza, evitación, reacciones de duelo	NE
Dominick et al. (2010)	86	ECA GE (Atención inmediata): 33 GC (Tratamiento habitual): 34	Muerte reciente (1-6 meses) de un pariente mayor. 4 ítems sobre reacciones de duelo en el último mes: 1) ¿qué probabilidad tienes de experimentar episodios de duelo?, 2) ¿hasta qué punto ha interferido el duelo en tus pensamientos cotidianos?, 3) ¿Con qué frecuencia te has sentido decaído, deprimido o sin esperanza?, 4) ¿Con qué frecuencia has tenido poco interés o placer en hacer las cosas? Otras medidas de actitud, autoeficacia y ansiedad (STAI)	<p>Making Sense of Grief:</p> <ol style="list-style-type: none"> Identificación del estilo de duelo Reconstrucción del significado, reacciones típicas del duelo y factores individuales Recursos: lista de sitios web y libros <ul style="list-style-type: none"> Administración mediante plataforma web Semanas NE 	NE	Actitud Autoeficacia STAI	<p>Eta-cuadrado</p> <p>$\eta^2 = .177$ ($p < .001$)</p> <p>$\eta^2 = .106$ ($p < .011$)</p> <p>$\eta^2 = .083$ ($p < .024$)</p>
Kersting et al. (2013, 2011)	228	ECA GE: 115 GC (LE 5 semanas): 113	Madres y padres tras la pérdida de un niño durante el embarazo Angustia asociada a un trauma específico (adaptado para la pérdida): IES - R Reacción de duelo: ICG - R Otras medidas de psicopatología general (BSI), depresión (BSI) y ansiedad (BSI)	<p>Tareas de escritura basadas en Lange et al. (2003):</p> <ol style="list-style-type: none"> Exposición a estímulos relacionados con la pérdida Reestructuración cognitiva Intercambio social <ul style="list-style-type: none"> Administración mediante plataforma web 5 semanas 	Adaptación de las tareas a cada caso por un terapeuta y comentarios sobre las tareas mediante la plataforma web. Comunicación puntual mediante correo electrónico si el paciente lo requiere	<p>IES - R GE</p> <p>IES - R GC</p> <p>ICG - R GE</p> <p>ICG - R GC</p> <p>BSI (Salud mental) GE</p> <p>BSI (Salud mental) GC</p> <p>BSI (Depresión) GE</p> <p>BSI (Depresión) GC</p> <p>BSI (Ansiedad) GE</p> <p>BSI (Ansiedad) GC</p>	<p>d Cohen (Pre x Post)</p> <p>1.02 ($p < 0.001$)</p> <p>n.s.</p> <p>.98 ($p < 0.001$)</p> <p>n.s.</p> <p>.78 ($p < 0.001$)</p> <p>n.s.</p> <p>.75 ($p < 0.001$)</p> <p>n.s.</p> <p>.59 ($p < 0.001$)</p> <p>n.s.</p>

Klinitzke, Dölemeyer, Steinig, Wagner, y Kersting (2013)	228	ECA GE: 115 GC (LE 5 semanas): 113	Madres y padres tras la pérdida de un niño durante el embarazo	Angustia asociada a un trauma específico (adaptado para la pérdida): IES - R Otras medidas de psicopatología general (BSI), depresión (BSI), ansiedad (BSI) y apoyo social (BSSS)	Tareas de escritura basadas en Lange et al. (2003): 1. Exposición a estímulos relacionados con la pérdida. 2. Reestructuración cognitiva 3. Intercambio social • Administración mediante plataforma web • 5 semanas	Adaptación de las tareas a cada caso por un terapeuta y comentarios sobre las tareas mediante la plataforma web. Comunicación puntual mediante correo electrónico si el paciente lo requiere	Apoyo percibido GE + GC (tras LE)	d Cohen (Pre x Post) .24 (p<0.007)
							Apoyo recibido GE + GC (tras LE)	.19 (p<0.036)
							Necesidad de ayuda GE + GC (tras LE)	.22 (p<0.017)
							Búsqueda de apoyo GE + GC (tras LE)	.20 (p<0.022)
Litz et al. (2014)	84	ECA GE: 41 GC (LE 6 semanas): 43	Cuidadores de personas fallecidas recientemente (tiempo < 12 meses)	Síntomas significativos de TDP y deterioro funcional (PG-13) Otras medidas de depresión (BDI-II), ansiedad (BAI) y TEPT (PCL-C)	Programa Healthy Experiences After Loss (HEAL): 1. Psicoeducación 2. Manejo de estrés y habilidades de afrontamiento 3. Activación comportamental 4. Objetivos personales 5. Prevención de recaídas • Administración mediante plataforma web • 6 semanas	Una llamada telefónica del terapeuta al comienzo y al final de la intervención. Correos electrónicos breves durante la intervención y llamada en caso de puntuación alta en angustia o si el paciente lo indicaba	PG-13 GE	d Cohen (Pre x Post) 1.10 (p<0.05)
							PG-13 GC	NE
							BDI-II GE	.71 (p<0.05)
							BDI-II GC	NE
							PCL GE	.91 (p<0.05)
PCL GC	NE							
BAI GE	.51 (p<0.05)							
BAI GC	NE							
Eisma et al. (2015)	47	ECA GE (exposición): 18 GC (activación comportamental): 17 GC (LE): 12	Muerte de un familiar de primer grado (tiempo > 6 meses)	Reacción de duelo (ICG) Rumiación sobre la pérdida (UGRS) Otras medidas de depresión y ansiedad (HADS) y TEPT (PSS)	1. Exposición 2. Activación comportamental • Administración mediante correo electrónico • 6-8 semanas	Comentarios de un terapeuta de cada tarea realizada mediante correo electrónico	<u>Exposición</u> GE:	d Cohen (Pre x Post)
							ICG	.8 (p<0.02)
							PSS	1.0 (p<0.003)
							HADS	.7 (p<0.03)
							(Depresión)	1.2 (p<0.02)
							UGRS	n.s.
							HADS (ansiedad)	n.s. (para todas las

								GC:	variables)
								<u>Activación</u> <u>comportamental</u> <u>GE:</u>	
								IGC	.9 (p<0.008)
								PTSD	.8 (p<0.003)
								UGRS	.8 (p<0.01)
								HADS (depresión)	n.s.
								HADS (ansiedad)	n.s.
								<u>GC:</u>	n.s. (para todas las variables)
									d Cohen (Pre x Post)
								Texas Revised Inventory of Grief GE	-0.88 (p<0.05)
								Texas Revised Inventory of Grief GC	-0.17 (p<0.05)
								BDI-II GE	-0.84 (p<0.05)
								BDI-II GC	-0.30 (p<0.05)
								BSI GE	-0.60 (p<0.05)
								BSI GC	-0.25 (p<0.05)
								Embitterment Scale GE	-0.45 (p<0.05)
								Embitterment Scale GC	-0.06 (p<0.05)
								De Jong Gierveld Short Scale GE	-0.63 (p<0.05)
								De Jong Gierveld Short Scale GC	-0.20 (p<0.05)
								SWLS GE	-0.16 (p<0.05)
								SWLS GC	-0.24 (p<0.05)
Brodbeck, Berger, Biesold, Rockstroh, y Znoj. (2019)	110	ECA GC: 61 GE (LE 12 semanas): 49	Pérdida de la pareja, separación o divorcio. Tiempo tras la pérdida ≥ 6 meses	Síntomas de duelo: Texas Revised Inventory of Grief – Versión alemana (Znoj, 2008) Otras medidas de depresión (BDI-II), angustia psicopatológica (BSI), amargura (Embitterment Scale; Znoj and Schnyder, 2014), soledad (De Jong Gierveld Short Scale; De Jong Gierveld and Van Tilburg, 2010), y satisfacción con la vida (SWLS)	1. Psicoeducación 2. Autocuidado y pensamientos y emociones positivas 3. Aceptación de recuerdos. 4. Restauración: nueva vida y relaciones sociales 5. Redefinición de la relación • Administración mediante plataforma web • 10 semanas	1 correo electrónico de apoyo por semana por parte de un terapeuta. Comunicación extra si el paciente lo requería			
Kersting, Dölemeyer,	228	ECA GE: 115	Madres y padres tras	Magnitud del luto tras la pérdida: MTS escala general	Tareas de escritura basadas en Lange et al. (2003):	Adaptación de las tareas a cada caso por un terapeuta y			d Cohen (Pre x Post)

Wagner, y Linde. (2017)	GC (LE 5 semanas): 113	la pérdida de un niño durante el embarazo	Tristeza, miedo a la pérdida, culpabilidad, ira y búsqueda de significado: MTS subescalas	<ol style="list-style-type: none"> Exposición a estímulos relacionados con la pérdida Reestructuración cognitiva Intercambio social <ul style="list-style-type: none"> Administración mediante plataforma web 5 semanas 	comentarios sobre las tareas mediante la plataforma web. Comunicación puntual mediante correo electrónico si el paciente lo requiere	Luto GE Luto GC Tristeza GE Tristeza GC Miedo a la pérdida GE Miedo a la pérdida GC Culpabilidad GE Culpabilidad GC Ira GE Ira GC Búsqueda de significado GE Búsqueda de significado GC	- .88 (p<0.001) - .21 (p<0.01) - .84 (p<0.001) - .18 (p=0.01) - .78 (p<0.001) - .15 (p=0.01) - .58 (p<0.001) - .17 (p<0.01) - .46 n.s. .19 (p=0.01) n.s.
Hoffmann et al. (2018)	≥ 128 ECA GC: NE GE (LE 5 semanas): NE	Pérdida de familiar por cáncer hematológico	Síntomas de duelo (ICG) Otras medidas de depresión (PHQ-9), TEPT (IES-R), ansiedad (GAD-7), calidad de vida (QRI), crecimiento postraumático (PGI), evitación (DAAPGQ), religiosidad (SBI-15R), ansiedad de separación (ASA-27), relaciones sociales (BSSS) y calidad de relación con los difuntos (DEQ)	Tareas de escritura basadas en Lange et al. (2003): <ol style="list-style-type: none"> Exposición a estímulos relacionados con la pérdida Reestructuración cognitiva Intercambio social <ul style="list-style-type: none"> Administración mediante página web 5 semanas 	Comentarios de un terapeuta de cada tarea mediante la plataforma web. Asistencia por correo electrónico o telefónica en casos de alta angustia o pensamientos suicidas	Todavía no cuenta con resultados de eficacia	

Nota. ECA: Ensayo controlado aleatorizado. GE: Grupo experimental. GC: Grupo control. LE: Lista de espera. NE: No especificado. TEPT: Trastorno de estrés postraumático. n.s.: No significativo. IES: Impact of Event Scale (Horowitz, Wilner, y Alvarez, 1979; Zilberg, Weiss, y Horowitz, 1982). BSI: Brief Symptom Inventory (Derogatis, 1992). SF-12: General mental and physical health (Ware, Kosinski, y Keller, 1996). ECR-R: Experiences in Close Relationships-Revised Questionnaire (Fraley, Waller, y Brennan, 2000). GCQ: Grief Cognitions Questionnaire (Boelen y Lensvelt-Mulders, 2005). PANAS: Positive Affect Negative Affect Schedule (Watson, Clark, y Tellegen, 1988). STAI: State-Trait Anxiety Inventory (Spielberger, Gorsuch, y Lushene, 1970). IES-R: Impact of Event Scale (Horowitz et al. 1979). ICG: Inventory of Complicated Grief (Prigerson et al., 1995). BSSS: Berliner Social Support Skalen (Schulz und Schwarzer, 2003). PG-13: Prolonged Grief Inventory (Prigerson et al., 2009). BDI-II: Revised Beck Depression Inventory (Beck et al., 1996). BAI: Beck Anxiety Inventory (Beck, Epstein, Brown, y Steer, 1988). PCL-C: Posttraumatic Checklist (Weathers, Litz, Huska, y Keane, 1994). UGRS: Utrecht Grief Rumination Scale (Eisma, Stroebe, et al., 2014). HADS: Hospital Anxiety and Depression Scale (Zigmond y Snaith, 1983; Dutch version: Spinhoven et al., 1997). PSS: PTSD Symptom Scale (Foa, Cashman, Jaycox, y Perry, 1997; Dutch version: Engelhard, Arntz, y van den Hout, 2007). SWLS: Satisfaction with life scale (Schumacher, 2003). MTS: Münchener Trauerskala (Beutel et al. 1995). PHQ-9: Patient Health Questionnaire (Kroenke, Spitzer RL, Williams JB., 2001). GAD-7: Generalized Anxiety Disorder Screener (Spitzer, Kroenke, Williams, Löwe, 2006). QRI: Quality of Relationships Inventory (Pierce, Sarason, Sarason, 1991). DAAPGQ: Depressive and Anxious Avoidance in Prolonged Grief Questionnaire (Boelen, van den Bout, 2013). SBI-15R: Systems of Belief Inventory (Holland et. al., 1998). ASA-27: Adult Separation Anxiety Questionnaire (Manicavasagar, et. al., 2003). DEQ: Depressive Experience Questionnaire (Beutel, et. al. 2004).

4. DISCUSIÓN

Que tengamos constancia, esta es la primera revisión que ofrece una visión general de la naturaleza y efectividad de intervenciones en salud mental basadas en internet para personas en duelo. Los resultados de esta investigación sugieren que estas intervenciones pueden ser un enfoque prometedor para el tratamiento y prevención del TDP, reduciendo tanto síntomas específicos de duelo como otros síntomas clínicos, en especial depresión y ansiedad.

En cuanto a la efectividad de los tratamientos basados en internet para el duelo, los resultados son predominantemente positivos. Se encontraron tamaños del efecto medianos y grandes en síntomas de duelo, ansiedad, depresión y otros síntomas relacionados con salud mental y física en la mayoría de los estudios revisados. Estos hallazgos se encuentran en la línea de otras investigaciones que indican altos tamaños del efecto comparables a los obtenidos en intervenciones cara a cara tradicionales en intervenciones cognitivo-conductuales basadas en internet para trastornos de ansiedad, síntomas depresivos y TEPT (Andersson et al., 2014; Andrews et al., 2018; Andrews et al., 2014; Sijbrandij et al., 2016).

En cuanto a la reducción de síntomas de duelo en el grupo control, en la mayoría de los estudios se observó un tamaño del efecto no significativo en las medidas pre-post lista de espera/control activo. Aun así, se ha observado que algunos síntomas mejoraban de forma significativa en el grupo control. Esto podría deberse a una recuperación espontánea que podría solaparse con los resultados terapéuticos, por lo que se necesitan más estudios en esta línea que evalúen la relación entre recuperación de síntomas clínicos y temporalidad en TDP.

Excepto en la intervención propuesta por van der Houwen, Schut, van den Bout, Stroebe, y Stroebe (2010), todos los protocolos contemplan algún grado de apoyo u orientación de un terapeuta durante el tratamiento. La literatura muestra la importancia de proporcionar este apoyo y refleja un tamaño del efecto mayor en tratamientos cognitivo-conductuales a través de ordenador o basados en internet que incluyen el apoyo de un terapeuta, en comparación con protocolos de tratamiento que no incluyeron soporte humano (Andersson y Cuijpers, 2009; Richards y Richardson, 2012). Se analizaron estudios que muestran tamaños del efecto menores que el resto, como es el caso de Klinitzke, Dölemeyer, Steinig, Wagner y Kersting, (2013). En este estudio evaluaron

apoyo social y necesidad de ayuda, aspectos que no se relacionan con síntomas centrales de duelo, ya que el proceso de duelo se caracteriza por intenso anhelo o dolor emocional, preocupación frecuente, pensamientos y recuerdos de la persona fallecida, sentimientos de incredulidad o incapacidad para aceptar la pérdida y dificultad para imaginar un futuro significativo sin la persona fallecida (Shear, 2015). Además, la intervención proporcionada en este estudio no estaba dirigida a un cambio en las dimensiones de apoyo social, por tanto, el motivo por el que los tamaños del efecto fueron menores que en otros estudios puede deberse a que el tratamiento no contempló específicamente el ámbito social.

Por otra parte, más de la mitad de los estudios utilizaron un enfoque de tratamiento adaptado al TDP denominado “INTERAPY”. Este enfoque se basa en la escritura y fue propuesto por Lange et al. (2003) como protocolo de intervención a través de internet para personas con TEPT. Este tratamiento para el TEPT produjo reducción de psicopatología general y síntomas relacionados con el trauma, con tamaños del efecto grandes. Estos resultados son similares a los obtenidos en algunos estudios revisados que utilizaron la intervención “INTERAPY” adaptada al duelo (Hoffmann et al., 2018; Kersting et al., 2013, 2017; Wagner et al., 2006), ya que en ellos se produjo una reducción de psicopatología general, así como de síntomas de duelo, con tamaños del efecto grandes. No obstante, en los estudios de Klinitzke et al. (2013) y van der Houwen et al. (2010), que también utilizaron este enfoque de tratamiento basado en la escritura, se obtuvieron tamaños del efecto bajos. Esto podría deberse a lo mencionado anteriormente: la evaluación de síntomas que no estaban directamente relacionados con el duelo (Klinitzke et al., 2013) y la falta de apoyo por parte de un terapeuta durante el tratamiento (van der Houwen et al., 2010).

En cuanto a las características de la muestra en los estudios revisados, en primer lugar, cabe destacar que no existió homogeneidad en relación a criterios temporales ya que cada investigación estableció un período de tiempo mínimo y/o máximo tras la pérdida. Esto puede deberse a varios motivos. Hay estudios que se plantean como preventivos del duelo complicado (Dominick et al., 2010; Litz et al., 2014) y establecen que la pérdida se tuvo que dar 6 meses antes de comenzar el tratamiento. Además, los criterios diagnósticos del duelo complicado no están claros ya que la CIE-11 (WHO, 2018) establece que los síntomas deben durar 6 meses o más, dependiendo de cultura y factores contextuales, mientras que el DSM-5 (Association American Psychiatric, 2013)

establece que los síntomas o circunstancias de la muerte han de durar más de 12 meses. Un estudio reciente que evaluó a 2.088 profesionales de salud mental determinó que un mayor número de estos profesionales preferían establecer un periodo de 12 meses tras la pérdida en lugar de 6 meses (Dietl et al., 2018). Por tanto, se necesitan más estudios en esta línea para asegurar que en investigaciones sobre el duelo futuras se utilicen los mismos criterios diagnósticos temporales, y así asegurar la homogeneidad de las muestras con TDP. Esto también permitirá establecer y delimitar criterios claros entre intervención preventiva y tratamiento del TDP. Por otro lado, tampoco existió homogeneidad en la muestra en relación al tipo de pérdida y las características de la misma, ya que se establecen diferentes perfiles en cada estudio: muerte de un ser querido (Wagner et al., 2006), muerte de un familiar de primer grado (Eisma et al., 2015; van der Houwen et al., 2010), muerte de un pariente mayor (Dominick et al., 2010), cuidadores de personas fallecidas (Litz et al., 2014), pérdida de pareja, separación o divorcio (Brodbeck et al., 2019), pérdida de un familiar por cáncer hematológico (Hoffmann et al., 2018) y pérdida de un hijo durante el embarazo (Kersting et al., 2013, 2017; Klinitzke et al., 2013). Aun así, todos los estudios establecieron que el duelo debía aparecer a raíz de una pérdida por fallecimiento, excepto en el estudio de Brodbeck et al., (2017), en el que se tiene en cuenta también la separación o divorcio de la pareja. Los criterios de la CIE-11 (WHO, 2018), así como los que se establecen en el DSM-5 (Association American Psychiatric, 2013) determinan que el TDP o TDCP aparece tras el fallecimiento de una persona cercana. Aun así, una ruptura o separación requiere adaptación a la pérdida y la formación de una nueva identidad y una nueva perspectiva para el futuro, ya que implica una disolución de lazos sociales y emocionales (Znoj, 2016), consecuencias similares a las padecidas tras una muerte por fallecimiento. Además, existen relativamente pocos tratamientos psicológicos establecidos para personas que han sufrido una pérdida por separación o divorcio (Bourassa, Manvelian, Boals, Mehl, y Sbarra, 2017). Por tanto, estos podrían ser algunos de los motivos por los cuales Brodbeck et al. (2017) incluyeran en su estudio pacientes con este perfil. En un estudio reciente realizado por Quero et al. (2019) se encontró una eficacia similar de un TCC aplicado cara a cara y apoyado por realidad virtual, mostrándose ambas condiciones de intervención superiores a un grupo control lista de espera en el tratamiento de trastornos relacionados con estrés (trastornos adaptativos y TDP). El evento estresante sufrido en el 25.93% de los pacientes fue una ruptura sentimental o divorcio. El principal objetivo del tratamiento aplicado fue la reconstrucción del significado tras el suceso estresante, con la finalidad de conseguir un

significado más positivo y, de este modo, permitir el crecimiento postraumático y el aprendizaje a partir de la experiencia negativa. En cualquier caso, está por determinar si diferentes tipos de pérdida y sus características puedan requerir variaciones en su intervención.

Otro aspecto importante a destacar es el hecho de que los resultados informan de una reducción significativa de síntomas relacionados con el duelo, pero también de síntomas relacionados con el estado de ánimo deprimido, pudiendo haberse dado un solapamiento entre el TDP y el Trastorno Depresivo Mayor (TDM). El TDM se asemeja al TDP, ya que ambos incluyen síntomas como tristeza, llanto, trastornos del sueño y pensamientos suicidas (Shear et al., 2011). Sin embargo, la mayoría de los estudios concluyen que existen diferencias importantes entre estos dos trastornos, afirmando que existe un alto porcentaje de personas (40%) con TDP que no cumple con los criterios de TDM (Melhem et al., 2001; Neria et al., 2007; Silverman et al., 2000; Simon et al., 2007). Además, los síntomas de TDP muestran poca respuesta a tratamientos específicos y bien estudiados para la depresión (Reynolds et al., 1999; K. Shear, Frank, Houck, y Reynolds, 2005a; Shear et al., 2001).

El modelo de duelo complicado basado en el apego entiende el TDP como un síndrome de respuesta al estrés resultante de la falta de integración de la información sobre la muerte de una figura de apego y/o la incapacidad de volver a retomar el sistema exploratorio en un mundo sin la persona fallecida, siendo la evitación de elementos relacionados con el fallecimiento un factor clave del modelo (Shear et al., 2007; Stroebe y Schut, 1999). Por tanto, este modelo expresa la existencia de diferencias fundamentales en los procesos básicos que se dan en el TDP y el TDM, y podría ser uno de los motivos por los que personas con TDP muestran una baja respuesta ante tratamientos específicos del TDM. Esto podría dar respuesta también al hecho de que en el estudio de Eisma et al. (2015) se produjera una reducción de síntomas depresivos solamente en la condición de tratamiento que incluyó exposición, frente a la condición que incluía exclusivamente activación comportamental, ya que esta última no abordaba los procesos básicos involucrados en el TDP (como la integración de la pérdida de la persona fallecida). Por ello, no es de extrañar que la mayoría de las intervenciones revisadas incluyan componentes específicos centrados en la elaboración y asimilación de la pérdida (p.ej. a través de la escritura) y en la exposición a estímulos relacionados con la pérdida. Estos hallazgos podrían apoyar en mayor medida el uso de intervenciones centradas en

aceptación/exposición/elaboración para el TDP en comparación con las relativas a activación comportamental, más propias de la intervención del TDM, y señalar la importancia de incluir dichos componentes específicos en su abordaje, reforzando la necesidad de distinguir la intervención del TDP y TDM.

4.1 Limitaciones del estudio

La búsqueda y posterior revisión de los artículos de este trabajo se realizó de manera sistematizada mediante bases de datos. No obstante, no se siguió rigurosamente las pautas PRISMA para revisión sistemática y meta-análisis (Moher, Liberati, Tetzlaff, y Altman, 2010). Además, el número de estudios es limitado y uno de ellos no cuenta todavía con resultados de eficacia, lo que dificulta llevar a cabo un análisis exhaustivo y más completo en este campo. Esto, junto al hecho de que no hay un consenso temporal claro para la distinción entre duelo normativo y duelo prolongado, dificulta que los resultados de esta revisión puedan ser totalmente generalizables. Por tanto, se necesitan más estudios en esta línea, que recojan datos de los estudios que están en marcha y las futuras investigaciones que se llevarán a cabo relacionadas con duelo y tratamientos a través de internet.

5. CONCLUSIÓN

Esta revisión aporta una aproximación sobre la naturaleza y efectividad de los protocolos de intervención a través de internet para personas con TDP. Los resultados de estas intervenciones son predominantemente positivos y apuntan a que este tipo de intervención es capaz de reducir de forma significativa síntomas de duelo, depresión, ansiedad, y otros síntomas de salud mental y fisiológica. Este es un resultado prometedor ya que sugiere que los protocolos de intervención a través de internet son eficaces para el tratamiento del duelo lo que, a su vez, supone que el uso de Internet nos puede ayudar a diseminar los tratamientos psicológicos que funcionan para este problema en el futuro. No obstante, este tipo de estudios son parte de un campo en desarrollo, por lo que se requieren más investigaciones al respecto.

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CHAPTER 2

An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in adults: A multiple-baseline single-case experimental design study

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An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in Adults: A Multiple-baseline Single-case Experimental Design Study

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ABSTRACT

The death of a loved one has physical, psychological, and social consequences. Between 9.8 and 21.5 % of people who lose a loved one develop Prolonged Grief Disorder (PGD). Internet- and computer-based interventions (i.e., Internet-delivered Cognitive-Behavioral Therapy, iCBT) are cost-effective and scalable alternatives that make it possible to reach more people with PGD. The main goal of the present investigation was to examine the effect and feasibility (usability and satisfaction) of an iCBT (GROW program) for adults with PGD. A secondary objective was to detect adherence to the app (Emotional Monitor) used to measure daily grief symptoms. The study had a single-case multiple-baseline AB design with six participants. The GROW program is organized sequentially in eight modules, and it is based on the dual-process model of coping with bereavement. Evaluations included a pre-to-post treatment assessment of depression, grief symptoms, and typical grief beliefs, along with daily measures of symptom frequency and intensity on the Emotional Monitor App. Treatment opinions and adherence to the App were also collected. Efficacy data were calculated using a Nonoverlap of All Pairs (NAP) analysis and Reliable Change Index (RCI). The mean age of the sample was 29.5 years (SD = 8.19). Two participants dropped out of the study. Adherence to the App varied across patients (4.8 % -77.8 %). Most participants (75 %) showed a clinically significant change (recovered) in depression, and 50 % obtained a clinically significant improvement (recovered) in symptoms of loss and typical beliefs in

complicated grief. The participants reported high usability and satisfaction with the treatment content and format. In sum, the GROw program was very well accepted and generally feasible, and it has strong potential for treating PGD. The results support scaling up the treatment by using more complex designs with larger samples (i.e., randomized controlled trials comparing GROw with active conditions).

Keywords: App; Internet-delivered Cognitive-Behavioral Therapy; Multiple-baseline single-case design; Prolonged Grief Disorder; iCBT.

1. INTRODUCTION

The death of a loved one has physical, psychological, and social consequences (Shear, 2015a). In particular, it has been associated with the development of multiple psychological disorders and other physical and psychological symptoms, such as panic disorder, physical symptoms such as pain, tiredness, and oversensitivity to noise, sleep disturbances, increased use of medications, and social and work interference, to name a few (Keyes et al., 2014; Lancel et al., 2020; Simon et al., 2007; Stroebe et al., 2007). Despite this, during a grief period, intense feelings of regret and longing are considered natural and usually diminish over time (Jordan and Litz, 2014; Shear et al., 2011). When the symptoms associated with grief do not diminish over time, however, they can develop into Complicated Grief (CG: Shear et al., 2011; Prigerson et al., 2009), also known as Prolonged Grief Disorder (PGD), as defined in the International Classification of Diseases 11th Revision (ICD-11) (World Health Organization, 2019), or Persistent Complex Bereavement Disorder (PCBD), according to the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (American Psychiatric Association, 2013).

In the ICD-11, PGD is defined as a persistent and pervasive grief response characterized by preoccupation about the deceased or longing for the deceased accompanied by intense emotional suffering. At least six months must elapse since the death of the loved one for this diagnosis to be made (WHO, 2019). Similarly, PCBD is defined as a severe and persistent grief and mourning reaction, and it is currently in the category of conditions for further study in the DSM-5 (American Psychiatric Association, 2013). We use the term PGD in this paper.

PGD is a frequent mental disorder among adults. The reported prevalence rates of PGD range between 9.8 % and 21.5 % across various samples and countries (Lundorff et al., 2017; Parro-Jiménez et al., 2021). This high diversity in the PGD rates might also be associated with the instrument used to assess PGD. The COVID-19 pandemic has made PGD an even more important public health concern worldwide (Eisma et al., 2020). The increase in the number of deaths as a result of the virus and the widespread implementation of social distancing and visitor restrictions in healthcare centers have complicated natural grief reactions (Diolaiuti et al., 2021; Nyatanga, 2020; Wallace et al., 2020). Moreover, other factors such as guilt for “not being there” for the loved one in the final days or having images of the loved one “struggling for life on some machine” have been strongly associated with adverse bereavement outcomes during the COVID-19 pandemic (Neimeyer and Lee, 2021). In addition, the pandemic situation not only affects people who have lost a loved one. It is also related to trauma- and stressor-related disorders. For example, health-related stressors, job loss, work-related stressors, and other stressors associated with the pandemic could increase the prevalence of adjustment disorders worldwide (Kazlauskas and Quero, 2020). In addition, the rates of post-traumatic stress disorder (PTSD) and subthreshold PTSD in patients hospitalized for COVID-19 are alarming (Tarsitani et al., 2021), and a recent meta-analysis shows that PTSD could affect up to 21.5 % of healthcare workers (Li et al., 2021).

Fortunately, several psychological treatments for PGD exist, using both individual (Boelen et al., 2007; Range et al., 2000; Shear et al., 2005; Shear et al., 2016) and group formats (Constantino et al., 2001; Lieberman and Yalom, 1992; Sikkema et al., 2004), and systematic reviews and meta-analyses show that psychological interventions are effective in reducing grief symptoms in bereaved adults (Bergman et al., 2017; Johannsen et al., 2019; Wittouck et al., 2011). However, research has also shown that the existence of effective psychological treatments does not ensure that these interventions reach the people who need them (Kazdin, 2014), and the majority of individuals who need psychotherapy do not receive professional support (Kazdin, 2016). Therefore, there is an urgent need for cost-effective, accessible, and scalable psychological treatments for PGD. In addition, the restrictions imposed due to the COVID-19 pandemic, forcing people to isolate and use social distancing, have increased the need for novel approaches to psychotherapy that can be implemented in these adverse conditions. These approaches

include, for example, Internet-based PGD treatments (Eisma et al., 2020) and telecommunication-based alternatives (Wallace et al., 2020).

Internet- and computer-based psychotherapies can be good alternatives to reach people who need treatment, especially during a pandemic situation. These interventions are cost-effective and often cheaper than face-to-face approaches (Musiat and Tarrier, 2014). They also facilitate access to care and involve less stigma compared to visits to mental health clinics (Aboujaoude et al., 2015; Andersson et al., 2019). Moreover, research shows that Internet- and computer-based psychological interventions are clearly superior to waiting list conditions (no treatment) and generally as effective as face-to-face psychotherapy (Andersson et al., 2014; Andersson et al., 2019; Andrews et al., 2010; Carlbring et al., 2018; Lewis et al., 2019; Sijbrandij et al., 2016).

Internet-delivered Cognitive-Behavioral Therapy (iCBT) is the most widely used psychological treatment using the Internet (Andersson, 2009). More than 200 randomized controlled trials have been published using this psychological approach (Carlbring et al., 2018), and they have shown that iCBTs are clinically more effective than waiting list conditions (Andersson et al., 2017) and safer than no-treatment conditions (Karyotaki et al., 2018b). In this type of intervention, patients log into a secure website to access, read, and download online materials organized in a series of lessons or modules (Lange et al., 2003). They can often do this at their own pace, anywhere they choose, and at no cost or very low cost to the patient. In the specific case of PGD, several Internet- and computer-based psychological interventions have also been developed to treat this problem, with promising results (Tur et al., 2019; Wagner et al., 2020). Despite this, few studies have been developed for PGD, and none of them have been adapted for use in Spanish populations.

The main aim of this study was to examine the effect and feasibility (adherence and usability) of an iCBT (GROw program) for adults with PGD using a multiple-baseline single-case experimental design. This stepped approach is recommended to avoid testing novel approaches in large samples when efficacy reports and potential feasibility problems are unclear (Margolis and Giuliano, 2019; Smith, 2012). As a secondary objective, adherence to the App (Emotional Monitor) used to measure daily grief symptoms was examined. We expected that the GROw program would be feasible in terms of treatment satisfaction, usability, and, ultimately, usefulness in significantly reducing symptoms of prolonged grief.

2. METHOD

2.1 Study design

A single-case multiple-baseline AB design, where A refers to the baseline phase and B corresponds to the treatment phase, was used in the study to evaluate the treatment outcomes. Because at least four replications of the effect (i.e., four participants) are recommended to enhance the credibility of the findings (i.e., external validity) (Kratochwill and Levin, 2010), six participants were recruited. Following the multiple-baseline design approach, participants were assigned to different lengths of the baseline phase (at least three different lengths of the baseline phase to ensure three replications of the treatment effect, according to the guidelines) (Tate et al., 2016). As recommended in the guidelines (Kratochwill et al., 2010), the possible duration of the baseline phase was set at between 8 and 16 days to ensure that sufficient assessment points would be obtained to reach the minimum of five evaluations in each phase and ensure the reliability of the data (which justifies the minimum of eight days in the baseline phase) and minimize the time without treatment (which justifies the maximum of 16 days in the baseline phase). All the participants started the baseline evaluation on the same day, after signing the informed consent sent by e-mail, but the treatment was provided at different times. In the present study, the duration of the baseline was assigned by an independent researcher and ranged from 9 to 15 days (11, 9, 14, 12, 9, and 15) of baseline evaluation before treatment onset.

Although participants had access to the treatment on the assigned days following the baseline evaluation, not all the participants accessed the online treatment on the assigned day. Therefore, the final baseline was estimated from the start of the baseline until the participants accessed treatment for the first time, which ranged from 9 to 33 days (17, 9, 19, 12, 19, and 33 days). This prolonged baseline evaluation did not affect the analysis of the results because all the participants started the baseline phase on the same day, and the requirement of a minimum of five assessment points in the baseline and treatment phases was satisfied (Kratochwill et al., 2010). The only consequence was that the waiting times until they received the treatment were longer than initially planned for some patients (patients No. 1, 3, 5, and 6). Although baseline extension was not an issue in terms of analyzing the effectiveness of the intervention, it was relevant to treatment feasibility (i.e., patients' availability to start the treatment when planned).

The study was registered at clinicaltrials.gov: NCT04376385 and approved by the Ethics Committee of Universitat Jaume I (CD/002/2019). The study was conducted at the Emotional Disorders Clinic of Universitat Jaume I (Spain).

2.2 Procedure

2.2.1. Eligibility criteria

Inclusion criteria included: (1) age ≥ 18 years; (2) meeting diagnostic criteria for PGD according to the ICD-11 (World Health Organization, 2019); (3) ability to understand and read Spanish; (4) ability to use a computer, having access to the Internet, and having an e-mail address; and (5) signing the informed consent.

Exclusion criteria: (1) presence of another severe mental disorder (i.e., substance abuse, psychotic disorder, or borderline personality disorder); (2) presence of self-destructive behaviors or suicide risk; (3) presence of a medical condition that prevents study participation; (4) receiving another psychological treatment during the study; (5) an increase and/or change in medication during the study period, which was evaluated at baseline (t1) and after the intervention (t2), and (6) not having daily access to an Android smartphone.

2.2.2. Recruitment and screening

Recruitment was carried out using non-professional (i.e., Facebook and Instagram) and professional social networks (i.e., LinkedIn). In addition, patients who attend the Emotional Disorders Clinic at Universitat Jaume I were screened for eligibility.

Interested participants who saw the announcement about the study online sent an enquiry by email, and an experienced clinician conducted a telephone assessment to determine whether they met the inclusion and exclusion criteria. During this call, potential participants were informed of the study conditions (duration, procedures, etc.). After accepting the terms and signing the informed consent, the participants were randomized to the different baselines by an independent researcher using the online platform [randomizer.org](https://www.randomizer.org). The participants did not receive financial compensation for participating.

2.3 Measures

2.3.1. Demographics and diagnostic measures

These data were collected by a therapist during a pre-treatment telephone interview. Demographic characteristics included age, sex, educational level, occupational status, and

marital status. A semi-structured interview developed for this study was used to assess some inclusion/exclusion criteria (e.g., Internet access, e-mail, etc.). For the diagnosis, two PGD assessment instruments were used. First, we administered the Structured Clinical Interview for Complicated Grief (SCI-CG) (Bui et al., 2015a), which evaluates symptoms of prolonged grief in people who lost a loved one six or more months ago. This tool was adapted to Spanish for this study following a back-translation procedure. In addition, we administered the Inventory of Complicated Grief (ICG) (Prigerson et al., 1995) adapted to Spanish (Limonero et al., 2009), which rates current feelings of grief and differentiates between normal and pathological grief. A total score on the ICG >25 was established in the present study because it indicates complicated grief.

2.3.2. Emotional Monitor App measures

The Emotional Monitor App was used for daily assessment. This App can be downloaded for free at the Google Play store and was developed in Android operating system

(<https://play.google.com/store/apps/details?id=monitoreemocional.code&hl=ca&gl=US>). The researchers gave participants an individual access code to use this App. When users accessed the App, the items appeared in a linear manner, always in the same order. The participants received daily reminders from the App to complete the assessment protocol.

Evaluation with the App took place once a day from the beginning of the baseline phase to the end of the treatment. The participants had a period of 2 h (8–10 pm) to access the app and answer 14 items related to their daily symptoms. A team of experienced clinicians adapted the items (see Table 1) from well-established measures, including the Inventory of Complicated Grief (ICG; Limonero Garcia et al., 2009; Prigerson et al., 1995) (Item 1), Prolonged Grief Disorder (PG-13) (Estevan et al., 2019; Prigerson et al., 2009) (Items 2–7), and The Frustration Discomfort Scale (Harrington, 2005) (Items 8 and 9). A set of items were also used from an App developed and validated by the authors of the study in previous research with individuals with pain and mood problems (Suso-Ribera et al., 2018) (Items 9–14).

Table 1. App assessment items

Item 1	How often have you thought TODAY that you can't believe your loved one is deceased?	
Item 2	How often have you intensely wished your loved one were with you TODAY?	
Item 3	How often have you remembered the absence of your loved one TODAY with enormous and deep sadness?	0 = At no time
Item 4	How often have you remembered the absence of your loved one TODAY with enormous and deep anger?	1 = At some point in time
Item 5	How often have you remembered the absence of your loved one TODAY with enormous and deep anxiety?	2 = At various times of the day
Item 6	How often have you remembered the absence of your loved one TODAY with enormous and deep guilt?	3 = Most of the time
Item 7	How often have you had pleasant memories of your loved one TODAY?	4 = All the time
Item 8	How often have you wanted to get rid of your unpleasant emotions related to your loved one TODAY?	
Item 9	How often have you tried TODAY to get rid of unpleasant thoughts related to your loved one?	
Item 10	Related to the death of your loved one; What intensity of sadness have you felt TODAY?	
Item 11	Related to the death of your loved one; What intensity of anger have you felt TODAY?	0 = None.....
Item 12	Related to the death of your loved one; What intensity of anxiety have you felt TODAY?	10 = Extremely high
Item 13	Related to the death of your loved one; What intensity of guilt have you felt TODAY?	
Item 14	Related to the death of your loved one; What intensity of grief did you feel TODAY?	

2.3.3. Other psychological and mental health outcomes

Three questionnaires related to depression and grief symptoms were self-administered using the web platform (<https://psicologiaytecnologia.labpsitec.es>) where the intervention was located. These evaluations took place immediately before and after the treatment:

Beck Depression Inventory - Second Edition (BDI-II) (Beck et al., 1996), validated in the Spanish population (Sanz et al., 2003): This is a widely used 21-item self-report measure for depression symptoms and characteristic attitudes associated with depression. The items are scored on a scale from 0 to 3. Cronbach's alphas for the BDI-II range from

0.76 to 0.95, and test-retest reliability estimates of around 0.8 have been obtained (Beck et al., 1996; Sanz et al., 2003).

Inventory of Complicated Grief (ICG) (Prigerson et al., 1995c), validated in the Spanish population (Limonero Garcia et al., 2009): This is a self-report, 19-item instrument that evaluates grief symptoms in adults using five response categories (Likert-type): 0 = never; 1 = rarely; 2 = sometimes; 3 = often; and 4 = forever. The ICG items measure the frequency of the emotional, cognitive, and behavioral grief symptoms. Cronbach's alphas of 0.88–0.94 have been reported in previous studies. The total ICG score ranges from 0 to 76, and a total score of >25 indicates complicated grief disorder.

Typical Beliefs Questionnaire (TBQ) (Skritskaya et al., 2017), translated into Spanish language for this study following a back-translation procedure: This is a self-applied, 25-item instrument that assesses maladaptive thinking common in people with complicated grief. It uses a Likert response format ranging from 0 (not at all) to 4 (very strongly). Psychometric properties include good internal consistency for the general scale ($\alpha = 0.83$) and good test-retest reliability.

2.3.4. Patient satisfaction and usability rating

Intervention satisfaction and usability rating items were administered by a therapist (by phone call) immediately after treatment completion.

The Treatment satisfaction scale (adapted from Borkovec and Nau, 1972) was administered by phone at the end of the intervention. It includes four items rated from 0 to 10 (0 = not at all; 10 = very much), namely: 1) “How logical did this treatment seem to you?”; 2) “How much do you think the treatment has been useful to you?”; 3) “How much would you recommend this treatment to a grieving friend?”; and 4) “How much do you think this treatment has been aversive (unpleasant, annoying) for you?”

The usability of the clinical content of the GROw program was measured on a scale from 0 to 10 (0 = not at all; 10 = very much), using items developed specifically for this study. Patients were asked to evaluate and provide feedback on the content of the intervention: motivation for change, slow breathing technique, psychoeducation, behavioral activation, exposure hierarchy, loss diary (reconstructing the meaning of loss), cognitive reappraisal (imaginary conversation with a friend with grief), questions about positive and negative aspects and memories of the deceased, imaginary conversations

with the deceased, self-care, guilt, and forgiveness, letter of projection towards the future, and relapse prevention.

We also asked participants to rate the weekly therapist calls, again using a scale from 0 to 10 (0 = not useful/not at all; 10 = very useful/very much). The questions were: 1) “How much did you like receiving a short weekly support phone call from the therapist?”; 2) “To what extent was the weekly support phone call useful?”; and 3) “To what extent did this weekly support phone call from the therapist help you to continue with the treatment?” Qualitative information on weekly calls was also recorded by asking “Why did you choose that score?” on every item.

2.4 Intervention

The individual, self-applied GROw program was accessible online via <https://psicologiaytecnologia.labpsitec.es>, a website designed by the LabPsiTec group (Laboratory of Psychology and Technology, Universitat Jaume I). Participants received their own username and password to access the GROw intervention. The treatment was organized sequentially in eight modules lasting approximately 60 min each (see Table 2). The treatment was intended to last between 8 and 10 weeks. However, if necessary, the treatment could be extended a few weeks due to the difficulty and intensity of some components. Any extension of the duration of the program was recorded and reported.

Table 2. Module names and therapeutic contents

Module/Session	Content
1. Welcome Module: Starting the Program	General explanation of the treatment. Presentation of grief cases to be used as examples. Motivation for change. Slow breathing technique
2. Understanding reactions to loss	Psychoeducation. Behavioral activation. Grief self-monitoring diary
3. Coping with loss	Mindfulness. Exposure hierarchy
4. Loss Integration and Restoration: first steps	Giving a metaphorical meaning to loss. Loss Diary (reconstructing the meaning of loss): Chapter 1, life before loss
5. Deepening integration and restoration of loss	Loss Diary (reconstructing the meaning of loss): 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	Loss Diary (reconstructing the meaning of loss): Chapter 3, life after loss. Imaginary conversations with the deceased
7. Self-care, guilt, and forgiveness in the grieving process	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	Review of the therapeutic achievements. Action plan for high-risk situations. Action plan to face difficult dates. Letter of projection towards the future

The GROW program contains texts, videos, photographs, diagrams, interactive exercises, and downloadable pdfs and audios (see Fig. 1). Participants can log in at any time to review the content, see the calendar where the session record appears, and view their progress through visual graphs (i.e., measures of grief, anxiety, depression, and positive and negative affect). A weekly support call lasting approximately 10–15 min was made by a trained clinician to: 1) review and reinforce the participants' effort and achievements, 2) motivate them to continue to work on the program content, and 3) clarify doubts and questions about the use of the GROW intervention.

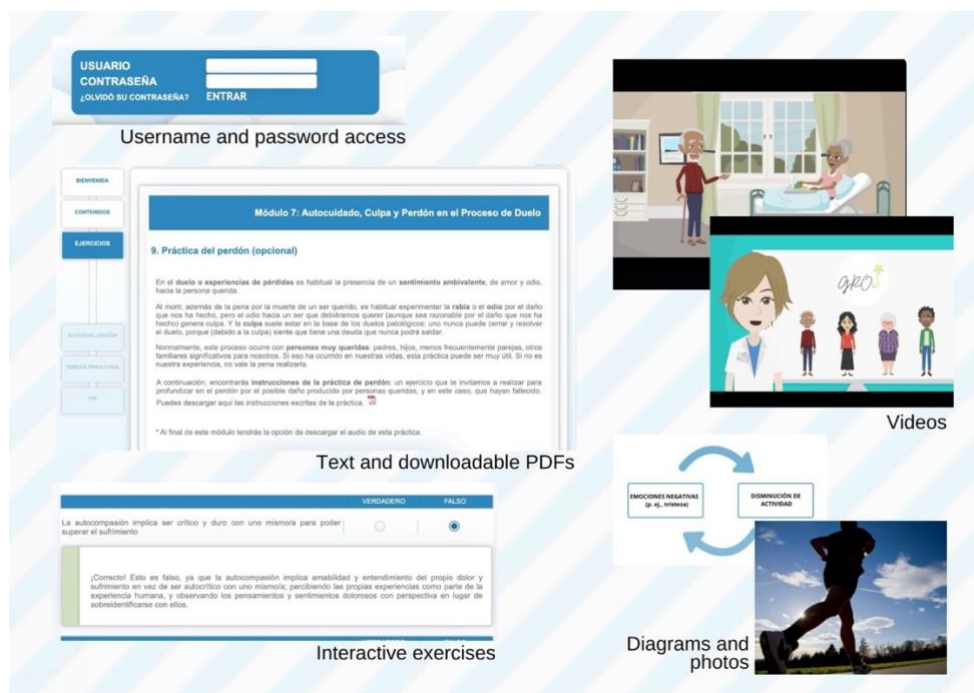


Fig 1. “Screenshots” of the “Psychology and Technology” web platform

The therapeutic content offered in this treatment was adapted from an original intervention protocol for complicated grief developed by the LabPsiTec group (Botella et al., 2008), based on Neimeyer's program for reconstructing the meaning of loss during complicated grief (Neimeyer, 2000; Neimeyer, 2001). When updating this treatment, we incorporated treatment components developed by Shear (2015a), based on the dual-process model of coping with bereavement (Stroebe and Schut, 1999). In addition, we included elements (i.e., cognitive reappraisal) of other computerized psychological treatments for grief (Hoffmann et al., 2018; Shear, 2015b; Wagner et al., 2006) and new mindfulness activities and compassion and self-compassion strategies (Campos et al., 2019; García-Campayo et al., 2016; García-Campayo et al., 2016; García-Campayo, 2018; Lopez-Montoyo et al., 2019; Navarro-Gil et al., 2020). More information about this treatment can be found in Tur et al. (2021).

2.5. Calculations and analyses

To quantify the effects of the intervention in this single-case experimental design, we calculated the Nonoverlap of All Pairs (NAP) and the Reliable Change Index (RCI).

The NAP is an index of data overlap between phases (baseline-to-posttreatment changes) that calculates the percentage of data that show an improvement or a deterioration, with a score from 0 to 100. High scores indicate greater treatment effectiveness (Parker and Vannest, 2009). In this study, the NAP was used to evaluate the results of the 14 daily-measured items included in the Emotional Monitor App. The NAP index for each item for each participant was calculated using the Single Case Research website (<http://www.singlecaseresearch.org/calculators/nap>). To provide a more specific interpretation of the results, cut-off points for each effect size have been proposed according to the study by Parker et al. (2011). These cut-off rates have been used in previous single-case studies (Fernandez-Alvarez et al., 2021; Gómez-Pérez et al., 2020). In the study by Parker et al. (2011), >60 articles that used an AB contrast were analyzed. The authors proposed a rank of 0–100 related to the NAP information, considering the percentile ranks of the evaluated studies. Based on these categories, it was established that NAP scores lower than 38 % would correspond to poor treatment effects (<25th percentile), NAP scores from 38 % to 68 % would reflect mild-to-moderate intervention effects (25th–50th percentile), NAP scores between 69 % and 96 % should be interpreted as moderate-to-large effects (50th–75th percentile), and scores above 96 % would correspond to very large treatment effects (> 75th percentile).

The calculation of RCI (Jacobson et al., 1986; Jacobson and Truax, 1991) requires estimates of a scale's internal consistency and the standard deviation for a given population, and it indicates patient change after an intervention. The clinically significant change occurs when a person with pathology returns to normal functioning, that is, when he/she becomes part of the functional population. First, we calculated the RCI for each participant and questionnaire.

If the RCI is $|1.96|$ or greater, the difference from pre-treatment to post-treatment is considered statistically significant (1.96 corresponds to the 95 % confidence interval). According to the different types of populations described (functional population, clinical population, or both) in each instrument and the characteristics of its distribution, functionality cut-off points are established for each questionnaire (Jacobson and Truax, 1991; McGlinchey et al., 2002). Finally, to classify the different types of responses to the therapeutic process, the results are then usually divided into four categories (recovered, improved, no change, and deteriorated) following the recommendations of Kupler (1991). A person is considered 'Recovered' when the change shown is significantly reliable ($ICF > |1.96|$) and the final score is within the functional distribution. An individual is considered 'Improved' when the change shown is significantly reliable ($ICF > |1.96|$), but the functional level is not reached. A person is considered to present 'No change' when the change is not significantly reliable ($ICF < |1.96|$). Finally, an individual is considered 'Impaired' if the change is significantly reliable ($ICF > |1.96|$), but in the opposite direction.

Adherence to the app was calculated as the number of days the participants answered the questions in relation to the total number of days the questions were prompted (% of the daily response).

3. RESULTS

3.1 Sample

The sample was composed of six individuals diagnosed with PGD: five females and one male. The mean age was 29.5 years ($SD = 8.19$), ranging from 19 to 44 years. Half (50 %) of the sample had lost a parent. Six to 12 months had passed since the death of their loved one for 50 % of the sample. More details are reported in Table 3.

Table 3. Characteristics of the sample

Participant ID	Age	Sex	Educational Level	Occupational status	Time after loss (months)	Civil status	Relationship with the deceased
1	44	Male	Elementary	Student	6-12	Widower	Partner
2	31	Female	University	Employed	12-24	In a relationship	Mother
3	29	Female	Elementary	Employed	>48	In a relationship	Grandmother
4	27	Female	Elementary	Student	6-12	In a relationship	Mother
5	27	Female	University	Student	>48	Single	Sister
6	19	Female	Elementary	Employed	6-12	Single	Father

As Table 4 indicates, two participants did not complete the treatment and dropped out in Modules 1 (Participant 1) and 6 (Participant 4).

Table 4. Results of the NAP analyses and adherence to *Emotional Monitor App* and *GROw*

Participant ID	Nonoverlap Index (%)														Compliance with the app (%)	Modules Completed (GROw)
	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14		
1	50.0	69.0 ^a	65.9	35.7	66.7	61.1	45.2	58.0	54.8	89.7 ^a	77.0 ^a	94.4 ^a	69.8 ^a	79.4 ^a	22.2	0
2	71.5 ^a	76.6 ^a	68.0	75.3 ^a	53.4	54.7	35.0	50.0	62.0	83.6 ^a	57.1	46.8	55.6	59.6	77.8	8
3	70.9 ^a	79.4 ^a	77.2 ^a	72.2 ^a	73.9 ^a	72.1 ^a	20.9	83.2 ^a	71.4 ^a	75.5 ^a	71.7 ^a	72.2 ^a	67.0	32.8	37.6	8
4	43.8	53.2	55.9	66.1	55.5	56.3	64.6	62.0	75.6 ^a	61.8	61.9	55.7	52.7	42.1	48.6	5
5	30.6	44.6	36.1	23.8	48.4	44.0	47.3	31.7	27.4	36.5	23.4	42.2	48.4	38.7	58.9	8
6	--	--	--	--	--	--	--	--	--	--	--	--	--	--	4.67	8

Note. ^a Moderate-to-large effects (NAP indices ≥ 69). Item 1: “can’t believe the death of the deceased”; Item 2: “wishes to be with the deceased”; Item 3: sadness frequency; item 4: anger frequency; Item 5: anxiety frequency; Item 6: guilt frequency; Item 7: pleasant memories frequency; Item 8: unpleasant emotions frequency; Item 9: unpleasant thoughts frequency; Item 10: intensity of sadness; Item 11: intensity of anger; Item 12: intensity of anxiety; Item 13: intensity of guilt; Item 14; intensity of grief.

3.2. Nonoverlap analyses (NAP)

According to the NAP analyses (Table 4), most of the sample (except Participant 5), including those who prematurely abandoned the treatment (Participants 1 and 4), experienced a moderate-to-large treatment effect on at least one of the outcomes. For example, Participant 1 showed a moderate-to-large improvement on almost half of the 14 items after accessing only Module 1. In contrast, Participant 4 only obtained a moderate-to-large effect on Item 9 (“How often have you tried TODAY to get rid of unpleasant thoughts related to your loved one?”) after completing five treatment modules.

Participant 2 obtained a moderate-to-large improvement in four of 14 outcomes, specifically on the items “not being able to believe that the loved one has passed away” (Item 1), “intensely wishing that your loved one was with you” (Item 2), “remembering his/her absence with anger” (Item 4), and “intensity of sadness” (Item 10).

Participant 3 obtained a significant treatment effect on most of the outcomes (11/14). The largest effect was observed on “intensely wished your loved one were with you” (Item 2), “remembering the absence of the deceased with enormous and deep sadness” (Item 3), and “get rid of unpleasant emotions related to the loved one” (Item 8).

Participant 5 did not obtain a significant treatment effect on any outcome and even presented a deterioration (NAP <50), especially on “remembering his/her absence with anger” (Item 4), “trying to avoid unpleasant thoughts related to the loved one” (Item 9), and “intensity of anger” (Item 11).

A minimum of five responses are required in the NAP analysis to ensure the reliability of the data (Kratochwill et al., 2010). Therefore, it was not possible to analyze the results of Participant 6 due to poor adherence to the app assessments.

Considering the analyzed data of the participants who finished the treatment, the outcomes on which they obtained the largest treatment effect corresponded to Item 2 (“intensely wishing that your loved one was with you”) and Item 10 (“intensity of sadness”). A visual example of item 10, related to the intensity of sadness, can be seen in Fig. 2, Fig. 3. In this item, the participant 2 showed a significant improvement, while the participant 5 showed a deterioration.

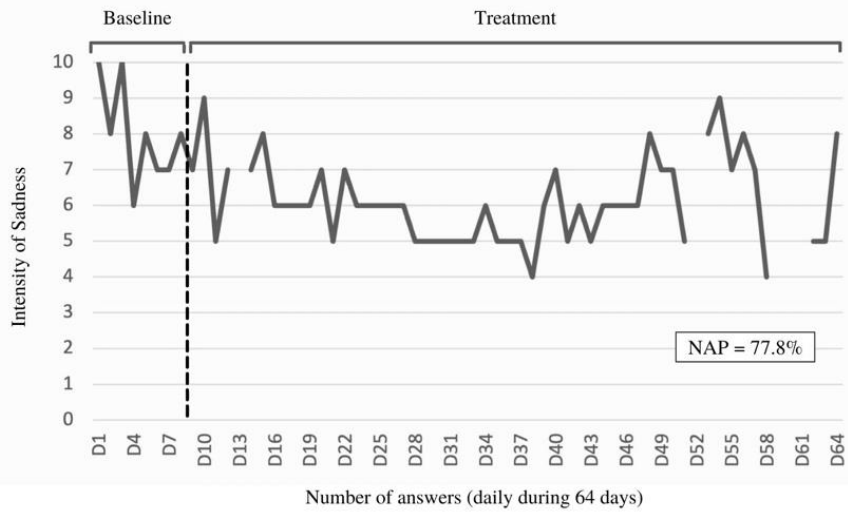


Fig 2. Participant 2: Evolution in item 10 (intensity of sadness). NAP: nonoverlap of all pairs

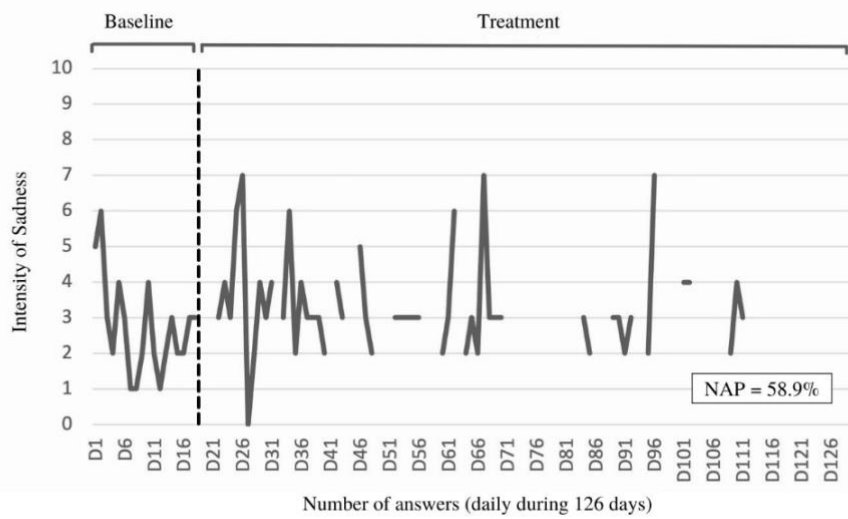


Fig 3. Participant 5: Evolution in item 10 (intensity of sadness). NAP: nonoverlap of all pairs

3.3. Clinically significant change: Reliable Change Index (RCI)

RCI analyses were conducted to evaluate the individual change (before and after treatment) in depression, grief symptoms, and grief beliefs (Table 5).

Table 5. RCI of the Individual test value (before and after treatment) and response to the therapeutic process

Participant ID	Depressive Symptoms			Symptoms of loss			Typical beliefs in complicated grief		
	X ₁	X ₂	Treatment response	X ₁	X ₂	Treatment response	X ₁	X ₂	Treatment response
1	22	-	-	36	-	-	61	-	-
2	19	8	Recovered	34	25	No significant change	45	40	No significant change
3	42	10	Recovered	51	5	Recovered	82	5	Recovered
4	44	-	-	36	-	-	70	-	-
5	22	18	No significant change	51	44	No significant change	66	53	No significant change
6	34	2	Recovered	44	1	Recovered	70	8	Recovered

Note. X₁: Individual test value (before treatment); X₂: Individual test value (after treatment)

The majority (75 %) of the participants who finished the treatment showed clinically significant changes in depression symptoms (BDI-II), and these participants, according to the classification proposed by Kupfer (1991), could be considered recovered (Table 5). Regarding the measures of bereavement (ICG and TBQ), 50 % of the participants who finished the treatment obtained a clinically significant change, also classifying them as recovered.

3.4. Adherence to the GROw intervention and the Emotional Monitor App

Although the duration of the treatment was initially estimated at between 8 and 10 weeks, it took the patients an average of 15.4 weeks to complete all the modules. Two-thirds (66 %) of the participants finished all the modules, whereas two of them dropped out in Modules 1 and 6, respectively. Regarding adherence to the Emotional Monitor App,

the participants who finished the treatment completed between 37.6 % and 77.8 % of the assigned evaluations (average of 55.7 % of measures completed; Table 4).

3.5. Usability

We found high user satisfaction among study participants who completed the intervention. All (100 %) the respondents scored “10 = very much” on the item “I would recommend this treatment to a friend or relative who has lost a loved one”. The participants also scored between 8 and 10 on the items related to their satisfaction about the usefulness and logic of the treatment. Regarding the question about whether the treatment seemed aversive (unpleasant or annoying) to them, half (three) of the participants answered “yes” and gave unpleasantness scores of 8, 7, and 4, respectively (0–10 range, where 10 is the highest level of unpleasantness).

Regarding the perceived usefulness of each therapeutic content, which was measured on a scale from 0 to 10 (0 = not useful at all; 10 = very useful), the participants responded that they found all the contents useful, with a total mean of between 8 and 10 points. The most highly valued content was the slow breathing technique, which obtained a 10 from all the participants who completed the treatment (n = 4). The least valued technique in terms of usefulness was behavioral activation, which obtained an average score of 8 points.

Finally, all the participants who completed the treatment (n = 4) gave the maximum score to the weekly calls from a therapist (10 out of 10). The items were related to the usefulness of the calls (0 = not useful; 10 = very useful), how much they liked receiving the weekly call (0 = not at all; 10 = very much), and how much it helped them to continue with the treatment (0 = not at all; 10 = very much). In addition, their qualitative opinion of the calls was recorded. Comments given included: “It is very necessary that you feel that the therapist is going to call you to ask how you are, or to ask questions”; “In case of doubts, it is much easier to solve them by telephone, I also think it is a way to avoid leaving therapy due to lack of motivation or laziness”; “*You feel that you are not doing it just for yourself but that there is someone with you, someone who supports you once a week and who is asking how you are doing. In the end, it's like a psychologist's therapy, but without going to the clinic*”; “*What I liked the most was being able to tell someone who doesn't judge everything that happens to me. The therapist gave a more global perspective*”.

4. DISCUSSION

The main goal of the study was to examine the effect and feasibility (usability and satisfaction) of an iCBT (GROw program) for adults with PGD and the adherence to the app (Emotional Monitor) used to measure daily grief symptoms.

Overall, we found that the GROw program was effective for some patients only. Half of the participants who finished the treatment obtained a clinically significant change on the bereavement measures (ICG and TBQ). Similarly, a moderate-to-large effect on four or more items measured with the App was observed in 50 % of the participants who finished the treatment (see Table 4). These results are frequent in the psychotherapy literature when the improvement is analyzed patient by patient and not at a global level, as approximately 40–60 % of patients respond poorly to psychological treatments (Cuijpers et al., 2014, Cuijpers et al., 2019; Ebert et al., 2013; Karyotaki et al., 2018a). These data show that the response rate to the treatment is similar in face-to-face and guided Internet-based interventions. However, Internet-based interventions have many advantages over traditional therapies. For example, they can be more accessible and associated with less stigma (no need to visit mental health clinics), and they can have lower financial costs for the patients (Aboujaoude et al., 2015; Andersson et al., 2019; Musiat and TARRIER, 2014).

To the best of our knowledge, no studies have evaluated Reliable Change in grief treatments, and so we cannot compare the data obtained in this investigation with similar studies of PGD. Even so, a systematic review and meta-analysis study on web-based bereavement care that analyzed outcomes of RCT studies concluded that web-based CBT for bereavement showed moderate to large effects on symptoms of grief and posttraumatic stress disorder (PTSD) and small effects on depression (Wagner et al., 2020). These data are consistent with those found in our research, where grief symptoms decreased significantly in half the sample. However, our results show that depression symptoms also decreased significantly in 75 % of the participants, and so the effect of this treatment on depression symptoms was not low. One of the reasons for this discrepancy could be that the GROw program is a comprehensive treatment that includes not only techniques specifically related to grief, but also techniques (e.g., behavioral activation and mindfulness) that have been shown to improve depression symptoms (Blanck et al., 2018; Reangsing et al., 2021; Stein et al., 2021).

The items measured on the app that generated a greater treatment effect were Item 2 (“intensely wishing that your loved one was with you”) and Item 10 (“intensity of sadness”). According to the literature, feelings of wishing that the deceased could be with you and deep sadness are associated with PGD (Boelen and Smid, 2017; Shear, 2015b). The components of the GROw program mainly focus on reconstructing the meaning of loss (see Table 2). This meaning reconstruction, along with the other elements of the treatment, could have helped the participants to remember their loved one with less sadness and decrease the feeling of wanting to be with the deceased.

Regarding adherence to treatment, 33 % of the sample (two participants) dropped out of the intervention. One of these participants obtained a moderate-to-large improvement in almost half the 14 items measured with the Emotional Monitor app at baseline and during the first module. The improvement in these variables could explain why the patient left the treatment because it may indicate that this patient perceived that he/she no longer needed the intervention. Overall, the dropout rate obtained in the current investigation is consistent with what was found in other similar studies using Internet-based interventions, where the dropout rates have been approximately 30 % (Rachyla et al., 2020; Van Ballegooijen et al., 2014).

Regarding adherence to the Emotional Monitor app, an average of 55.7 % of the daily monitoring measurements was completed. This percentage is slightly lower than those obtained in other studies with similar apps (Gómez-Pérez et al., 2020). The fact that the participants had to respond on a large number of days (the treatment lasted an average of 15.4 weeks) and that they only had a short period of time during the day to respond (8–10 pm) could explain these response rates.

An important characteristic associated with adherence to Internet-delivered therapy is the involvement of a human therapist. Providing online support and guidance from a therapist during online therapy has been found to improve participant adherence (Andersson, 2009; Christensen et al., 2009; Spek et al., 2007). In this study, all the participants received pre- and posttreatment assessments and a weekly telephone follow-up from an experienced therapist, which might explain why dropout rates were similar to those found in previous research.

Regarding quantitative analysis of treatment discontinuation, qualitative studies on experiences of non-adherence in Internet interventions have shown that participants' perception that therapists cared for them was important for adherence (Johansson et al., 2015). This is consistent with the qualitative results of our study, which showed that the participants perceived that the weekly telephone support was useful and reported that they liked it and it helped them continue with the treatment: (“...it is a way to avoid leaving therapy due to lack of motivation or laziness”; “you feel that you are not doing it just for yourself but that there is someone with you, someone who supports you...”). Similar to the satisfaction with the human support, all the participants who finished the intervention reported high usability of the therapeutic contents and format of the treatment.

5. STRENGTHS

The Reliable Change Index and Non-overlap analysis were used to assess the effect of the GROw program. These analyses can measure the impact of the treatment on each participant, rather than providing a summary measure of the treatment effects. Group-based effect sizes (standardized mean differences at post-treatment) have dominated the literature on treatment effectiveness due to overreliance on randomized controlled trials. This type of analysis, however, has been criticized due to the focus on pooled group scores and the fact that it is not useful to estimate causal effects (Cummings, 2011), the clinical importance of the treatment, or the number of patients in remission or recovery (Cuijpers et al., 2014). A strength of the present study was that each patient's response was evaluated separately. This allowed us to provide a more idiographic conclusion, which is more consistent with the idea proposed by John Grimley Evans more than two decades ago: “Managers and trialists may be happy for treatments to work on average; patients expect doctors to do better than that.” (Evans, 1995).

Another advantage of the study design is related to collecting daily measurements with the Emotional Monitor app. This method allowed us to record data on each variable measured for each participant across time. Although Internet- and mobile-based interventions for many disorders have been well established, comprehensive knowledge about the impact of such treatments on underlying psychopathology processes is pending (Domhardt et al., 2020). Thanks to the use of the Emotional Monitor App, both outcome (e.g., severity of depression and anxiety levels) and process variables (e.g., avoidance of thoughts and emotions) were measured throughout the treatment process. Analyzing the results of this study may be an initial approximation to understanding the mechanisms of

change involved in treatments for people with PGD, but it cannot provide solid conclusions in this regard. Even so, the design of this study, using the App as a daily measure, can serve as a precedent for future studies that analyze the mediators responsible for therapeutic change in Internet-based interventions for adults with PGD. Another important strength is that this study presents qualitative and quantitative data on the participants' satisfaction with the treatment. GROw is a comprehensive multi-component program with techniques that have been found to be effective in reducing grief symptoms and other associated psychological problems and it was created based on the most recent findings related to the treatment of PGD (e.g., Campos et al., 2019; Hoffmann et al., 2018; Shear et al., 2016). Lastly, this iCBT program can reach more people than a face-to-face intervention and, therefore, might be cost-effective. The GROw program is one of the few online self-applied treatments created for adults with PGD, and, as far as we know, it is the first iCBT for PGD created in the Spanish language. This program could reach many people in Spanish-speaking countries.

6. LIMITATIONS

One of the limitations of this study is related to the sample size because efficacy and satisfaction data were obtained from a small sample of four individuals. However, it has been argued that this number is sufficient to generate an adequate number of replications of the treatment effect (Dallery and Raiff, 2014). Another limitation is related to the reason for dropping out, given that this information could not be obtained despite several attempts to contact patients by mail and telephone. Qualitative information about the Emotional Monitor app was not reported either.

It should be noted that the diagnostic interview used in this study (The Structured Clinical Interview for Complicated Grief; SCI-GC) was published in 2015 (Bui et al., 2015b), whereas the PGD diagnostic category was introduced in the ICD-11 in 2019 (World Health Organization, 2019). Despite this, the SCI-GC was created based on the criteria proposed for the DSM-5 and the ICD-11 (Prigerson et al., 2009). In fact, the SCI-GC is an evaluation instrument that follows the symptom (e.g., longing for the deceased) and time (at least 6 months from death) criteria proposed in the ICD-11.

Finally, efficacy results of this investigation were inconsistent in the participants on the different measured variables, and so more studies are needed. The results support scaling up the treatment using more complex designs with larger samples (i.e.,

randomized controlled trials comparing GROW with active conditions) that also include non-active control groups to evaluate the influence of the passage of time without intervention. Even though the implementation of different lengths of baseline assessments minimizes the threats to internal validity, we cannot absolutely guarantee that the changes are not related to spontaneous recovery in some of the cases.

In sum, despite the limitations, the present study clearly shows strong potential for this intervention as an alternative to face-to-face therapy for PGD. Patients reported high usability and satisfaction with the intervention, making it possible for more people in need to easily access an evidence-based treatment for PGD.

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DECLARATION OF COMPETING INTEREST

The authors declare that they have no competing interests.

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CHAPTER 3

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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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.

1. 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 longing are considered natural and usually diminish over time (Jordan & Litz, 2014). Unfortunately, 9.8% of the adult non-psychiatric population who suffer a loss develop prolonged grief disorder (PGD) (Lundorff et al., 2017). PGD is described by the International Statistical Classification of Diseases and Related Health Problems (World Health Organization, 2019) as a persistent and pervasive grief response characterized by longing for the deceased or persistent preoccupation with the deceased, accompanied by intense emotional pain. In addition, at least six months must have elapsed since the death of the loved one to make this diagnosis. Chronically disabling and distressing grieving symptoms are also formally recognized in the DSM-5 (American Psychiatric Association, 2013) 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 (American Psychiatric Association, 2013). 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 (e.g., panic disorder, physical health problems, sleep disturbances, increased use of medications, increased social and work interference) (Keyes et al., 2014; Lancel et al., 2020; Simon et al., 2007; Stroebe et al., 2007).

In the past decade, several studies have tested different interventions for grief symptoms and PGD: Cognitive Behavioral Therapies (CBTs) (Barbosa et al., 2014; Boelen et al., 2007; Bryant et al., 2014; Papa et al., 2013; Rosner et al., 2014; Shear et al., 2005; Shear et al., 2014, 2016), Expressive Writing therapies (O'Connor et al., 2003; Range et al., 2000; Kovac & Range, 2000), Group Interventions (e.g., Constantino et al.,

2001; Lieberman & Yalom, 1992; Sikkema et al., 2004), and Mindfulness and compassion-based interventions (Alonso-Llácer et al., 2020; Huang et al., 2019). Results from a recent meta-analysis show that psychological interventions are effective for reducing grief symptoms in bereaved adults (Johannsen et al., 2019).

However, most people in need of treatment do not receive any services (Kazdin, 2016). The existence of effective psychological treatments does not ensure that these treatments reach the people who need them (Kazdin, 2014). Different ways of administering treatments are needed to improve their dissemination and reach a larger number of underserved people (Kazdin, 2014, 2016). Less than 50% of the people who need treatment receive it, even in high-income countries (Chisholm et al., 2016). Therefore, Internet- and computer-based interventions are becoming increasingly popular. These interventions involve greater access to care and less stigma, compared to visiting mental health clinics (Aboujaoude et al., 2015; Andersson et al., 2019a). They are cost-effective and often cheaper than face-to-face interventions (Musiat & Tarrier, 2014). Meta-analytic evidence has shown that Internet-based interventions are effective, showing evidence of greater effects compared to control groups, and they are as effective as face-to-face psychotherapy (e.g., Andersson et al., 2014, 2019; Andrews et al., 2018; Carlbring et al., 2018; Lewis et al., 2019; Sijbrandij et al., 2016). Particularly, Internet-delivered Cognitive-Behavioral Therapy (iCBTs) belongs to the Internet- and computer-based intervention category. In iCBTs, patients log into a secure website to access, read, and download online materials organized in a series of lessons or modules (Lange et al., 2003). iCBTs are the most widely researched treatment models provided by the Internet (Andersson, 2009), and more than 200 randomized controlled trials have been published about them (Carlbring et al., 2018). iCBTs have been shown to be clinically effective compared to controls (Andersson et al., 2017), and they have a lower rate of negative symptom results than control conditions (Karyotaki et al., 2018).

In addition, COVID-19 has made PGD a major public health concern worldwide (Eisma et al., 2020). The pandemic has produced widespread implementation of social distancing and visitor restrictions in healthcare centers, thus complicating grief problems (Nyatanga, 2020; Wallace et al., 2020). 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 (Kang et al., 2020). 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 (Eisma et al., 2020), and telecommunication-based alternatives are proposed as important components for supporting bereaved people (Wallace et al., 2020).

To date, there are several Internet- and computer-based interventions for the treatment and prevention of grief symptoms and PGD (e.g., Eisma et al., 2015; Litz et al., 2014; Wagner et al., 2006), with promising results in reducing symptoms associated with grief (Tur et al., 2019). These studies have used treatment through email (Eisma et al., 2015; van der Houwen et al., 2010; Wagner et al., 2006) or an online platform (Brodbeck et al., 2017; Dominick et al., 2010; Kersting et al., 2013; Litz et al., 2014). 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 (e.g., Greenwald et al., 2017; Holtslander et al., 2016; Patel et al., 2019; Scocco et al., 2019), but almost none focus on Internet- and computer-based interventions. Related to this, we found the study by Schladitz et al. (Schladitz et al., 2020), which evaluates the user acceptance of an Internet-based self-help program for grief and loss in elderly people, showing high user acceptance of the program. As far as we know, none of these studies, whether feasibility studies or randomized control trials, 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 to 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; 4) to assess if we can recruit the target population; 5) to explore whether the assessment is too burdensome; 6) 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 defined as the intra-group changes of symptoms related to PGD from baseline to posttest and follow-ups, and being the baseline-posttest the main comparison.

2. METHOD

2.1 Study design and procedure

This study is a two-arm randomized trial testing the feasibility of an Internet-delivered Cognitive-Behavioral Therapy (iCBT) for PGD. The diagnosis of PGD will be based on an interview following the criteria of the ICD-11 (WHO, 2019) and a score >25 on the 19-item inventory of CG (ICG) (Limonero Garcia et al., 2009; Prigerson et al., 1995). 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 (e.g., Brodbeck et al., 2017; Litz et al., 2014; Wagner et al., 2006). 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 randomization. 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 (e.g., 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=, July 8 2020) and will be conducted following the extension of the Consolidated Standards of Reporting Trials (CONSORT) statement for pilot and feasibility studies (Eldridge et al., 2016), the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth guidelines (Eysenbach & CONSORT-EHEALTH Group, 2011), and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan, Tetzlaff, Altman, et al., 2013; Chan, Tetzlaff, Gøtzsche, et al., 2013).

2.2. Participants

2.2.1 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) (Limonero Garcia et al., 2009; Prigerson et al., 1995) and meeting diagnostic criteria for PGD according to the ICD-11 (World Health Organization, 2019); (3) ability to understand and read Spanish; (4) ability to use a computer and having access to the

Internet; (5) having an e-mail address; and (6) signing an informed consent. Exclusion criteria are: (1) presence of risk of suicide or self-destructive behaviors; (2) presence of another severe mental disorder (i.e., substance abuse or dependence, psychotic disorder, dementia or bipolar disorder); (3) presence of severe personality disorder (e.g. 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.

2.2.2 Sample Size

Based on an estimated number of dropouts of 30% (Andrews et al., 2010; Rachyla et al., 2020; Van Ballegooijen et al., 2014) and considering that the secondary objective is to explore the potential effectiveness defined as the pretest-posttest 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 $d = .50$) (Cohen, 1988) with a power of .80 and an alpha of .05. The effect size was defined as the pretest-posttest mean change divided by the standard deviation of change scores. In a review of 50 meta-analyses on the effectiveness of psychological interventions, (Rubio-Aparicio et al., 2018) 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 sized of $d = 0.50$ was assumed. G*Power 3 software was used to perform power analysis calculations (Faul et al., 2007).

2.2.3 Recruitment and screening

Recruitment will be conducted using professional social networks (i.e., LinkedIn) and non-professional social networks (e.g., Facebook and Instagram). The study will be announced on the Universitat Jaume I website and other media (e.g., 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 randomized, using EPIDAT 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://psicologiatecnologia.labpsitec.es/>) and phone call interviews. Participants will access the study voluntarily, and they will not receive financial compensation for participating.

2.3 Intervention

2.3.1 Therapeutic components

Both groups will receive the same therapeutic content, but applied in different formats. The treatment is organized 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: motivation for change, psychoeducation, behavioral 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. (Botella et al., 2008). This protocol was based on Neimeyer's program, which fosters meaning reconstruction in complicated grief (CG) (Neimeyer, 2000; Neimeyer, 2001) and includes elements of the Foa and Rothbaum (Foa & Rothbaum, 1998) program for treating trauma-like symptoms and Linehan's (Linehan, 1993) guidelines for mindfulness strategies. In updating this treatment, elements of the intervention developed by Shear (Shear, 2015), which has shown efficacy in different controlled studies (Shear et al., 2005; Shear et al., 2014, 2016), have been included. This intervention is based on the dual-process model of coping with bereavement (Stroebe & Schut, 1999), which identifies two types of stressors, loss- and restoration-oriented, and proposes that adaptive coping is composed of confrontation-avoidance of loss and restoration stressors. Specific elements (i.e., cognitive reappraisal) of other computerized psychological treatments for grief have also been included (e.g., Hoffmann et al., 2018; Shear, 2015; Wagner et al., 2006). Lastly, the

treatment contains new mindfulness activities and compassion and self-compassion strategies (Campos et al., 2019; García-Campayo, 2018; García-Campayo et al., 2016; García-Campayo, 2019; Lopez-Montoyo et al., 2019; Navarro-Gil et al., 2020).

2.3.2 iCBT for PGD (GROw)

This individual self-applied program 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 two weeks due to their difficulty. The treatment will last 8-10 weeks. The program 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 (i.e., measures of grief, anxiety, depression, and positive and negative affect). A weekly support call from a trained clinician will be made (maximum 10 minutes) in order to: 1) review and reinforce participants' effort and achievements, 2) motivate them to continue to work on the program 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 minutes of therapeutic support. No additional clinical content will be released during the phone calls.

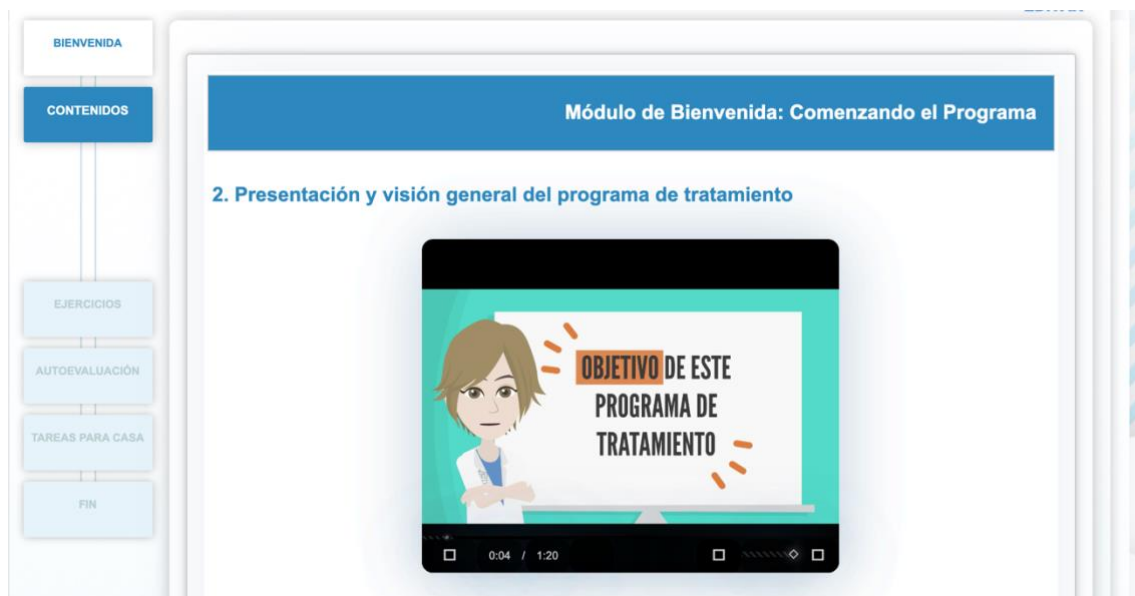


Fig 1. “Screenshot” of the “Psychology and Technology” web platform

2.3.3 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 centers and associations (e.g., Valencia or Alicante). Each session will last approximately 60 minutes. There will be weekly individual sessions, and the content from 4-6 sessions could require two weeks due to its difficulty. The treatment lasts up to 8-10 weeks. No weekly support call will be provided.

Table 1. Specific objectives and therapeutic contents of the intervention

Module/Session	Objective	Content
1. Welcome Module: Starting the Program	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 Behavioral activation Grief self-monitoring diary
3. Coping with loss	Recognize 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

2.4 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 time point, administration type, and group.

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
Semi-structured 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 Usability and Acceptance Questionnaire</i>	t1, t2	Phone interview	GROw Face-to-Face
WAI	t2	web	GROw
Semi-structured 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

Note. t1 = baseline. t2 = immediately after the intervention. t3 = 3-month follow-up. t4 = 12-month follow-up. POSTm/s = post module/session. GROw = Grief-Online, internet-based self-applied treatment for PGD. SCI-GC = Structured Clinical Interview for Complicated Grief. SCID-I = Structured Clinical Interview for DSM-IV. ADIS = Anxiety Disorders Interview Schedule. ICG = Inventory of Complicated Grief. BDI-II = Beck Depression Inventory - Second Edition. OASIS = Overall Anxiety Severity and Impairment Scale. ODSIS = Overall Depression Severity and Impairment Scale. PANAS = Positive and Negative Affect Schedule. QLI = Quality of Life Index. WSAS = Work and Social Adjustment Scale. PTGI = Posttraumatic

Growth Inventory. PIL-10 = Purpose-In-Life Test. FFMQ-15 = Five-Facet Mindfulness Questionnaire. SCS-SF = Self-Compassion Scale Short Form

2.4.1 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 semi-structured interview developed for this study will be used to assess some inclusion/exclusion criteria (e.g., Internet access, e-mail, 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 (Limonero et al., 2009; Prigerson et al., 1995). The Structured Clinical Interview for Complicated Grief (SCI-CG) (Bui et al., 2015) evaluates symptoms of prolonged grief in people who lost a loved one six 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) (First, Spitzer, Gibbon, & Williams, 1999) 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 clinician's severity rating scale (Di Nardo et al., 1994). A clinical team of mental health professionals with extensive experience in diagnosing and treating stress-related disorders will oversee all cases.

2.4.2 Primary outcomes: Measures of feasibility

Participant adherence (i.e., 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 & Nau (Borkovec & Nau, 1972), usability with the *Usability and Acceptance Questionnaire* (Campos et al., 2018; Castilla et al., 2016), and alliance with the *Working Alliance Inventory (WAI)*, adapted from Horvath & Greenberg (Horvath & Greenberg, 1989) for online self-administered treatments.

Finally, a semi-structured opinion interview with quantitative and qualitative questions was specifically developed 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 (e.g., 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 semi-structured 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; (6) an open question about adverse or unexpected effects in the iCBT group; (7) an open question about adverse or unexpected effects due to the health crisis produced by COVID-19; and 8) two semi-structured questions about the acceptance of the evaluation procedure and the materials used (from 0; not burdensome at all to 10; extremely burdensome).

2.4.3 Psychological and mental health outcomes

Grief symptoms will be assessed using the Inventory of Complicated Grief (ICG) (Limonero et al., 2009; Prigerson et al., 1995), and depression symptoms will be assessed using the Beck Depression Inventory - Second Edition (BDI-II) (Beck et al., 1996; Sanz et al., 2003). To assess the maladaptive thinking common in people with complicated grief, the Typical Beliefs Questionnaire (TBQ) (Skritskaya et al., 2017) will be used. The Overall Anxiety Severity and Impairment Scale (OASIS) (Campbell-Sills et al., 2009; González-Robles et al., 2018) and the Overall Depression Severity and Impairment Scale (ODSIS) (Bentley et al., 2014; Mira et al., 2019) 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) (Díaz-García et al., 2019; Watson et al., 1988). To assess health-rated quality of life, the Quality of Life Index (QLI) (Mezzich et al., 2000) will be used. The Work and Social Adjustment Scale (WSAS) (Echezarraga et al.,

2019; Mundt et al., 2002) will be used to assess psychosocial functional impairment. Post-trauma growth and self-improvement will be assessed using the Posttraumatic Growth Inventory (PTGI) (Tedeschi & Calhoun, 1996; Weiss & Berger, 2006). The Purpose-In-Life Test (PIL- 10) (García-Alandete et al., 2013) will be used to assess the personal experience of meaning in life. The Five-Facet Mindfulness Questionnaire (FFMQ-15) (Asensio-Martínez et al., 2019) and the Self-Compassion Scale-Short Form (SCS-SF) (Garcia-Campayo et al., 2014; Raes et al., 2011) will be used to assess the ability to be aware in experiencing the moment and the capacity for self-compassion, respectively.

2.5 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 (Eldridge et al., 2016) to guide for reporting this information. Attrition and drop-out rates will be calculated using the missing data. In the experimental group, the number of times each patient uses the program 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 posttest and follow-ups. In addition, effect sizes and their respective 95% confidence intervals (CI) for intra-group 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 version 25.0.

2.6 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.

3. 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://psicologiaytecnologia.labpsitec.es>. 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 (IF) 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.

4. DISCUSSION

The main aim of this study is to investigate the feasibility of an iCBT for people with PGD -GROW- compared to 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 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- and computer-based interventions for PGD (e.g., Eisma et al., 2015; Litz et al., 2014; Wagner et al., 2006), and almost none of them have focused on iCBT (Brodbeck et al., 2017; Dominick et al., 2010; Kersting et al., 2013; Litz et al., 2014).

The current situation, due to the Coronavirus (COVID-19) pandemic, has made PGD a major public health problem worldwide (Eisma et al., 2020). Increased PGD rates are expected (Eisma et al., 2020) 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) (Castle & Phillips, 2003); 2) the possible feeling that the loved one's death was distressing and not peaceful (Lobb et al., 2010); 3) widespread implementation of social distancing and visitor restrictions in health centers (Nyatanga, 2020; Wallace et al., 2020); and 4) the fact that disasters with many victims produce higher levels of grief symptoms (Eisma et al., 2020).

Therefore, psychological treatments for PGD are necessary, but the existence of these treatments does not ensure that they reach the people who need them (Kazdin, 2014). 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 to 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 (Aboujaoude et al., 2015). In addition, there is no need for a therapy room, a lesson/module can be repeated (Andersson et al., 2019b), and they are cost-effective (Donker et al., 2015) and often cheaper than face-to-face interventions (Musiat & Tarrier, 2014).

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 (Lundorff et al., 2017) and is becoming a major public health concern worldwide due to the COVID-19 (Eisma et al., 2020).

GROw has been developed based on larger and more recent studies on the treatment of PGD (e.g., Shear et al., 2014, 2016; Wagner et al., 2006). 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 (Baumeister et al., 2014; Cuijpers et al., 2019). 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.

4.1 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 (e.g., conduct videoconferencing sessions). These adaptations would be taken into consideration for the future large-scale RCT. Secondly, high dropout rates are expected (30%) according to the literature (Andrews et al., 2010; Rachyla et al., 2020; Van Ballegooijen et al., 2014). For this reason, dropout rates have been taken into account in the sample size considerations. Finally, for the secondary aim of this feasibility randomized trial, conclusions will be limited to exploring its potential effectiveness in terms of intra-group changes (changes from baseline to post-intervention and follow-ups), with baseline-posttest being the main comparison, without considering between-group comparisons.

AUTHOR CONTRIBUTIONS

The manuscript was drafted by CT with important contributions from SQ, DC^a and RH, who provided extensive comments/feedback to improve the manuscript. SQ, DC^a, CT, SM, AL-M, and RH developed the contents of the iCBT for PGD, and the treatment was adapted to the online platform by CT, DC^b, and RH. All authors participated in the review and revision of the manuscript and approved the final manuscript for publication.

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CONFLICTS OF INTEREST

The authors declare that they have developed the Internet-delivered Cognitive-Behavioral Therapy (iCBT) for PGD called GROW with no commercial or financial interests. The authors declare no conflicts of interest that could have influenced the work reported in this paper.

ETHICS APPROVAL

This study has been approved by the Ethical Committee of the Universitat Jaume I (Castellón, Spain) (06 March 2019) (file number CD/002/2019).

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CHAPTER 4

Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Adults with Prolonged Grief Disorder (PGD): a Randomized Feasibility Trial

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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: Losing a loved one is a painful process characterized by feelings of longing and regret that usually diminish over time. Nevertheless, one in ten bereaved adults is at risk of developing Prolonged Grief Disorder (PGD), and the SARS-CoV-2 coronavirus (COVID-19) has made disturbed grief a major public health concern worldwide. There are effective treatments for PGD, but they do not always reach the people who need them. Internet delivered cognitive-behavioral therapies (iCBTs) make it possible to reach people who need treatment, and they are cost-effective and clinically effective. The aim of this study is to investigate the feasibility of an iCBT for people with PGD (GROw) compared to the same intervention for PGD delivered in a face-to-face videoconferencing format. As a secondary objective, the potential effectiveness of GROw is explored.

Method: This study is a two-arm feasibility randomized trial. A total of 31 participants with PGD were randomized to the experimental group (N = 16) (iCBT: GROw) and the active control group (N = 15) (face-to-face videoconferencing treatment). There were five assessment points: baseline (t1); immediately after the intervention (t2); 3-month follow-up (t3); 12-month follow-up (t4); and an evaluation of people who dropped out of the treatment (t5). Consistent with the objectives, the measures are related

to feasibility outcomes for the main aim of the study and mental health outcomes for the secondary analyses.

Results: Both GROw and the face-to-face videoconferencing treatment were well-accepted in terms of preferences, expectations, satisfaction, and opinions about the usefulness of the intervention. The dropout rate was 50% in the GROw group and 33.33% in the face-to-face videoconferencing group. The main reasons for dropout were related to lack of time, needing to avoid emotions that arose during the treatment, and the need for more therapeutic support. Both GROw and the face-to-face videoconferencing intervention showed significant reductions in symptomatology, with large effect sizes on most of the evaluated symptoms.

Conclusions: GROw is a feasible, well-accepted iCBT for the treatment of PGD, and it has promising results related to its potential effectiveness. The results of this study support the inclusion of more human support in the treatment, for example, by blending online self-applied modules and brief face-to-face CBT sessions. Based on these results, future investigations should scale up the treatment using larger samples and more complex designs, as in randomized controlled trials.

1. INTRODUCTION

Losing a loved one is a painful process that is unique to each individual (Boelen & Smid, 2017; Stroebe et al., 2017) and has psychological, physical, and social ramifications (Shear, 2015a). Feelings of regret and longing are considered natural in the experience of losing a loved one to death, and they usually diminish over time (Jordan & Litz, 2014). However, a percentage of grievors develop long-term and disturbing reactions that interfere with life. Thus, 2-53% of people who lose a loved one develop long-term reactions (He et al., 2014; Kersting et al., 2011; Lundorff et al., 2017; Parro-Jiménez et al., 2021). This range varies because the data depend on the samples, the cause of the death, the country, and the evaluation measures used. For example, the percentage in a Chinese representative population-based sample was 3.7% (He et al., 2014), the same percentage as in the German population (Kersting et al., 2011). In Spain, the prevalence ranged from 7.67 to 10.68% if the assessment was carried out using diagnostic instruments, and it reached 28.77% if symptomatic instruments were used. Lundorff et al. (2017) concluded that, worldwide, one in ten bereaved adults is at risk for long-term and disturbing grief. In recent decades, different terms have been used to describe long-

term and disturbing reactions related to death. Shear et al. (2011) proposed the term “Complicated Grief (CG)”, which refers to unusually severe and prolonged grief with characteristic symptoms that include intense yearning, longing, or emotional pain, frequent thoughts of preoccupation and memories of the deceased person, a feeling of disbelief or inability to accept the loss, and difficulty imagining a meaningful future without the deceased person. Another widely used term is “Persistent Complex Bereavement Disorder (PCBD)”, which was recently included in the text revision of the Diagnostic and Statistical Manual of Mental Disorders 5 in 2022 (DSM-5-TR: Boelen et al., 2020; Prigerson et al., 2021). PCBD is defined as daily intense longing for the deceased person and/or preoccupation with thoughts or memories of the deceased person, as well as other symptoms (e.g., identity disruption since the death and avoidance of reminders that the person is dead) and clinically significant distress or impairment that clearly exceeds expected social, cultural, or religious norms for the individual’s culture and context. For a diagnosis of PCBD, the loss had to occur at least 12 months ago. Finally, the term “Prolonged Grief Disorder (PGD)”, proposed by Prigerson et al. (2009) and Maercker et al. (2013) and included with some modifications in the eleventh edition of the International Classification of Diseases (CIE-11; World Health Organization [WHO], 2019), is one of the most commonly used terms today. PGD is defined as a disturbance in which, following the death of a close person, there is a persistent and pervasive grief response characterized by longing for the deceased or persistent preoccupation with the deceased, accompanied by intense emotional pain (e.g., sadness, guilt, or anger), and the response clearly exceeds expected social, cultural, or religious norms for the individual’s culture and context and causes significant impairment. For a diagnosis of PGD, the loss had to occur at least six months ago. This investigation follows the PGD criteria for the diagnosis of long-term and disturbing grief, and so the term PGD will be used in this manuscript.

Since its appearance in December 2019, the SARS-CoV-2 coronavirus (COVID-19) has made disturbed grief a major public health concern worldwide (Eisma et al., 2020). Regarding the prevalence of disturbing and disabling grief related to deaths caused by COVID-19, recent studies have concluded that over one-third of relatives developed PGD (Tang & Xiang, 2021). The experience of living through the grief process in isolation and the circumstances related to a death caused by COVID-19 are associated with developing mental health problems. Situations such as being unable to visit the loved

one in the hospital or health clinic (Diolaiuti et al., 2021; Kokou-Kpolou et al., 2020; Nyatanga, 2020; Wallace et al., 2020), being unable to perform a funeral ceremony (Kokou-Kpolou et al., 2020; Lazzerini & Putoto, 2020), experiencing the unexpected death of the loved one (Delor et al., 2021), or having difficulties visiting cemeteries (Diolaiuti et al., 2021) are related to developing psychopathological conditions.

Group (e.g., Constantino et al., 2001; Lieberman & Yalom, 1992; Sikkema et al., 2004) and individual interventions (e.g., Boelen et al., 2007; Range et al., 2000; Shear et al., 2005; Shear et al., 2016) to treat and prevent PGD have shown good results in reducing PGD symptoms in bereaved adults (Bergman et al., 2017; Johannsen et al., 2019; Wittouck et al., 2011). Interventions that include therapeutic components such as experiential exposure (e.g., Acierno et al., 2021; Boelen et al., 2007; Bryant et al., 2014), behavioral activation (e.g., Acierno et al., 2021; Eisma et al., 2015; Litz et al., 2014), or writing assignments about emotional experiences and thoughts (e.g., Kalantari et al., 2012; Lichtenthal & Druess, 2010; Wagner et al., 2006) have shown good efficacy in treating or preventing PGD symptoms. However, even in high-income countries (Chisholm et al., 2016), the majority of people who need treatments do not receive any services, and the number of people affected by mental disorders is large and growing (Harvey & Gumport, 2015; Kessler et al., 2005). The barriers to accessing psychological treatments are related to socioeconomic factors, geographical factors such as distance, waiting lists, the type of medical insurance, and patient characteristics such as educational level, age, and preferences (Borson et al., 2019; López-Lara et al., 2012). Moreover, the isolation related to the COVID-19 pandemic increased geographical barriers, producing situations such as difficulty visiting cemeteries (Diolaiuti et al., 2021), problems performing funeral ceremonies (Kokou-Kpolou et al., 2020; Lazzerini & Putoto, 2020), and reduced social and physical contact (Brooks et al., 2020). Internet-delivered cognitive-behavioral therapies (iCBTs) make it possible to reach people who need treatment. They are cost-effective and cheaper than face-to-face therapy, and they use a well-established therapy format that has shown clinical efficacy compared to control groups and active conditions in the short and long term (Andersson et al., 2014, 2017; Carlbring et al., 2017, 2018; Cuijpers et al., 2008; Donker et al., 2015; Hedman et al., 2011; Karyotaki et al., 2018; Komariah et al., 2022; Musiat & Tarrier, 2014; Wang et al., 2020; Xiong et al., 2022). iCBTs can also overcome isolation problems and geographical barriers (Griffiths et al., 2006; Griffiths & Christensen, 2007). There are a few Internet

and computer-based interventions (e.g., Brodbeck et al., 2017; Eisma et al., 2015; Kersting et al., 2011; Litz et al., 2014; Wagner et al., 2006) to treat and prevent PGD, with promising results (Tur et al., 2019; Wagner et al., 2020). However, as far as we know, none of these interventions has been tested in the Spanish population using a feasibility or randomized control trial (RCT) methodology. The iCBT evaluated in this study – called GROw – was originally developed for the Spanish-speaking population.

The main aim of this study was to investigate the feasibility of an iCBT for people with PGD (GROw), compared to the same intervention for PGD delivered in a face-to-face videoconferencing format. Specifically, the objectives were: (1) to explore patients' opinions of GROw and the face-to-face videoconferencing intervention as treatments for PGD (preferences and opinions comparing the two types of intervention formats, expectations, satisfaction, and participants' opinions about the usefulness of the intervention); (2) to explore the reasons for dropout in both formats, GROw and the face-to-face videoconferencing intervention; (3) to assess whether we can recruit the target population; (4) to estimate the rate of recruitment and retention in order to provide information for a large-scale RCT. Additionally, as a secondary objective, the potential effectiveness of GROw was explored. This is defined as the intragroup (from baseline to post-test) and between-group changes in symptoms related to PGD. Some modifications were made in the objectives proposed in the published protocol for this study (Cintia Tur et al., 2021). The objective of exploring the participants' opinions about the study design, materials, and assessment was removed. However, we included the objective of exploring the reasons for dropping out and the secondary objective of performing a between-group change analysis to explore potential effectiveness.

2. METHOD

2.1 Study design

A two-arm randomized trial study of an iCBT intervention for PGD was conducted. After signing the informed consent, participants were randomly assigned to two conditions with the same therapeutic content presented in different formats: 1) experimental group (iCBT: GROw) and 2) active control group (face-to-face videoconferencing intervention). The diagnosis of PGD was based on two criteria: 1) a score ≥ 25 on the 19-item Inventory of CG (ICG) (Limonero et al., 2009; Prigerson et al., 1995); and 2) a diagnosis of PGD based on an interview using ICD-11 criteria. This study

was approved by the Ethical Committee of the Universitat Jaume I (Castellón, Spain) (06 March 2019) (file number CD/002/2019) and registered on the clinicaltrials.gov database (NCT04462146, 8 July 2020). This research was conducted following the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth guidelines (Eysenbach & CONSORT-EHEALTH Group, 2011), the extension of the Consolidated Standards of Reporting Trials (CONSORT) statement for pilot and feasibility studies (Eldridge et al., 2016), and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan, Tetzlaff, Altman, et al., 2013; Chan, Tetzlaff, Gøtzsche, et al., 2013).

Participants received reminder emails about assigned assessments during the treatment to promote participant retention. The assessment points were: baseline (t1), immediately after the intervention (t2), 3-month follow-up (t3), 12-month follow-up (t4), and evaluation of participants who dropped out of the treatment (t5). Modifying the published protocol for this study (Tur et al., 2021), the evaluation of reasons for dropping out was included to collect additional information, and potential effectiveness was explored using a mixed-model analysis approach. Furthermore, follow-up measures are not presented in this manuscript because this evaluation is currently in progress.

According to the CONSORT statement for feasibility studies (Eldridge et al., 2016), a formal sample size calculation is not required. For the secondary objective of this study (explore the potential effectiveness of GROw), a sample of 48 people (24 per group) was proposed in the protocol for this study (Tur et al., 2021), based on an estimated 30% dropout rate (Andrews et al., 2010; Rachyla et al., 2020; Van Ballegooijen et al., 2014). Finally, 31 participants were recruited for this study.

2.2 Participants

2.2.1 Recruitment, screening, and eligibility criteria

People who were interested in the study contacted the researchers through a specific email and/or telephone account associated with the project. Recruitment was conducted using non-professional social networks (i.e., Facebook, Twitter, and Instagram), professional social networks (i.e., LinkedIn), local media (i.e., newspaper, radio, and podcast), and posters placed in different nearby places (Universitat Jaume I and Universitat de València). In addition, patients were recruited from the Emotional Disorders Clinic at Universitat Jaume I. Telephone assessments were conducted by

experienced therapists to determine whether individuals who were interested in the study met the inclusion and exclusion criteria. Inclusion criteria were as follows: (1) age ≥ 18 years; (2) meeting diagnostic criteria for PGD according to the ICD-11 (World Health Organization, 2019) and having a total score of >25 on the 19-item inventory of CG (ICG) (Limonero et al., 2009; Prigerson et al., 1995); (3) understanding spoken and written Spanish; (4) having an email address (5) basic ability (i.e., Internet searches and use of email account) to use a computer and having access to the Internet; and (6) signing an informed consent. Because GROw is not culturally adapted to other countries, a new inclusion criterion that was not proposed in the published study protocol (Tur et al., 2022) was included: (8) living in Spain or being Spanish but residing in another country. Exclusion criteria were as follows: (1) presence of risk of suicide or self-destructive behaviors; (2) presence of another severe mental disorder (e.g., substance abuse or dependence, psychotic disorder, dementia, borderline personality disorder) or medical condition whose severity or characteristics prevent participation in treatment; (3) receiving another psychological treatment during the study; and (4) an increase and/or change in medication during the study period. The data for people who increased and/or changed their medication during the study period (from baseline to 12-month follow-up) were excluded from the statistical analyses in this study. The medication was evaluated during the study at all the assessment points, except in the dropout evaluation (t5). During the screening phone call, participants were informed of the study conditions (duration, format conditions, etc.). Participants who met the criteria were randomized to one of the two conditions (GROw and face-to-face videoconferencing treatment) by an independent researcher using EPIDAT V.4.2. Participants agreed to participate in the study voluntarily, they did not receive any financial compensation for participating, and they were able to leave the study at any time. All participants were assigned to the assessments through phone call interviews and a specific online platform (<https://psicologiatecnologia.labpsitec.es/>). Participants who dropped out were contacted for a telephone interview by an independent researcher.

2.3 Intervention

2.3.1 Therapeutic components

Both groups (experimental and control) received the same therapeutic components but in a different format. The main components were adapted from Neimeyer's program for reconstructing the meaning of loss during complicated grief (Botella et al., 2008;

Neimeyer, 2000, 2001), and they include components of the Complicated Grief Treatment by Shear (2015) (i.e., memories form, imaginary conversation with the deceased person), elements from other computerized psychological treatments (i.e., exercises for cognitive reappraisal) (Hoffmann et al., 2018; Wagner et al., 2006; Wagner & Maercker, 2007), and mindfulness activities and compassion and self-compassion strategies (Campos et al., 2019; García-Campayo et al., 2016; García-Campayo Javier, 2019; García-Campayo, 2018; Lopez-Montoyo et al., 2019; Navarro-Gil et al., 2020). The treatment was designed and adapted from previous studies by a team of clinical psychologists with experience in trauma, stress-related disorders, and PGD. The treatment is composed of different therapeutic components: motivation to change, psychoeducation, behavioral activation, experiential exposure, mindfulness and compassion strategies, writing assignments for reconstructing the meaning of loss, cognitive reappraisal, and relapse prevention. More information about the therapeutic components of the intervention can be found in Tur et al. (2021).

2.3.2 ICBT for PGD (GROw)

GROw is an individual self-applied program that can be accessed with a username and password on the website (<https://psicologiaytecnologia.labpsitec.es>). Participants can log in to the program at any time to see new content, review past content, view the calendar with the record of the sessions, and see their progress through visual graphs (i.e., measures of grief, depression, anxiety, and positive and negative affect). Therapeutic contents are sequentially organized in eight modules (estimated to last approximately 60 minutes each). Participants were instructed to complete one module per week, with the possibility of extending modules 4, 5, or 6 (dedicated to writing assignments for reconstructing the meaning of loss) for two weeks due to their complexity and length. The estimated time needed to perform the treatment was 8-10 weeks. The GROw program contains videos, texts, audios, photos, downloadable pdfs, personalized diagrams, and self-assessment questions about the therapeutic content (see Figure 1). In addition to access to the platform, participants received a brief weekly phone call (10-15 minutes) from a therapist (always from the same assigned trained therapist). The objectives of the phone calls were: 1) to motivate the participants to continue with the program, 2) to clarify doubts about content and program format, and 3) to review and reinforce effort and achievements.



Fig 1. “Screenshots” of the “Psychology and Technology” web platform

2.3.3 Face-to-face videoconferencing treatment

This treatment was administered in weekly sessions through videoconference (approximately 60 minutes each session) by a trained therapist. The therapeutic components were the same ones included in the GROw group, but they were explained by a therapist rather than by videos, images, etc. At the end of the session, participants received a summary of the session and the weekly assigned tasks by mail. For some sessions (i.e., mindfulness, compassion, and self-compassion), the participants also received meditation audios. This treatment was designed to be carried out in weekly sessions for 8-10 weeks. Participants were instructed to do one session per week, although Sessions 4, 5, or 6 (dedicated to writing assignments for reconstructing the meaning of loss) could be completed in two weeks due to their complexity and length. A weekly support call was not provided in this condition.

2.4 Outcome measures

Participants were assessed through semi-structured telephone interviews and self-administered questionnaires on a web platform (<https://psicologiaytecnologia.labpsitec.es>) (see Table 1). The evaluation was the same in both groups (GROw and face-to-face videoconferencing group). The interviews were administered by clinicians with experience in stress-related disorders. A clinical team of

mental health professionals oversaw all the cases. Automatic reminder emails for each assessment were sent to clinicians and participants.

2.4.1 Screening, diagnostic measures, and demographics

Some inclusion and exclusion criteria (e.g., age, Internet access, email address) were assessed using an interview specifically designed for this study. For the diagnosis of PGD, the Inventory of Complicated Grief (ICG: Limonero et al., 2009; Prigerson et al., 1995) was self-administrated. A total ICG score ≥ 25 indicates complicated grief. The ICG has 19 Likert-type items with 4 points (from “never” to “always”) that assess the frequency of emotional, cognitive, and behavioral symptoms. The ICG has good psychometric properties in the original version (Cronbach’s alpha coefficient = 0.94 and test-retest reliability = 0.80) (Prigerson et al., 1995) and the Spanish adaptation (Cronbach’s alpha coefficient = 0.88 and test-retest reliability = 0.81) (Limonero et al., 2009). In addition to the ICG, an experienced clinician administered the Structured Clinical Interview for Complicated Grief (SCI-CG: Bui et al., 2015), which was translated into the Spanish language following a back-translation procedure. The SCI-CG is a 31-item clinician-administered instrument to assess the relationship with the deceased, cause of death, time since the death (<6months, between 6 and 12 months, or>12 months), and the presence of complicated grief symptoms. Each of the 31 items is rated on a 3-point Likert-type scale: 1: not present, 2: unsure, or 3: present. The SCI-CG has good psychometric properties in the original English version (good internal consistency, interrater and test–retest reliability, and convergent validity in a sample of individuals with complicated grief). The level of distress-interference in functioning (from 0: absent to 8: very severely disturbing/disabling) was assessed with the Anxiety Disorders Interview Schedule (ADIS) severity rating scale (Di Nardo et al., 1994). Based on the information from the ICG, SCI-CG, and ADIS severity rating scale, a team of clinicians and researchers with experience in stress-related disorders determined whether each participant met the diagnostic criteria for PGD (WHO, 2019).

Demographic data were assessed through the phone interviews and included age, sex, civil status, occupation, educational level, and place of residence (see Table 2).

2.4.2 Primary outcomes: measures of feasibility

Feasibility was assessed in terms of adherence and opinion/acceptance (preferences and opinions comparing the two intervention formats, expectations, satisfaction, and

participant' opinions about the usefulness of the intervention) of the treatment in both groups (GROw and face-to-face videoconferencing treatment).

Adherence was assessed considering the number of sessions/modules completed, dropout percentages, and in the iCBT format (GROw), time spent on each module and how many times the participants accessed and reviewed the modules. In both conditions, an independent researcher held a phone-interview with participants who dropped out of the treatment to discuss: 1) the reasons for dropping out (e.g., lack of time, difficulty of the treatment, lack of human support); 2) their opinion of the treatment through qualitative questions: (What would you like to change?; What elements would you include in the treatment?; What do you think the main barriers of the program are?; How could we improve adherence to the program?); and 3) opinions about format preferences (from face-to-face to self-applied without the intervention of a therapist).

The preferences and opinions comparing the two intervention formats (GROw vs. face-to-face videoconferencing treatment) were assessed using a 5-point questionnaire created specifically for this study that evaluated: format preference, subjective effectiveness, intervention logic, subjective aversiveness, and recommendation to other family members or friends. Preferences were measured before and after treatment. Before treatment, a brief explanation of the content and format of the two treatments (GROw and face-to-face videoconferencing) was given in both groups.

The opinions related to participants' expectations and satisfaction were assessed using the Expectations and Satisfaction Questionnaire adapted from Borkovec and Nau (1972). This questionnaire has six items, rated on a scale from 0 (nothing) to 10 (very much), that assess the opinions about the logic of the intervention, satisfaction with the treatment, recommending the treatment to family or friends, usefulness for treating other problems, usefulness to them, and aversiveness. This questionnaire was administered before and after the intervention. A brief explanation of the content and format of the treatment was given in both groups before the treatment. In contrast to the questionnaire on preferences and opinions comparing the two intervention formats, these questions focused only on the opinions about the assigned treatment (GROw or face-to-face videoconferencing).

Other questions about their opinion of the treatment were assessed after the intervention using a semi-structured opinion interview with quantitative and qualitative

questions administered in both conditions: GROw and the face-to-face videoconferencing treatment. This interview included a list of nine points (e.g., motivation to change, mindfulness, exposure) about the usefulness of each therapeutic content (assessed from 0: not at all useful to 10: maximum usefulness). Moreover, for the GROw group, a list of four 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), three semi-structured questions asking for their opinion of the weekly calls from a therapist (satisfaction and usefulness related to subjective recovery and adherence to the treatment on a scale from 0 “not at all” to 10 “very much”), and an open question about unexpected effects (including unexpected effects due to the health crisis produced by COVID-19) were included.

Modifications were made in the evaluation proposed in the published protocol for this study (Tur et al., 2021). The results related to the Usability and Acceptance Questionnaire (Campos et al., 2018; Castilla et al., 2016) and the Working Alliance Inventory (WAI) (Horvath & Greenberg, 1989) are not included in this manuscript. Participants were not asked questions about the acceptance of the evaluation procedure and materials used, but a phone-interview assessment of the reasons for dropping out was included.

2.4.3 Psychological and mental health outcomes

Psychological and mental health outcomes were assessed using the Inventory of Complicated Grief (ICG) (Limonero et al., 2009; Prigerson et al., 1995), the Beck Depression Inventory—Second Edition (BDI-II) (Beck et al., 1996; Estevan et al., 2019), the Typical Beliefs Questionnaire (TBQ) (Skritskaya et al., 2017), the Overall Anxiety Severity and Impairment Scale (OASIS) (Campbell-Sills et al., 2009; González-Robles et al., 2018), the Overall Depression Severity and Impairment Scale (ODSIS) (Bentley et al., 2014; Mira et al., 2019), the Positive and Negative Affect Schedule (PANAS) (Díaz-García et al., 2020; Watson et al., 1988), the Quality of Life Index (QLI) (Mezzich et al., 2000), the Work and Social Adjustment Scale (WSAS) (Echezarraga et al., 2019; Mundt et al., 2002), the Posttraumatic Growth Inventory (PTGI) (Tedeschi & Calhoun, 1996; Weiss & Berger, 2006), the Purpose-In-Life Test (PIL-10) (García-Alandete, 2014), the Five-Facet Mindfulness Questionnaire (FFMQ-15) (Asensio-Martínez et al., 2019), and the Self-Compassion Scale-Short Form (SCS-SF) (García-Campayo et al., 2014; Raes et al., 2011). Table 1 shows the assessment time, measurement source, and assessed group.

Table 1. Measures, group, assessment point, and assessment source

Measures	Group, assessment point, and assessment source
Sociodemographic data	GROw and face-to-face videoconferencing Screening Phone Interview
Semi structured interview about inclusion/exclusion criteria	GROw and face-to-face videoconferencing Screening Phone Interview
SCI-CG	GROw and face-to-face videoconferencing Screening, t2, t3, t4 Phone Interview
ADIS clinician's severity rating scale	GROw and face-to-face videoconferencing Screening, t2, t3, t4 Phone Interview
ICG	GROw and face-to-face videoconferencing Screening, t1, t2, t3, t4 Web
BDI-II	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
TBQ	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
OASIS	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
ODSIS	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
PANAS	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
QLI	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web

WSAS	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
PTGI	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
PIL-10	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
FFMQ-15	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
SCS-SF	GROw and face-to-face videoconferencing t1, t2, t3, t4 Web
Expectations and Satisfaction Questionnaires	GROw and face-to-face videoconferencing t1, t2 Phone Interview
Semi-structured opinion interview: preferences and usefulness of content	GROw and face-to-face videoconferencing t1, t2 Phone Interview
Semi-structured opinion interview: Usefulness of each element of the web	GROw t2 Phone interview
Semi structured opinion dropouts' interview	GROw and face-to-face videoconferencing (dropouts) t5 Phone Interview

Note. 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; PTGI, Post-traumatic Growth Inventory; QLI, Quality of Life Index; SCI-GC, Structured Clinical Interview for Complicated Grief; SCS-SF, Self-Compassion Scale Short Form; TBQ, Typical Beliefs Questionnaire; t1, baseline; t2, immediately after the intervention; t3,12 months after leaving the study; t4, 12-month follow-up; WSAS, Work and Social Adjustment Scale.

2.5 Statistical analysis

Given that the main aim of this study is to assess feasibility, the data have been narratively illustrated using the CONSORT 2010 statement (Eldridge et al., 2016) to

guide the reporting of this information. One-way ANOVA for continuous data and chi-square tests for categorical variables were used to verify significant differences between groups in the sociodemographic measures. To verify the normality of the sample distribution, Shapiro-Wilk tests were performed.

Means, standard deviations, and percentages/frequencies were used to explore the feasibility measures: preferences and opinions comparing the two intervention formats (GROw vs. face-to-face videoconferencing), expectations, satisfaction, and participants' opinions about the usefulness of the intervention. Non-parametric analyses were used to explore significant differences between groups and pre-post treatment changes in these feasibility measures. Chi-square tests were used to explore differences between groups in their preferences and opinions when comparing the two intervention formats. Mann-Whitney U tests were conducted to explore differences between the groups in their expectations, satisfaction, and opinions about the usefulness of the intervention. Wilcoxon tests were performed to explore significant changes in the expectations (pretreatment) and satisfaction (post-treatment) in both groups. Attrition and dropout rates were also calculated to explore the feasibility by reporting percentages and patterns of missing data. In the GROw group, the number of times each patient used the program was employed as the measure of adherence. In the face-to-face videoconferencing group, the number of times each patient attended the sessions was used as the measure of adherence. In addition, means and standard deviations were used to explore adherence to GROw, considering the number of times each patient reviewed each program module and the time spent in each.

To assess the reasons for dropout, and according to Consensus Qualitative Research (CQR) (Hill et al., 2005), an independent researcher attempted to contact all the participants who dropped out of the study for a telephone interview. After conducting the interviews, two researchers independently analyzed the transcripts of the call. Once this independent analysis was completed, the conclusions reached by each independent investigator were discussed with a third judge who was an expert in the field of iCBTs. A series of domains, categories, and illustrative ideas were established. In order to construct suitable categories, a cross analysis was used, which made it possible to classify the categories as general (if they applied to all the participants), typical (if they applied to at least half of the participants), and variants (if they applied to less than half of the participants).

For the secondary objective of this study, intent-to-treat mixed-model analyses without any ad hoc imputations were used to explore the potential effectiveness (Salim et al., 2008). This analysis makes it possible to handle missing data due to participant dropout (Chakraborty & Gu, 2009). The analysis compares the study groups based on the treatment to which they were randomly allocated. It does not assume that the last measurement is stable, it does not involve any substitution of missing values with supposed or estimated values, and it is conducted using all the available observations, thus reducing the biases and loss of power caused by the simple deletion or random imputation of incomplete data. Mixed-model analyses are appropriate for RCTs with multiple time points and pre-post designs, and it is robust to violations of distributional assumptions (Salim et al., 2008; Schielzeth et al., 2020). A linear mixed-effects model for each outcome measure was implemented using the MIXED procedure, with one random intercept per subject. An identity covariance structure was specified to model the covariance structure of the intercept. For each outcome, time (baseline and post-intervention) was treated as a within-group factor, and group (GROw and face-to-face videoconferencing group) as a between-group factor, and significant effects were followed up with pairwise comparisons (adjusted by Bonferroni correction). Between-group and intra-group effect sizes were calculated using Cohens *d* and their respective 95% Confidence Intervals (CI) (Cohen, 1988; Cumming & Calin-Jageman, 2017). Sensitivity analyses were performed to ensure the robustness of the statistical methods applied and their adequacy (Thabane et al., 2013; Viel et al., 1995). Modifying the statistical plan proposed in the published protocol for this study (Tur et al., 2022), comparisons of the GROw and face-to-face videoconferencing groups were carried out using intent-to-treat mixed-model analyses and between-group effect size analyses to increase the data available to explore the potential efficacy, based on author recommendations and due to the large amount of missing data. The IBM SPSS Statistic (V.25) was used for all the statistical analyses.

3. RESULTS

3.1 Baseline and participant characteristics

Participants' sociodemographic information is presented in Table 2. No significant differences were found at baseline. Overall, the mean age of the sample was 39.13 (SD; 12.57), and participants were mostly women (93.5%).

Table 2. Participants' sociodemographic information

	GROw (N=16)	Face-to-face videoconferencing (N=15)	Total (N=31)	Between-group comparison
Gender (n,%)				
Female	16 (100%)	13 (86.7%)	29 (93.5%)	$\chi^2(1) = 2.28,$ $p = .131$
Male	0 (0%)	2 (13.3%)	2 (6.5%)	
Age mean (SD)	37.63 (12,20)	40.73 (13,18)	39.13 (12,57)	$F(1,29) = .465,$ $p = .501$
Educational level (n,%)				
Elementary education	2 (12.5%)	0 (0%)	2 (6.5%)	$\chi^2(2) = 2.36,$ $p = .307$
Secondary education	5 (31.3%)	7 (46.7%)	12 (38.7%)	
Higher education	9 (56.3%)	8 (53.3%)	17 (54.8%)	
Relation to the deceased (n,%)				
Grandfather/grandmother	3 (18.8%)	2 (13.3%)	5 (16.1%)	$\chi^2(5) = 3.23,$ $p = .665$
Father/mother	9 (56.3%)	8 (53.3%)	17 (54.8%)	
Brother/sister	2 (12.5%)	2 (13.3%)	4 (12.9%)	
Partner	1 (6.3%)	1 (6.7%)	2 (6.5%)	
Son/daughter	0 (0%)	2 (13.3%)	2 (6.5%)	
Uncle/aunt	1 (6.3%)	0 (0%)	1 (3.2%)	
Time since loss (n,%)				
>6 months	6 (37.5%)	3 (20%)	9 (29%)	$\chi^2(3) = 1.37,$ $p = .713$
12-24 months	5 (31.3%)	5 (33.3%)	10 (32.3%)	
24-48 months	1 (6.3%)	1 (6.7%)	2 (6.5%)	
>24 months	4 (25%)	6 (40%)	10 (32.3%)	
Type of death				
Illness	14 (87.5%)	13 (86.7%)	27 (87.1%)	$\chi^2(3) = 2.00,$ $p = .571$
Natural death	1 (6.3%)	0 (0%)	1 (3.2%)	
Suicide	1 (6.3%)	1 (6.7%)	2 (6.5%)	
Accident	0 (0%)	1 (6.7%)	1 (3.2%)	

3.2 Feasibility results

3.2.1 Participants' flow diagram and adherence

Recruitment of participants began in December 2020 and ended in April 2022. The flow diagram of the participants is presented in Figure 2. Eighty-seven people were interested in participating in the study, and 41 of them completed a telephone evaluation by a professional with experience in stress and trauma-related disorders. Of these participants, 31 met all the inclusion/exclusion criteria for the study and were randomly assigned to the GROw group (N=16) or the face-to-face videoconferencing group (N=15). Regarding the recruitment process, 38.70% of the participants found out about the study from other people, 35.48% through social networks (Twitter and Instagram), 16.13% through local media (newspaper), and 6.45% from posters at Universitat Jaume I. In addition, 3.23% were patients at the Emotional Disorders Clinic at Universitat Jaume I.

Thirteen people (41.93%) dropped out of the study before finishing treatment: eight participants in the GROw group and five participants in the face-to-face videoconferencing group. The dropout rate in the GROw group was 50%, and the dropout rate in the face-to-face videoconferencing group was 33.33%. In the GROw group, the mean number of weeks to finish treatment was 16.86 (118 days; SD = 51.4). In the face-to-face videoconferencing group, the mean number of weeks to complete the treatment was 10.70 (75.38 days; SD = 8.33).

In the GROw group, three people (18.70%) dropped out of the treatment before completing Module 1, two people (12.5%) dropped out after completing Module 3, two people (12.5%) dropped out after completing Module 4, and one person (6.3%) dropped out after completing Module 5. In the face-to-face videoconferencing group, none of the five participants who dropped out of the study completed the first treatment session; dropouts occurred after randomization and before starting the intervention.

Table 3 shows the number of times participants in the GROw group accessed and reviewed the modules and the mean time spent on each.

Table 3. Number of participants, access times, time spent, and reviewed times per module (Grow group)

	N	Module access Mean (SD)	Reviews Mean (SD)	Time (minutes) Mean (SD)
Module 1	13	2.23 (1.74)	.92 (.95)	340.77 (103.95)
Module 2	13	2.62 (3.84)	.54 (.97)	358.23 (126.35)
Module 3	13	3.08 (5.45)	.46 (.97)	364.31 (207.285)
Module 4	11	8.73 (9.89)	.45 (.93)	351.27 (141.79)
Module 5	9	2.67 (3.97)	.11 (.33)	317.22 (157.43)
Module 6	8	7.38 (10.08)	.13 (.35)	321.75 (186.53)
Module 7	8	3.88 (6.01)	.25 (.71)	568.75 (276.23)
Module 8	8	1.63 (2.07)	.13 (.35)	374.25 (197.31)

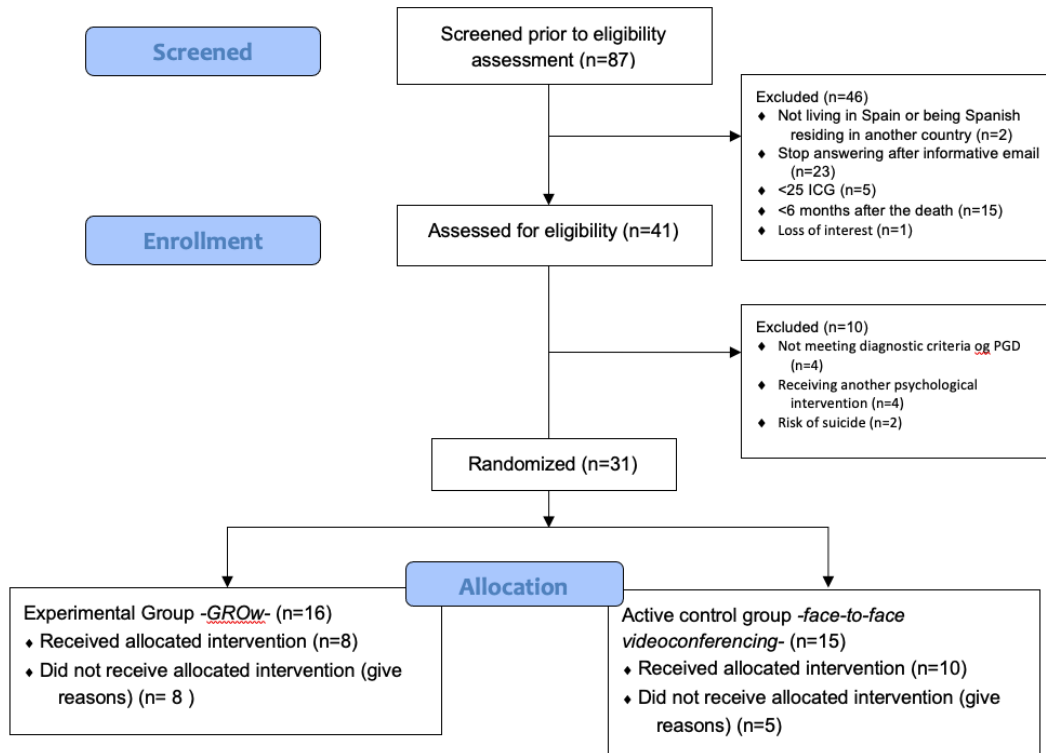


Fig 2. Participants' flow diagram

3.2.2 Preferences and opinions comparing the two intervention formats

Table 4 shows participants' preferences about the type of treatment (GROw and face-to-face videoconferencing) and their opinions about which one they thought was more effective, logical, aversive, and recommended. Participants were asked for their preferences before and after the intervention.

Table 4. Participants' preferences about the treatment before and after the intervention

	Before treatment (n=30)		After treatment (n=16)	
	GROw (n=16)	Face-to-face videoconferencing (n=14)	GROw (n=5)	Face-to-face videoconferencing (n=11)
Preference				
GROw	7 (41.2%)	5 (35.7%)	4 (80%)	1 (9.1%)
Face-to-face videoconferencing	9 (52.9%)	9 (64.3%)	1 (20%)	10 (90.9%)
Subjective effectiveness				

GROw	3 (17.6%)	4 (28.6%)	4 (80%)	0 (0%)
Face-to-face videoconferencing	13 (76.5%)	10 (71.4%)	1 (20%)	11 (100%)
Logic				
GROw	2 (11.8%)	2 (14.3%)	1 (20%)	0 (0%)
Face-to-face videoconferencing	14 (82.4%)	12 (85.7%)	4 (80%)	11 (100%)
Subjective aversiveness				
GROw	4 (23.5%)	6 (42.9%)	5 (100%)	4 (36.4%)
Face-to-face videoconferencing	12 (70.6%)	8 (57.1%)	0 (0%)	7 (63.3%)
Recommendation				
GROw	4 (23.5%)	4 (28.6%)	5 (100%)	0 (0%)
Face-to-face videoconferencing	12 (70.6%)	10 (71.4%)	0 (0%)	11 (100%)

Overall, a larger number of participants chose the face-to-face videoconferencing treatment over GROw. In addition, participants perceived the face-to-face videoconferencing treatment as more effective and logical, and they would recommend it to a friend or family member. Regarding subjective aversiveness, before treatment, a greater number of participants perceived the face-to-face videoconferencing treatment as more aversive. After treatment, the GROw participants perceived this treatment as more aversive.

Chi-squared tests revealed no statistically significant differences between groups before the treatment. After treatment, statistically significant differences were obtained in three variables: preferences ($\chi^2(2) = 9.52, p = .009$), subjective effectiveness ($\chi^2(2) = 12.99, p = .002$), and recommendation ($\chi^2(2) = 17.00, p = .000$).

3.2.3 Expectations and satisfaction

Table 5 shows participants' expectations (pretreatment) and satisfaction with the intervention (post-treatment), divided by group.

Table 5. Participants' expectations and satisfaction with the intervention

	GROw		Face-to-face videoconferencing	
	Pretreatment expectations	Post-treatment satisfaction	Pretreatment expectations	Post-treatment satisfaction
	M (SD) (n=14)	M (SD) (n=5)	M (SD) (n=14)	M (SD) (n=11)
Intervention logic	7.73 (1.67)	9.40 (0.89)	9.14 (1.01)	9.18 (1.08)
Treatment satisfaction	8.57 (1.60)	9 (1)	9.07 (1.54)	8.82 (1.17)
Treatment recommendation	9.43 (0.94)	10 (0)	9.29 (1.20)	9.45 (0.82)
Useful to treat other problems	8.07 (1.82)	9 (1)	9.29 (0.91)	7.91 (1.81)
Useful to themselves	8.07 (1.82)	9 (0.71)	9.07 (1.21)	8.64 (1.12)
Aversiveness	5.29 (3.48)	3 (4.12)	4.79 (3.40)	5.09 (3.73)

Results showed high expectation (pretreatment) and satisfaction (post-treatment) scores on most of the items. The item related to “Aversiveness” showed low to medium mean scores in both the GROw and face-to-face videoconferencing groups.

Statistically significant differences were found (Mann-Whitney's U, $p < .05$) between the means of the groups on two variables at pretreatment (expectations): intervention logic (higher score for the face-to-face videoconferencing treatment) and treatment recommendation (higher score for the GROw treatment). No statistically significant differences were found (Mann-Whitney's U, $p > .05$) between the means of the groups at post-treatment (satisfaction).

Considering both the GROw and face-to-face videoconferencing groups, Wilcoxon tests showed no statistically significant differences in expectations and satisfaction from pretreatment to post-treatment ($p > .05$ in all variables). Specifically for each group, Wilcoxon tests showed a statistically significant mean increase in the GROw group from pretreatment to post-treatment in the intervention logic variable ($z = -2.01$, $p = .038$) and a statistically significant mean decrease in the face-to-face videoconferencing intervention group from pretreatment to post-treatment in the usefulness for treating other problems variable ($z = -2.23$, $p = .026$).

3.2.4 Qualitative interview

Results showed that, on average, the participants perceived the therapeutic components of the treatment as useful in both groups, with a mean score greater than 7.5 (0 = not useful; 10 = very useful) in all the components (Table 6). In the GROw group, the components that obtained the highest scores were experiential exposure and the writing assignments, whereas in the face-to-face videoconferencing group, the component that was perceived as most useful were the writing assignments. No significant differences were found between the means of the groups on all the variables related to the usefulness of the therapeutic components (Mann-Whitney's U, $p > .05$ in all comparisons).

Only the participants in the GROw group answered the questions about the different elements of the web platform. On average, the participants perceived all the elements (images, videos, audios, and written information) as useful, with a mean score greater than 8.5 (0 = not useful; 10 = very useful) on all of them. Written information was the most highly valued element, with an average of 9 (0 = not useful; 10 = very useful).

On average, participants in the GROw group perceived the weekly follow-up phone calls as useful, and they showed high satisfaction with the phone calls (see Table 6). In addition, their qualitative opinion of the calls was recorded. Comments included: "the call was a connection between the work I was doing and listening to a voice that understood me and answered my questions, asking me how this week was. Not feeling detached and alone with the computer screen, but a person to have a chat with"; "It helps you move forward; it pushes you to keep up, it gives you support and confidence in case you have doubts"; "useful to remove all doubts. Being able to talk and get feedback. I tried to do a module every week, and it helped me a lot to understand why I was not able to continue with an exercise or what was happening with me emotionally in relation to the module"; "It makes you not completely disconnect; you have an obligation and the support of the person, you can solve doubts, if you have any problem, you have that person."

An open question about unexpected effects (including unexpected effects due to the health crisis produced by COVID-19) was included, and no one in either the GROw or face-to-face videoconferencing groups reported adverse effects.

Table 6. Participants' ratings in the qualitative interview about the usefulness of therapeutic components, usefulness of GROw program characteristics, and usefulness/satisfaction with the weekly follow-up phone calls

	GROw (n=4) M (SD)	Face-to-face videoconferencing (n=10) M (SD)
Usefulness of motivation to change	8.25 (1.26)	7.9 (1.91)
Usefulness of psychoeducation	8.25 (1.71)	8.5 (1.35)
Usefulness of behavioral activation	8.50 (1.29)	8.3 (1.16)
Usefulness of experiential exposure	9.50 (0.58)	8.4 (1.84)
Usefulness of mindfulness	8.25 (0.50)	8.1 (1.73)
Usefulness of compassion strategies	7.50 (1.73)	8.6 (1.08)
Usefulness of writing assignments	9.50 (0.58)	8.9 (1.2)
Usefulness of cognitive reappraisal	9.25 (0.96)	8.8 (1.4)
Usefulness of relapse prevention	8.25 (1.5)	8.5 (1.08)
Usefulness of images	8.50 (1.73)	-
Usefulness of videos	8.75 (0.96)	-
Usefulness of audios	8.75 (0.96)	-
Usefulness of written information	9 (0.82)	-
Satisfaction with the weekly follow-up phone calls	9.50 (1)	-
Usefulness of weekly follow-up phone calls	9 (1.4)	-
Usefulness of weekly follow-up phone calls for adherence	9 (2)	-

3.2.5 Reasons for dropping out

Nine participants (4 from the GROw group and 5 from the face-to-face videoconferencing group) who dropped out of the study were contacted to assess their reasons for dropping out, treatment barriers, and potential improvements. Tables 7 and 8 show the results obtained. In the case of problems related to the GROw program, the participants said that they lacked time, needed more therapeutic support, or felt the need to avoid emotions generated during treatment. With regard to problems related to the face-to-face videoconferencing treatment, the participants also concluded that they lacked time and needed to avoid the emotions generated during the treatment. Regarding the preferences for the therapy model, the answers were varied in both groups. The proposed improvement strategies included getting help on demand and having weekly follow-up video-conferencing calls in the GROw group. The proposed improvement strategies in the face-to-face videoconferencing group also involved having videoconferencing meetings instead of just phone calls and the possibility of choosing the treatment model. Finally, other reasons for dropout were starting another treatment, loss of contact, and familiarity with the profession.

Table 7. Domains, categories, and illustrative core ideas (GROw group)

GROw (n=4)		
Domain	Categories (N)	Illustrative core ideas
Problems with GROw program	Lack of time (1) Variant	<i>PA1: "I get home almost every day at 10 at night, I am preparing civil service exams and as such... I never found the time."</i>
	Need for therapeutic support (3) Typical	<i>PA3: "If you go to the gym alone, it is not the same as if you have a personal trainer, or if you go with a friend... This is the same. With a therapist, in the end, a bond or something social is generated, which, as it were, the emotion is better grasped"</i>
	Emotional avoidance (2) Typical	<i>PA3: "I kind of felt like I was kind of forcing myself to think about my mom. You know, I wasn't doing well then."</i>
	Traditional face to face (3) Typical	

Preference for the therapy model	Videoconference (2) Typical	
	Online	
	Indifferent (1) Variant	
Improvement strategies	Help on demand (1) Variant	<i>PA4: "Like a 24-hour chat, or I don't know, something in which you are doing the module and it is causing you anxiety or you are having a bad time, being able to have contact with someone at that moment."</i>
	Weekly video call instead of phone call (2) Typical	<i>PA4: "By video call it would have been closer. It would have given rise to commenting more on the problems. Because even per call it was colder."</i>
Other	Starting another treatment for another main reason (1) Variant	<i>PA2: "I had to leave the program because there was a certain incompatibility since I had to start another psychological treatment. So, it was no longer objective."</i>
	Loss of contact during evaluation (1) Variant	<i>PA3: "I didn't even get started. I notified by email and so on..."</i>
	Familiarity with the profession (2) Typical	<i>PA4: "Many of the things I was seeing, well, I already knew them. So, it was a bit like hmm... I don't know how to tell you, not studying, but like reading the same thing."</i>

Table 8. Domains, categories, and illustrative core ideas in the face-to-face videoconferencing group

Face-to-face videoconferencing (n=5)		
Domain	Categories (N)	Illustrative core ideas
Problems with face-to-face videoconferencing treatment	Lack of time (2) Typical	<i>PT3: "I didn't have time to be at a decent hour because I'm working and studying at the same time."</i>
	Emotional avoidance (1) Variant	<i>PT2: "For me, for example, it was difficult to write forgiveness letters. For this reason, it would be like focusing more on the aspects that the person finds it difficult to perform"</i>

	Traditional face-to-face (2) Typical	
Preference for the therapy model	Videoconference (2) Typical	
	Online (2) Typical	
	Indifferent (2) Typical	
Improvement strategies	Videoconferences in both modalities (1) Variant	<i>PT2: "I think the fact that it's via videoconference is better than just you having the information and then a call to see how you're doing."</i>
	Choice of treatment version (1) Variant	<i>PT5: "That I could choose the option I wanted, which was self-help. Through the questionnaire..."</i>
Other	Starting another treatment for another main reason (1) Variant	<i>PT2: "We were almost at the end, and I really had many tools to continue working with it. At that time, I needed something else."</i>
	Loss of contact during evaluation (2) Typical	<i>PT4: "I think he changed my time, he sent me an email... well, there was a mix-up..."</i>

3.3 Potential effectiveness results

Within-group comparisons (Table 9) showed a significant reduction in symptomatology from pre- to post-treatment on more than half of the variables measured in the GROw group, with large effect sizes ($d > .50$) (Norcross & Lambert, 2018) on most of them. In the face-to-face videoconferencing group, within-group comparisons showed a significant reduction in symptomatology from pre- to post-treatment on almost half of the measures, with large effect sizes ($d > .50$) (Norcross & Lambert, 2018) on most of the variables with a significant reduction.

A significant effect of time (pretreatment and post-treatment) was found on all the measures, except WSAS, SCSSF, and FMQ15: BDI-II [(F (1, 18.77) = 48.48; $p < .001$)], ICG [(F (1, 15.74) = 45.92; $p < .001$)], TBQ [(F (1, 16.26) = 51.07; $p < .001$)], PTGI [(F (1, 16.91) = 15; $p < .001$)], OASIS [(F (1, 15.55) = 44.86; $p < .001$)], ODSIS [(F (1, 16.61) = 16.37; $p < .001$)], PANAS+ [(F (1, 18.32) = 25.98; $p < .001$)], PANAS- [(F (1, 21.35) = 22.09; $p < .001$)], QLI [(F (1, 17.7) = 18.39; $p < .001$)], PIL10 [(F (1, 18.19) = 13.27; $p < .01$)]. A group effect was found on the PIL10 [(F (1, 25.40) = 7.5; $p < .05$)].

An interaction time*group effect was found on two measures: ICG [(F (1, 15.74) = 4.99; p < .05)] and PANAS+ [(F (1, 18.32) = 5.13; p < .05)].

Table 9. Means, standard deviations, effect of time, and within-group effect sizes (pretreatment and post-treatment)

Measures	GROw				Face-to-face videoconferencing			
	Pre M(SD) (N=15)	Post M(SD) (N=7)	F (df)	d (95% CI)	Pre M(SD) (N=12)	Post M(SD) (N=9)	F (df)	d (95% CI)
BDI-II	23.33 (9.29)	9.57 (9.47)	24.30 (1,19.01)***	1.40 (0.76,2.04)	28.83 (10.61)	17 (8.99)	24.23 (1,18.51)****	1.04 (0.31,1.72)
ICG	38 (11.23)	21.43 (15.97)	38.12 (1,15.8)***	1.40 (0.76,2.03)	42.42 (13.42)	34.22 (15.3)	11.04 (1,15.67)**	0.57 (0.15,0.98)
TBQ	56.2 (17.41)	35.86 (22.89)	28.28 (1,16.31)***	1.10 (0.59,1.62)	64.42 (11.87)	50.33 (15.84)	22.80 (1,16.19)***	1.10 (0.49,1.71)
PTGI	30.8 (20.1)	53.14 (32.38)	10.06 (1,17.04)**	-1.05 (- 1.53,- 0.57)	35.08 (18.74)	44 (20.84)	5.19 (1,17.77)*	-0.44 (- 0.90,0.02)
OASIS	9.47 (4.82)	4.57 (4.35)	29.76 (1,15.6)***	-0.20 (- 0.53,0.13)	10.50 (4.21)	6.89 (4.51)	15.78 (1, 15.49)** *	0.80 (0.3,1.3)
ODSIS	8.67 (6.1)	3.71 (4.54)	12.57 (1,16.74)**	0.77 (0.38,1.15)	10 (4.37)	7.6 (4.22)	4.56 (1,16.49)*	0.51 (- 0.07,1.09)
PANAS+	19.60 (6.84)	29 (11.18)	25.48 (1,1853)***	-1.30 (- 1.89,- 0.71)	18.42 (5.50)	21.56 (6.15)	4.28 (1,18.08)	-0.53 (- 0.93,- 0.13)
PANAS-	29.47 (6.66)	17.57 (8.44)	17.84 (1,21.96)***	1.69 (0.88, 2.50)	27.58 (9.14)	21.22 (6.02)	5.63 (1,20.69)*	0.65 (0.06,1.24)
QLI	4.77 (1.85)	6.64 (1.63)	16.12 (1,17.86)***	-0.96 (- 1.4,-0.51)	4.32 (1.72)	5.08 (1.82)	3.95 (1,17.51)	-0.41 (- 0.72,- 0.11)
PIL10	42.87 (10.16)	55.29 (10.1)	12.97 (1,18.57)**	-1.16 (- 1.80,- 0.51)	36.75 (10.41)	40 (7.35)	2.22 (1,17.76)	-0.29 (- 0.49,- 0.09)
WSAS	16.47 (8.53)	15.57 (13.69)	0.58 (1,16.65)	0.10 (- 0.13,0.33)	18.92 (8.89)	19.56 (11.89)	0.03 (1,16.53)	-0.07 (- 0.36,0.22)
SCSSF Self Compassion	2.62 (0.84)	3.04 (1.09)	1.64 (1,16.90)	-0.47 (- 0.75,- 0.19)	2.35 (1)	2.69 (0.72)	2.59 (1,16.58)	-0.21 (- 0.66,0.24)

SCSSF Humanity	2.82 (0.52)	3.29 (0.95)	2.32 (1, 24.01)	-0.85 (- 1.49,- 0.22)	2.79 (0.80)	2.97 (0.71)	0.42 (1, 21.74)	-0.21 (- 0.84,0.42)
SCSSF Mindfulness	2.57 (0.62)	3.04 (0.82)	2.37 (1,22.8 1)	-0.72 (- 1.30,- 0.13)	2.56 (0.81)	2.47 (0.69)	0.25 (1,21.1)	0.10 (- 0.36,0.57)
FMQ15 Observe	2.47 (1.14)	3.29 (1.13)	4.74 (1,17.1 6)*	-0.68 (- 1.15,- 0.19)	2.72 (0.80)	2.75 (0.96)	0.07 (1,16.26)	-0.03 (- 0.3,0.23)
FMQ15 Describe	3.67 (1.04)	3.42 (0.99)	0.21 (1,21.3 0)	0.23 (- 0.28,0.74)	3.33 (1.1)	3.19 (1,16)	0.007 (1,18.69)	0.12 (- 0.51,0.75)
FMQ15 Consistency	3.18 (1.09)	3.86 (0.74)	2.22 (1,17.8 2)	-0.59 (- 1.11,- 0.07)	2.89 (0.79)	3.08 (0.94)	0.15 (1,16.22)	-0.22 (- 0.70,0.25)
FMQ15 Not judge	3.52 (1.03)	3.51 (1.05)	0.03 (1, 18.29)	0.01 (- 0.13,0.16)	3.42 (0.87)	2.7 (1.03)	4.81 (1,16.76) *	0.77 (0.08,1.4 6)
FMQ15 Non- reactivity	2.42 (0.64)	2.57 (0.66)	0.03 (1,19.1 1)	-0.22 (- 0.93,0.49)	2.72 (0.58)	2.83 (0.82)	0.12 (1,17.40)	-0.18 (- 0.47,0.12)

Note. Pre = Pretreatment; Post = Post-treatment; M = Mean; SD = Standard deviation; N = Number of participants; BDI-II = Beck Depression Inventory—Second Edition; ICG = Inventory of Complicated Grief; TBQ = Typical Beliefs Questionnaire; PTGI = Post-traumatic Growth Inventory; OASIS = Overall Anxiety Severity and Impairment Scale; ODSIS = Overall Depression Severity and Impairment Scale; PANAS = Positive and Negative Affect Schedule; QLI = Quality of Life Index; PIL-10 = Purpose-In-Life Test; WSAS = Work and Social Adjustment Scale; SCS-SF = Self-Compassion Scale Short; FFMQ-15 = Five-Facet Mindfulness Questionnaire.

*** P<.001, ** P<.01, * p<.05

Table 10 shows between-group effect sizes at post-treatment in both the GROw and face-to-face videoconferencing groups. There were no differences between groups except on the ICG, PANAS+, and PIL10, with a greater reduction in symptoms in the GROw group.

Table 10. Between-group effect sizes at post-treatment

	GROw vs. face-to- face videoconferencing	d (95% CI)
BDI	F(1,38.67)=2.36	-.76 (-1.79,0.26)
ICG	F(1,35.94)=5.343*	-.78 (-1.80,0.25)
TBQ	F(1,36.02)=2.85	-.54 (-1.55,0.46)
PTGI	F(1,37.88)=0.02	0.33 (-0.67,1.32)
OASIS	F(1,35.72)=2.13	-0.49 (-1.50,0.51)

ODSIS	F(1,37.7)=1.80	-0.84 (-1.87,0.19)
PANAS+	F(1,38.58)=6.37*	0.81 (-0.22,1.84)
PANAS-	F(1,38.98)=1.15	-0.48 (-1.48,0.52)
QLI	F(1,38.29)=3.81	0.36 (-0.64,1.35)
PIL10	F(1,38.90)=8.37**	1.67 (0.53,2.82)
WSAS	F(1,36.19)=0.48	-0.30 (-1.29,0.70)
SCSSF Self Compassion	F(1,38.11)=0.28	0.37 (-0.63,1.36)
SCSSF Humanity	F(1,38.92)=0.67	0.37 (-0.63,1.36)
SCSSF Mindfulness	F(1,38.97)=2.72	0.70 (-0.30,1.74)
FMQ15 Observe	F(1,36.61)=0.97	0.49 (-0.51,1.50)
FMQ15 Describe	F(1,33.58)=0.47	0.20 (-0.79,1.19)
FMQ15 Consistency	F(1,37.8)=2.52	0.86 (-0.17,1.89)
FMQ15 Not judge	F(1,29.83)=4.44	0.74 (-0.28,1.76)
FMQ15 Non- reactivity	F(1,37.86)=1.62	-0.33 (-1.32,0.67)

Note. BDI-II = Beck Depression Inventory—Second Edition; ICG = Inventory of Complicated Grief; TBQ = Typical Beliefs Questionnaire; PTGI = Post-traumatic Growth Inventory; OASIS = Overall Anxiety Severity and Impairment Scale; ODSIS = Overall Depression Severity and Impairment Scale; PANAS = Positive and Negative Affect Schedule; QLI = Quality of Life Index; PIL-10 = Purpose-In-Life Test; WSAS = Work and Social Adjustment Scale; SCS-SF = Self-Compassion Scale Short; FFMQ-15 = Five-Facet Mindfulness Questionnaire.

*** P<.001, ** P<.01, * p<.05

4. DISCUSSION

The main goal of the study was to examine the feasibility of an iCBT for people with PGD (GROw) compared to the same intervention delivered face-to-face through videoconferencing. Specifically, the aims were: to explore patients' opinions about GROw and the face-to-face videoconferencing intervention as a treatment for PGD (preferences and opinions comparing the two intervention formats, expectations, satisfaction, and participants' opinions about the usefulness of the intervention); to explore adherence and reasons for dropping out in both formats (GROw and face-to-face videoconferencing intervention); and to assess whether the target population could be recruited and explore the rate of recruitment and retention in order to provide information for a future large-scale RCT. As a secondary objective, the potential effectiveness of GROw was explored.

According to patients' preferences and opinions when comparing the two intervention formats (see Table 4) before the treatment, in general, a greater number of participants chose the face-to-face videoconferencing treatment over GROw, and the face-to-face videoconferencing treatment was perceived as more effective and logical and would be recommended more to a friend or family members. Most of the participants in the GROw group (80%) preferred the face-to-face videoconferencing intervention before the treatment, whereas at the end of the treatment, 80% of the participants who finished the GROw treatment preferred GROw to the face-to-face videoconferencing intervention. In the face-to-face videoconferencing group, 64.3% preferred this group and 35.7% preferred the GROw group before the intervention, whereas at the end of the treatment, 90.9% of these participants preferred the face-to-face videoconferencing group, and 9.1% preferred the GROw group. Differences in post-treatment preferences between groups were statistically significant; thus, after the treatment, participants generally preferred the group to which they had been assigned. This result disagrees with other studies that conclude that treatment preferences remain stable over time (Delevry & Le, 2019). All the participants who completed the GROw treatment would recommend this treatment to a friend or relative instead of the face-to-face videoconferencing treatment, whereas all the people who completed the face-to-face videoconferencing treatment would recommend this intervention to a relative or friend instead of GROw. The differences between groups in their recommendations were statistically significant. Regarding the subjective effectiveness, at pretreatment, 76.5% of the GROw group and 71.4% of the face-to-face videoconferencing group chose the face-to-face videoconferencing treatment as more effective. After the treatment, 80% of the people in the GROw group chose this treatment as more effective, and 100% of the people in the videoconferencing group chose the face-to-face videoconferencing intervention as more effective. Between-group differences in subjective effectiveness at post-treatment were statistically significant. The data obtained in this study show that the preferences and opinions when comparing the two intervention formats generally improved in favor of GROw once this treatment had ended. It is important to note that, in the GROw group, the dropout rate was 50%, whereas the face-to-face videoconferencing group had a 33% drop-out rate. Patients' preferences may be associated with the start of treatment and adherence (Brenes et al., 2021; Delevry & Le, 2019; Raue et al., 2009). Although more studies are needed, the results of this study indicate that there is a tendency to choose face-to-face treatments (in this case by videoconference), but once the iCBT (GROw) has been tested, this tendency changes in

favor of the iCBT. Therefore, it is necessary to improve the dissemination and information about these types of treatments and how they can help people with PGD.

Regarding expectations and satisfaction with the treatment (see Table 5), participants showed high expectation (pretreatment) and satisfaction (post-treatment) scores on most of the items in both groups. These results are consistent with other studies that showed high expectations (Botella et al., 2016; Campos et al., 2018; Mor et al., 2022) and satisfaction (Botella et al., 2016; Campos et al., 2018; McGoron et al., 2019; Mor et al., 2022; Palacios et al., 2018; Richards et al., 2016; Seitz et al., 2014) with Internet-based treatments. Before starting the intervention, people assigned to the face-to-face videoconferencing treatment perceived this intervention as logical, with a mean score of 9.14/10 (SD = 1.08), whereas people assigned to the GROw treatment perceived the GROw intervention as logical, with a mean score of 7.73/10 (SD = 1.67). The differences in the mean scores between the two groups were statistically significant. A statistically significant mean increase in the GROw group from pretreatment to post-treatment on the intervention logic variable was also found. GROw group participants perceived this treatment as more logical once it was completed. This is consistent with other Internet-based treatment studies in that the participants' mean opinion of the treatment logic increases after the intervention is over (Botella et al., 2016). Before starting the intervention, people assigned to the face-to-face videoconferencing treatment would recommend this intervention, with a mean score of 9.29/10 (SD = 1.20), whereas people assigned to the GROw treatment would recommend this intervention, with a mean score of 9.43/10 (SD = .94). The differences in the mean scores between the two groups were statistically significant. This is consistent with other studies that showed high scores on recommending Internet-based programs (Botella et al., 2016; Campos et al., 2018; Mor et al., 2022). A statistically significant mean decrease was found in the face-to-face videoconferencing group from pretreatment to post-treatment on the "useful to treat other problems" variable. This might be because, although it was a face-to-face intervention, there was a guide for each session that was clearly focused on the specific treatment of PGD.

Because the therapeutic contents were the same in both groups, all the participants were asked about the usefulness of each component (see Table 6). Participants rated the usefulness of all the components with a mean of 7.5/10 or higher. The treatment components that obtained higher means in the GROw group were experiential exposure

(9.5/10), writing assignments (9.5/10), and cognitive reappraisal (9.25/10). In the face-to-face videoconferencing group, the highest means were obtained for the therapeutic components of writing assignments (8.9/10), cognitive reappraisal (8.8/10), and compassion strategies (8.6/10). Experiential avoidance, behavioral avoidance, and expressive suppression are associated with disturbing grief symptoms (Eisma & Stroebe, 2021; Williams et al., 2019). The therapeutic components related to experiential exposure and writing assignments help patients to expose themselves to situations, memories, and emotions that they have been avoiding. The participants' subjective perceptions of these components as useful are consistent with other studies that incorporated exposure strategies and obtained promising results in terms of symptom reduction, in both face-to-face treatments and Internet-based treatments (Johannsen et al., 2019; Wagner et al., 2020). It is possible that the components related to cognitive reappraisal and compassion strategies, which are highly rated by the participants in terms of usefulness, gave the participants emotional regulation tools. Putative adaptive emotional regulation strategies (e.g., cognitive reappraisal and mindfulness) are generally negatively associated with disturbing grief symptoms (Eisma & Stroebe, 2021). Other studies that incorporated cognitive reappraisal strategies into their Internet-based treatments obtained promising results in reducing grief-related symptoms (Hoffmann et al., 2018; Kersting et al., 2013; van der Houwen et al., 2010; Wagner et al., 2006). Regarding compassion strategies, compassion-based therapies such as "Compassion-Focused Therapy (CFT)" lead to a greater ability to tolerate distress and allow openness and receptivity to painful aspects that can help to rebuild a life after the loss of a loved one (Harris, 2021). Patients' subjective opinions about the therapeutic components of treatments are currently poorly studied. Future studies should continue to explore this topic in order to develop treatments for people with PGD that, in addition to reducing symptoms, are satisfactory and promote patients' adherence.

The usefulness of the different elements available on the web platform (images, videos, audios, and written information) was highly rated, with an average score of 8.5/10 or more (see Table 6). Written information was the most valued element (medium score of 9/10). It should be noted that most of the information on the platform was presented in written format, and the participants could access and review the information at any time. Few studies have focused on the usefulness of each component of an Internet-based intervention. McGoron et al. (2019) analyzed a pragmatic Internet-based intervention to

promote positive parenting, and they showed that the participants appreciated that the information on the platform was easy to understand, useful, and well-organized. Future studies can focus on which specific characteristics of each element are more useful and satisfactory to the participants.

The weekly telephone follow-up by a therapist was also highly valued by the participants in the GROw group (see Table 6). The involvement of a human therapist and participants' perception that therapists care about them are important characteristics related to adherence to Internet-based interventions (Andersson, 2009; Christensen et al., 2009; Johansson et al., 2015; Spek et al., 2007). This is consistent with the qualitative results of our study, which showed that the participants perceived that the weekly telephone support was satisfactory and useful and helped their adherence (“...it helped me a lot to understand why I was not able to continue with an exercise or what was happening with me emotionally in relation to the module”, “it makes you not completely disconnect...”, “...you have that person”). Other qualitative studies showed similar results for Internet-based interventions. As in these qualitative results, Mor et al. (2022) concluded that a weekly follow-up by a therapist could be useful (“I think I needed a basic weekly follow-up by a therapist so he/she could have guided me to solve the problems...”, “maybe having more monitoring of the patients could help so you would not be so alone while doing the intervention”).

The results obtained in this study related to participants' expectations, satisfaction, and opinions about the usefulness of the intervention are consistent with a preliminary study that explored the feasibility of GROw through a multiple-baseline single-case experimental design study with six participants (Tur et al., 2022). In this study, the participants who finished the treatment (66%) showed high scores on satisfaction with GROw and perceived the therapeutic content of the treatment and the follow-up phone calls as highly useful.

Regarding the recruitment of participants, it took two years and four months, and the number of participants who entered the study was lower than expected (31/48) in the published study protocol (Tur et al., 2021). The prevalence of PGD is one in ten in bereaved adults (Lundorff et al., 2017) worldwide, and in Spain between 7.67 – 10.68% of people who have lost a loved one suffer from PGD. The prevalence of PGD is lower than that of other psychological disorders, such as anxiety disorders and mood disorders, which represent 20-28% of the total population, with comorbidity rates ranging between

40 and 80% (Kessler et al., 2005). This may be one reason for the difficulty in recruiting a larger number of participants. In addition, according to the ICD-11, at least six months have to pass since the death of the loved one for a diagnosis of PGD. Thus, 17.34% of the people who wanted to access the study were directly excluded based on this exclusion criterion. Regarding the recruitment strategies, 38.70% of the participants found out about the study from other people, 35.48% through social networks (Twitter and Instagram), 16.13% through local media (newspaper), and 6.45% through posters at Universitat Jaume I. Additionally, 3.23% were patients at the Emotional Disorders Clinic at Universitat Jaume I. Samples recruited with exclusively online strategies may not be representative of the general population (Glasgow et al., 2007; Whitehead, 2007). Other clinical centers and associations related to bereavement were contacted to recruit participants, but they refused to participate in the study. Future studies could achieve collaboration with clinical centers to increase the sample and make it more representative of the general population.

We defined dropouts as participants who were randomized and assigned to a group but did not access or complete the treatment. Almost half of the participants (41.94%) dropped out of the study (50% in the GROw group and 33.3% in the face-to-face videoconference group). This is consistent with the results obtained in other studies on Internet-based treatments for grief, which concluded that dropout rates ranged from 10.3 to 58.8%. This is also consistent with a preliminary study that evaluated the effectiveness of GROw in reducing symptoms in a multiple-baseline single-case experimental design study in which 34% of the participants dropped out of the GROw treatment (Tur et al., 2022). However, extra information on dropouts was obtained to improve the dropout rate in future studies. Nine participants (4 from the GROw group and 5 from the face-to-face videoconferencing group) were interviewed to obtain qualitative information about their reasons for dropping out (see Table 7 and 8). Some of the main reasons for leaving the study were lack of time, the need for more therapeutic support, or feeling the need to avoid emotions that arose during treatment. The need for more support from the therapist was expressed by the participants in the GROw group, who received support from a therapist in a weekly follow-up call. Increasing the intervention of a therapist in the GROw group could be a good way to reduce dropout rates. The surveyed participants proposed increasing the intervention of a therapist through help on demand and/or a weekly video call rather than phone calls. This result agrees with other studies that found

that guided iCBTs are associated with lower dropout rates (Andersson et al., 2015; Baumeister et al., 2014; Furukawa et al., 2021; Mewton et al., 2014). Increasing therapist support could help them to stop avoiding situations, emotions, and thoughts, and keep them from abandoning treatment for this reason. Blending online and face-to-face CBT might help to solve these problems by increasing therapist support while maintaining the cost-effectiveness relationship. Blended CBT may increase adherence, have comparable clinical effects to those of standard CBT (Kooistra et al., 2014), be well-accepted by therapists (Titzler et al., 2018), save clinician time compared to stand-alone face-to-face therapy, and be feasible (Erbe et al., 2017). Another proposal for improvement in the face-to-face videoconferencing group was to be able to choose the treatment format (self-applied vs. face-to-face with a therapist). Offering the possibility of choosing the self-applied treatment could be a good option for people who indicate that they lack time. Future studies can explore which people benefit most from an iCBT or blended CBT, in order to improve the effect and dissemination of these treatments.

According to the adherence data, in the GROw group, the mean number of weeks needed to finish the treatment was 16.86 (118 days; SD = 51.4), whereas in the face-to-face videoconferencing group, the mean number of weeks needed to complete the treatment was 10.70 (75.38 days; SD = 8.33). Participants in the face-to-face videoconferencing group were more closely monitored by a therapist, and this may be one reason that the time spent on the treatment was more aligned with the planned timing. The treatment modules in the GROw group were designed to take approximately one hour, but the results indicated that the participants needed an average of 317 to 568 minutes (depending on the treatment module) to complete each module. According to the literature, the mean number of treatment sessions for disturbing or disabling grief in other published face-to-face and Internet-based interventions is 10, ranging from 1 to 20 (Johannsen et al., 2019). Treatments with good efficacy results, such as the "Complicated Grief Treatment" (CGT) (Shear, 2015a), require a 16-week intervention. This is closer to the time spent on the GROw treatment. Future research should take this into account to adjust the timing of the treatment. For example, for a blended CBT intervention, 10-15 days (per module) could be allocated to reviewing the information and doing the exercises on the web platform after a brief session with a therapist. Taking into account other bereavement treatments that have shown efficacy (e.g., Shear et al., 2005; Shear et al., 2014, 2016) and the mean number of days that GROw participants needed to complete

the intervention (118 days), 10-15 days for each module is a feasible proposal to adapt the temporality of GROw program in future studies.

With regard to the secondary aim of the study, and considering the data collected, promising results were obtained on the potential efficacy of the treatment in both groups (see Table 9 and 10). Both groups showed a significant reduction in symptoms of grief and depression (BDI-II, ICG and TBQ), with large effect sizes ($d > .50$). These findings are consistent with a preliminary study that evaluated the effect of GROw in reducing symptoms in a multiple-baseline single-case experimental design study (Tur et al., 2022). In this study, symptoms of grief and depression were assessed using the ICG, TBQ, and BDI-II. Half of the participants showed clinically significant changes (symptom reduction) on the ICG and TBQ, and 75% of the participants showed clinically significant changes (symptom reduction) on the BDI-II. Regarding the differences between groups, effect sizes at post-treatment, comparing GROw and the face-to-face videoconferencing treatment, showed that there were no differences between the groups, except on the ICG, PANAS+, and PIL10, with greater reductions in symptoms in the GROw group. The GROw group also showed a significantly higher effect on more variables than the face-to-face videoconferencing intervention in the within-group analyses. These results are consistent with the available literature showing that Internet-based treatments for the prevention and treatment of PGD had promising results in reducing bereavement-related symptoms (Tur et al., 2019; Wagner et al., 2020). It is important to note that the total intervention time was greater in the GROw group (Mean = 16.86 weeks) than in the face-to-face videoconferencing group (Mean = 10.70 weeks). The effect of time was not controlled in this study, and it could be an important variable in improving grief-related symptoms because grief symptoms can decrease naturally over time (Jordan & Litz, 2014). The exploratory results on the preliminary efficacy of this study should be interpreted with extreme caution, and more studies are needed in order to generalize these conclusions to the general population.

The results of this study showed that GROw is a feasible and well-accepted iCBT with promising results in terms of grief-related symptom reduction. iCBTs are cost-effective and cheaper than face-to-face therapy, and they make it possible to reach more people who need therapy. iCBT is a well-established therapy format that shows clinical efficacy compared to control groups and active conditions in the short and long term (Andersson et al., 2014, 2017; Carlbring et al., 2017, 2018; Cuijpers et al., 2008; Donker

et al., 2015; Hedman et al., 2011; Karyotaki et al., 2018; Komariah et al., 2022; Musiat & TARRIER, 2014; Wang et al., 2020; Xiong et al., 2022), and it can overcome geographical barriers and isolation problems (Griffiths et al., 2006; Griffiths & Christensen, 2007), such as those caused by COVID-19, which has made disturbed grief a major public health concern worldwide (Eisma et al., 2020).

5. LIMITATIONS AND FUTURE PERSPECTIVES

This study has several limitations that should be highlighted. One of the limitations is related to the sample size. Smaller sample sizes and higher dropout rates were obtained than the study protocol proposed (Tur et al., 2021). For this reason, the results were obtained from a smaller sample than expected. In addition to the sample size limitations, the influence of the time that passed without intervention was not measured. Therefore, the results on the potential effect of the treatment obtained in this study must be viewed with caution.

Other changes were made in the published study protocol (Tur et al., 2021): 1) Due to the length of the evaluation, the objective of exploring participants' opinions about the study design, materials, and assessment was not included; 2) Because there was already extensive and sufficient information about the feasibility of this study, the data obtained from the Usability and Acceptance Questionnaire (Campos et al., 2018; Castilla et al., 2016) and the Working Alliance Inventory (WAI) (Horvath & Greenberg, 1989) were not included in this manuscript; 3) The data from the 3- and 12-month follow-ups were not included in this manuscript because the evaluation of the follow-ups is still being carried out; 4) Because GROw is not culturally adapted to other Spanish-speaking countries, a new inclusion criterion was incorporated (living in Spain or being Spanish but residing in another country); 5) To improve the quality of the feasibility results obtained, the objective of exploring the reasons for dropping out was included; 6) To improve the quality of the exploratory results on the potential efficacy of the treatment, the objective of performing a between-group change analysis was included; and 7) Due to the pandemic situation caused by COVID-19 and related to the mobility restrictions, the face-to-face sessions were held by videoconference rather than in person.

In sum, despite the limitations, the results of this study showed that GROw is a feasible well-accepted iCBT for the treatment of PGD, and it has promising results related to its potential effectiveness. GROw showed strong potential as an iCBT for PGD and a

cost-effective alternative to face-to-face interventions. The results of this study support scaling up the treatment using larger samples and more complex designs in randomized controlled trials comparing GROw with active controls and including non-active control groups to evaluate the influence of time without intervention. The results of this study also support including more human support in the treatment, for example, blending online self-applied modules and brief face-to-face CBT sessions. These data contribute to allowing people with PGD who need treatment to easily access an evidence-based intervention.

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GENERAL DISCUSSION

The main aim of this doctoral thesis was to explore the feasibility of GROw, a novel Internet-delivered cognitive-behavioral therapy (iCBT) for adults with prolonged grief disorder (PGD). The secondary aim was to explore the potential effectiveness of GROw in treating grief-related symptoms. In order to achieve these general aims, specific objectives were proposed.

The first specific objective was to conduct a literature review of the published investigations that have tested the effect of Internet-based treatments for the prevention and treatment of disturbing and disabling grief using randomized controlled trial study designs (Chapter 1). An exploration and summary of the characteristics of the sample, evaluation, and treatment were carried out, considering 10 selected studies with a total sample of approximately 1400 people. Regarding the characteristics of the sample and, specifically, the type of loss, each investigation established a different profile: people who had experienced the death of a loved one, death of a first-degree relative, death of an older relative, caregivers of deceased people, loss of a partner, separation or divorce, loss of a relative due to hematological cancer, and loss of a child during pregnancy. For the time elapsed after the loss, different criteria were also established: more than six months before starting the intervention, at least 12 months before the intervention, between 1-6 months before the intervention, or no time criteria. As the summary reveals, the characteristics of the sample were heterogeneous. One of the reasons for the heterogeneity of the sample may be related to the fact that many of the studies were carried out before the addition of the “Prolonged Grief Disorder (PGD)” category in the eleventh edition of the International Classification of Diseases (CIE-11; World Health Organization [WHO], 2019) and the addition of the “Persistent Complex Bereavement Disorder (PCBD)” category in the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5-TR; Boelen et al., 2020; Prigerson et al., 2021). These two diagnostic tags establish specific characteristics studies can use to further homogenize the sample. Even so, recent analyses have concluded that the two diagnostic tags are not similar enough to be considered equal (Eisma et al., 2022). Therefore, the heterogeneity of the sample may still be a problem in future research if common guidelines are not established. According to the evaluation, each study assessed bereavement symptoms differently, using specific items created for

the study from the literature, scales, selected parts of scales, or other questionnaires not specifically created for bereavement symptomatology. The Inventory of Complicated Grief [ICG-(R); Prigerson et al., 1995; Prigerson & Jacobs, 2001] was the most widely used scale in the studies. This assessment summary is similar to the data obtained in the systematic review and meta-analysis conducted in 2020 by Wagner et al. (2020) that evaluated web-based bereavement care interventions. A systematic review and meta-analysis by Johannsen et al. (2019) that analyzed 32 studies on psychological interventions for grief (face-to-face treatments and Internet-based interventions) concluded that half of the studies (53%) had used the ICG-(R) (Prigerson et al., 1995; Prigerson & Jacobs, 2001) or the Prolonged Grief (PG-13) instrument (Prigerson et al., 2009) to measure grief symptoms. Therefore, the ICG is one of the most widely used instruments in bereavement studies. This assessment instrument also has good psychometric properties: Cronbach's alpha of 0.94 in the original version (Prigerson et al., 1995) and 0.88 in the Spanish adaptation (Limonero et al., 2009). The Spanish adaptation of the ICG (Limonero et al., 2009) was used, among others, to evaluate grief-related symptoms in the rest of the studies included in this doctoral thesis (Chapters 2, 3, and 4). Finally, depending on the treatment, five different intervention programs were identified in the literature review. More than half used a writing-based intervention adapted from "INTERAPY", which was developed for the treatment of post-traumatic stress disorder (PTSD) (Lange et al., 2003) and adapted for grief. "INTERAPY" contains three modules: (1) exposure to loss-related stimuli, (2) cognitive restructuring, and (3) loss integration and restoration. The rest of the programs include other elements such as grief psychoeducation, stress management, behavioral activation, personal goals, self-care, and positive psychology. Wagner et al. (2020) provided similar data in their systematic review and meta-analysis of web-based bereavement care interventions. In their analysis, they concluded that the main therapeutic contents of the treatments were exposure, cognitive reappraisal, and behavioral activation. Wagner et al. (2020) also concluded that more than half of the studies used a treatment adapted from "INTERAPY" (Lange et al., 2003). Considering the effect of Internet-based treatments in reducing grief symptoms, the literature review included in this doctoral thesis (Chapter 1) concludes that the results are promising. This is congruent with the conclusions of Wagner et al. (2020) in their systematic review and meta-analysis study, whose methodology is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009), which are more rigorous than those used in a literature

review. Their conclusion was *"Internet-based treatments based on cognitive behavioral therapy (CBT) can help to reduce the symptoms related to the loss of a significant person in a relatively short time. However, more qualitative randomized control trials (RCTs) with adequate power on that topic are needed"* (Wagner et al., 2020, p. 11). Coinciding with the conclusions of the literature review carried out in this doctoral thesis, Wagner et al. (2020) recommends conducting more studies related to this topic. These types of studies are part of a developing field, and so more research is required in this regard. The literature review presented in this doctoral thesis provided valuable information to fulfill the rest of the objectives. On the one hand, it highlighted the importance of carrying out further research on Internet-based treatments for PGD. On the other hand, this review provided valuable information that was useful in developing a new iCBT for adults with PGD in the Spanish language. The first hypothesis of this doctoral thesis was achieved. All the published studies that tested an Internet-based treatment for PGD using randomized clinical trial study designs were included, providing a synthesis of the characteristics and effects of each intervention.

To achieve the second specific aim of this thesis, an iCBT for people with PGD (GROw) was created, taking into consideration the available treatments for disturbing and disabling grief (face-to-face and Internet-based). This iCBT is an individual self-applied program that is accessible online via a website. The website <https://psicologiytecnologia.labpsitec.es> was designed by Labpsitec (Laboratory of Psychology and Technology, Universitat Jaume I, and Universitat de València). Each participant had a personal username and password sent to their email address. GROw contains eight treatment modules (one module per week), in accordance with other treatments for grief in adults where the mean number of sessions was 10 with a range from 1 to 20 (Johannsen et al., 2019). GROw contains videos, texts, diagrams, interactive exercises, audios, photos, and downloadable pdfs. The platform offers the possibility of logging in at any time to view and review content, and it includes a calendar with the record of the sessions and visual graphs to follow the symptoms' progression (grief, depression, positive and negative affect, and anxiety). In addition to access to the platform, GROw included a weekly follow-up call from a therapist (always the same person). This call lasted between 10 and 15 minutes. The objectives of the follow-up calls were: 1) to motivate people to continue to work on the program content, 2) to clarify doubts, and 3) to review the participants' progress and reinforce their achievements.

Regarding the therapeutic content of GROw, its main elements are psychoeducation, motivation for change, exposure, mindfulness and compassion strategies, cognitive reappraisal, behavioral activation, integration and restoration of loss (reconstructing the meaning of loss), and relapse prevention. These therapeutic elements help patients to expose themselves to thoughts, emotions, sensations, and activities that they have been avoiding. Therapeutic elements such as experiential exposure have been used successfully in many other treatments to reduce symptoms of grief (Johannsen et al., 2019; Wagner et al., 2020). In addition, writing-based exercises focused on reconstructing the meaning of the loss also help to expose patients to their thoughts, emotions, and sensations. According to the literature, experiential avoidance, behavioral avoidance, expressive suppression, rumination, and worry are associated with disturbing grief symptoms and posttraumatic stress disorder (PTSD) symptoms (Eisma & Stroebe, 2021; Williams et al., 2019). Related to this, mindfulness strategies were included in GROw to help patients get in touch with their thoughts, emotions, and sensations. Furthermore, putative adaptive emotion regulation strategies (e.g., cognitive reappraisal and mindfulness) are generally negatively associated with disturbing grief symptoms (Eisma & Stroebe, 2021). In accordance with the cognitive-behavioral conceptualization of complicated grief (Boelen et al., 2006), poor elaboration and integration of the loss into the personal biography is crucial in the development and maintenance of disturbing and disabling grief. The writing-based loss-reconstruction assignments included in GROw are made up of several elements. First, the patient is encouraged to write a "loss diary" consisting of three chapters. In Chapter one, patients are instructed to write about their life with the relative before the loss. In Chapter two, patients are instructed to write about the moment of loss (what happened, how they found out about it, what the first moments were like). Finally, in Chapter 3, patients are instructed to write about what life has been like since the loss. In addition to the "loss diary", there are exercises that include reflection questions (e.g., how your life has changed, how you see the world now, how your priorities have changed). These exercises help patients to connect with their thoughts, emotions, and sensations and integrate the loss into their personal biography. Regarding the cognitive reappraisal therapeutic component included in GROw, a writing-based exercise adapted from INTERAPY was used that has been used in several Internet-based treatments for grief (Hoffmann et al., 2018; Kersting et al., 2013; van der Houwen et al., 2010; Wagner et al., 2006). Patients were instructed to write a letter of support and encouragement to a hypothetical friend or family member who has suffered a similar loss

and is experiencing similar difficulties. The goal of this assignment is to develop new perspectives by looking at the event from a different view. The behavioral activation therapeutic component has also been used in several interventions for grief with promising results (e.g., Acierno et al., 2021; Eisma et al., 2015; Litz et al., 2014). The dual-process model of coping with bereavement (Stroebe & Schut, 1999) was also considered to elaborate the therapeutic components of GROw. According to this model, there are coping strategies that make it easier to accept the loss and avoid serious health consequences, whereas other coping strategies are detrimental to health. This model explains that the oscillation (as a dynamic back-and-forth process) between loss-focused and restoration-focused activities represents an adaptive coping with the death of a loved one, composed of confrontation-avoidance of loss and restoration stressors. Loss-focused refers to processing aspects of the loss experience itself with respect to the deceased person (e.g., looking at old photos or crying over the death of a loved one), and restoration-focused refers to doing tasks that the deceased had undertaken (e.g., finances), doing new things, or organizing one's life, etc. For this reason, in addition to including elements related to the reconstruction of the meaning of loss and exposure, behavioral activation was included in GROw. It is important to point out that, in designing GROw, the "Complicated Grief Treatment" (CGT) (Shear, 2015b), which has shown its efficacy in several randomized controlled trials (Shear et al., 2005; Shear et al., 2014, 2016) and is based in the dual-process model of coping with bereavement (Stroebe & Schut, 1999), was taken into account. The loss-reconstruction work carried out in this treatment with a face-to-face therapist was adapted to be self-applied through the writing assignments. Lastly, compassion strategies in the treatment of disturbing and disabling grief have been studied very little. However, there are findings suggesting that bereaved people with more self-compassion experience less severe psychopathology (Lenferink et al., 2017). In conclusion, for Objective 2, GROw was developed from the information collected in the literature review (Chapter 1) and from a deep investigation carried out by the Labpsitec team. All the Internet-based treatment studies and many of the face-to-face treatment studies were reviewed. In addition, the scientific literature related to grief models and mediators and moderators of grief symptomatology was reviewed. Thanks to all of this, the second hypothesis of this doctoral thesis was achieved. GROw, an Internet-delivered cognitive-behavioral therapy (iCBT) accessible via a web platform (psicologiaytecnologia.labpsitec.es) was developed in the Spanish language for adults with PGD.

Once GROw had been designed and the second hypothesis achieved, the following objectives were proposed to test this treatment. Objective 3 (Chapter 2) was to assess the feasibility (usability and satisfaction) of GROw using a multiple-baseline single-case experimental design. Six adult participants with PGD were randomized to different baselines. With regard to adherence to the treatment, 66% of the participants finished all the GROw modules. The dropout rate obtained (34%) was consistent with those found in other similar studies, where dropout rates have been approximately 30% (Rachyla et al., 2020; Van Ballegooijen et al., 2014). GROw was well accepted in terms of expectations, satisfaction, and opinions about the usefulness of the intervention. These results are consistent with other studies that showed high expectations (Botella et al., 2016; Campos et al., 2018a; Mor et al., 2022) and satisfaction (Botella et al., 2016; Campos et al., 2018a; McGoron et al., 2019; Mor et al., 2022; Palacios et al., 2018; Richards et al., 2016; Seitz et al., 2014) with Internet-based treatments. Notably, all the participants gave a score of 10 out of 10 when asked about satisfaction, and they perceived the weekly follow-up calls as highly useful. This is in line with other studies that showed that the involvement of a human therapist was an important element in adherence to treatments (Andersson & Cuijpers, 2009; Christensen et al., 2009; Johansson et al., 2015; Spek et al., 2007). The qualitative opinions about the weekly phone calls were also recorded: *“It is very necessary that you feel that the therapist is going to call you to ask how you are, or to ask questions”*; *“In case of doubts, it is much easier to solve them by telephone, I also think it is a way to avoid leaving therapy due to lack of motivation or laziness”*; *“You feel that you are not doing it just for yourself but that there is someone with you, someone who supports you once a week and who is asking how you are doing. In the end, it's like a psychologist's therapy, but without going to the clinic”*; *“What I liked the most was being able to tell someone who doesn't judge everything that happens to me. The therapist gave a more global perspective”*. Other qualitative studies showed similar results for Internet-based interventions. For example, Mor et al. (2022) concluded that a weekly follow-up by a therapist could be useful for the patients involved in an Internet-based intervention (*“I think I needed a basic weekly follow-up by a therapist so he/she could have guided me to solve the problems...”*, *“maybe having more monitoring of the patients could help so you would not be so alone while doing the intervention”*). Regarding the effect of the GROw intervention on grief-related symptoms, this study showed that the GROw program was effective for some patients. Half of the participants obtained a clinically significant reduction in the symptomatology on the bereavement measures assessed with

the Inventory of Complicated Grief (ICG) (Limonero et al., 2009; Prigerson et al., 1995) and the Typical Beliefs Questionnaire (TBQ) (Skritskaya et al., 2017), and 75% of the participants showed a clinically significant reduction in depression symptomatology measured with the Beck Depression Inventory—Second Edition (BDI-II) (Beck et al., 1996; Estevan et al., 2019). These results are in line with other studies that found that 40-60% of the patients responded poorly to psychological treatments (Cuijpers et al., 2014, 2019; Ebert et al., 2013; Karyotaki et al., 2018). These data show that the response rate to the treatment is similar in Internet-based interventions and face-to-face interventions. However, Internet-based interventions have advantages over face-to-face interventions because they are more accessible and cost-effective (Aboujaoude et al., 2015; Andersson et al., 2019; Musiat & Tarrier, 2014). Hypotheses 3 and 4 (Chapter 2) were achieved. GROw was well-accepted by the participants because they reported high usability and satisfaction (adherence, expectations, satisfaction, and good opinions about the usefulness of the intervention), and the GROw program showed strong potential as an alternative to face-to-face therapy for treating PGD. Even so, more studies are needed to further evaluate this novel program and provide stronger data on its feasibility and effectiveness.

Based on the conclusions established in Objectives 3 and 4 (Chapter 2), which established that more studies were necessary, Objectives 5 and 6 (Chapters 3 and 4) were proposed. Objective 5 (Chapters 3 and 4) consisted of assessing the feasibility (adherence, preferences, expectations, satisfaction, and qualitative opinions about the usefulness of the treatment) of GROw, compared to the same intervention delivered face-to-face through videoconference, using a randomized feasibility trial study design. All participants (N = 31) were randomly allocated to two interventions with the same therapeutic contents but different application formats: iCBT (GROw) (N=16) and face-to-face videoconferencing treatment (N=15). In terms of adherence, 42% of the participants dropped out of the intervention (50% in the GROw group and 33.3% in the face-to-face videoconferencing group). This is a slightly higher dropout rate than the one obtained in the multiple-baseline single-case study (Chapter 2). Even so, it is consistent with the results obtained in other studies that concluded that the dropout rates in interventions for PGD ranged from 10.3 to 58.8% (Wagner et al., 2020). Nine participants (4 from the GROw group and 5 from the face-to-face videoconferencing group) were interviewed to obtain qualitative information about their reasons for dropping out. The main reasons for abandoning the study were lack of time, needing more therapeutic

support, and the need to avoid emotions that arose during the treatment. Participants' perception that therapists care for them is important for adherence (Johansson et al., 2015), and, as mentioned above, many studies show that the involvement of a human therapist is an important characteristic in generating adherence (Andersson & Cuijpers, 2009; Christensen et al., 2009; Johansson et al., 2015; Spek et al., 2007). Incorporating more support from a therapist could lower the dropout rate in future studies. Blending online and face-to-face CBT might be an option to solve these problems, increasing the support of a therapist and maintaining the cost-effectiveness relationship. Blended CBT might increase adherence, it has comparable clinical effects to standard CBT (Kooistra et al., 2014), it is well-accepted by therapists (Titzler et al., 2018), it may save clinician time compared to stand-alone face-to-face therapy, and it is feasible (Erbe et al., 2017). According to patients' preferences and opinions when comparing the two types of intervention formats, a greater number of participants chose the face-to-face videoconferencing treatment over GROw before treatment, and the face-to-face videoconferencing treatment was perceived as more effective and logical and would be recommended to a friend or family members. At the end of the treatment, 80% of the participants who finished the GROw treatment preferred GROw to the face-to-face videoconferencing intervention, and 90.9% of the participants who finished the face-to-face videoconferencing intervention preferred this intervention to GROw. These data indicated that, after treatment, participants generally preferred the intervention format to which they had been assigned. This contradicts other studies that concluded that treatment preferences remain stable over time (Delevry & Le, 2019). Regarding the subjective effectiveness at pretreatment, 76.5% of the people in the GROw group and 71.4% in the face-to-face videoconferencing group chose the face-to-face videoconferencing treatment as more effective. After treatment, 80% of the people in the GROw group chose this treatment as the most effective, and 100% of the people in the videoconferencing treatment chose the face-to-face videoconferencing intervention as the most effective. These data indicated that the preferences and opinions when comparing the two intervention formats generally improved in favor of GROw once this treatment was over. Although more studies are needed, these results indicate that there is a tendency to choose face-to-face treatments (in this case by videoconference), but once the iCBT (GROw) has been tested, this tendency changes in favor of the iCBT. With regard to expectations and satisfaction, participants showed high expectations (pretreatment) and satisfaction (post-treatment). As in the results obtained in the multiple-baseline single-case experimental

study (Chapter 2), these results are consistent with other studies that showed high expectations (Botella et al., 2016; Campos et al., 2018a; Mor et al., 2022) and satisfaction (Botella et al., 2016; Campos et al., 2018a; McGoron et al., 2019; Mor et al., 2022; Palacios et al., 2018; Richards et al., 2016; Seitz et al., 2014) with Internet-based treatments. According to the perceived logic of the intervention, a statistically significant mean increase in the GROw group from pretreatment to post-treatment was found, indicating that participants perceived the GROw intervention as more logical once it was completed. This is consistent with other Internet-based treatment studies in that the participants' mean opinion of the treatment logic increases after the intervention is over (Botella et al., 2016). The participants also showed high satisfaction with the therapeutic components of the program. The treatment components that obtained the highest means were experiential exposure, writing assignments, cognitive reappraisal, and compassion strategies. The therapeutic components related to experiential exposure and writing assignments help patients expose themselves to situations, memories, and emotions they have been avoiding. These components are crucial in the treatment of PGD because experiential avoidance, behavioral avoidance, and expressive suppression are associated with disturbing grief symptoms (Eisma & Stroebe, 2021; Williams et al., 2019). Other studies that have incorporated exposure strategies obtained promising results in terms of symptom reduction, both in face-to-face treatments and Internet-based treatments (Johannsen et al., 2019; Wagner et al., 2020). Components related to cognitive reappraisal and compassion strategies, which were highly rated by the participants in terms of usefulness, gave them emotion regulation tools, and putative adaptive emotion regulation strategies (e.g., cognitive reappraisal and mindfulness) are generally negatively associated with disturbing grief symptoms (Eisma & Stroebe, 2021). Other studies that have incorporated cognitive reappraisal strategies into their Internet-based treatments have obtained promising results in terms of reducing grief-related symptoms (Hoffmann et al., 2018; Kersting et al., 2013; van der Houwen et al., 2010; Wagner et al., 2006). Regarding compassion strategies, compassion-based therapies, such as “Compassion-Focused Therapy (CFT)”, lead to a greater ability to tolerate distress and allow openness and receptivity to painful aspects that can help rebuild a life after the loss of a loved one (Harris, 2021). Only a few studies have evaluated the effect of including compassion strategies in the treatment of PGD, and their results in reducing PGD symptoms have been promising (Jahani et al., 2022; Johannsen et al., 2022). Including compassionate strategies in the treatment of PGD is novel and has hardly been studied, but it offers

promising results for the reduction of PGD symptoms. Regarding the usefulness of the elements available on the web platform (images, videos, audios, and written information), the participants' opinions showed a high perceived usefulness of all the elements. Few studies have focused on the usefulness of the different components of an Internet-based intervention, but these results are in line with other investigations, such as the study conducted by McGoron et al. (2019), which analyzed a pragmatic Internet-based intervention to promote positive parenting and showed that the participants rated the information on the platform as easy to understand, useful, and well-organized. Rachyla et al. (2017) also evaluated the opinions about the different elements (texts, images, illustrations, and videos) of a web-based self-help intervention for adjustment disorders (A_jD). The results of this research also showed that the participants perceived all the elements as useful. All these data show that Hypothesis 5 was achieved (Chapters 3 and 4). The randomized feasibility trial study showed that GROw was well accepted by the participants in terms of adherence, preferences, expectations, satisfaction, and qualitative opinions about the usefulness of the intervention. Regarding the secondary aim of the study (Objective 6), and considering the data collected, promising results were obtained for the potential efficacy of the treatment in both formats. Both groups showed a significant reduction in grief-related symptoms, with large effect sizes ($d > .50$) on most of the measured variables. This is consistent with the results obtained in the multiple-baseline single-case experimental design study (Chapter 2). Comparing the two groups, the results showed that GROw had a clinically significant effect on more variables than the face-to-face videoconferencing intervention. These results are consistent with the available literature showing that Internet-based treatments for the prevention and treatment of PGD showed promising results in reducing bereavement-related symptoms (Tur et al., 2019; Wagner et al., 2020). It is important to consider that the total intervention time was longer in the GROw group (mean = 16.86 weeks) than in the face-to-face videoconferencing group (mean = 10.70 weeks). The effect of the time spent on the treatment was not controlled in this study, and it could be an important variable in grief-related symptom improvement because grief symptoms can decrease naturally over time (Jordan & Litz, 2014). The exploratory preliminary efficacy results from this study should be interpreted with extreme caution, and more studies are needed in order to generalize these results to the general population. Based on these data, it can be concluded that Hypothesis 6 was achieved (Chapters 3 and 4). GROw showed promising results in

reducing grief-related symptoms, compared to the same intervention delivered face-to-face through videoconference, in the randomized feasibility trial study.

To our knowledge, GROw is the first iCBT program available in the Spanish language that could reach people from Spanish-speaking countries. An iCBT program can reach more people than a face-to-face intervention and might be more cost-effective. These interventions can overcome geographical barriers and isolation problems (Griffiths et al., 2006; Griffiths & Christensen, 2007) such as the isolation and geographical barriers experienced during the SARS-CoV-2 coronavirus (COVID-19) pandemic. During the pandemic, the circumstances surrounding the death of the deceased (e.g., not being able to visit the relative in the hospital) (Diolaiuti et al., 2021; Kokou-Kpolou et al., 2020; Nyatanga, 2020; Wallace et al., 2020) and the consequences of living through the grieving process under quarantine may have produced guilt and other disturbing emotions. Guilt is a predictor of the severity of somatization after the loss (Kokou-Kpolou et al., 2018). The situation caused by COVID-19 could also produce poor mental health because some people lived with fears about their own health and/or fears of infecting others, loss of their usual routine, reduced social and physical contact, isolation from the rest of the world, inadequate basic supplies (e.g., accommodation, clothes, food, water), stigma toward others, inadequate or poor information from public health authorities, and financial loss for having to interrupt professional activities with no advanced planning (Brooks et al., 2020). The COVID-19 pandemic has made disturbed grief a major public health concern worldwide (Eisma et al., 2020). In addition to all these advantages, the scientific literature confirms that iCBT is a well-established therapy format that shows clinical efficacy compared to control groups and active conditions in the short and long term (Andersson et al., 2014, 2017; Carlbring et al., 2017, 2018; Cuijpers et al., 2008; Donker et al., 2015; Hedman et al., 2011; Karyotaki et al., 2018; Komariah et al., 2022; Musiat & Tarrier, 2014; Wang et al., 2020; Xiong et al., 2022).

In summary, for the first time in the Spanish language, an iCBT (GROw program) for adults with PGD was developed by performing an exhaustive analysis of the scientific literature related to disturbing and disabling grief. After that, GROw was tested through two studies (a multiple-baseline single-case experimental design with 6 participants and a randomized feasibility trial study design with 31 participants) in order to provide an initial estimation of the feasibility and potential efficacy of the program. GROw showed strong potential as an iCBT for PGD, and it is a cost-effective alternative to face-to-face

interventions. The last hypothesis of this doctoral thesis was achieved. The results of these studies support scaling up the treatment by using larger samples and more complex designs such as randomized controlled trials comparing GROw with active controls and including non-active control groups to evaluate the influence of the passage of time without intervention. The results of this study also support including more human support in the treatment, for example, by blending online self-applied modules and brief face-to-face CBT sessions. This doctoral thesis contributes to allowing people with PGD in need of treatment to easily access an evidence-based intervention.

Strengths

- A new iCBT for people with PGD (GROw) was designed and developed.
- As far as we know, GROw is the first iCBT for PGD in the Spanish language.
- Studies to test GROw were approved by the Universitat Jaume I Ethics Committee.
- The multiple-baseline single-case experimental design was registered in [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04376385) (NCT04376385).
- The randomized feasibility trial study design was registered in [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04462146) (NCT04462146).
- The randomized feasibility trial was conducted following the CONSORT (Consolidated Standards of Reporting Trials) statement for pilot and feasibility studies, the CONSORT-EHEALTH guidelines, and the SPIRIT guidelines (Standard Protocol Items: Recommendations for International Trials).
- The randomized feasibility trial study protocol was published in *BMJ Open* to ensure transparency.
- Non-overlap of All Pairs (NAP) analyses were conducted in the multiple-baseline single-case experimental study to evaluate the results of 14 daily items measured with an App (*Emotional Monitor App*).
- Reliable Change Index (RCI) analyses were conducted in the multiple-baseline single-case experimental study to indicate patients' changes and classify the responses to the therapeutic process (recovered, improved, no change, and deteriorated).
- Effect sizes using Cohen's *d* were calculated and reported in the randomized feasibility trial study to provide an estimation of the effect of the treatment.

- Intent-to-treat (ITT) analyses were calculated and reported using mixed-models analysis in the randomized feasibility trial study to provide an estimation of the effect of the treatment.
- Qualitative opinions about the usefulness of GROw were evaluated in both the multiple-baseline single-case experimental study and the randomized feasibility trial study.
- Opinions about the expectations (pretreatment) and satisfaction (post-treatment) were evaluated in both the multiple-baseline single-case experimental study and the randomized feasibility trial study.
- Opinions about the preferences comparing the two formats, GROw and face-to-face videoconferencing intervention, were evaluated in the randomized feasibility trial study.
- Qualitative information about the reasons for dropping out of the randomized feasibility trial study was evaluated by an independent researcher.
- Both the multiple-baseline single-case experimental study and the randomized feasibility trial study concluded that GROw was generally well-accepted in terms of preferences, expectations, satisfaction, and opinions about the usefulness of the intervention.
- Both the multiple-baseline single-case experimental study and the randomized feasibility trial study concluded that GROw has strong potential for improving grief-related symptoms.
- The results obtained in both the multiple-baseline single-case experimental study and the randomized feasibility trial study make it possible to continue to investigate GROw, scaling up the treatment by using larger samples and more complex designs, such as randomized controlled trials comparing GROw with active controls and including non-active control groups to evaluate the influence of the passage of time without intervention.

Limitations

To interpret the results of this doctoral thesis, the following limitations must be considered:

- The literature review did not follow all the statements in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

- The literature review included only 10 studies, and one of them was a study protocol with no efficacy results.
- In the literature review study, the characteristics of the samples of the included studies were heterogeneous in terms of type of loss and time elapsed after the loss.
- In the multiple-baseline single-case experimental study, the efficacy and satisfaction data were obtained from a small sample of four individuals.
- Qualitative information about the reasons for dropping out of the multiple-baseline single-case experimental study was not assessed.
- In both the multiple-baseline single-case experimental study and the randomized feasibility trial study, a non-active control group to evaluate the influence of the passage of time was not included.
- Due to the COVID-19 pandemic, adaptations were made in the randomized feasibility trial study, and the active control group changed from being held face-to-face to being held face-to-face via videoconference.
- In the randomized feasibility trial study, the expected sample (48 participants, 24 participants per group) could not be recruited.
- In the randomized feasibility trial study, the dropout rate was higher than expected (41.94%: 50% in the GROw group, and 33.3% in the face-to-face videoconference group).

Future lines of research

As mentioned above in this doctoral thesis, there are few Internet-based treatments for bereaved people. Only one systematic review and meta-analysis has evaluated web-based bereavement treatments using a randomized controlled trial design (Wagner et al., 2020). In addition, the studies available on this topic have heterogeneous samples, which makes it difficult to generalize the results. The recent incorporation of the diagnosis of PGD in the ICD-11 and the diagnosis of PCBD in the DRM-5-TR could help to obtain more homogenous samples in future studies. More research on this topic is needed to perform large systematic reviews and meta-analyses, and future research should consider that the sample will have to be more homogenous in order to promote the generalization of the results obtained.

The main conclusion of this doctoral thesis is that, based on the data obtained, GROw is a feasible, well-accepted iCBT for adults with PGD that has promising results

in terms of symptom reduction and can be tested in the future using more complex designs with larger samples (i.e., randomized controlled trials). In order to carry out larger future studies to evaluate GROw, several elements should be considered. First, an effective recruiting strategy is needed. Grief usually has a gradual and natural recovery, and disturbing and disabling grief occurs in one in ten bereaved adults worldwide (Lundorff et al., 2017). Thus, it is less prevalent than other psychological disorders, such as anxiety and mood disorders, which represent between 20-28% of the total population (Kessler et al., 2005). This could be one reason it took more than two years to recruit 31 people in the randomized feasibility trial. For a larger trial (i.e., a randomized controlled trial), which requires large samples, recruiting 31 people every two years might take too long. In the randomized feasibility trial, nearly 40% of the participants learned about the study from other people. Future studies should obtain information about where these people obtained information about the study in order to improve recruitment strategies. Apart from this, the strategy that worked best was social networks (Twitter and Instagram), which reached 35.48% of the study participants. Future studies should not obtain samples only from social networks because samples recruited using online strategies may not be representative of the general population (Glasgow et al., 2007; Whitehead, 2007). Clinical centers and related associations were unsuccessfully asked to collaborate in the randomized feasibility trial study. Thus, contacting more centers and improving strategies to ensure their collaboration may be a useful suggestion for future studies. According to the results obtained in this doctoral thesis, the participants were very satisfied with having support from a therapist, and some of them dropped out of the study because they needed more therapist support. Greater support from a therapist could make GROw more satisfying and achieve greater adherence. Blending online and face-to-face CBT might be a way to solve these problems. As a suggestion for adapting GROw to a blended CBT intervention, 10-15 days (per module) could be allowed to review information and do the exercises through the web platform after a brief session with a therapist. Taking into account other bereavement treatments that have shown their efficacy (e.g., Shear et al., 2005; Shear et al., 2014, 2016), and the mean number of days GROw participants needed to complete the intervention (118 days), 10-15 days for each module is a feasible proposal to adapt the temporality of the GROw program in future studies. The involvement of a human therapist and participants' perceptions that the therapists cared for them are important program characteristics for generating adherence (Andersson & Cuijpers, 2009; Christensen et al., 2009; Johansson et al., 2015; Spek et al., 2007). Regarding the duration

of the treatment, although the treatment was designed to last between 8-10 weeks, most of the participants who finished the GROw program took more than 8 weeks to complete the intervention. This is in line with other effective treatments for disturbing and disabling grief that included more than 10 treatment sessions, such as the “Complicated Grief Treatment” (CGT) (Shear, 2015b), which is a manualized 16-session protocol. Blending online and face-to-face CBT might also be an option to solve these problems, making it possible to extend the treatment time and ensuring the support of a therapist to guide participants through the process during the entire intervention.

With regard to the treatment content, GROw is a comprehensive iCBT that includes several therapeutic elements. As a recommendation, future studies could examine not only whether the intervention works, but which components are more strongly related to reductions in the symptomatology. In this way, it will be possible to ensure that people with PGD who need treatment will have easier access to a cost-effective, adapted, effective, and efficient treatment.

The results of this doctoral thesis provide strong and valuable information about iCBTs in general and, more specifically, iCBTs for adults with PGD. Based on these data, future studies can continue to investigate this important topic, which has been poorly investigated in the scientific literature compared to other psychological problems and disorders. These data contribute to making sure that people with PGD who need treatment can easily access an evidence-based intervention.

Conclusions:

- A literature review was carried out of the published investigations that have tested the effect of Internet-based treatments for the prevention and treatment of disturbing and disabling grief using randomized control trial study designs, providing a summary of the characteristics of the sample, evaluation, and treatment of each investigation.
- A literature review was carried out of the published investigations that have tested the effect of Internet-based treatments for the prevention and treatment of disturbing and disabling grief using randomized control trial study designs, concluding that Internet-based treatments have promising results in improving grief-related symptomatology.

- GROw, an iCBT self-applied program sequentially organized in eight modules, was developed for adults with PGD after a comprehensive review of the literature.
- A multiple-baseline single-case experimental study with six participants and a randomized feasibility trial study with 31 participants were performed, concluding that patients reported high usability and satisfaction with GROw in terms of adherence, preferences, expectations, satisfaction, and opinions about the usefulness of the program.
- A multiple-baseline single-case experimental study with six participants and a randomized feasibility trial study with 31 participants were carried out, concluding that GROw has strong potential for treating grief-related symptomatology.
- The results obtained in this doctoral thesis make it possible to continue to investigate GROw and scale up the treatment using larger samples and more complex designs, such as randomized controlled trials comparing GROw with active controls and including non-active control groups to evaluate the influence of the passage of time without intervention
- Although more investigations are needed, GROw showed strong potential as an iCBT for PGD, and, therefore, we suggest that this approach may be a cost-effective alternative to face-to-face interventions.
- The data obtained contribute to helping people with PGD in need of treatment to easily access an evidence-based intervention.

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ANNEXES

ETHICAL APPROVAL



Sra./Sr. Soledad Quero Castellano
Dept./Unit. Predep. de Psicologia Bàsica, Clínica i Psicobiologia
Facultat de Ciències de la Salut

Us comuniquem que la Comissió Deontològica de la Universitat Jaume I ha emès informe FAVORABLE sobre el projecte amb núm. expedient CD/002/2019 "GROw: Una Intervención Basada en TICs para el Tratamiento Psicológico del Duelo Prolongado", el personal investigador principal del qual és Soledad Quero Castellano, per considerar que compleix les normes deontològiques exigides.

La Comissió indica, però, les següents observacions:

No hi ha observacions

Atentament,

Beatriz Tomás Mallén
Secretària de la Comissió Deontològica
Universitat Jaume I

Castelló de la Plana, 6 de març de 2019

SAMPLE RECRUITMENT



¿HAS PERDIDO A UN SER QUERIDO?

¿Necesitas un espacio para procesar todo lo que ha ocurrido?

DESDE LA UNIVERSITAT JAUME I TE OFRECEMOS
TRATAMIENTO PSICOLÓGICO
GRATUITO A TRAVÉS DE
INTERNET

Si quieres participar en un estudio de investigación para personas que han sufrido la pérdida de un ser querido por fallecimiento, mándanos un mail a la cuenta:

growuji@gmail.com

o llama al **96 438 76 44**

INFORMED CONSENT



Estimado/a participante de GROW.

A continuación encontrarás información relevante sobre las condiciones con las que se lleva a cabo el estudio.

Lee con atención lo que viene a continuación, es la explicación del estudio:

Tu participación en este estudio implica el acceso al programa GROW.

- El objetivo de este programa de tratamiento es permitir que las personas que lo utilicen aprendan estrategias y herramientas que les permitan afrontar la pérdida de un ser querido, así como aumentar su capacidad de enfrentarse a otras pérdidas que puedan darse en el futuro.
- GROW consta de 8 módulos. En cada módulo aprenderás diferentes técnicas que te ayudarán a conseguir las habilidades necesarias para adaptarte a la pérdida.
- En el estudio habrá dos grupos. Uno de los grupos tendrá acceso al programa en la condición cara a cara por videoconferencia con un terapeuta. El otro grupo tendrá acceso al programa GROW a través de una plataforma web, en formato auto-aplicado.
- La asignación a cada uno de los grupos será aleatoria a través de un programa informático. Te informaremos por teléfono a qué grupo perteneces.

Antes de continuar lee también esta información, es el consentimiento informado que aceptarás si continúas adelante:

- Entiendo la naturaleza y el propósito de los procedimientos que entrañan el presente estudio que se me han comunicado previamente.
- Entiendo que la investigación está diseñada para promover el conocimiento científico y que la Universitat Jaume I de Castellón usará los datos que yo le proporcione sólo y exclusivamente para esta investigación.
- Entiendo que los datos que proporcione serán considerados como confidenciales.





A continuación, podrás encontrar información sobre el tratamiento de los datos de los participantes en el estudio:

He sido informado/a de que el Servicio de Asistencia Psicológica / LABPSITEC de la Universidad Jaume I llevará a cabo el tratamiento de mis datos personales de acuerdo con el Reglamento General de Protección de Datos (UE) 2016/679.

Responsable del tratamiento	Universidad Jaume I Servicio de Asistencia Psicológica / Grupo de investigación LABPSITEC
Finalidad del tratamiento	Gestión de la historia clínica de los pacientes tratados por el Servicio de Asistencia Psicológica – Para los pacientes que den su consentimiento, sus datos, que previamente serán completamente anonimizados, podrán ser utilizados con la finalidad de investigación científica por el grupo de investigación LABPSITEC
Legitimación	Prestación de asistencia médica (psicológica). Investigación científica con consentimiento.
Destinatarios	No se cederán los datos a terceras partes a menos que se trate de una obligación legal.
Derechos	Puede ejercer sus derechos de acceso, rectificación, supresión y portabilidad, y a la limitación u oposición al tratamiento, dirigiéndose a la Secretaria General de la Universidad Jaume I mediante el Registro Electrónico (https://ujiapps.uji.es/reg/rest/publicacion/solicitud_generica) o, presencialmente, en la Oficina de Información y Registro (Infocampus), situada en el Ágora Universitaria – Locales 14-15.
Información adicional	Puede consultar la información adicional y detallada sobre este tratamiento de datos en https://www.uji.es/protecciondades/clausules/?t=I001

Información detallada sobre protección de datos

¿Quién es el órgano responsable del tratamiento de sus datos?
Identidad: Universidad Jaume I Servicio de Asistencia Psicológica Responsable: Azucena García Palacios Dirección postal: Av. de Vicent Sos Baynat, s/n 12071 Castellón de la Plana Teléfono: 964387638 Correo electrónico: sap@uji.es Contacto DPD: protecciondatos@uji.es
¿Con qué finalidad tratamos sus datos personales?
Gestión de la historia clínica de los pacientes tratados por el Servicio de Asistencia Psicológica. Para los pacientes que dan su consentimiento, sus datos, que previamente serán completamente anonimizados, podrán ser utilizados con la finalidad de investigación científica por el grupo de investigación LABPSITEC
¿Cuánto tiempo conservaremos sus datos?
Los datos personales proporcionados se conservarán durante un mínimo de 5 años. Después de este tiempo, y en virtud de criterios clínicos, se considerará la posibilidad de destruir el historial clínico. Se podrá solicitar la supresión de los datos personales antes de 5 años mediante los mecanismos descritos para ejercer los derechos.
¿Cuál es la legitimación para el tratamiento de sus datos?
La legitimación se basa en el artículo 9.2.j del RGPD: "El tratamiento es necesario con finalidades de investigación científica" y la disposición adicional decimoséptima de la Ley orgánica 3/2018, del 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales.
¿A qué destinatarios se comunicarán sus datos personales
No se cederán datos a terceras partes, a menos que se trate de una obligación legal.

¿Cuáles son sus derechos?

- Cualquier persona tiene derecho a obtener confirmación sobre si en la Universidad Jaume I estamos tratando sus datos personales que le conciernen o no.
- Las personas interesadas tienen derecho a acceder a sus datos personales, así como a solicitar la rectificación de los datos inexactos o, en su caso, solicitar la supresión, entre otros motivos, cuando los datos ya no sean necesarios para las finalidades por las cuales se recogieron.
- En determinadas circunstancias previstas en el artículo 18 del RGPD las personas interesadas podrán solicitar la limitación del tratamiento de sus datos. En este caso, únicamente se conservarán para ejercer o defender reclamaciones.
- En virtud del derecho a la portabilidad, las personas interesadas tienen derecho a obtener sus datos personales en un formato estructurado de uso común y lectura mecánica y a transmitirlos a otra persona responsable.
- En determinadas circunstancias previstas en el artículo 21 del RGPD, las personas interesadas pueden solicitar la oposición al tratamiento, siempre que no haya motivos legítimos imperiosos para el tratamiento o para ejercer o defender reclamaciones.
- En caso de que el tratamiento esté legitimado por el consentimiento de la persona interesada, esta tiene derecho a retirar dicho consentimiento en cualquier momento, sin que ello afecte a la licitud del tratamiento previo a su retirada.

Puede ejercer sus derechos en la Secretaría General de la Universidad Jaume I mediante el Registro Electrónico (https://ujiapps.uji.es/reg/rest/publicacion/solicitud_generica) o, presencialmente, en la Oficina de Información y Registro (InfoCampus), situada en el Ágora Universitaria - Locales 14-15.

Puede obtener información adicional sobre sus derechos o presentar una reclamación, si lo considera oportuno, en la Agencia Española de Protección de Datos.

Categorías de datos

Datos identificativos

Datos socioeconómicos

Datos especialmente protegidos de salud (estado físico, psíquico, hábitos y consumos, etc.)



Las entrevistas de evaluación podrán ser grabadas en audio, previo aviso y consentimiento verbal, con la finalidad de:

- Analizar y trabajar en el proceso terapéutico de un caso concreto por parte de los distintos terapeutas que componen el Servicio de Asistencia Psicológica.
- Utilizar la información dada para distintos estudios que se estén llevando a cabo (p.ej., validación de instrumentos de evaluación).
- Confirmación de diagnóstico y evaluación de concordancia entre evaluadores.

Las grabaciones seguirán el procedimiento de tratamiento de datos que se especifica en el cuadro anterior.

Si decides **ACEPTAR Y CONTINUAR** formando parte del estudio, por favor, haz click en la flecha que aparece a continuación.

Si decides **NO CONTINUAR** formando parte de este estudio, por favor, cierra esta encuesta sin hacer click en la flecha que aparece a continuación.



CO-AUTHORS AGREEMENTS



Soledad Quero, como coautor/coautora doy mi **autorización** a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

Tur, C., Campos, D., & Quero, S. (2019). Tratamientos Psicológicos Basados en Internet para el Duelo: Revisión de la Literatura/ Internet-Based Psychological Treatments for Grief: Review of Literature. *Revista Argentina de Clínica Psicológica*, 884.

Tur, C., Campos, D., Suso-Ribera, C., Kazlauskas, E., Castilla, D., Zaragoza, I., & Quero, S. (2022). An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in Adults: A multiple-Baseline Single-case Experimental Design Study. *Internet Interventions*, 29, 100558.

Tur, C., Campos, D., Herrero, R., Mor, S., López-Montoyo, A., Castilla, D., & Quero, S. (2021). Internet-delivered Cognitive-Behavioral Therapy (iCB) for Adults with Prolonged Grief Disorder (PGD): A Study Protocol for a Randomized Feasibility Trial. *BMJ Open*, 1–11.

Tur, C., Campos, D., Díaz-Sanahuja, L., Herrero, R., Quero, S. (2022). Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Adults with Prolonged Grief Disorder (PGD): a Randomized Feasibility Trial. [Manuscript in preparation]

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Lugar, fecha y firma

SOLEDAD|
QUERO|
CASTELLANO

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Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

“(…)

4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.

Daniel Campos Bacas, como coautor/coautora doy mi **autorización** a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

Tur, C., Campos, D., & Quero, S. (2019). Tratamientos Psicológicos Basados en Internet para el Duelo: Revisión de la Literatura/ Internet-Based Psychological Treatments for Grief: Review of Literature. *Revista Argentina de Clínica Psicológica*, 884.

Tur, C., Campos, D., Suso-Ribera, C., Kazlauskas, E., Castilla, D., Zaragoza, I., & Quero, S. (2022). An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in Adults: A multiple-Baseline Single-case Experimental Design Study. *Internet Interventions*, 29, 100558.

Tur, C., Campos, D., Herrero, R., Mor, S., López-Montoyo, A., Castilla, D., & Quero, S. (2021). Internet-delivered Cognitive-Behavioral Therapy (iCB) for Adults with Prolonged Grief Disorder (PGD): A Study Protocol for a Randomized Feasibility Trial. *BMJ Open*, 1–11.

Tur, C., Campos, D., Díaz-Sanahuja, L., Herrero, R., Quero, S. (2022). Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Adults with Prolonged Grief Disorder (PGD): a Randomized Feasibility Trial. [Manuscript in preparation]

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Zaragoza, 03 de noviembre de 2022

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BACAS
DANIEL -
204744085**

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Nombre de reconocimiento
(DN): c=ES,
serialNumber=IDCES-204744
085, givenName=DANIEL,
sn=CAMPOS BACAS,
cn=CAMPOS BACAS DANIEL -
204744085
Fecha: 2022.11.03 16:02:19
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Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión n° 8/2020 del Consejo de Gobierno de 02 /10/2020):

"(...)

4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.

Alba López-Montoyo, como coautor/coautora doy mi **autorización** a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

Tur, C., Campos, D., Herrero, R., Mor, S., López-Montoyo, A., Castilla, D., & Quero, S. (2021). Internet- delivered Cognitive- Behavioral Therapy (iCB) for Adults with Prolonged Grief Disorder (PGD): A Study Protocol for a Randomized Feasibility Trial. *BMJ Open*, 1–11.

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

ALBA|
LOPEZ|
MONTOYO|
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MONTOYO
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Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

(...)

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Carlos Suso-Ribera, como coautor/coautora doy mi **autorización** a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

Tur, C., Campos, D., Suso-Ribera, C., Kazlauskas, E., Castilla, D., Zaragoza, I., & Quero, S. (2022). An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in adults: A multiple-baseline single-case experimental design study. *Internet Interventions*, 29, 100558.

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

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Lugar, fecha y firma

CARLO
S|SUSO|
RIBERA

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CARLOS|SUSO|
RIBERA
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11:56:19 +02'00'

Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

"(...)

4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.

Diana Castilla López, como coautor/coautora doy mi **autorización** a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:


Tur, C., Campos, D., Herrero, R., Mor, S., López-Montoyo, A., Castilla, D., & Quero, S. (2021). Internet- delivered Cognitive- Behavioral Therapy (iCB) for Adults with Prolonged Grief Disorder (PGD): A Study Protocol for a Randomized Feasibility Trial. *BMJ Open*, 1–11.

Tur, C., Campos, D., Suso-Ribera, C., Kazlauskas, E., Castilla, D., Zaragoza, I., & Quero, S. (2022). An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in adults: A multiple-baseline single-case experimental design study. *Internet Interventions*, 29, 100558.

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

DIANA
VIRGINIA|
CASTILLA|
LOPEZ



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Nombre de reconocimiento (DN):
cn=DIANA VIRGINIA|CASTILLA|LOPEZ, serialNumber=34833268K,
givenName=DIANA VIRGINIA,
sn=CASTILLA LOPEZ,
o=CIUDADANOS, ou=ACCY, c=ES
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En Valencia a 3 de Octubre de 2022

Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

"(...)

4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.

Evaldas Kazlauskas, como coautor/coautora doy mi **autorización** a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

Tur, C., Campos, D., Suso-Ribera, C., Kazlauskas, E., Castilla, D., Zaragoza, I., & Quero, S. (2022). An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in adults: A multiple-baseline single-case experimental design study. *Internet Interventions*, 29, 100558.

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Lugar, fecha y firma

Prof. Evaldas Kazlauskas



Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

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Irene Zaragoza, como coautor/coautora doy mi autorización a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

Tur, C., Campos, D., Suso-Ribera, C., Kazlauskas, E., Castilla, D., Zaragoza, I., & Quero, S. (2022). An Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Prolonged Grief Disorder (PGD) in adults: A multiple-baseline single-case experimental design study. *Internet Interventions*, 29, 100558.

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

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ZARAGOZÁ
ALVAREZ,
IRENE (FIRMA)

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ALVAREZ, IRENE
(FIRMA)
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18:02:39 +02'00'

Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02/10/2020):

“(…)

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Laura Díaz-Sanahuja, como coautor/coautora doy mi **autorización** a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

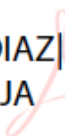
Relación de publicaciones:

Tur, C., Campos, D., Díaz-Sanahuja, L., Herrero, R., Quero, S. (2022). Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Adults with Prolonged Grief Disorder (PGD): a Randomized Feasibility Trial. [Manuscript in preparation]

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Castellón de la Plana, 5 de octubre de 2022

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por LAURA[DIAZ]
SANAHUJA
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09:46:40 +02'00'

Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

“(…)

4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.

Rocío Herrero Camarano, como coautor/coautora doy mi **autorización** a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

Tur, C., Campos, D., Herrero, R., Mor, S., López-Montoyo, A., Castilla, D., & Quero, S. (2021). Internet- delivered Cognitive- Behavioral Therapy (iCB) for Adults with Prolonged Grief Disorder (PGD): A Study Protocol for a Randomized Feasibility Trial. *BMJ Open*, 1–11.

Tur, C., Campos, D., Díaz-Sanahuja, L., Herrero, R., Quero, S. (2022). Internet-delivered Cognitive-Behavioral Therapy (iCBT) for Adults with Prolonged Grief Disorder (PGD): a Randomized Feasibility Trial. [Manuscript in preparation]

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

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CAMARAN
O ROCIO -
21800529W

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CAMARANO ROCIO -
21800529W
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10:01:15 +02'00'

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"(...)

4. *En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.*

Sonia Mor, como coautor/coautora doy mi autorización a Cintia Tur Domenech para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

Tur, C., Campos, D., Herrero, R., Mor, S., López-Montoyo, A., Castilla, D., & Quero, S. (2021). Internet- delivered Cognitive- Behavioral Therapy (iCB) for Adults with Prolonged Grief Disorder (PGD): A Study Protocol for a Randomized Feasibility Trial. *BMJ Open*, 1–11.

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

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Castellón, a 3 de octubre de 2022



Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

"(...)

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