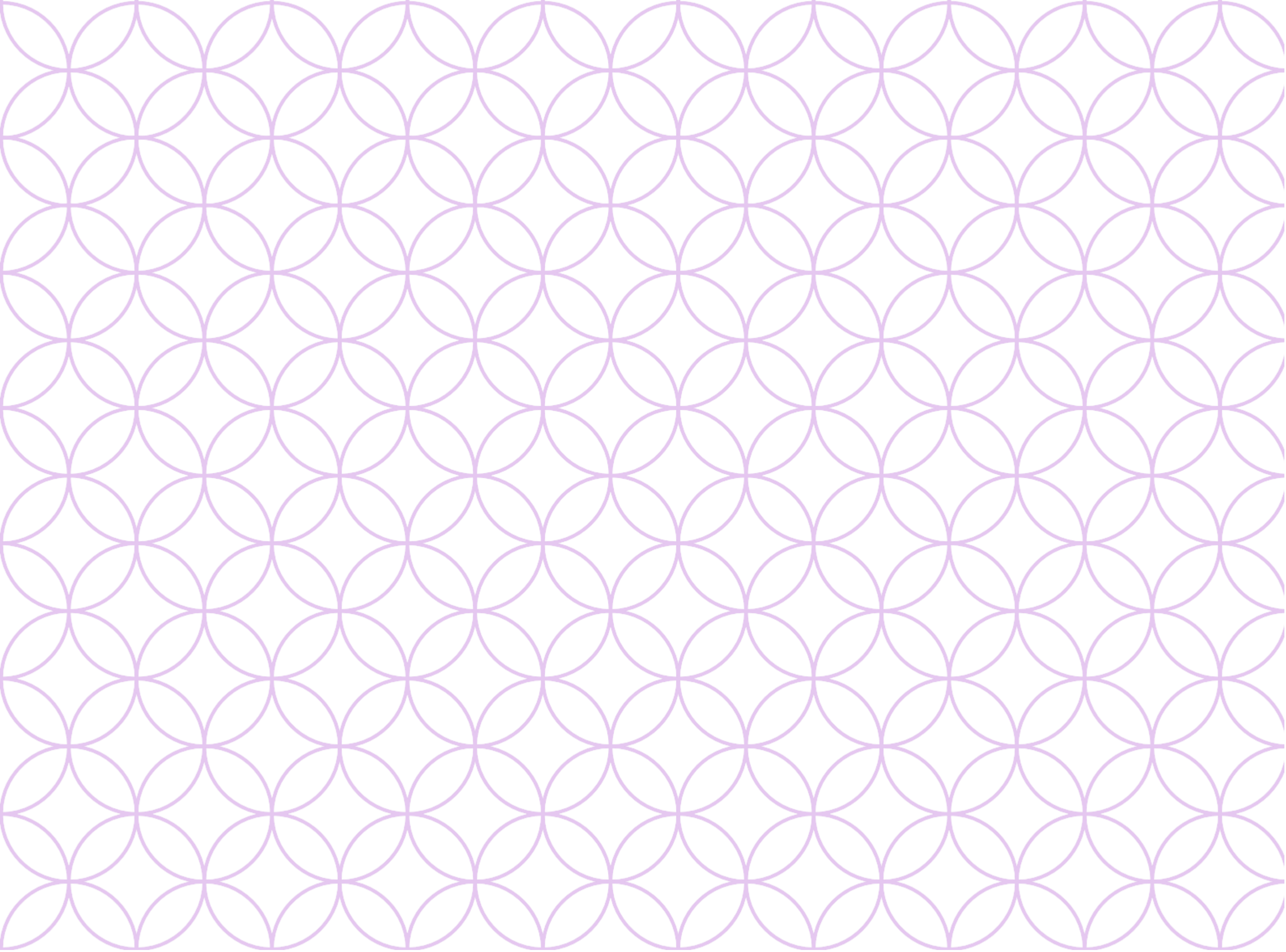
Design and validation of “Family Connections”:

a Dialectical Behavioral Therapy-based skills training program supported by an App for relatives of people with borderline personality disorder



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Castellón, September 2022

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Programa de Doctorado en Psicología

Escuela de Doctorado de la Universitat Jaume I

Design and validation of *Family Connections*: A Dialectical Behavioral Therapy-based skills training program supported by an App for relatives of people with borderline personality disorder.

Memoria presentada por Isabel Fernández Felipe para optar al grado de doctor/a por la Universitat Jaume I

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Castelló de la Plana, Septiembre de 2022

GOBIERNO DE ESPAÑA
MINISTERIO DE EDUCACIÓN, CULTURA Y DEPORTE
GENERALITAT VALENCIANA
UNIVERSITAT JAUME I

FUNDING

The present doctoral thesis has been carried out thanks to the grant awarded by the Ministry of Education, Culture and Sport (FPU) (FPU17/04210). In addition, the project "*Who takes care of the caregiver? Treatment for family members of people with borderline personality disorder*" was supported by the Ministry of Innovation, Universities, Science and Digital Society (Generalitat Valenciana): I + D + I projects developed by Emerging groups (GV/2019/148). This support made possible the publication of the articles that make up this doctoral thesis, as well as the presentation of the results derived from it in different national and international congresses, increasing the visibility and dissemination of the project.

Thesis by compendium of publications:

1. **Fernández-Felipe, I.**, Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302. https://doi.org/10.1186/s12888-020-02708-8. JIF: 3.630

2. **Fernández-Felipe, I.**, García-Palacios, A., Marco, H., & Guillén, V. (2022). "Family Connections", a Program for Relatives of People with Borderline Personality Disorder, Versus Treatment As Usual in Specialized Care: A randomized controlled trial. *Submitted*.

3. **Fernández-Felipe, I.**, Guillén, V., Castilla, D., Navarro-Haro, M. & García-Palacios, A. A smartphone application of "Family Connections" to increase the use of skills and the improving of psychological symptoms in relatives of people with borderline personality disorder: a study protocol for a randomized controlled trial. *Internet Interventions, 29*(3), 100546. https://doi.org/10.1016/j.invent.2022.100546. JIF: 4.333.

4. **Fernández-Felipe, I.**, Díaz-García, A., Marco, H., García-Palacios, A. & Guillén, V. (2022). "Family Connections", a DBT-based program for relatives of people with borderline personality disorder during the COVID-19 pandemic: a focus group study. *International Journal of Environmental Research and Public Health, 19*, 79. https://doi.org/10.3390/ijerph19010079. JIF: 3.390

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.

AGRADECIMIENTOS

Quizás estas sean las páginas que escribo con mayor ilusión tras esta etapa de cuatro años que comenzó con una gran pasión sobre el mundo de las personas con desregulación emocional. Un día cualquiera retumbó la palabra *doctorado* en mi cerebro y me planté en el despacho de Cristina con una mochila inmensa depreguntas y curiosidades sobre la personalidad y el mundo emocional. Inicié esta aventura subiendo sola por el pasillo acristalado del laboratorio y hoy me veo bajandoesas escaleras con muchas personas a mi alrededor. Estas palabras van dirigidas con todo mi cariño y agradecimiento a todas las que me habéis enseñado a flotar.

En primer lugar, quiero agradecer a mis directoras de tesis, Azu y Vero, por haberme impulsado y guiado durante esta experiencia en la que me habéis brindado confianza, autonomía, oportunidades y muchas facilidades para compaginar la investigación y la clínica, dedicándome a aquello que más me llena. Muchas veces no apreciaba la obra y entre las dos habéis subido el telón para hacerme ver que no todo es tan complicado y que relativizar es la mejor herramienta. También quería agradecer a Helio por haber sido un pilar fundamental en la elaboración de todo este gran proyecto, pero también por su humanidad compartida conmigo y su mente sabia, que me ayudó a encontrar la mía.

También quiero agradecer a todas las personas que me han ayudado infinitamente a crecer como profesional y que escucharon todos mis proyectos, mis ideas fugaces o mis ganas de seguir aprendiendo. Más que compañeros o tutores, me gustaría mencionarlos como mentores ya que me habéis ofrecido la posibilidad de ayudarme y guiarme desde todos vuestros grandes conocimientos. Aquellos que me acompañaron en las estancias (Quim, Juan Carlos, Javi, Eli y Diana) y a mi equipode consultoría *DBT Integra* (Toni, Manon, Carla, Juan, Dani e Iñaki). También a Mariví,por haber contado conmigo en tantas ilusiones que aparecían en el sendero del mundo de la DBT y por haberme apoyado en los momentos más críticos de mi carreracomo clínica.

En segundo lugar, quiero agradecer a toda mi familia por haberme repetido persistentemente desde que iba al colegio que conseguiría todo lo que me propusiera y por recordarme cada día lo orgullosos que estáis de mí. Aunque no supierais bien que estaba haciendo exactamente (*Hija, ¿pero tú estás estudiando o trabajando?; ¿Qué es eso del DLP? ¿o DLT? ¿TDP?; ¿Entonces tú ayudas a las familias y a los hijos o a todos?*) la muestra de interés ha estado presente desde que empecé. Sobre todo, a ti, mamá, que te quiero mucho y sin tu apoyo incondicional no estaría aquí escribiendo estas líneas.

En tercer lugar, mencionar a mis amistades íntimas que, desde el humor y el constante apoyo, han sido las muletas que tantas veces he necesitado. Habéis aguantado mis lágrimas, mis brotes, mi ansiedad y mis episodios intensos sobre la vida. Me siento muy afortunada de poder compartir la efimeridad de la existencia a vuestro lado. Davinia, Clara, Alicia, Joan, Xumi, Iñaki, Sara, Sandra, Andrea, Marina y Delia, os quiero con locura.

A Nelson, guau-guau.

Y dicen que lo mejor se deja para el final. Sabemos que el camino del doctorado es una carrera de obstáculos que no sabemos dónde ni cuándo van a aparecer y sentirse identificada es, a veces, idóneo para que las emociones no se derramen. Ayuda a generar un vínculo. Cuidándonos, porque nunca hemos estado solas en esto. Os he tenido a mi lado desde que pisé el laboratorio. Sois muchas las personas que habéis formado esta sensación. Y si hay algo durante esta etapa que me ha dejado huella es, sin duda, esta red de apoyo. No quería terminar sin mencionar a mis maravillosas compañeras que siempre me han tendido la mano: Cintia, Rosa, Patri, Javi, Jorge, Eva, Sonia, Isa, Amanda, Carlos, Araceli, Desi, Laura, Sara y Vero.

“Siento que cada uno se tiene que subir a su tren, que no es el mismo que el mío, pero ahora me siento acompañada en la estación.”

Una familiar que participó en uno de los grupos.

"I feel that everyone has to get on their own train, which is not the same as mine, but now I feel accompanied at the station."
A family member who participated in one of the groups.

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PRESENTATION

The present doctoral dissertation is presented as a compendium of four publications. Three of them have already been published in three different indexed journals, whereas the other one has been submitted to a scientifically relevant journal. The co-authors of all the articles have expressed their agreement to present the aforementioned manuscripts as part of this doctoral dissertation.

The studies included in this doctoral dissertation will be presented in four separate chapters. Moreover, two additional sections have been included: a general introduction section to provide an overview of the research field of interest and define the main aims of the current investigation; and a final discussion to summarize and discuss the overall findings of this research work in greater detail.

Following the current standards of Universitat Jaume I (regulated by Royal Decree 99/2011) to obtain recognition as an international doctorate, the present thesis was written in English, the most commonly used language to communicate scientific knowledge in Psychology.

GENERAL INTRODUCTION

This chapter encompasses a general preface to the thesis in order to highlight the previous evidence and existing gaps in the current literature that justify the importance of this research.

First, the theoretical background for the present work will be presented. This dissertation is framed within the field of psychological interventions for relatives of people with borderline personality disorder. That is, it focuses on the study of the impact of their loved ones' disorder on caregivers, the effectiveness of a skills training program based on Dialectical Behavior Therapy, the experiences during the COVID-19 pandemic, and the use of technological support to enhance the program (through a smartphone app). This chapter will delve into the concepts of borderline personality disorder, the impact of BPD on family members, the *Family Connections* skills training program, and the development of the App.

Finally, two other sections will define the general aim and the specific research questions of the present dissertation. Moreover, an outline of the thesis will be presented in order to explain the articles included in more detail, with each article constituting a separate chapter of this dissertation.

THEORETICAL BACKGROUND

Borderline Personality Disorder

One of the most complex mental disorders in terms of assessment, diagnosis, and treatment is Borderline Personality Disorder (BPD). The main characteristic of this mental disorder is a generalized pattern of emotional dysregulation that affectsdifferent areas and produces alterations in identity and interpersonal relationships (Bohus et al., 2021). The term *borderline* was coined in 1938 by Adolf Stern, who placed the disorder at the boundary between neurosis and psychosis. However, the BPD was first considered a mental disorder in 1980 when it appeared in the Diagnosticand Statistical Manual of Mental Disorders, 3rd edition (DSM-III) (American PsychiatricAssociation, 1980). Fortunately, many advances have been made in understanding the disorder and in its specific treatment over the years.

In the past ten years, there have been many changes in the description, understanding, and classification of personality disorders. Currently, BPD can be understood from four different classification systems: (a) the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5); (b) an alternative classification model in section III of the DSM-5; and (c) and the models presented in the International Classification of Diseases, 10th and 11th revisions (ICD-10 and ICD-11) (American Psychiatric Association, 2013; World Health Organization, 2013). The DSM-5 provides a categorical and traditional diagnosis where at least five criteria, defined by symptoms from a list of nine criteria, must be met. On the other hand, in both the ICD-11 and the alternative classification model in section III of the DSM-5, the diagnosis of the disorder is made from a much more dimensional perspective. The level of severity of general (personal and interpersonal) personality function is assessed, and the dysfunctional pattern of borderline personality is described based on five dimensional domains.

BPD is a very heterogeneous disorder. In fact, if we combine all the classification possibilities according to the DSM-5, we obtain more than 200 types of BPD. However, current research indicates that this disorder has three key domains: emotional instability and intensity, including impulsivity, inconsistent identity, and difficulties in interpersonal relationships. Many of the maladaptive behaviors that recurrently appear in people with BPD, such as non-suicidal self-harm, suicide attempts, or physical or verbal aggression, can be understood as maladaptive coping strategies or immediate consequences in one of these three domains of the disorder (Gunderson et al., 2018; Lieb et al., 2004). In addition, people with BPD often present comorbidity with other mental disorders. An epidemiological study conducted in the United States by Tomko et al. (2014) concluded that high rates of anxiety disorders (84.5%), mood disorders (82.7%), and substance use disorders (78.2%) are common in people with BPD.

It should be highlighted that early intervention in individuals with this disorder is of paramount public health importance (Chanen et al., 2017) because BPD symptoms proliferate in early adolescence and progress in this developmental period until reaching early adulthood, where symptoms tend to remit (Winsper et al., 2015). The development of BPD encompasses a series of internalizing symptoms (such as anxiety or depression) and externalizing symptoms (such as impulsive behaviors, substance use, or hyperactivity) that develop together. These symptoms are associated with poor academic performance and job loss, difficulties with social relationships and little or no long-term interpersonal bonding, risky sexual behaviors, poor social support, low life satisfaction, and high rates of health service use and hospital admissions (Wertz et al., 2020). In addition, the outcome of these behaviors in BPD, resulting in prolonged use of health services, entail high economic costs, including different emergency interventions and the need for multidisciplinary teams (Meuldijk et al., 2017; Amianto et al., 2011; Sansone et al., 2011).

Regarding treatment for BPD, evidence-based guidelines, such as the National Institute for Health and Care Excellence (NICE) guidelines, refer to psychological intervention as the treatment of choice (National Health and Medical ResearchCouncil, 2013; National Institute for Health and Care Excellence, 2018). The two treatments with the most empirical support are Dialectical Behavior Therapy (DBT) and Mentalization-Based Treatment (MBT), which have effects on several dimensionsthat affect the symptomatology of the disorder, such as interpersonal functioning or depression (Christea et al., 2017; Oud et al., 2018; Storebø et al., 2020). Moreover, Transference-Focused Psychotherapy (Kernberg, 1978, 1985, 1988) is an evidence-based treatment that uses a psychodynamic approach centered on object relations theory for BPD, and it is classified, according to NICE guidelines, as type B (diagnostic test studies with an evidence level of II). Also classified in this section is Schema Theory (Young, 1994), which integrates attachment theories, Gestalt currents, constructivism, some elements of psychoanalysis, and cognitive-behavioral bases. In addition, group therapy seems to be a good format for treating BPD. Linehan et al. (2015) conducted a dismantling study, indicating that skills training in group format had better and faster treatment effects than individual treatment.

Caregivers of people with Borderline Personality Disorder

BPD is a disorder that impacts many vital areas, such as work, social life, and family, with the latter being one of the most affected areas. Dysfunctional patterns produce disturbances in the routines in the family environment that affect the daily life of both family members and their loved ones (Giffin, 2008). Multiple studies have suggested that family members of people with BPD suffer much more in terms of mental health than the general population. (Scheirs & Bok, 2007). Family members of people with BPD often have high levels of distress and burden due to their loved one's illness, and studies indicate that, as a consequence, dysfunctional communication patterns arise within the family environment and have effects on the etiology and maintenance of the disorder (Fruzzetti et al., 2005; Hoffman et al., 1999). Research on caregivers indicates that relatives of people with BPD are more likely to develop psychological problems (Hoffman and Fruzzetti, 2007) and often report a lack of information, confusion, and incompetence in managing relationships with their relative (Hoffman et al., 2003). Furthermore, this lack of information about the diagnosis and evolution of their loved ones results in an increased burden of illness and depression for caregivers. When professionals include caregivers in the treatment, well-being in the family environment increases, and patient relapse decreases (Rajalin et al., 2009). Empirical findings from different studies reveal a variety of symptoms and difficulties with the environment in these family members. A study by Giffin (2008) showed that parents of people with BPD show exhaustion (due to lack of sleep), guilt, persistent and traumatic stress, and social isolation. In another study, Regalado et al. (2011)

found that 95.3% of family members presented somatic symptoms, anxious-depressive symptoms, overload, obsessions and compulsions, and paranoid ideation. These results were replicated in another study by Schiers and Bok (2007) where, in addition, symptomatology increases considerably when the family member with BPD has made suicide attempts. Following along the lines of these studies, Goodman (2011) indicated that 88% of family members of people with BPD stated that their emotional health was severely affected, and that they had work, interpersonal, and physical health problems. As early as 1996, Gunderson and Lyoo argued that family members often had severe psychopathological disturbances.

In addition, another major challenge that family members of people with BPD face is the stigma surrounding this disorder. Stigma in mental health is a problem that involves not only the people who suffer from these psychological problems, but also their family members (Girma et al., 2014). A qualitative study by Meshkinyazd et al. (2021) showed that family members of people with BPD who participated in the study were reluctant to talk about their loved one's illness. They felt that the label of this mental disorder would affect how others view them and that they would be treated differently. In addition, in this study, family members also expressed concern about negative beliefs held by others that generated shame and hopelessness.

These difficulties arising at both the social and family level show the need to include family members in treatment. Unfortunately, caregivers often deal with the self-injuries and suicidal behaviors of their loved ones in a severely resource-constrained system (Gunderson, 2001; Krawitz et al., 2004; Oldham, 2006). It is important to emphasize that professionals, in addition to focusing attention on the most urgent and severe symptomatology, should not underestimate the need to pay attention to dysfunctional dynamics that have serious consequences for the family nucleus. For all these reasons, psychological support and psychological treatment and/or skills training programs for all the family members and relatives who need them are a priority.

Psychological interventions for relatives of people with Borderline Personality Disorder

There are a number of psychological interventions for family members that have demonstrated empirical support, most of them group-based, but they vary greatly in the number of sessions, the type of psychological approach, and their content.

With regard to psychoeducational interventions, we found two studies with two different approaches (Guillén et al., 2021), the first resulting from a combination of cognitive analytic therapy with general psychiatric care (Pearce et al., 2017) and the second based on a relational model of personality disorders (Grenyer et al., 2019). Pearce et al. (2017), through a pre- and post-treatment study with a repeated measures design, conducted a psychoeducational intervention with three sessions lasting two hours each. The results indicated an increase in the understanding of the disorder and a decrease in the subjective burden of the illness on their loved ones. Grenyer et al. (2019) conducted a randomized clinical trial comparing a psychoeducation group ("Staying Connected") versus a waitlist control group. The experimental condition consisted of 10 sessions with DVD support. Results indicated a significant increase in family empowerment and dyadic insight and significant decreases in family criticism in the experimental group, and these results were maintained at 12-month follow-up.

Within the mentalization approach, there is a mentalization-based intervention that provides psychoeducation about BPD and coping and management skills for common problems that arise in the family environment. A randomized clinical trial by Bateman and Fonagy (2018) carried out a mentalization-based program for families of people with BPD, comparing two groups: psychoeducation groups and mentalization-based family support with skills delivered by trained family members in an immediate intervention versus a delayed intervention group. Family members in the immediate intervention showed a significant reduction in reported adverse incidents with the identified patient in the second phase of treatment, compared to those randomized to the delayed intervention.

Most studies about interventions for BPD caregivers address skills training programs mostly based on DBT or adapted DBT strategies (Ekdahl et al., 2014; Flynn et al., 2017; Guillén et al., 2022; Hoffman et al. 2005; Hoffman & Fruzzetti, 2007; Liljedahl et al., 2019; Miller & Skerven, 2017; Regalado et al., 2011; Wilks et al., 2017). These programs differ in their structures and in the number of sessions. Most of them consist of DBT adaptations with 10-12 sessions in which family members are trained in DBT mini-skills. A naturalistic pilot study by Miller and Skerven (2017) resulted in significant decreases in depression, hopelessness, and interpersonal sensitivity from pre- to post-treatment. In addition, Regalado et al. (2011), in a pre-experimental pilot study, found a significant decrease in burden, somatic symptoms, and psychological distress. Finally, a study by Wilks et al. (2017) with a group who received skills training for six months found significant improvements in interpersonal outcomes, stress reactivity, and emotion dysregulation. A third mixed descriptive study with two groups of caregivers (with or without relevant clinical symptoms) resulted in a significant decrease in psychological variables in the subgroup with clinical symptoms after the intervention (Ekdahl et al., 2014). The following study by Flynn et al. (2017) consists of a non-randomized controlled study with pre-treatment and post-treatment measures and 3-, 12-, and 19-month follow-ups. They compared FC to a psychoeducation group and found similar results to those discussed above. In addition, a non-randomized comparative study by Liljedahl et al. (2019) with pre-treatment, post-treatment, and 6-month follow-up measures indicated that caregivers in the FC group had significant decreases in illness burden, reduced mental health difficulties, and improved overall family functioning. Finally, Guillén et al. (2022) conducted a non-randomized pilot study with two conditions (face-to-face and online FC) and found improvements in burden and psychological symptoms such as depression, anxiety and stress, empowerment and family functioning, and quality of life. There were no differences based on the format.

The program with the most empirical support is Family Connections (FC), a DBT strategy-based skills training program for family members of people with BPD (Hoffman et al., 2005). This program was developed within the National Alliance for Borderline Personality Disorder Education (Hoffman et al., 2005; Hoffman & Fruzzetti, 2007), and its main objectives are: (a) to provide psychoeducation on BPD, (b) to provide training in coping skills within the family relationship, and (c) to create an emotional support network among family members with similar experiences (Hoffman

& Fruzzetti, 2007). The FC program lasts 12 weeks and consists of 6 modules with 2 sessions each. It can be delivered by clinicians or family members who have been trained in FC. So far, in the literature, we find five uncontrolled clinical trials with pre-treatment, post-treatment, and follow-up measures. The first pilot study was conducted by Hoffman et al. (2005), with pre-treatment, post-treatment, and 6-month follow-up measures of a group. The results indicate a significant reduction in disease burden and distress and a significant increase in family empowerment. Two years later, Hoffman et al. (2007) replicated the study and extended it, with the difference that the follow-up was at three months. The results suggest a significant increase in well-being variables and a significant decrease in depression.

The efficacy findings for FC indicate significant increases in family members' empowerment and mastery, family functioning, and measures of well-being, as well as significant decreases in psychological variables such as depression and anxiety and burden due to the illness of their loved ones. Moreover, these outcomes were stable or improved at the 3- or 6-month follow-ups. These results could be explained by the fact that this program provides training in the validation of the skill behaviors ofpeople with BPD, decreases anxiety and depression, provides updated information about the disorder, generates empowerment in family members, and decreases the stigma that family members perceive (Liljedahl et al., 2019).

The use of Ecological Momentary Assessment and Ecological Momentary Intervention to improve mental health

The widespread impact of Information and Communication Technologies (ICTs), such as computers, smartphones, the Internet, and mobile applications, has produced a major shift in the psychological treatment of mental disorders. In the field of research, psychological treatments with ICTs have attracted numerous investigations, many of them randomized controlled trials and systematic reviews (Ebert et al., 2018; Lindhiem et al., 2015; Sander et al., 2016). In addition, ICTs have great potential as treatments in public health (Fairburn and Patel, 2014), whether performed autonomously or together with non-specialized support. Accessibility through the Internet cuts across many of the barriers to help, such as scarcity of resources, cost, and mental health stigma and its consequences (Muñoz et al., 2016).

One of the relevant aspects we want to initiate with the development of this doctoral thesis is the use of ICTs, in this case a smartphone application, to support an intervention for family members. In recent years, two very promising models for the use of mobile apps have appeared: the Ecological Momentary Assessment (EMA) (Shiffman et al., 2008) and the Ecological Momentary Intervention (EMI) (Heron & Smyth, 2010). EMAs collect data as the experience happens through alerts that are scheduled during the day where participants must answer several questions (the study measures) through a smartphone. Because the data collection takes place in real time, participants respond by describing thoughts, emotions, and actions at the moment they experience them within their natural context. This enhances the ecological validityof the assessment and cuts through the difficulties of recall bias or memory inconsistencies (Shiffman et al., 2008). In addition, EMAs also collect information about the time relationship between different psychological variables, and they allow a better understanding of the actual experiences of the individuals using them (Torouset al., 2018; Van Os, 2013). Both EMAs and EMIs can enhance the effects, clinical utility, and acceptability of psychological interventions because help can be provided at the moment the person needs it in her/his natural context (Balaskas et al. 2021).

Due to the widespread use of mobile applications and the Internet in general, we expect a relevant change to occur in mental health treatments in the future (Fairburn & Patel, 2017). This paradigm shift is expected to break through the barriers found in the current model of the healthcare system, which has insufficient human resources and geographical limitations, making it possible to significantly increase the accessibility and availability of psychological treatments (Kazdin, 2015). Mobile app treatments have multiple advantages over other digital treatments such as treatments from web-based platforms where real-time symptom management is included and delivered when needed at the time and place of the user's choice (Stolz et al., 2018). In addition, the accessibility of these technologies allows them to be used by a large number of people, and their use is quite easy and adaptable. These technologies also have a great capacity for user anonymity and a great potential for the visualization of high-quality video and audio using common equipment (such as TVs or portable speakers).

Different mobile apps for people with mental health problems are designed to instruct, provide adaptive self-help strategies, and record alarms. In a meta-analysis of randomized clinical trials, Linardon et al. (2019) found that app treatment groups were significantly superior to control groups in improving different psychological variables such as stress, depression, generalized anxiety and social anxiety, quality of life, psychological distress, and positive affect. In addition, in studies where the app treatment was based on cognitive-behavioral therapy (CBT) along with reminders and professional counseling, the treatment had greater effects on different variables. An integrative review by Chan and Honey (2022) collected user perceptions of mobile digital applications for mental health from 17 studies. The results of this review indicate that people with mental health problems use apps to support their health. The review also identified that the interface and ease of use of the device are the most important factors for users. In addition, users reported high acceptance of the use of these mobile apps.

Although many studies use ICTs in psychological treatment for different mental disorders, the literature on this type of intervention for family members is still very scarce. Some studies have conducted internet-based interventions for relatives of people with depression (Bijker et al., 2017) and neurocognitive disorders (Duceppe et al., 2018). Users positively evaluated usability and ease of use, and the intervention had a significant effect on the relative's mental health and relationship with the patient. However, we have not found any ICT-based interventions for family members of people with BPD.

To our knowledge, only one study has explored the use of Apps for caregivers of people with mental health problems. Fuller-Tyszkiewicz et al. (2020) developed an EMI app for caregivers of people with physical and/or mental disabilities that resulted in decreases in stress and depression and increases in emotional and subjective well-being, optimism, self-esteem, and family support. One of the objectives of our work is to design and validate an FC mobile application through EMAs and EMIs. Regarding

EMA, the goal is to collect real-time emotional and behavioral data in a naturalistic setting with multiple repeated measures, such as disease burden, psychological variables (anxiety, depression, and stress), validation, family functioning, quality of life, and emotional regulation. The EMIs will have a direct link to these EMAs; that is, the software recommends to the family member what skill to perform based on the EMA scores. In addition, within the App, family members will be able to find a virtual "Library" where they can find multimedia material for each skill and, thus, better understand and practice the different skills when they need them.

Impact of the COVID-19 pandemic on caregivers

In the past two years, we have lived through difficult times as a consequence of the worldwide COVID-19 pandemic. This complex phenomenon impacted the mental health of the population due to restrictive measures, such as physical and social isolation, that were imposed to contain the spread of the virus. Isolation led to strong feelings of loneliness and a significant decrease in interactions with others, which has created a risk of some mental disorders such as depression. In addition, fear, anxiety, and depression have intensified due to uncertainty about future consequences and concerns about one's own health or that of loved ones. In addition, the extension of these mental health problems may increase the risk of immediate care mental disorders, such as trauma-related disorders, obsessive-compulsive disorder, panic disorder, or stress-related disorders (Fiorillo and Gorwood, 2020; Unützer et al., 2020). A study by Pfefferbaum and North (2020) suggests thatpandemics directly affect well-being by generating economic instability, social isolation, and disease. Moreover, well-being has declined compared to before this pandemic (Vindegaard & Benros, 2020). In many countries, COVID-19 led to the total confinement of the population for more than two months, resulting in high levels of depression, stress, fear, boredom, anger, and stigma (Brooks et al., 2020).

One area that has been strongly affected by this pandemic is the family. Family problems have been very different due to the many factors that can influence the virus and well-being, such as physical and mental health, politics and economics, individual and community resources, country of residence, and race and/or ethnicity (Berkowitz et al., 2020; CDC COVID-19 Response Team, 2020; Dooley et al., 2020; Hsiang, 2020; Van Dorn et al., 2020). In addition, many families' health was affected, and complex intrafamilial situations arose, such as family and domestic violence, inaddition to the loss of loved ones, which produced high anxiety and sadness, among others (Weingarten & Worthen, 2018). Furthermore, a study by Du et al. (2021) indicated that, in a large sample of adolescents in psychiatric hospitals, following the pandemic, the number of NSSI behaviors increased (from 29.2% in 2016 to 95.9% in2021) and were carried out at younger ages. In addition, the disorder lasted longer, thus increasing its severity. Another factor that has influenced family caregivers is theexperience of bereavement in non-standard conditions. A study by Vachon et al. (2020) indicates that the accumulation of stressors arising from health restrictions, theenvironment surrounding the death, and the lack of social recognition of the death canlead to a very complicated bereavement process for family members.

Regarding relatives of people with mental disorders, caregivers often suffer unfavorable consequences resulting in higher levels of depression and anxiety and poorer physical conditions compared to other populations (Schulz & Martire, 2004). In addition, during these times, there is an added risk of being infected with COVID-19, and a study by Chung et al. (2005) found that caregivers who are in contact with people with diseases such as SARS also suffer from anxious symptoms, fatigue, fear, loneliness, and sleep difficulties, among others. Multiple factors may be related to these psychological problems, such as isolation caused by confinement or loss of loved ones (Schwerdtle et al., 2017).

OBJECTIVES OF THE THESIS

In recent years, there has been an increase in the study of BPD and, more specifically, in the development and testing of psychological interventions that consider patients’ family members. So far, there is evidence suggesting the importance of including family members in the treatment of people with BPD as well as in skills training programs. However, despite the increasing body of studies exploring family interventions for people with BPD, discussed in the previous sections, several questions remain unanswered.

The general aim of the present thesis is to expand our knowledge about FC, a program for relatives of people with BPD, considering the gaps existing in the previous literature and considering the efficacy of this program in the Spanish population. Therefore, we decided to translate and adapt the FC program to Spanish and compare it with an active treatment in a randomized controlled trial to demonstrate its efficacy. An additional objective was to design a smartphone app to support this treatment.

This doctoral dissertation is a compendium of four publications. Two of them consist of study protocols for randomized controlled trials, the first one to demonstrate the efficacy of FC versus Treatment as Usual (TAU) and the second one to demonstrate the efficacy of the program with the support of a mobile app. The other two articles describe experimental studies consisting of a randomized controlled trial and a qualitative focus group study during the COVID-19 pandemic.

RESEARCH QUESTIONS

The research questions in the present dissertation are formulated considering the three time frames in which the different studies were carried out: the comparison of FC versus TAU, the design and support of a mobile App for family members of people with BPD, and the experiences during the confinement due to COVID-19 after carrying out the FC program.

1. *Comparison of FC versus TAU*: FC is the skills training program for relatives of people with BPD that has received the most empirical support (Hoffman et al., 2005). To our knowledge, six uncontrolled clinical trials have been performed with pre- and post-treatment and follow-up assessments (Ekdahl et al., 2014; Flynn et al., 2017; Guillén et al., 2022; Hoffman et al. 2005, 2007; Liljedahl et al., 2019). In all these studies, the results were robust, indicating significant decreases in psychological variables (depression and anxiety), hopelessness, and burden of illness, and significant increases in family mastery and empowerment, subjective well-being, and family functioning. However, none of them were compared to another active treatment in a randomized clinical trial; nor were the measurements of people with BPD considered.

2. *Design of a mobile App for family members of people with BPD:* We know that BPD affects both the patients and their families and is an important public mental health problem that has a great impact on psychological symptoms and burden in relatives of people with BPD (Fruzzetti et al., 2005; Wilks et al., 2017). Therefore, it is necessary to develop useful and accessible interventions specifically addressed to caregivers. Smartphone interventions with Ecological Momentary Assessment (EMA) and Ecological Momentary Interventions (EMI) offer several potential advantages in this regard (Heron & Smyth, 2010; Shiffman et al., 2008). For example, real-time symptom management is included, as well as exercise delivery when needed and access at the time and place of the user's choice (Stolz et al., 2018).

3. *Experiences during the confinement due to COVID-19 after participating in the FC program:* The COVID-19 pandemic has had a significant impact on the family environment due to hardships produced by job loss, death, increased rates of family and domestic violence, poor mental health outcomes, and estrangement in personal relationships (Pfefferbaum & North, 2020; Weingarten & Worthen, 2018). There is a great interest in knowing the experiences of family members during confinement after a skills training program and how they rate the program’s usefulness and their satisfaction with it.

Accordingly, the research questions addressed by the present dissertation are the following:

1. *Comparison of FC versus TAU*: Is FC superior to TAU while retaining the same results as other studies, and will the results be maintained or improved at 6-month follow-up? Do the changes observed in family members have any relationship with the clinical evolution of their loved ones with BPD?

2. *Design of a mobile App for family members of people with BPD and design of a randomized clinical trial to test the utility of the App:* Will the support of the mobile app in conjunction with the FC program result in significant reductions in symptoms and psychological burden and significant improvements in family functioning and quality of life? Will the mobile app be significantly more acceptable and satisfying to family members than a paper manual?

3. *Experiences during the confinement due to COVID-19 after participating in the FC program:* What experiences have family members of people with BPD had with their loved ones during the period of confinement caused by the COVID-19 pandemic? What FC program skills (validation, radical acceptance, emotion regulation, problem management, and relationship mindfulness) did family members use during confinement? What is the degree of acceptability and satisfaction with the FC program?

OUTLINE OF THE THESIS

The present doctoral dissertation consists of a compendium of four articles, each of them published or submitted for publication in a scientific journal (see **Table 1.1**). Prior to the development of each study, a general introduction to all the work carried out during the doctoral thesis is presented.

Chapter 1 describes the adaptation of the FC program in a study protocol comparing this program with an active treatment (TAU) to demonstrate its efficacy in a randomized clinical trial in a Spanish population.

Chapter 2 is a randomized clinical trial comparing FC versus TAU in relatives of people with BPD. This chapter shows the efficacy results of the doctoral dissertation.

Chapter 3 consists of a study protocol describing the design of the FC mobile app that aims to demonstrate its effectiveness as a medium for the program.

Chapter 4 is a qualitative study, more specifically, a focus group of family members recounting their experiences during COVID-19 confinement after completing the FC program and describing the use and usefulness of the skills learned.

A final chapter with a general discussion will also be provided, which includes a critical examination of the findings of the present dissertation as well as possible directions for future research.

Table 1.1: Doctoral dissertation as a compendium of publications

Chapter	*Article*
1	**Fernández-Felipe, I.**, Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of “Family Connections”, a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302.
2	**Fernández-Felipe, I.**, García-Palacios, A., Marco, H., & Guillén, V. (2022). “Family Connections”, a Program for Relatives of People with Borderline Personality Disorder, Versus Treatment As Usual in Specialized Care: A randomized controlled trial. *Submitted*.
3	**Fernández-Felipe, I.**, Guillén, V., Castilla, D., Navarro-Haro, M. & García-Palacios, A. A smartphone application of “Family Connections” to increase the use of skills and the improving of psychological symptoms in relatives of people with borderline personality disorder: a study protocol for a randomized controlled trial. *Internet Interventions, 29*(3), 100546*.*
4	**Fernández-Felipe, I.**, Díaz-García, A., Marco, H., García-Palacios, A. & Guillén, V. (2022). "Family Connections", a DBT-based program for relatives of people with borderline personality disorder during the COVID-19 pandemic: a focus group study. *International Journal of Environmental Research and Public Health, 19*, 79.

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CHAPTER 1

Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial

This chapter has been published as:

Fernández-Felipe, I., Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302.

Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial

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ABSTRACT

Background: Patients with borderline personality disorder (BPD) experience significant affect regulation difficulties that cause serious consequences in their work, emotional, and social environments. This dysfunctional pattern also produces great suffering and a heavy burden on their relatives. Fortunately, some studies show that treatment of relatives of people with BPD begins to be important in the patients' recovery and in improving family dynamics. One of the treatments that has obtained the most empirical support is Family connections (FC). This 12-session program is an adaptation of different Dialectical Behavior Therapy strategies. To test the efficacy of FC, five uncontrolled clinical trials were conducted, with pre-post treatment and follow-up assessments. The results of these studies and subsequent replications showed an improvement in family attitudes and caregiver burnout. Our research team adapted FC for delivery in the Spanish population. We intend to test the efficacy of this program versus a treatment as usual condition. Moreover, we aim to test the efficacy of this program and study its effectiveness (in terms of participants' acceptance). This paper presents the study protocol. **Methods:** The study is a randomized controlled trial. The participants will be recruited in a Personality Disorders Unit and randomly assigned to one of two treatment conditions: Family Connections group (FC) or Treatment As Usual (TAU). Primary outcome measures will be the BAS and FAD-GFS. Secondary outcomes will include DASS-21, FES, GS, and QLI. Participants' treatment acceptance and degree of satisfaction will also be measured. Participants will be assessed at pre-, post-treatment, and 6-month follow-up. Intention to treat and per protocol analyses will be performed. **Discussion:** This is the first study on FC for relatives of people with borderline personality disorder (BPD) compared to an active condition (TAU), and this is the first time relatives' and patients' data will be analyzed. In addition, it is the first study to test the efficacy of the program in Spain. This intervention could contribute to improving the efficiency and effectiveness of current treatment programs for relatives of people with BPD, help to decrease burden, and improve the family connection. **Trial registration:** ClinicalTrials.gov ID: NCT04160871. Registered November 15th 2019.

KEY WORDS: Borderline personality disorder; Burden; Caregivers; DBT; Family connections; Intervention; Relatives.

INTRODUCTION

Borderline personality disorder (BPD) is one of the most challenging and complex mental disorders. BPD is related to high suicide and self-harm rates. Persistent suicidal behavior is described in 69–80% of people with BPD (Schneider et al., 2008). A longitudinal study across 24 years comparing BPD and other personality disorders found that a total of 5.9% of BPD sufferers died by suicide and 14% by other causes, compared to 1.4 and 5.5% in a sample of people with other personality disorders (Temes et al., 2019). BPD also involves high rates of hospital admissions and health service use. BPD is associated with a high economic burden due to the long-term use of health services (Bender et al., 2001; Meuldijk et al., 2017; Sansone et al., 2011; Soeteman et al., 2008), including interventions in emergency settings and the need for the services of several different professionals (Amianto et al., 2011; Dimeff & Koerner, 2007; Meuldijk et al., 2017). Furthermore, BPD is an important public mental health problem that produces great suffering for patients and their relatives (Fruzzetti et al., 2005). For this reason, there is a need to provide specialized care.

The symptoms of BPD and their consequences lead to high levels of discomfort and burden for their relatives (Bradley, 1979; Hoffman et al., 1999; Links et al., 1988; Pope et al., 1983; Shachnow et al., 1977). Additionally, there is evidence that maladaptive family communication patterns play a role in the etiology and maintenance of BPD (Hoffman et al., 1999; Links, 1990).

Family members of people with BPD are more likely to have psychological problems (Hoffman & Fruzzetti, 2007; Noh & Turner, 1987), and they describe feelings of confusion, lack of awareness, and incompetence (Hoffman, 1999; Hoffman et al., 1999; Hoffman et al., 2003). Studies with relatives of people with BPD showed that the levels of burden and depression can increase due to lack of clear knowledge about the diagnosis and the evolution of the disorder (Hoffman et al., 2003; Rajalin et al., 2009). Moreover, when family members participate in treatment, patient relapse decreases, recovery is easier, and wellbeing in the family improves (Dixon et al., 2001; Rajalin et al., 2009).

Currently, there are interventions for family members with empirical support. All these programs are offered in group format, but they differ in the type of orientation and contents. So far, two of these studies present only psychoeducational contents; one is based on mentalization (Bateman & Fonagy, 2019), and the other combines cognitive analytical therapy with general psychiatric care (Pearce et al., 2017). Regarding the programs that offer skills training, almost all are DBTbased programs or DBT adaptations. These DBT skills training studies have different structures and numbers of sessions. They use either adaptations of DBT in 10–12 sessions where parents receive training in DBT miniskills (Flynn et al., 2017; Hoffman et al., 2005; Hoffman & Fruzzetti, 2007; Miller & Skerven, 2017; Regalado et al., 2011) or group therapy where skills are taught for 6 months (Wilks et al., 2017).

Family Connections (FC) is the most empirically supported program (Hoffman et al., 2005) for relatives of patients with BPD. The program can be carried out by clinicians or trained relatives. To date, five uncontrolled clinical trials have been performed with pre- and post-treatment and follow-up assessments (Ekdahl et al., 2014; Flynn et al., 2017; Hoffman et al., 2005; Hoffman & Fruzzetti, 2007; Liljedahl et al., 2019). In all the replications, the results of the FC program were consistent, showing significant decreases in burden, grief, anxiety, and depression, and significant increases in the participants' subjective experience of mastery, empowerment, well-being variables, and family functioning. Furthermore, these variations were maintained or improved at 3- or 6-month follow up. The good results for family functioning could be due to the fact that FC validates patients' skillful behaviors, decreases their psychological symptoms, improves interpersonal relationships between family members and patients, increases understanding of the problem, reduces perceived stigma, and enhances family empowerment (Liljedahl et al., 2019).

FC is a program for relatives of people with BPD that was developed within the National Education Alliance for Borderline Personality Disorder (Hoffman et al., 2005; Hoffman & Fruzzetti, 2007). This program links three important needs for relatives: first, education about the disorder and family functioning; second, individual and family skills to manage negative reactions in the family and improve well-being in the relationship; and, finally, social support from other relatives participating in the same group who have had very similar experiences (Hoffman & Fruzzetti, 2007).

A pilot study by Hoffman et al. (2005), with pre-, post-, and 6-month follow-up of one group, suggests that this program promotes significant reductions in grief and burden and a significant increase in mastery. A replication and extension study of FC by Hoffman et al. (2007), with a pre-, post-, and 3-month follow-up of one group, shows improvements in well-being variables and depression. Another descriptive mixed study (qualitative and quantitative data) with two groups (family members with and without clinically relevant symptoms) showed that the subgroup with clinically relevant symptoms had a significant decrease in depression and anxiety symptoms at follow-up, and women showed a decrease in both anxiety and depression symptoms before and after the intervention (Ekdahl et al., 2014). Flynn et al. (2017) found similar results in a non-randomized controlled study (pre-, post-, 3-, 12-, or 19-month follow-up) that compared FC with a psychoeducation group. Finally, in a non-randomized comparison study with pre-, post-, and 6-month followup assessments, participants who received FC reported fewer mental health difficulties, a lower perceived burden of caring, and higher overall family functioning (Liljedahl et al., 2019).

Therefore, considerable progress has been made in this line of work, which had not previously been considered. However, it would be desirable to advance in this direction by comparing FC to active treatments in larger samples and, if possible, examine the impact of the treatment on both family members and patients. Another important issue is the dissemination of FC to other cultural contexts. This study will provide the first efficacy data on the comparison of FC with an active treatment condition in a randomized controlled trial. Another contribution of this study is the measurement of the evolution of the family climate in relation to the improvements of both relatives and patients. Finally, this is the first study on FC carried out in a Spanish-speaking population.

This study has several objectives. First, we aim to test the efficacy of FC for relatives of patients with BDP in an RCT with a sample of participants from specialized care in Spain, compared to Treatment as Usual (TAU), that is, an active treatment condition. Second, we will study the feasibility and acceptance of this intervention protocol in family members of patients with BPD. Third, we intend to study whether changes in family members’ disease burden and clinical symptoms are related to the improvements observed in patients with BPD. Fourth, we aim to study whether the changes that may occur in relatives with regard to disease burden and clinical symptoms are related to the family climate. Finally, we will study the perceptions and opinions of families and patients about both intervention protocols.

We hypothesize that: a) both interventions will result in significant reductions in distress and burden and improvements in overall family functioning at post-treatment, and these results will be maintained at the 6-month follow-up; b) the FC program will significantly outperform the TAU intervention on measures of subjective burden, validation skills, family functioning, and quality of life; c) both protocols will be well accepted, but FC will be rated significantly higher by the participants; d) the improvement that may occur in the family members with regard to disease burden and clinical symptoms will have a positive influence on the family climate; e) in an exploratory way, given the lack of specific data in the literature, we hypothesize that the changes observed in the relatives will be related to the clinical evolution of the patients. In this article, we present the study protocol.

METHODS

Study design

We will conduct a two-armed randomized controlled trial (RCT). Participants will be randomly assigned to one of two conditions: Family Connections (FC) or Treatment As Usual (TAU). Block randomization will be carried out among the three clinical centers, considering that if a patient has more than one family member who attends the group, they will be randomized together to be included in the same condition. Measures will be taken before starting the intervention, after the intervention, and at the 6-month follow-up to determine whether improvements after the intervention are maintained in the long term. The study flowchart appears in Fig.
1. We will follow the CONSORT statement (Consolidated Standards of Reporting Trials, http://www.consort-statement.org) (Moher et al., 2001, 2010) and the SPIRIT

guidelines (Standard Protocol Items: Recommendations for Interventional Trials) (Chan et al., 2013, 2013).

Sample size

To determine the sample size, the effect sizes found in the literature on the subject have been considered. The controlled study by Grenyer et al. (2019), which tested a group psychoeducation protocol for caregivers of people with BPD, reported medium to large effect sizes (dyadic adjustment, d = .78; family empowerment, d = 1.4). In addition, on measures of burden, Grenyer et al. (2019) reported significant improvements between post assessment and the 12-month follow-up, with medium effect sizes (Burden Assessment Scale, d = .45). These effects are consistent with the literature on psychological treatments for other psychiatric disorders, such as the meta-analysis of psychological interventions for caregivers of people with bipolar disorders (Burden, g = −.80) (Baruch et al., 2018).

Taking these data into account, in the present study, adopting a conservative approach, an effect size of 0.60 is expected because our design includes two experimental conditions. Considering an alpha of 0.05 and a statistical power of 0.80 on a 2-tailed t test, the total sample size needed to reach an effect size of 0.60 for burden is 90 participants (45 participants per experimental condition). To control the maximum possible loss of participants during treatment, based on the literature about programs for family members of patients with BPD, a 29% dropout rate is expected (Flynn et al., 2017; Hoffman et al., 2005; Pearce et al., 2017; Rajalin et al., 2017; Regalado et al., 2011). Thus, the required sample size should be a total of 116 participants (58 participants per group). These calculations were made with the software program G*Power 3.1 (Faul et al., 2007).

Study population, recruitment, and eligibility criteria

The sample will consist of relatives of people with BPD. Recruitment will be carried out among relatives of patients treated at clinical centers specializing in the treatment of BPD in the Valencian region. Inclusion criteria will include the following: a) being 18 years old or more; b) having a family member diagnosed with BPD; c) ability to understand and read Spanish; and d) providing written informed consent.

Participants will be recruited by clinicians working in these clinical centers in three Spanish cities (Castellón, Valencia, and Alicante), until the required sample is complete. Clinicians will offer patients' families the opportunity to participate in the study and, after explaining it, obtain their informed consent. All the psychologists who participate in this research will have at least a master's degree in Clinical Psychology and specialized FC training.

Figure 1. Flowchart of the study

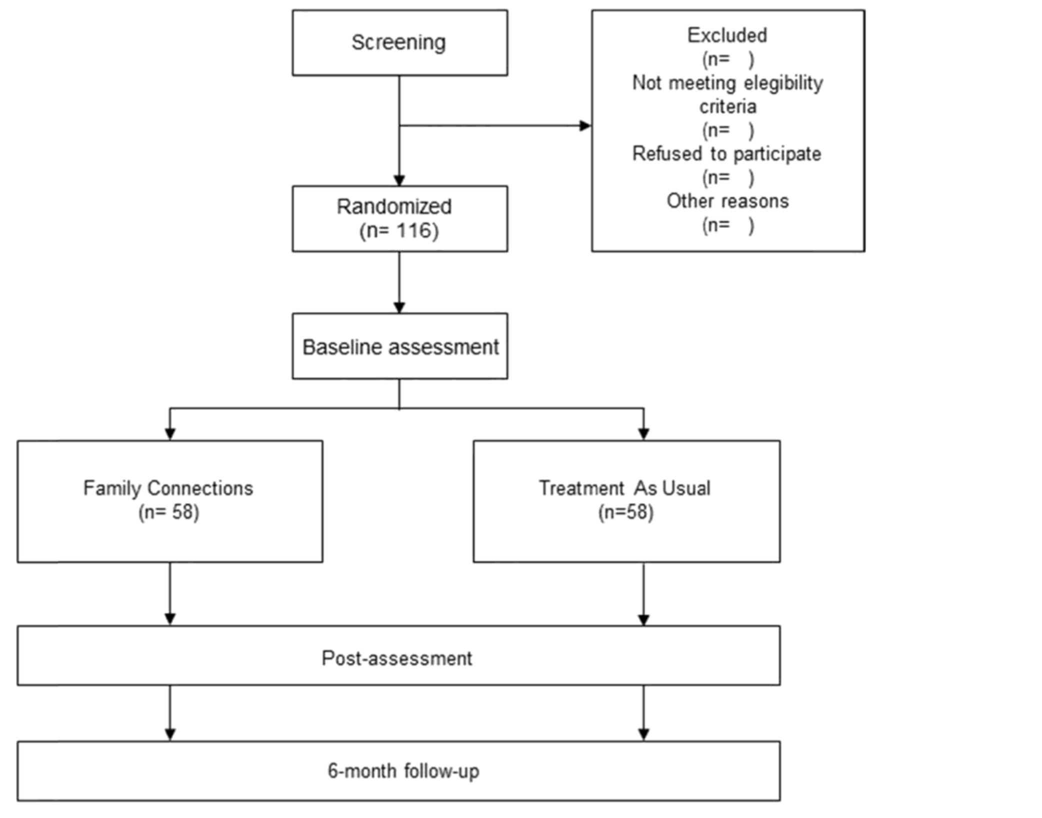

Fig. 1 Flowchart of the study

A psychologist will contact the participant to determine his/her inclusion in the study. At that time, the researcher will collect the baseline data and determine whether the inclusion criteria are met (see Table 1). Then the psychologist will contact a person outside the research group who will perform the individual randomization and inform the assessor of a code that corresponds to the type of treatment. This psychologist will be unaware of the characteristics of the study.

The psychologist will ensure that the participant has understood the characteristics of the study, and he/she will answer any questions the participant has. Participants will agree (or not) to participate before knowing which intervention condition they will be assigned to. The participants will also be informed that they can leave the study whenever they wish, and that in no case will there be any negative consequences for their family member who is receiving treatment at the center.

The psychologists who will participate in this study have extensive experience in implementing the DBT program for patients and will receive training in the FC program.

Table 1. Study measures and evaluation times

Participant	Measure	Aim	Evaluation time
Caregiver	S-D Interview	Diagnosis	BL
	BAS	Severity of burden symptoms	BL, Post-T and FU
	FAD-GFS	Familiar Global Functioning	BL, Post-T and FU
	DASS-21	Depression, anxiety and stress symptoms	BL, Post-T and FU
	FES	Family empowerment	BL, Post-T and FU
	QLI-Sp	Quality of life	BL, Post-T and FU
	OTSM	Treatment opinion and acceptance	PM
Patient	FAD-GFS	Familiar Global Functioning	BL, Post-T and FU
	DASS-21	Depression, anxiety and stress symptoms	BL, Post-T and FU
	DERS	Difficulties in emotional regulation	BL, Post-T and FU
	LEAP	Emotional availability of parents	BL, Post-T and FU
	VIRS	Validating and invalidating responses	BL, Post-T and FU

BL Baseline; Post-T Post-treatment; FU 6-month follow up; OTSM Opinion of Treatment Scale by Modules; S-D interview Socio-Demographic Interview; BAS Burden Assessment Scale; FAD-GFS Family Assessment Device – Global Functioning Scale; DASS-21 Depression, Anxiety and Stress Scale; DERS Difficulties in Emotion Regulation; FES Family Empowerment Scale; QLI-SP Quality Life Inventory-Spanish version; GS Grief Scale; LEAP Lum Emotional Availability of Parents; VIRS Validating and Invalidating Responses Scale

Ethics

The study will follow the Declaration of Helsinki Guidelines and existing guidelines in Spain and the European Union for the protection of participants in clinical trials. The Ethics Committee of the University of Valencia (Valencia, Spain) has approved this study. The trial was registered at clinicalstrial.gov as NCT04160871, registered the 15th of November of 2019.

Sample recruitment will be carried out by qualified clinicians. Researchers will explain the study to the participants, and they will sign the consent form as volunteer participants with the possibility of dropping out at any time. If our hypotheses are confirmed, the FC condition will be offered to participants assigned to the TAU condition after the 6-month follow-up. Special difficulties are not expected, based on the literature. If a participant drops out of the trial due to unwanted events, s/he will have the opportunity to participate the next time the treatment groups for family members are offered.

To protect information, personal data (e.g. age, sex, address, mail, phone) will be collected by the researchers participating in this study, and data will be replaced by codes. Personal data will be strictly separated from other data, and it will only be available to researchers responsible for the study, always considering and protecting the right to privacy of the participants.

Interventions

We translated the FC protocol for relatives of people with BPD into Spanish. It is one of the first programs designed to be applied directly to relatives of patients with BPD. The program is an adaptation of different Dialectical Behavior Therapy strategies, one of the most researched and empirically supported treatments for BPD people (Flynn et al., 2017; Stoffers et al., 2012). It is composed of six modules divided into 12 sessions lasting approximately 2 h each. The intervention protocol is structured in a caregiver handbook (Hoffman et al., 2005). In the following section, the modules in each treatment program are briefly described.

The FC protocol includes components aimed primarily at reducing distress and burden and improving overall family functioning: relationship mindfulness skills, family environment skills, validation skills, and problem management skills. Furthermore, the program includes Psychoeducation about borderline personality disorder.

Family connections (FC)

This intervention program consists of six modules with two sessions each, designed to improve family attitudes and reduce family exhaustion. Each module has specific objectives and practical exercises, as well as videos with examples of people suffering from BPD and their relatives:

1. *Introduction.* The objective of this module is to provide information about the aims of the program, weekly format and guidelines, statement of rights, and criteria and symptoms of BPD. The central role of emotion regulation is also presented.
2. *Family Education.* The purpose of this module is to present treatment programs for BPD and comorbid disorders, biosocial factors related to the etiology of the disorder, the difficulties BPD provokes in the family members, and the need for help. It also shows the transactional model of the development of BPD and related disorders.
3. *Relationship Mindfulness Skills.* This module aims to define a validating family environment, being mindful of the relationship, emotion regulation skills, and states of mind.
4. *Family Environment Skills.* The aim is to understand the relationship between the individual and the family's welfare, the importance of maladaptive ways of thinking related to blame, and the concept of radical acceptance.
5. *Validation Skills*. The objective of this module is to understand what validation means and learn validation and self-validation skills. Moreover, in this module, the relatives learn how to set clear limits and achieve self-respect.
6. *Problem Management Skills.* This module focuses on interpersonal efficacy, defining problems and solutions, and problem management skills.

Adaptation to Spanish

The FC program has been translated into Spanish by the Puerto Rican research group directed by Dr. Domingo Marqués, and adapted to the Spanish spoken in Spain by our research team. This translation was performed by clinical experts who were familiar with both DBT (Linehan, 1993, 2015) and the FC program. The translation included the FC program manual, as well as the videos that accompany the program (they were subtitled in Spanish) and the brochures, leaflets, and handouts.

Treatment as usual (TAU)

Treatment as usual is the program routinely offered to BPD patients' relatives in the clinical centers participating in this trial. The intervention includes 12 therapeutic sessions in six modules. Each module has specific objectives and practical exercises.

1. *Introduction*. This module consists of an overview of the treatment and the aims of the group. Furthermore, it focuses on the definition of personality disorders, BPD and its clinical characteristics, the role of emotion regulation, and comorbid disorders.
2. *Family Education*. The aim of this module is to explain the diagnostic criteria for BPD, associated problems (alcohol and substance use and eating disorders), the DBT model, and the main goals of the treatment.
3. *Validation Skills*. The purpose of this module is to explain what validating and invalidating environments are, the consequences of an invalidating environment, and how to use validating skills.
4. *Crisis Management Skills*. This module aims to prevent crises by explaining how to manage anger and learning how to act in the presence of selfinjuring and suicidal behaviors. Moreover, acceptance skills are shown in this module.
5. *Problem Management Skills*. This module helps the relative to know how to deal with problems and set clear limits, handle conflict in everyday situations, confront unacceptable behavior, and manage emotionally charged conversations.
6. *Relapse Prevention*. It aims to strengthen the strategies learned throughout the program, schedule future practice, and teach the participants how to identify and cope with future high-risk situations.

Measures

Table 1 presents a summary of the measures.

Caregiver measures (participants)

Sociodemographic interview

Demographic variables questionnaire: age, family constellation, sex, educational level, income, marital status, number / age of children, and psychiatric history.

Primary outcomes

Burden assessment scale (BAS) (Horwitz & Reinhard, 1992)

It consists of 19 items that assess the caregivers' objective and subjective burden in the past 6 months. Items are rated on a 4-point Likert scale ranging from 1 to 4, and higher values indicate a heavier burden. Internal reliability of the scale ranges from .89 to .91, and it shows adequate validity (Reinhard et al., 1994). This scale is not validated in Spanish and it will be an objective of this work.

Family assessment device – global functioning scale (FADGFS) (Epstein et al., 1983)

It is a self-report questionnaire consisting of 60 items related to family functioning. It is composed of seven subscales: Problem-Solving, Communication, Roles, Affective Responsiveness, Affective Involvement, Behavior Control, and General Functioning. Cronbach's alphas range from .72 to .83 for the subscales, and.92 for general functioning, and test-retest reliabilities for the FAD scales were adequate (Miller et al., 1985). This scale is not validated in Spanish and it will be an objective of this work.

Secondary outcomes

Depression, anxiety and stress scale (DASS-21) (Lovibond & Lovibond, 1995)

This scale has 42 items about negative emotional symptoms. They proposed a short version with 21 items. The DASS-21 showed good factor structures. Regarding the internal consistency, Cronbach's alphas were excellent for the DASS-21 subscales: Depression (α = .94), Anxiety (α = .87), and Stress (α = .91) (Antony et al., 1998). We used the Spanish version validated by Daza, Novy, Stanley and Averill (Daza et al., 2002).

Family empowerment scale (FES) (Koren et al., 1992)

It consists of 34 items divided into three subscales: family, service system, and involvement in community, which refer to three forms of empowerment: attitudes, knowledge, and behaviors. Items are rated on a scale from 1 to 5, and higher scores indicate a greater sense of empowerment. The psychometric properties are the following: regarding the internal consistency of the FES subscales, the coefficients ranged from .87 to .88, and validity and reliability were adequate. This scale is not validated in Spanish and it will be an objective of this work.

Quality of life index-Spanish version (QLI-Sp) (Mezzich et al., 2000)

This index consists of 10 items that assess perceived quality of life, including physical and emotional wellbeing, self-care and independent functioning, occupational and interpersonal functioning, social-emotional and community support, personal and spiritual fulfillment, and a global perception of quality of life. Higher scores indicate higher quality of life. This instrument has good psychometric properties, with a Cronbach's alpha of .89 and high test–retest reliability (r = 0.87).

Opinion of treatment scale by modules (OTSM)

The Opinion of Treatment Scale by Modules is an instrument developed by our research team and adapted from Borkovec and Nau (Borkovec & Nau, 1972). It is designed to assess the participants' opinion and acceptance of the program. Furthermore, it evaluates the level of change obtained with regard to the therapeutic modules. Questions involve how logical the treatment seemed, degree of satisfaction, if they would recommend the program, if they think this program would be useful to treat their problems or others, and expectations about the program. It evaluates the six treatment modules in the two conditions. There are two subscales: one evaluates the learning of the skills taught in the module and is rated from 0 (not at all) to 10 (a lot), and the other evaluates how the module has helped the caregiver to improve several aspects, such as knowing and understanding the problem, understanding emotions, mindfulness of the relationship with their relative, acceptance, family atmosphere, and problem solving, and it is rated from 1 (not at all) to 4 (a lot). Additionally, there is an expectation question only at the end of the first module, where the participants answer the question: "In general, what expectations do you have about the program?"

Patient measures

Sociodemographic interview

Family Assessment Device – Global Functioning Scale (FAD-GFS) (Epstein et al., 1983).

Depression, Anxiety and Stress Scale (DASS-21) (Lovibond & Lovibond, 1995).

Difficulties in emotion regulation scale – Spanish version (DERS) (Hervás & Jódar, 2008)

The authors adapted the scale to spanish and they reduced the items from 36 to 28 with five subscales: emotional lack of control, life interference, lack of emotional attention, emotional confusion, and emotional rejection. All the items have a Likert type design, with a score between 1 and 5, where 1 means "Hardly Ever" and 4 "Usually", where higher score means more difficulties. Internal consistency was excellent (α = .93) and good test-retest reliability (pl = .74, p < .001).

Lum emotional availability of parents (LEAP) (Lum & Phares, 2005)

It consists of 15 items that measure mothers' and fathers' emotional availability perceived by the patient. Items are rated on a 6-point Likert scale ranging from 1 (never) to 6 (always). Internal consistency was excellent in a non-clinical sample for the mother form (α = .96) and the father form (α = .97); and in a clinical sample, for the mother form (α = .92) and the father form (α = .93). This instrument has adequate test–retest reliability for the mother form (r = .92) and the father form (r = .85). This scale is not validated in Spanish and it will be an objective of this work.

Validating and invalidating responses scale (VIRS) (Fruzzetti, 2007)

The Validating and Invalidating Responses Scale is a 16- item self-report that evaluates levels of validation and invalidation of caregivers' responses. This instrument has two subscales: validation and invalidation responses. These two subscales are moderately correlated. Items are rated on a 5-point Likert scale, ranging from 0 (never) to 4 (almost all the time), and higher scores indicate more perceived validation or invalidation from the caregiver who is assessed. There are no psychometric properties available on the VIRS yet. This scale is not validated in Spanish and it will be an objective of this work.

Study measures and evaluation times are summarized in Table 1.

Data analyses

In order to analyze whether there are differences between the experimental conditions before the application of the treatment, Student's t tests will be performed for the continuous variables, and chi-square tests for the categorical variables. To compare the effectiveness of the two treatment conditions, we will perform a multivariate analysis of variance for repeated measures (MANOVA) for the variables with subscales, and ANOVA for the single variables, taking the pretreatment, posttreatment and follow-up moments as within-subject factor and the treatment condition (FC vs TAU) as between-subject factor.

Moreover, between-group changes will be computed by calculating standardized effect sizes (Cohen's d). Finally, we will perform zero-order correlations and linear regression analyses between the measures of the caregivers and the measures of the patients.

Because the trial is still going on, the state of the art in analytic methodology for RCT will be reviewed before analyzing the data, and so variations in the selection of the most appropriate analytic procedures may occur.

DISCUSSION

FC is an intervention program for relatives of people with BPD that has been adapted to Spanish by our research team. FC was designed to train relatives of people with BPD to improve global family functioning, empowerment, resilience, validation, and mindfulness skills, and decrease grief, burden, hopelessness, and psychological symptoms (Hoffman et al., 2005).

The first aim of this study is to provide data from an RCT about the efficacy of this intervention protocol in a Spanish sample of participants consisting of family members of patients with BPD who are treated at clinical centers specializing in the treatment of this disorder, compared to an active condition (TAU). A second objective is to study the acceptability (expectations and opinions) of this program among the participants. Another aim is to analyze whether there are changes in relatives' burden and psychological symptoms related to the improvement observed in patients. The fourth aim consists of studying whether these changes are related to the family climate. Finally, we will examine the opinions and perceptions of relatives and patients about both intervention protocols.

The study aims to contribute to the existing literature on the efficacy and effectiveness of intervention programs for relatives of BPD patients, specifically FC. In addition, it aims to assess whether the improvements obtained in the relatives are related to those obtained by the patients themselves. Moreover, this study will help to facilitate access to this type of intervention for Spanish-speaking people, which is important due to the lack of options for many people who suffer from this problem, not only in Spain, but also in many countries in South America, in the United States, or in other countries with a significant number of Spanish-speaking citizens. The study will offer data that can be compared to those obtained in other studies carried out in English Speaking countries.

The data obtained in this study can be compared to results obtained in studies with DBT skills protocol programs for relatives. Several studies have found improvements in mental health patients' relatives and the relationship with their loved ones, but further research is needed. One of the aims of this study is to examine the effect of the treatment components on increasing global family functioning and decreasing burden and distress, which will mean an important change in the research and treatment of relatives of people with BPD. To our knowledge, this is the first RCT study to compare FC to an active condition (TAU) and include a 6-month follow-up.

An important aim of the study is to identify methods to improve access to FC, as well as providing psychological support to everyone who needs it. We are living in a new era in the field of personality disorders, where BPD is given more and more attention. Researchers and clinicians are already crossing the barriers of traditional classifications and treatments, and we can now use these new protocols with significant and encouraging results. The use of the treatment in group format (a more costeffective format than individual therapy) can help to disseminate and increase the access to these family interventions.

To conclude, in this study, the effectiveness of the application of the FC program will be tested by measuring the acceptability of this program and each specific module in relatives of patients with BPD.

An important strength of this study is that it is the first RCT of FC compared to an active intervention, and it is carried out in a routine clinical care context, an ecological setting. If the hypotheses are confirmed, we expect a fast implementation of FC in these centers and other similar settings. It is also the first study carried out in a Spanish-speaking population, thus facilitating the dissemination of the program in other Spanish-speaking countries or populations.

However, this study has some limitations. We do not expect to have recruitment difficulties because our research team collaborates with different clinical centers, but even so we would have liked to increase the number of centers participating in the study. This was not possible for funding and logistic reasons. Another limitation is that we included a follow-up at 6 months. We would have liked to carry out a long term follow-up, but due to the conditions of the centers, it is difficult to contact relatives or patients who leave treatment or are discharged.

Finally, the aim of this study is to contribute to the literature on the efficacy of the FC program for relatives of people with BPD. We hope that this study contributes to the exploration of the efficacy and acceptability of programs designed to improve global family functioning and reduce family members’ burden. It will also contribute to improving our understanding of the relationships that may exist between the clinical evolution of the family members receiving the program and the evolution of the patients. If significant results are achieved, there will be an effect on the design and application of future family intervention programs, as a way to improve the overall functioning of the family climate and reduce the burden and distress they face. Finally, this study will allow the possible application of the program to Spanish-speaking populations in other countries.

ABBREVIATIONS

BPD: Borderline personality disorder; FC: Family connections; TAU: Treatment as usual; DBT: Dialectical behavior therapy; RCT: Randomized controlled trial; BAS: Burden assessment scale; FAD-GFS: Family assessment device-global functioning scale; DASS-21: Depression, anxiety and stress scale; FES: Family empowerment scale; QLI-Sp: Quality of life index-spanish version; OTSM: Opinion of treatment scales by modules; DERS: Difficulties in emotion regulation scale; LEAP: Lum emotional availability of parents; VIRS: Validating and invalidating responses scale; S-D: Socio-demographic; BL: Baseline; PostT: Post-treatment; FU: Follow-up; MANOVA: Multivariate analysis of variance; ANOVA: Analysis of variance.

ACKNOWLEDGEMENTS

We would like to thank the participating treatment center (ITA-PREVI) and the therapists and researchers participating in this trial.

AUTHORS’ CONTRIBUTIONS

IF-F drafted the manuscript with important contributions from AG-P and VG. IF-F, in collaboration with AG-P, VG, HM, AD-G and CB, designed the study and participated in each of its phases. AG-P, VG, CB, HM, IF-F and AD-G translated and adapted the FC program. MJ contributed to the method section. RB reviewed the content of the manuscript. All authors participated in the revision of the manuscript and have approved the final manuscript to be published.

FUNDING

Funding for the study was provided by grants: the Ministry of Innovation, Universities, Science and Digital Society (Generalitat Valenciana): I + D + I projects developed by Emerging groups. GV/2019/148 has been awarded to VG as the main investigator of the project and PhD grant has been awarded to IF-F from the Ministry of Education, Culture and Sport (FPU) (FPU17/ 04210) to produce a doctoral thesis. The study protocol was reviewed by the Generalitat Valenciana: the Ministry of Innovation, Universities, Science and Digital Society. Call for papers: Emerging research groups.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study follows the guidelines of the Declaration Helsinki and existing guidelines in Spain and the European Union for the protection of patients in clinical trials. All participants interested in participating signed an informed consent form. The Ethics Committee of the University of Valencia (Valencia, Spain) has approved this study. The trial was registered at ClinicalTrial.gov as NCT04160871.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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CHAPTER 2

“Family Connections”, a Program for Relatives of People with Borderline Personality Disorder, Versus Treatment As Usual in Specialized Care: A randomized controlled trial.

This chapter has been sent as:

Fernández-Felipe, I., García-Palacios, A., Marco, H. & Guillén, V. (2022). “Family Connections”, a Program for Relatives of People with Borderline Personality Disorder, Versus Treatment As Usual in Specialized Care: A randomized controlled trial. *Submitted.*

“Family Connections”, a Program for Relatives of People with Borderline Personality Disorder, Versus Treatment As Usual in Specialized Care: A randomized controlled trial.

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ABSTRACT

Family members of people with borderline personality disorder (BPD) often experience high levels of psychological symptomsb as depression or anxiety and burden. Family Connections (FC) is a pioneer program designed for relatives of people with BPD, so far, the most empirically supported treatment (Hoffman et al., 2005). The aim of this study is to confirm the efficacy of FC in relatives of people with BPD compared with a treatment as usual (TAU) in a Spanish population sample; and to test whether changes in psychological symptoms are related to the improvement of people with BPD. The sample consisted of 89 relatives of 42 patients. A two-arm randomized controlled trial (RCT) with repeated measures pre- and post-treatment. The analyses indicate that family members in the FC group obtained significant improvements with respect to TAU in the measures of burden (p = .028), family mastery and empowerment (p = .002) and the emotional inattention subscale of emotional regulation (p = .013). Regarding the patients, the FC group obtained statistically significant differences with respect to TAU in depression, anxiety and stress (p = .042). The results indicate that the intervention helps both patients and relatives to improve on key issues. It is essential to consider and offer support to the families of people with severe psychological disorders. This type of programme is a major step forward in improving the care that can be provided to both patients and their families.

KEY WORDS: caregivers, relatives, borderline personality disorder, Family Connections, skills.

INTRODUCTION

One of the most challenging and difficult to treat mental disorders is borderline personality disorder (BPD), partly due to the high rates of self-harm and suicide linked to this disorder, given that 69-80% of people with BPD have persistent suicidal behaviors (Schneider et al., 2008). A longitudinal study comparing a sample with BPD to samples with other personality disorders over a period of 24 years showed that 5.9% of people with BPD died by suicide, compared to 1.4% of people with other personality disorders (Temes et al., 2019). In addition, people with BPD consume many of the long-term health care resources, with greater use of these services and high rates of hospital admissions leading to a large economic expenditure (Bender etal., 2001; Meuldijk et al., 2017; Sansone et al., 2011; Soeteman et al., 2008), includingemergency services and the need for multidisciplinary clinical teams (Amianto et al., 2011; Dimeff & Koerner, 2007; Meuldijk et al., 2017). Because of this, BPD is a very important public mental health problem with great repercussions. It causes great suffering to the affected people, but also to their relatives (Fruzzetti et al., 2005), so that both the literature and clinical practice suggest the need to provide specialized care. The results of different studies show high levels of suffering, psychological problems (Hoffman & Fruzzetti, 2007; Noh & Turner, 1987), and burden of illness in relatives of people with BPD (Bradley, 1979; Hoffman et al., 1999; Links et al., 1988; Pope et al., 1983). A relationship between the etiology and maintenance of BPD and maladaptive family communication patterns has also been observed (Hoffman et al., 1999; Links, 1990). In addition, lack of information and understanding about BPD andits course lead to increased levels of depression and caregiver burden (Hoffman et al.,2003; Rajalin et al., 2009). However, lower levels of relapse, better recovery, and family well-being are found when family members participate in treatment (Dixon et al., 2001; Rajalin et al., 2009).

Today, different empirically supported family treatments are presented in group format with different program contents and therapeutic orientations. Two studies only present psychoeducational contents, one referring to mentalization (Bateman & Fonagy, 2019) and the other to a combination of cognitive analytic therapy and general psychiatric care (Pearce et al., 2017). There are also skills training programs specifically designed for family members. Most of them are based on Dialectical Behavior Therapy (DBT) or have been adapted from it. These programs differ in their structure, in the number of sessions, and in the duration of each session. The literature shows several studies that examine 10-12 session programs that provide training in adapted DBT skills (Flynn et al., 2017; Hoffman et al. 2005; Hoffman & Fruzzetti, 2007; Miller & Skerven, 2017; Regalado et al., 2011) and one study that offers a longer (6 months) skills training (Wilks et al., 2017).

The most empirically supported skills training for family members of people with BPD is Family Connections (FC) (Hoffman et al., 2005), which offers a program that can be run by both professionals and trained family members. This program was designed and developed by the National Alliance for Borderline Personality Disorder Education (Hoffman et al., 2005; Hoffman & Fruzzetti, 2007). FC has three main objectives: a) psychoeducation about BPD; b) skills training for family and individual functioning; and c) providing support from other family members in the group with similar problems (Hoffman & Fruzzetti, 2007). Regarding the efficacy of FC, to date, five uncontrolled clinical trials have been conducted with pre-, post-treatment, and follow-up results (Ekdahl et al., 2014; Flynn et al., 2017; Hoffman et al., 2005; Hoffman & Fruzzetti, 2007; Liljedahl et al., 2019). The results of these studies on FC were consistent and maintained or improved at follow-ups (3 or 6 months), with significant decreases in psychological symptoms such as anxiety and depression, illness burden, and grief, as well as significant increases in caregivers’ perceived mastery and empowerment, well-being, and functioning within the family environment. These promising results could be due to the fact that FC helps to understand the problems of persons with BPD, improves caregivers' perceived mastery and empowerment, decreases suffering and psychological problems, improves interpersonal relationships, teaches validation to their loved ones, and decreases perceived stigma (Liljedahl et al., 2019).

Given the data obtained so far, it seems necessary to take this line of research one step further by testing the program in a controlled study. The present study aims to advance in exploring the efficacy of FC by carrying out a randomized controlled trial. To our knowledge, this is the first randomized clinical trial to provide efficacy data comparing FC with another treatment for family members of people with BPD. In addition, this study also contributes to the measurement of the family climate in relation to improvements in both relatives and patients. Moreover, this is the first study on FC in a Spanish population. So far, two pilot studies (Hoffman et al., 2005; Hoffman & Fruzzetti, 2007), a mixed descriptive study (Ekdahl et al., 2014), and two non-randomized controlled studies Flynn et al., 2017; Liljedahl et al., 2019) have been published. Great progress has been made on this issue, but it is desirable to continue to advance by carrying out studies in larger samples and exploring to what extent the training of family members impacts patients.

This randomized clinical trial has several objectives. The first is to confirm the efficacy of FC in relatives of people with BPD in a randomized clinical trial versus an active treatment as usual (TAU) condition in specialized care in a Spanish population sample. The second is to compare the acceptance, satisfaction, and feasibility of the two conditions. In addition, we aim to test whether changes in psychological symptoms, illness burden, and global family functioning of relatives are related to improvements in people with BPD. The hypotheses of this study are: (a) Both FC and TAU will significantly reduce psychological symptoms, illness burden, and global family functioning at post-treatment, and these outcomes will be maintained at follow-up (6 months); (b) The FC condition will be significantly superior to the TAU condition on all the psychological variables; and (c) At an exploratory level, because the literature is still scarce, we expect that the changes found in relatives will be related to clinical improvements in people with BPD.

METHODS

Study design

A two-arm randomized controlled trial (RCT) with repeated measures, pre- and post-treatment and 6-month follow-up, was designed following the CONSORT guidelines (Consolidated Standards of Reporting Trials, http://www.consort-statement.org) (Moher et al., 2001, 2010). Participants were randomly assigned in a double-blinded way to one of two conditions: Family Connections (FC) or Treatment as Usual (TAU). This was a multicenter randomized controlled trial registered on

ClinicalTrials.gov (NCT04160871). The original study protocol was modified because we added the Emotion Regulation and Resilience measures at the last time point. The flow diagram of the study following CONSORT guidelines is shown in Fig. 1.

Participants

The randomized clinical trial was conducted in three Specialized Units for Personality Disorders in Spain, which provide psychological treatments to people with personality disorders and support for their relatives. A total of 121 relatives of people with borderline personality disorder were evaluated in these three clinical centers during recruitment. All these participants were randomized by block of families using a randomized number generated by an independent statistician (who was not part of the research team). Inclusion criteria for the study were: a) being over 18 years of age, b) having a family member diagnosed with BPD according to the Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition (DSM-5); c) having the ability to understand and read Spanish and provide informed consent.

The sample size was calculated from effect sizes from studies with caregivers of people with BPD. A controlled study by Grenyer et al. (2019) found medium to large effect sizes (dyadic adjustment, d = 0.78; family empowerment, d = 1.4) in a psychoeducational group for caregivers of people with BPD. In addition, in this study, another measure that appears is burden of illness, where significant improvements were obtained between post-treatment and 12-month follow-up, with medium effect sizes (burden, d = 0.45). Moreover, these results are in line with other studies on psychological interventions for other mental disorders. An example is a meta-analysis of different psychological interventions for caregivers of people with bipolar disorders (Burden, g = -.80) (Baruch et al., 2018). Based on these results, we can expect an effect size of 0.60 because the study design has two experimental conditions. Considering an alpha of 0.05 and a statistical power of 0.80 in a two-tailed t-test, we would need a total sample size of 90 participants (45 participants per group). However, being conservative about dropouts, and given that a dropout rate of 29% is expected based on the literature on treatments for family members of people with BPD (Flynn et al., 2017; Hoffman et al., 2005; Pearce et al., 2017; Rajalin et al. 2009; Regalado et al., 2011), the total sample size should contain at least 116 participants (58 for each experimental condition). Sample size calculations were performed using the G*Power 3.1 software (Faul et al., 2007).

Interventions

The FC program is one of the pioneer programs designed for family members of people with BPD. This program arises from the adaptation of multiple strategies of DBT, the most empirically supported treatment for people with BPD (Flynn et al., 2017; Stoffers et al., 2012). This program is divided into six modules with two sessions each (12 sessions in all), and each session lasts two hours. The FC intervention protocol is explained in a manual for caregivers (Hoffman et al., 2005) that our research team translated and adapted to Spanish in collaboration with the Puerto Rican research group headed by Dr. Domingo Marqués. Experts on both DBT (Linehan et al., 1993, 2015) and the FC program carried out this translation. In addition to the manual, the videos that support the program were also translated (Spanish subtitles). The TAU intervention consists of 12 sessions lasting 2 hours each. This program was created by the clinical center, and for the most part, it consists of psychoeducation sessions of BPD and all that it encompasses as well as family management guidelines. Table 1 describes the objectives and contents of each session in the two experimental conditions.

Table 1. Content of Interventions (Family Connections and Treatment As Usual)

	Theme	**Goals**	**Content**
Family Connections	**Module 1:** Introduction	Introduction to the aims of the program and the guidelines, as well as brief information about BPD.	• Commitment to participate in the program. • Information about the program and the guidelines. • Family members' rights. • Research on FC. • Symptoms and criteria of BPD. • Emotional Dysregulation Model by Linehan (1993). • Basic assumptions to be effective. • Videos and Homework.
	Module 2: Family Education	Providing information on aspects related to BPD.	• Updated information about BPD. • Treatment settings for BPD. • Types of treatment for BPD. • Comorbidity with other mental disorders. • Study of Expressed Emotions. • Biosocial Model of BPD. • Stigma. • Transactional Developmental Model of BPD and related disorders. • Videos and Homework.
	Module 3: Relationship Mindfulness Skills	Learning to be mindful with personal relationships and	• Definition of a validating environment. • Education about Relationship Mindfulness. • "What" and "How" techniques. • States of mind.

		emotion regulation strategies.	• Education about Emotions. • Emotion regulation strategies. • Decreasing emotional vulnerability and emotional reactivity. • Opposite Action strategy. • Videos and Homework.
	Module 4: Family Environment Skills	Understanding the relationship between individual and family well-being, as well as correcting maladaptive ways of thinking about blame. Additionally, learning how to practice radical acceptance.	• Relationship between individual and family well-being. • The blame game. • Transactional process. • Dialectic tensions. • Basic assumptions to be effective. • Radical Acceptance. • Videos and Homework.
	Module 5: Validation Skills	Understanding what validation is and learning validation and self-validation skills. Also, an introduction to interpersonal efficacy.	• Definition of validation. • Types of validation. • Validation aims. • Levels of validation. • Warning signs of invalidation. • How to validate. • Definition of self-invalidation. • Self-validating skills. • Observing your limits. • Interpersonal Efficacy. • DEAR MAN, GIVE, and FAST strategies. • Videos and Homework.
	Module 6: Problem Management Skills	Learning interpersonal efficacy strategies and problem management skills.	• Finding the right time. • Definition of the “problem”. • 8 steps of problem management. • Chain analysis. • Goals to change something you did. • 3 steps to True Acceptance. • Videos and Homework.
Treatment As Usual	**Module 1:** Introduction	Providing an overview of the treatment and goals of the group as well as information on personality disorders, their clinical features, and comorbidity with BPD.	• Definition and types of Personality Disorders. • Definition of BPD. • Evolution of BPD. • Comorbidity with other mental disorders. • Information about alcohol and other drugs related to BPD.
	Module 2: Family Education	Information about the biosocial model of emotion dysregulation and treatment for BPD.	• Biosocial Model of Emotion Dysregulation by Linehan (1993). • Types of treatment for BPD.
	Module 3: Validation	Understanding the difference between validating and invalidating environments	• Definition of an invalidating environment. • 5 key messages of validation.
	Module 4: Crisis Management Skills	Preventing crises by managing anger skills and learning how to manage self-injuring and suicidal behaviors.	• Definition of crises. • Anger management. • Education about self-injuring and suicidal behaviors. • Self-injuring and suicidal behavior skills.
	Module 5: Problem Management	Learning problem management skills and setting limits.	• Information about problem management of people with BPD. • Guide to confronting an unacceptable problem.
	Module 6: Relapse Prevention	Strengthening the strategies learned throughout the program and preventing relapses.	• Recall learned skills and resolve doubts. • Schedule future practice. • Teach the participants how to identify and cope with future high-risk situations.

Measurement and Instruments

Caregiver Measurements (participants)

Sociodemographic interview

Demographic variables questionnaire: age, genogram, sex, educational level, income, marital status, number / age of children, and psychiatric history.

Primary Outcomes Measures

Burden assessment scale (BAS) (Horwitz & Reinhard, 1992).

This instrument is composed of 19 items that measure the objective and subjective burden of caregivers of people with illnesses in the past 6 months. Items are rated on a 4-point Likert scale (1-4). Higher scores show higher levels of burden. Cronbach's alpha has been shown to be between .89 and .91, and it has adequate validity (Reinhard et al., 1994).

Family assessment device – global functioning scale (FADGFS) (Epstein et al., 1983).

This scale is composed of 60 items on family functioning, divided into the following subscales: Problem Solving, Communication, Roles, Affective Responsiveness, Affective Involvement, Behavioral Control, and General Functioning. The internal consistency is good (Cronbach's alphas between .72 and .83) for the subscales, with a Cronbach's alpha of .92 for general functioning. In addition, test-retest reliability is adequate (Miller et al., 1985).

Secondary Outcomes Measures

Depression, anxiety and stress scale (DASS-21) (Lovibond & Lovibond, 1995).

It consists of 42 items about psychological symptoms such as depression, anxiety, and stress. We used the short version, DASS-21, which shows excellent internal consistency: depression ($\alpha = .94$), anxiety ($\alpha = .87$), and stress ($\alpha = .91$) (Antony et al., 1998). We used the Spanish validation by Daza, Novy, Stanley and Averill (Daza et al., 2002).

Family empowerment scale (FES) (Koren et al., 1992).

This 34-item scale measures family empowerment and mastery (attitudes, knowledge, and behaviors) through three subscales: family, service system, and community participation. Items are rated on a 5-point Likert scale (1-5), and higher scores indicate a greater feeling of empowerment. Internal consistency ranged from .87 to .88, and validity was adequate.

Multicultural Quality of Life Index (MQLI) (Mezzich et al., 2000).

This 10-item questionnaire measures perceived quality of life (physical and emotional well-being, self-care and independent functioning, occupational and interpersonal functioning, social-emotional and community support, personal and spiritual fulfilment, and an overall perception of quality of life). Higher scores indicate higher quality of life. The internal consistency is good (Cronbach's alpha of .89), and test-retest reliability is high (r = .87).

Difficulties in Emotion Regulation Scale (DERS) (Hervás & Jódar, 2008).

The Spanish validation was used, with a reduction in the number of items from the original questionnaire (from 36 to 28 items). It consists of five subscales: lack of emotional control, vital interference, lack of emotional attention, emotional confusion, and emotional rejection. Items are rated on a Likert-type scale from 1 to 5 (1 = "Almost never" and 5 "Almost always". Higher scores indicate greater difficulties with emotion regulation. Psychometric properties were adequate with very good internal consistency (α = .93) and good test-retest reliability (pl = .74, p < .001).

The Connor-Davidson Resilience scale (CD-RISC) (Connor & Davidson, 2003).

This 25-item scale is measured with a 5-point Likert scale (0-4), with higher scores reflecting greater resilience. Items on resilience consisted of personal competence, trust in one’s instinct, tolerance of negative affect, positive acceptance of change, control, and spiritual influences. This scale has adequate psychometric properties, with a Cronbach's alpha of .89.

Patient Measures

Sociodemographic interview

Demographic variables questionnaire: age, genogram, sex, educational level, income, marital status, number / age of children, and psychiatric history.

Family Assessment Device – Global Functioning Scale (FAD-GFS) (Epstein et al., 1983).

Depression, Anxiety and Stress Scale (DASS-21) (Lovibond & Lovibond, 1995).

Difficulties in emotion regulation scale – Spanish version (DERS) (Hervás & Jódar, 2008).

Lum emotional availability of parents (LEAP) (Lum & Phares, 2005).

This 15-item questionnaire measures the emotional availability of mothers and fathers as perceived by the person assessing their relatives. Items are rated on a 6-point Likert scale (1 = never and 6 = always. The psychometric properties are very good, and for a clinical sample, excellent internal consistency is observed (mother an α = .92 and for father an α = .93). In addition, the questionnaire shows adequate test-retest reliability for the mother's form (r = .92) and the father's form (r = .85).

Validating and invalidating responses scale (VIRS) (Fruzzetti, 2007).

This is a 16-item scale that assesses the levels of perceived validation and invalidation in family members' responses divided into two subscales (validating and invalidating responses). The items are rated on a 5-point Likert scale (0 = never and 4 = almost always). Higher scores indicate greater perceived validation or invalidation in the responses of the caregiver being assessed.

Therapists and Treatment Fidelity

Eight psychologists participated in this study. They all had at least a master's degree in Clinical Psychology, and four of them had a Ph.D. in psychology as well. They all had training and extensive experience with DBT, and they had received specific training on the FC program.

Ethical Consideration

The randomized clinical trial was registered on clinicalstrial.gov as NCT04160871 on November 15, 2019. For protection of data of study participants, this research followed the Declaration of Helsinki Guidelines and guidelines existing in both Spain and the European Union. This study was approved by the Ethics Committee of the University of Valencia (Valencia, Spain). For participant recruitment, qualified clinicians explained the study to the family members, who signed an informed consent form expressing their agreement to participate voluntarily and acknowledging that they could leave the study at any time they wished.

In addition, participants who dropped out of the trial due to unwanted events were offered the opportunity to participate in groups at another time. For the protection of personal data, data were collected by the investigators on this team, and identification data were replaced with codes. These data were separated from other data, and they were only available to the principal investigators of the study, in order to protect the participants' confidentiality and privacy.

Statistical Methods

Separate statistical analyses were performed for caregivers and patients. For caregivers, due to the existence of statistical dependence between members of the same family, mixed-effects two-way ANOVAs were carried out to check whether the FC and TAU groups were balanced on the dependent variables at pretest. In these analyses, the dependent variable was the score on the pretest, the fixed-effects factor was the type of treatment (FC vs. TAU), and the random-effects factor was the family. To compare the effectiveness of the two treatment conditions, mixed-effects, two-way ANCOVAs were performed. In these analyses, the dependent variable was the score on the posttest, the covariate was the score on the pretest, the fixed-effects factor was the type of treatment (FC vs. TAU), and the random-effects factor was the family. In addition, pretest-posttest change in each treatment group was assessed by applying dependent-samples t-tests.

For patients, independent-samples t-tests were carried out to check whether the two treatment groups were balanced on the pretest. To compare the effectiveness of the two treatments, one-way ANCOVAs were used. In these analyses, the dependent variable was the score on the posttest, the covariate was the score on the pretest, and the fixed-effects factor was the type of treatment (FC vs. TAU). In addition, the pretest-posttest change in each treatment group was assessed by performing dependent-samples t-tests.

Both for caregivers and patients, statistical significance tests were complemented by calculating effect sizes. In particular, several versions of Cohen's d were applied. For comparisons between the two treatments, standardized mean differences were calculated, taking the means of the FC and TAU groups. To test the pretest-posttest improvements in each treatment group, standardized mean differences were calculated, taking the pretest and posttest means. For ANCOVAs, the standardized mean differences were calculated using the adjusted means of the FC and TAU groups. In all cases, d values of about 0.20, 0.50, and 0.80 (in absolute values) were assessed as exhibiting small, moderate, and large clinical significance, respectively. Cohen's ds for independent-samples comparisons were calculated, so that positive ds indicated better performance of the FC group than TAU group, and vice versa. Cohen's ds for dependent-samples comparisons were calculated, so that positive values indicated better performance on the posttest than on the pretest, and vice versa.

RESULTS

The research team recruited 121 participants who met the eligibility criteria, signed the informed consent, completed the baseline measures, and were randomized into one of the two study conditions. Of them, 89 relatives participated in the two interventions, with the total losses from pretreatment to posttreatment reaching 26.45%. The follow-up sample consisted of 37 family members (FC = 25 and TAU = 12), with the total losses from post-treatment to six-month follow-up reaching 41.57%.

Characteristics of Study Participants

Demographics and baseline characteristics of caregivers are shown in Table 2. Most of the relatives were primary caregivers (70.2% of the FC group, and 73.8% of the TAU group) and women (64.9% of the FC group, and 58.3% of the TAU group), which coincides with the general profile of caregivers of people with mental illness. The mean age was 56.89 years in the FC group and 56.69 years in the TAU group. Most of the relatives had a qualified job and upper education and were married. Most of them did not have a diagnosis of a mental disorder.

Table 2. Characteristics of study participants (N=89).

Variable	FC group (n=47)	TAU group (n=42)	Statistical test
Primary caregiver, n (%)			$\chi^2(1) = 0.14$, $p = .706$

Yes	33(70.2)	31(73.8)	
No	14(29.8)	11(26.2)	
Caregiver gender, n (%)			$\chi^2(1) = 0.33$, $p = .566$
Man	13(35.1)	15(41.7)	
Woman	24(64.9)	21(58.3)	
Caregiver occupation, n (%)			$LR(6) = 3.88$, $p = .693$
Qualified job	17(45.9)	21(60)	
Non-qualified job	7(18.9)	3(8.6)	
Unemployed	3(8.1)	4(11.4)	
Retired	7(18.9)	5(14.3)	
Student	1(2.7)	1(2.9)	
Disabled	1(2.7)	0(0)	
Housekeeper	1(2.7)	1(2.9)	
Caregiver education, n (%)			$LR(3) = 7.22$, $p = .065$
Primary	6(16.2)	14(38.9)	
Secondary	11(29.7)	7(19.4)	
Higher	18(48.6)	15(41.7)	
No studies	2(5.4)	0(0)	
Caregiver marital status, n (%)			$LR(4) = 6.74$, $p = .150$
Single	3(8.1)	0(0)	
Couple	0(0)	1(2.8)	
Married	25(67.6)	28(77.8)	
Divorced	8(21.6)	5(13.9)	
Widowed	1(2.7)	2(5.6)	
Diagnosis Axis I, n (%)			$LR(4) = 3.33$, $p = .505$
No diagnosis	26(83.9)	28(84.4)	
Bipolar & related	0(0)	1(3)	
Depression	2(6.5)	3(9.1)	
Anxiety	2(6.5)	1(3)	
More than one	1(3.2)	0(0)	
Diagnosis Axis II, n (%)			$LR(4) = 4.52$, $p = .211$
No diagnosis	27(90)	32(100)	
Borderline	1(3.3)	0(0)	
Dependent	1(3.3)	0(0)	
More than one	1(3.3)	0(0)	
Interference with health[a]	34.65	32.35	$U = 506.50$, $p = .617$
Interference with family[a]	32.44	34.56	$U = 579.50$, $p = .647$
Age (years)[b]	56.89(10.50)	56.69(9.15)	$t(71) = 0.089$, $p = .932$

χ^2 = statistic for testing differences between FC and TAU groups. *LR* = likelihood ratio statistical test. *U* = independent-samples Mann-Whitney statistic. [a]Values for FC and TAU groups are the mean ranks.

[b]Values for FC and TAU groups are the means (and standard deviations). *t* = independent *t*-test for comparing means.

For patients, the demographic characteristics are shown in Table 3. Most of the patients were women (85% of the FC group, and 81.8% of the TAU group), and the mean age was 30.80 years in the FC group and 29.09 in the TAU group. We can observe differences in occupation and education between groups, but they are not significant. Most of them had BPD as a single diagnosis (80% in the FC group and 95.5% in the TAU group), but 20% of the FC group and 4.5% of the TAU group had more than one personality diagnosis, including BPD.

Table 3. Characteristics of patients (N=42).

Variable	FC group (n=20)	TAU group (n=22)	Statistical test
Patient gender, n (%)			*LR*(1) = 0.08, *p* = .782
Man	3(15)	4(18.2)	
Woman	17(85)	18(81.8)	
Patient occupation, n (%)			*LR*(4) = 8.52, *p* = .074
Qualified job	1(7.7)	1(6.7)	
Non-qualified job	1(7.7)	0(0)	
Unemployed	1(7.7)	8(53.3)	
Student	6(46.2)	4(26.7)	
Disabled	4(30.8)	2(13.3)	
Patient education, n (%)			*LR*(3) = 2.89, *p* = .408
Primary	3(23.1)	1(6.7)	
Secondary	6(46.2)	9(60)	
Higher	4(30.8)	4(26.7)	
No studies	0(0)	1(6.7)	
Patient marital status, n (%)			*LR*(2) = 4.01, *p* = .135
Single	9(69.2)	10(66.7)	
Couple	2(15.4)	0(0)	
Married	2(15.4)	5(33.3)	
Diagnosis Axis I, n (%)			*LR*(7) = 5.54, *p* = .594
No diagnosis	9(56.3)	10(47.6)	
Schizophrenia & related	1(6.3)	0(0)	
Bipolar & related	0(0)	1(4.8)	
Depression	1(6.3)	2(9.5)	
Trauma & stress	1(6.3)	0(0)	

Eating disorders	1(6.3)	2(9.5)	
Substances	1(6.3)	1(4.8)	
More than one	2(12.5)	5(23.8)	
Diagnosis Axis II, n (%)			*LR*(1) = 2.51, *p* = .113
BPD	16(80)	21(95.5)	
More than one	4(20)	1(4.5)	
Diagnosis cluster, n (%)			*LR*(1) = 2.51, *p* = .113
BPD	16(80)	21(95.5)	
Cluster B	4(20)	1(4.5)	
Toxic use, n (%)			*LR*(1) = 0.31, *p* = .580
Yes	3(21.4)	4(30.8)	
No	11(78.6)	9(69.2)	
Hospital admissions[a]	12/1.25/1.49	12/2.00/2.99	*t*(22) = -0.78, *p* = .444
Suicide attempts[a]	8/5.25/10.17	12/2.42/3.06	*t*(18) = 0.92, *p* = .372
Self-injury last year[a]	8/2.88/2.90	12/6.75/12.05	*t*(18) = -0.89, *p* = .388
Age (years)[a]	20/30.80/13.63	22/29.09/11.54	*t*(40) = 0.44, *p* = .662

χ^2 = statistic for testing differences between FC and TAU groups. *LR* = likelihood ratio statistical test. *U* = independent-samples Mann-Whitney statistic. [a]Values for FC and TAU groups are sample size/mean/standard deviation. the mean ranks. [b]Values for FC and TAU groups are the means (and standard deviations). *t* = independent *t*-test for comparing means.

ANOVA linear mixed models in Caregivers

The following results consist of the pretest comparisons of the two groups on all the analyzed measures presented in Table 4. The unit of analysis chosen is the caregiver (primary or not) because there could be more than one caregiver for the same patient. Therefore, a two-factor mixed-effects ANOVA was performed through the application of intention-to-treat analyses. These analyses were performed taking the condition (FC or TAU) as the fixed-effects factor, the family as the random-effects factor, and the pretest scores as the dependent variable, in order to consider the statistical dependence that arises from including more than one family member per patient. No statistically significant differences were observed between the two groups. In addition, the standardized mean difference (Cohen's *d*) between the pretest means was calculated. The results show a trend in the experimental group with a positive sign, which means that, on average, the FC group had better pretest scores than the TAU group. Some of the variables have a Cohen's d score equal to or higher than 0.20, which would indicate a difference between the means with some practical relevance. These measures refer to general functioning (*d* = 0.24), quality of life (*d* =

0.23), emotional inattention (*d* = 0.36), and emotional confusion (*d* = 0.23). On some of the study variables, we observed a significant discrepancy between the pretest means (although there were no statistically significant differences). This imbalance led us to perform ANCOVAs, choosing the pretest variable as covariate.

Table 4. Caregivers' results on the Pretest: ANOVA linear mixed models.

	FC		TAU				
Outcome	Mean	*SE*	Mean	*SE*	*F*	*p*	Cohen's *d*
BAS							
Objective Dimension	2.269	0.116	2.365	0.118	0.329	.566	0.10
Subjective Dimension	2.230	0.109	2.329	0.112	0.402	.526	0.12
Disrupted Activities	2.420	0.124	2.484	0.126	0.134	.714	0.07
Personal Distress	1.704	0.134	1.872	0.137	0.762	.383	0.16
Time Perspective	2.782	0.111	2.852	0.112	0.189	.664	0.08
Guilt	2.202	0.138	2.255	0.141	0.071	.790	0.05
Basic Social Functioning	2.119	0.135	2.238	0.134	0.388	.533	0.11
Total	41.869	1.948	43.927	1.983	0.549	.459	0.13
FAD-GFS							
Problem Solving	2.170	0.089	2.126	0.082	0.133	.715	-0.07
Communication	2.300	0.054	2.297	0.055	0.002	.969	-0.01
Role	2.446	0.053	2.521	0.053	1.000	.317	0.18
Affective Response	2.056	0.085	2.139	0.085	0.482	.488	0.13
Affective Involvement	2.029	0.070	2.167	0.069	1.985	.159	**0.26**
Behavioral Control	2.028	0.065	2.103	0.061	0.706	.401	0.15
General Functioning	2.064	0.063	2.184	0.064	1.753	.185	**0.24**
Total	15.086	0.311	15.531	0.319	0.996	.318	0.18
DASS-21							
Stress	0.951	0.134	0.968	0.116	0.009	.925	0.02
Depression	0.681	0.096	0.778	0.096	0.506	.477	0.13
Anxiety	0.547	0.087	0.480	0.089	0.287	.592	-0.10
Total	2.180	0.262	2.203	0.266	0.004	.951	0.01
FES							
Family	40.754	1.135	40.024	1.159	0.203	.652	0.08
Service System	38.557	1.200	39.819	1.229	0.540	.462	-0.13
Communication/Political	23.241	0.966	22.936	0.992	0.048	.826	0.04
Total	102.644	3.029	102.832	3.094	0.002	.965	-0.01

MQLI	68.024	2.460	63.714	2.375	1.560	.213	**0.23**
DERS							
Emotional Refusal	13.095	0.870	13.856	0.876	0.381	.537	0.11
Emotional Dyscontrol	14.824	0.820	15.601	0.851	0.433	.511	0.12
Emotional Interference	9.798	0.537	9.255	0.558	0.491	.483	-0.13
Emotional Inattention	8.882	0.514	10.326	0.526	3.857	**.050**	**0.36**
Emotional Confusion	7.172	0.427	7.954	0.442	1.621	.203	**0.23**
Total	53.692	2.338	57.069	2.429	1.004	.316	0.18
CD-RISC	2.659	0.077	2.561	0.078	0.803	.370	0.16

FC = Family Connections group. TAU = Treatment As Usual group. *SE* = standard error of the mean. *F* = mixed-effects ANOVA *F*-statistic for testing the statistical significance between FC and TAU groups on the pretest. Cohen's *d* = standardized mean difference between FC and TAU groups on the pretest. Positive *d* values indicate a better level for the FC group on the pretest; and vice versa. In bold type, *d* indices equal to or larger than 0.20 (in absolute value) are highlighted, as well as statistically significant *p* values ($p \leq .05$). Sample size for FC group = 63. Sample size for TAU group = 58.

Pretreatment to Posttreatment Effects in Caregivers

Dependent means comparison t-tests for each group separately evaluated the changes from pretest to posttest, and the results are shown in Table 5. In addition, Cohen's d for dependent samples was also calculated by comparing the pretest and posttest means.

Regarding the FC group, the results show a statistically significant improvement from pretest to posttest on the measures of burden ($p < .001$), depression, anxiety, and stress ($p = .031$), family mastery and empowerment ($p < .001$), and emotion regulation ($p = .047$). No significant improvements were found in global family functioning, quality of life, or resilience. In contrast, the results for the TAU group were statistically significant for the quality of life measure ($p = .006$) and communication/political of family mastery and empowerment ($p = .009$). However, some variables that did not reach statistical significance in the TAU group obtained clinically relevant Cohen's ds, such as measures of depression, anxiety, and stress ($d = 0.23$), family mastery and empowerment ($d = 0.22$), and emotion regulation ($d = 0.24$).

Table 5. Results for caregivers: Pretest – Posttest change in each treatment group.

	Pretest-Posttest change for FC			Pretest-Posttest change for TAU		
Outcome	*t*	*p*	*d*	*t*	*p*	*d*
BAS						
Objective Dimension	2.660	**.008**	**0.34**	-0.100	.921	-0.01
Subjective Dimension	3.378	**< .001**	**0.43**	0.983	.329	0.13
Disrupted Activities	3.273	**.001**	**0.41**	0.002	.998	0.00
Personal Distress	2.103	**.047**	**0.26**	0.240	.812	0.03
Time Perspective	2.683	**.008**	**0.34**	1.407	.161	0.18
Guilt	2.637	**.009**	**0.33**	0.850	.396	0.11
Basic Social Functioning	1.528	.129	0.19	-0.186	.853	-0.02
Total	3.579	**< .001**	**0.45**	0.465	.642	0.06
FAD-GFS						
Problem Solving	0.181	.861	0.02	0.027	.980	0.00
Communication	0.887	.376	0.11	-0.567	.575	-0.07
Role	1.459	.145	0.18	0.956	.343	0.13
Affective Response	0.364	.717	0.05	0.133	.895	0.02
Affective Involvement	0.250	.804	0.03	0.402	.689	0.05
Behavioral Control	0.935	.356	0.12	0.955	.351	0.13
General Functioning	1.379	.175	0.17	0.947	.344	0.12
Total	1.342	.188	0.17	0.731	.467	0.10
DASS-21						
Stress	1.180	.264	0.15	1.412	.160	0.19
Depression	1.769	.079	**0.22**	1.449	.148	0.19
Anxiety	1.654	.103	**0.21**	1.273	.204	0.17
Total	2.197	**.031**	**0.28**	1.782	.075	**0.23**
FES						
Family	-4.514	**< .001**	**0.57**	-1.430	.154	0.19
Service System	-3.889	**< .001**	**0.49**	-0.239	.811	0.03
Communication/Political	-5.109	**< .001**	**0.64**	-2.632	**.009**	**0.35**
Total	-5.486	**< .001**	**0.69**	-1.710	.087	**0.22**
MQLI	-1.026	.337	0.13	-2.765	**.006**	**0.36**
DERS						
Emotional Refusal	1.509	.136	0.19	1.241	.221	0.16
Emotional Dyscontrol	0.807	.420	0.10	1.034	.301	0.14

Emotional Interference	2.915	**.004**	**0.37**	0.831	.407	0.11
Emotional Inattention	0.493	.623	0.06	0.778	.437	0.10
Emotional Confusion	1.566	.117	**0.20**	1.794	.073	**0.24**
Total	1.985	**.047**	**0.25**	1.842	.065	**0.24**
CD-RISC	-1.650	.110	**0.21**	-0.188	.853	0.02

FC = Family Connections group. TAU = Treatment As Usual group. t = t statistic for testing the statistical significance of the pretest-posttest change scores for each group. p = probability level of the t statistic. d = Cohen's d for within-group pretest-posttest change scores. In bold type, statistically significant p values are highlighted ($p \leq .05$), as well as d values equal to or larger than 0.20 (in absolute value). Sample size for the FC group = 63. Sample size for the TAU group = 58.

Effectiveness of Family Connections: ANCOVA linear mixed models

The main results of the randomized clinical trial are shown in two-factor mixed-effects ANCOVAs performed on the caregivers' data. In each ANCOVA, the treatment condition has been included as a fixed effects factor, the family as a random effects factor (considering the statistical dependence produced by the fact that some caregivers are from the same family or patient), the scores on the posttest as a dependent variable, and the scores on the pretest as covariate. These results are shown in Table 6. This table shows the adjusted means (by the pretest) on the posttest, in addition to the adjusted standard deviations, as well as the results of the F-test, which assesses whether there are statistically significant differences between the adjusted posttest means of the two conditions (FC and TAU), along with their p- value.

Regarding the significant results for the experimental group, the analyses indicate that family members in the FC group obtained significant scores on the measures of burden (p = .028), family mastery and empowerment (p = .002), and the emotional inattention subscale of emotion regulation (p = .013). No significant results were found between groups on global family functioning, depression, anxiety and stress, quality of life, emotion regulation, or resilience.

The Cohen's d results indicate that the FC group scored better, on average, on the posttest than the TAU group. In addition, the calculation of Cohen's *d* shows that, although some variables did not become statistically significant, the Cohen's *d* result indicates clinical relevance when it is above .20. That is, due to lack of statistical power, the *F* did not reach statistical significance, but there was a clinically relevant effect in favor of FC on the variables indicated.

Table 6. Caregivers' results on the Posttest: ANCOVA linear mixed models.

	FC		TAU				
Outcome	Mean	*SE*adj	Mean	*SE*adj	*F*	*p*	Cohen's *d*
BAS							
Objective Dimension	1.986	0.107	2.359	0.136	4.550	**.037**	**0.39**
Subjective Dimension	1.901	0.107	2.176	0.116	3.024	.084	**0.32**
Disrupted Activities	2.060	0.130	2.471	0.160	3.671	.061	**0.35**
Personal Distress	1.457	0.141	1.806	0.162	2.667	.113	**0.30**
Time Perspective	2.422	0.124	2.638	0.128	1.638	.201	**0.23**
Guilt	1.828	0.143	2.097	0.145	1.677	.198	**0.34**
Basic Social Functioning	1.915	0.123	2.242	0.135	3.371	.070	**0.33**
Total	36.103	1.895	42.444	2.002	4.906	**.028**	**0.40**
FAD-GFS							
Problem Solving	2.117	0.285	2.122	0.286	0.000	.988	0.00
Communication	2.240	0.069	2.337	0.084	0.841	.363	0.17
Role	2.360	0.052	2.449	0.064	1.044	.314	0.19
Affective Response	2.029	0.083	2.108	0.088	0.394	.534	0.11
Affective Involvement	2.012	0.096	2.117	0.082	0.764	.388	0.16
Behavioral Control	1.975	0.067	2.006	0.096	0.080	.780	0.05
General Functioning	1.972	0.068	2.104	0.062	2.421	.120	**0.28**
Total	14.723	0.317	15.236	0.306	1.538	.217	**0.23**
DASS-21							
Stress	0.659	0.183	0.727	0.132	0.079	.782	0.05
Depression	0.491	0.087	0.614	0.093	0.994	.320	0.18
Anxiety	0.372	0.078	0.350	0.075	0.038	.846	-0.04
Total	1.517	0.211	1.695	0.204	0.350	.554	0.11
FES							
Family	46.112	0.979	41.524	1.018	11.263	**< .001**	**0.61**
Service System	42.785	0.974	39.820	1.047	4.235	**.040**	**0.37**
Communication/Political	28.039	0.920	25.294	0.964	4.223	**.040**	**0.37**
Total	117.122	2.451	106.613	2.490	9.236	**.002**	**0.55**
MQLI	72.969	4.420	72.045	2.899	0.032	.859	0.03

DERS							
Emotional Refusal	11.734	0.879	12.732	0.941	0.556	.459	0.14
Emotional Dyscontrol	14.163	0.724	14.808	0.739	0.387	.534	0.11
Emotional Interference	8.438	0.435	8.756	0.482	0.262	.609	0.09
Emotional Inattention	8.509	0.442	10.096	0.451	6.190	**.013**	**0.45**
Emotional Confusion	6.476	0.354	7.152	0.363	1.740	.187	**0.24**
Total	49.345	1.967	53.428	2.033	2.068	.151	**0.26**
CD-RISC	2.870	0.128	2.588	0.152	1.899	.181	**0.25**

FC = Family Connections group. TAU = Treatment As Usual group. M_{adj} = adjusted mean on the posttest (adjusted as a function of the pretest). SE_{adj} = adjusted standard error of the mean. F = mixed-effects ANCOVA F-statistic for testing statistical significance between FC and TAU groups on the posttest. Cohen's d = adjusted standardized mean difference between FC and TAU groups on the posttest. Positive d_{adj} values indicated a better level for the FC group on the posttest, and vice versa. In bold type, d_{adj} indices equal to or larger than 0.20 are highlighted (in absolute value). In bold type, statistically significant p-values are highlighted ($p < .05$). Sample size for the FC group = 63. Sample size for the TAU group = 58.

Follow-up Effects

At 6-month follow-up, data on the variables were obtained from 37 participants (FC = 25; TAU = 12), representing a loss of 41.57% of the participants with respect to post-treatment. With this high percentage of loss, the use of missing data imputation methods is discouraged (Jakobsen et al., 2017), and so analyses were performed using the completers' data.

The main results of the follow-ups are shown, comparing the two groups (FC and TAU), where the unit of analysis is the caregiver. Because there can be more than one caregiver for the same patient, a two-factor mixed-effects ANCOVA was performed to resolve statistical dependence, taking the group (FC vs. TAU) as fixed-effects factor, the family as random-effects factor, the pretest scores as covariate, and the follow-up scores as the dependent variable. Table 7 shows that, after controlling for pretest scores, the FC group with completers' data exhibited a better result than the TAU group on all the variables except the burden variable.

Table 7. Caregivers' results in the Follow-up: ANCOVA linear mixed models.

	FC		TAU				

Outcome	*n*	M_{adj}	SE_{adj}	*n*	M_{adj}	SE_{adj}	*F*	*p*	Cohen's d_{adj}
BAS									
Objective Dimension	25	1.591	0.169	12	1.911	0.224	1.302	.264	**0.40**
Subjective Dimension	25	1.644	0.168	12	1.966	0.224	1.320	.260	**0.40**
Disrupted Activities	25	1.642	0.182	12	1.987	0.243	1.298	.265	**0.40**
Personal Distress	25	1.292	0.168	12	1.804	0.226	3.293	.081	**0.64**
Time Perspective	25	2.010	0.192	12	2.147	0.256	0.184	.671	0.15
Guilt	25	1.630	0.201	12	1.946	0.266	0.900	.351	**0.33**
Basic Social Functioning	25	1.537	0.174	12	1.835	0.232	1.058	.313	**0.36**
Total	25	30.400	3.013	12	36.624	3.991	1.549	.224	**0.44**
FAD-GFS									
Problem Solving	24	1.954	0.102	12	2.213	0.135	2.348	.138	**0.54**
Communication	24	2.059	0.108	12	2.294	0.139	1.773	.194	**0.47**
Role	24	2.252	0.072	12	2.521	0.102	4.673	**.038**	**0.76**
Affective Response	24	1.700	0.101	12	2.196	0.140	8.243	**.009**	**1.01**
Affective Involvement	24	1.674	0.082	12	2.297	0.106	21.831	<	**1.64**
Behavioral Control	24	1.669	0.103	12	1.905	0.134	1.949	**.001**	**0.49**
General Functioning	24	1.646	0.100	12	2.174	0.132	10.100	.174	**1.12**
Total	24	12.940	0.543	12	15.609	0.711	8.896	**.004**	**1.05**
								.006	
DASS-21									
Stress	25	0.303	0.090	12	0.637	0.120	4.932	**.035**	**0.78**
Depression	25	0.280	0.114	12	0.588	0.151	2.652	.115	**0.57**
Anxiety	25	0.120	0.063	12	0.369	0.085	5.526	**.027**	**0.83**
Total	25	0.703	0.243	12	1.600	0.322	4.933	**.035**	**0.78**
FES									
Family	25	50.056	1.291	12	39.304	1.798	23.597	<	**1.71**
Service System	25	45.771	1.523	12	38.689	2.024	7.816	**.001**	**0.98**
Communication/Political	25	31.281	1.198	12	23.146	1.632	18.363	**.009**	**1.50**
Total	25	127.554	3.426	12	101.064	4.620	21.208	<	**1.62**
								.001	
								<	
								.001	
MQLI	25	78.274	2.369	12	65.725	3.374	9.263	**.006**	**1.07**
DERS									
Emotional Refusal	25	8.835	0.593	12	12.235	0.800	11.661	**.002**	**1.20**

Emotional Dyscontrol	25	10.320	0.492	12	13.667	0.711	14.985	<	**1.36**
Emotional Interference	25	6.240	0.577	12	7.917	0.833	2.737	**.001**	**0.58**
Emotional Inattention	25	6.312	0.534	12	12.145	0.721	42.273	.107	**2.28**
Emotional Confusion	25	4.633	0.336	12	6.913	0.463	15.864	<	**1.40**
Total	25	36.480	1.655	12	52.667	2.389	31.021	**.001**	**1.96**
								<	
								.001	
								<	
								.001	
CD-RISC	25	3.212	0.122	12	2.328	0.162	19.067	<	**1.53**
								.001	

FC = Family Connections group. TAU = Treatment As Usual group. *n* = sample size for FC and TAU groups. M_{adj} = adjusted means in the follow-up by the pretest. SE_{adj} = adjusted standard error of the mean. *F* = mixed-effects ANCOVA *F*-statistic for testing statistical significance between FC and TAU groups in the follow-up. Cohen's d_{adj} = adjusted standardized mean difference between FC and TAU groups in the follow-up. Positive *d* values indicated a better level for the FC group in the follow-up; and vice versa. In bold type, d_{adj} indices equal to or larger than 0.20 (in absolute value) and statistically significant *p* values ($p \leq .05$), are highlighted.

Table 8 shows the analysis of the results, for each group separately, of the t-tests for the comparison of dependent means to evaluate pretest-follow-up changes. In the FC group, statistically significant improvements were found in all the variables. In the TAU group, statistically significant improvements were found in the time and perspective of disease burden, depression, anxiety and stress, quality of life, and emotion regulation.

Table 8. Caregivers' results: Pretest – Follow-up change for each treatment group.

	Pretest-Follow-up change for FC			Pretest-Follow-up change for TAU		
Outcome	*t*	*p*	*d*	*t*	*p*	*d*
BAS	5.334	< **.001**	**1.07**	1.263	.233	**0.37**
FAD-GFS	3.271	**.003**	**0.67**	1.709	.115	**0.49**
DASS-21	3.683	**.001**	**0.74**	2.280	**.044**	**0.66**
FES	-4.595	< **.001**	**0.92**	-0.362	.724	-0.10
MQLI	-3.847	< **.001**	**0.77**	-2.611	**.024**	**0.75**
DERS	4.142	< **.001**	**0.83**	5.153	< **.001**	**1.49**
CD-RISC	-4.061	< **.001**	**0.81**	-0.402	.696	0.12

FC = Family Connections group. TAU = Treatment As Usual group. *t* = *t* statistic for testing the statistical significance of the pretest-follow-up change scores for each group. *p* = probability level of the *t* statistic. *d* = Cohen's *d* for within-group pretest-follow-up change scores. In bold type, statistically significant *p* values ($p \leq .05$) and *d* values equal to or larger than 0.20 (in absolute value) are highlighted. Sample size for the FC group = 25. Sample size for the TAU group = 12.

Patients Effects

Means and standard deviations on the pretest and posttest measures

The results shown in Table 9 contain the means and standard deviations on the pretest and posttest of the loved ones of the family members who participated in both treatment groups. There was a 56.1% sample loss from the pretest to the posttest.

Table 9. Means and standard deviations on the pretest and posttest measures.

	FC group					TAU group				
		Pretest		Posttest			Pretest		Posttest	
Outcome	*n*	Mean	*SD*	Mean	*SD*	*n*	Mean	*SD*	Mean	*SD*
FAD-GFS										
Problem Solving	17	2.35	0.63	2.31	0.53	19	2.61	0.45	2.53	0.50
Communication	17	2.51	0.47	2.27	0.61	19	2.66	0.37	2.54	0.42
Role	17	2.54	0.36	2.39	0.38	19	2.58	0.38	2.57	0.32
Affective Response	17	2.39	0.64	2.27	0.46	19	2.52	0.51	2.43	0.57
Affective	17	2.33	0.38	2.10	0.43	19	2.29	0.49	2.19	0.49
Involvement	17	2.16	0.40	1.99	0.38	19	2.28	0.48	2.21	0.41
Behavioral Control	17	2.29	0.54	2.09	0.38	19	2.35	0.40	2.23	0.51
General	17	16.58	2.59	15.43	2.16	19	17.30	1.90	16.71	2.06
Functioning										
Total										
DASS-21										
Stress	17	1.95	0.83	1.38	0.82	19	1.75	0.65	1.65	0.68
Depression	17	1.85	0.93	1.23	0.85	19	1.73	0.80	1.59	0.83
Anxiety	17	1.47	0.77	1.01	0.75	19	1.27	0.83	1.25	0.92
Total	17	5.27	2.34	3.61	2.12	19	4.76	1.92	4.50	2.14
DERS										
Emotional Refusal	17	26.71	9.76	24.70	10.01	19	23.48	7.04	19.79	7.25
Emotional	17	31.47	9.41	29.35	9.67	19	29.88	10.52	27.18	9.38
Dyscontrol	17	15.88	4.47	14.35	4.72	19	15.65	4.22	15.58	4.09
Emotional	17	14.94	3.65	14.76	3.54	19	14.00	4.16	13.95	3.58
Interference	17	11.71	2.42	11.59	2.72	19	11.24	2.44	10.96	2.66
Emotional	17	100.71	23.59	94.82	24.24	19	94.25	18.99	87.46	19.27
Inattention										
Emotional										
Confusion										
Total										
LEAP										
Mother	15	68.07	21.88	66.01	20.72	17	60.91	18.84	59.74	18.67
Father	13	53.23	30.32	53.38	26.02	16	50.80	21.41	53.79	21.40
Total	15	114.20	39.65	112.28	30.64	19	98.33	36.60	98.75	39.65
VIRS										
Validating	15	28.85	10.57	32.33	8.79	19	28.28	8.46	30.47	8.17
Invalidating	15	7.33	5.25	6.00	3.89	19	7.37	4.52	5.71	3.39

n = sample size for FC (Family Connections) and TAU (Treatment As Usual) groups. *SD* = standard deviation.

Pretreatment to Posttreatment Effects in Patients

The results of the patient measurements can be found in Table 10. For the analysis of the results, independent means comparison t-tests were performed between the FC and TAU groups on the pretest, and no statistically significant differences are observed on any dependent variable on the pretest. In addition, Cohen's d was also calculated between the means of the two groups on the pretest. The results indicate that, although no statistically significant differences were found, Cohen's d was found to be equal to or greater than .20, indicating an imbalance between the two groups on the pretest. These results can be observed in themeasures of global family functioning (*d* = 0.32), depression, anxiety, and stress (*d* = -0.24), emotion regulation (*d* = -0.30), and parental emotional availability (*d* = 0.42). This statistical imbalance leads to the application of ANCOVAs for the comparison of the two groups on the posttest by choosing the pretest variable as a covariate. In addition, the results of t-tests for comparison of means to evaluate the pretest - posttest change in each study group can be observed. Regarding the FC group, statistically significant differences are observed in depression, anxiety and stress (*p* = .005), the emotional interference subscale of the DERS (*p* =.028), and the validation subscale of the VIRS (*p* =.042). No statistically significant differences were found in global family functioning, emotion regulation, or parental emotional availability. However, the results of Cohen's d test indicate that, except for the LEAP scale, all the scores showed an improvement from pretest to posttest, despite not obtaining a statistically significant result. On the other hand, in the TAU group, a statistically significant result was observed on emotional refusal (*p* = .022). However, with the exception of the LEAP scale, all Cohen's *d*'s indicated improvement from pretest to posttest, although no statistically significant results were obtained.

Table 10. Pretreatment to Posttreatment Effects in Patients.

Outcome	Pretest between-groups difference			Pretest-Posttest change for FC			Pretest-posttest change for TAU		
	t	*p*	*d*	*t*	*p*	*d*	*t*	*p*	*d*
FAD-GFS									
Problem Solving	1.45	.156	**0.48**	0.26	.798	0.06	1.07	.297	**0.25**
Communication	1.08	.290	**0.36**	1.77	.097	**0.45**	1.09	.292	**0.25**
Role	0.33	.746	0.11	2.00	.063	**0.49**	0.04	.970	0.01
Affective	0.66	.513	**0.22**	1.02	.322	**0.25**	0.84	.413	0.19
Response	-0.24	.816	-0.08	2.05	.058	**0.50**	0.84	.413	0.19
Affective	0.77	.446	**0.26**	1.38	.188	**0.33**	0.82	.424	0.19
Involvement	0.37	.713	0.12	1.66	.116	**0.40**	1.31	.205	**0.30**

Behavioral	0.96	.343	**0.32**	1.72	.105	**0.42**	1.54	.142	**0.35**
Control									
General									
Functioning									
Total									
DASS-21									
Stress	-0.79	.438	**-0.26**	2.58	**.020**	**0.63**	0.77	.454	0.18
Depression	-0.39	.698	-0.13	2.69	**.016**	**0.65**	0.76	.458	0.17
Anxiety	-0.74	.464	**-0.25**	2.96	**.009**	**0.72**	0.17	.869	0.04
Total	-0.72	.480	**-0.24**	3.24	**.005**	**0.79**	0.74	.469	0.17
DERS									
Emotional Refusal	-1.13[a]	.270	**-0.38**	1.23	.236	**0.30**	2.52	**.022**	**0.58**
Emotional	-0.48	.636	-0.16	1.16	.263	**0.28**	1.64	.118	**0.38**
Dyscontrol	-0.16	.873	-0.05	2.43	**.028**	**0.59**	0.09	.931	0.02
Emotional	-0.72	.478	**-0.24**	0.19	.852	0.05	0.07	.944	0.02
Interference	-0.57	.574	-0.19	0.23	.822	0.06	0,40	.692	0.09
Emotional	-0.91	.370	**-0.30**	1.66	.117	**0.40**	1.79	.091	**0.41**
Inattention									
Emotional									
Confusion									
Total									
LEAP									
Mother	0.99	.328	**0.35**	-0.51	.621	-0.13	-0.23	.823	-0.06
Father	0.25	.802	0.09	0.03	.977	0.01	1.18	.258	**0.29**
Total	1.21	.235	**0.42**	-0.26	.802	-0.07	-0.08	.939	-0.02
VIRS									
Validating	0.17	.864	0.06	2.24	**.042**	**0.58**	1.25	.226	**0.29**
Invalidating	0.02	.983	0.01	1.47	.164	**0.38**	1.70	.106	**0.39**

[a] Satterthwaite correction was applied because the homoscedasticity assumption was not met.

ANCOVA linear mixed models in Patients

The ANCOVA results for linear mixed models in patients are presented in Table 11. The study condition (FC and TAU) was taken as a factor, posttest scores as a dependent variable, and pretest scores as covariate. The results indicate that a statistically significant result was only obtained for the DASS-21 total score (depression, anxiety, and stress) (p = .042). In addition, Cohen's d was calculated as the difference between the adjusted posttest means of the two groups. These results indicate that better results were obtained in the FC group, compared to the TAU group, on the measures of global family functioning (d = 0.50), depression, anxiety, and stress (d =0.71), the DERS subscale of emotional interference (d = 0.47), and the VIRS validation subscale (d = 0.25). No differences were found in parental emotional availability. However, the TAU group scored better on the emotional refusal subscale of the DERS (*d* = -0.42).

Table 11. ANCOVA linear mixed models in patients.

	FC group		TAU group				
Outcome	M_{adj}	SD_{adj}	M_{adj}	SD_{adj}	*F*	*p*	d_{adj}
FAD-GFS							
Problem Solving	2.36	0.49	2.48	0.49	0.50	.483	**0.24**
Communication	2.32	0.48	2.51	0.48	1.39	.246	**0.39**
Role	2.40	0.28	2.56	0.28	3.02	.091	**0.58**
Affective Response	2.31	0.41	2.40	0.41	0.36	.556	**0.20**
Affective	2.09	0.43	2.20	0.43	0.57	.454	**0.25**
Involvement	2.02	0.36	2.19	0.36	2.09	.158	**0.48**
Behavioral Control	2.11	0.39	2.22	0.39	0.66	.423	**0.27**
General Functioning	15.60	1.90	16.56	1.90	2.28	.140	**0.50**
Total							
DASS-21							
Stress	1.33	0.66	1.70	0.66	2.81	.103	**0.56**
Depression	1.20	0.75	1.62	0.75	2.75	.107	**0.55**
Anxiety	0.93	0.61	1.32	0.60	3.60	.067	**0.63**
Total	3.45	1.69	4.65	1.69	4.49	**.042**	**0.71**
DERS							
Emotional Refusal	23.51	6.20	20.91	6.19	1.55	.221	**-0.42**
Emotional	28.78	6.72	27.70	6.72	0.23	.635	-0.16
Dyscontrol	14.26	2.96	15.66	2.96	2.02	.165	**0.47**
Emotional	14.51	3.01	14.17	3.00	0.11	.740	-0.11
Interference	11.46	2.42	11.08	2.41	0.23	.637	-0.16
Emotional	92.27	15.08	89.75	15.07	0.25	.621	-0.17
Inattention							
Emotional Confusion							
Total							
LEAP							
Mother	63.96	16.73	61.56	16.72	0.16	.690	0.14
Father	52.37	13.66	54.61	13.66	0.19	.665	-0.16
Total	105.97	24.49	103.73	24.42	0.07	.795	0.09
VIRS							
Validating	32.14	6.11	30.62	6.11	0.51	.479	**0.25**
Invalidating	6.01	2.94	5.70	2.94	0.09	.766	-0.10

DISCUSSION

This first RCT with relatives of people with BPD and their loved ones demonstrates that FC is more effective than TAU in reducing burden and increasing family mastery and empowerment and emotional attention. Linear mixed-model analysis showed no significant differences in the benefits on the outcomes of family functioning, psychological symptoms, emotion regulation, resilience, or quality of life between the two groups. However, in independent mean comparison analyses with t-tests, statistically significant results were observed for burden, depressive, anxiety, and stress symptoms, family mastery and empowerment, and emotion regulation in the FC group. No significant improvements were obtained in global family functioning, quality of life, or resilience. In the TAU group, significant improvements were obtained in quality of life and the communication/policy of family mastery and empowerment. There were clinically relevant effects on symptoms of depression, anxiety, and stress, family empowerment and mastery, and emotion regulation, although they were not statistically significant.

FC is a program that adapts to the specific needs of family members of people with BPD, and both its format and objectives make it fully applicable and accessible for implementation in the public health system. The finding that the emotional support network among family members with similar issues and specific skills training lead to greater empowerment and decreased burden is highly relevant because most caregivers of people with BPD have few support resources and limited opportunities to share their experiences with others. Given the impact of this problem on the family climate and its interference in the psychological health of family members, these findings put a greater emphasis on the need for a skills training program of this type. Furthermore, it would be relevant to be able to test this program in relatives of people with other diagnoses where emotion dysregulation may exist, such as suicidal behaviors, eating disorders, or other personality disorders.

The results obtained at the six-month follow-up indicated that the FC group showed better results on all variables than the TAU group, except for burden in the interaction analyses between groups. The analyses of the two groups were performed separately, obtaining statistically significant improvements on all variables in the FC group. The TAU group indicated significant improvements in burden, symptoms of depression, anxiety and stress, quality of life, and emotion regulation. However, the results of these comparisons are based on follow-ups with a large sample loss, and therefore they should be interpreted with extreme caution due to possible bias in the estimates of the effects caused by losses.

Regarding patient outcomes, in the analyses comparing the change from the beginning of the relatives' program to the end of the program, it is observed that patients whose relatives participated in the FC group obtained statistically significant differences in depression, anxiety and stress, emotional interference, and validation. No statistically significant differences were found in global family functioning, emotion regulation, or parental emotional availability. In addition, clinically relevant effects were obtained on global family functioning and emotion regulation, although there was not enough statistical power to indicate a statistically significant result. On the other hand, in the patients whose relatives participated in the TAU group, a statistically significant result for emotional rejection was observed. Clinically relevant effects were obtained for all the variables, except parental availability, although there was not enough statistical power to indicate a statistically significant result. However, it was not possible to perform interaction analyses between the two groups, which would allow us to draw conclusions about improvements in people with BPD depending on the training received by their relatives, due to the large sample loss in the post-treatment data collection.

Adherence to treatment in relatives of people with mental disorders (Flynn et al., 2017; Hoffman et al., 2005; Pearce et al., 2017; Rajalin et al., 2009; Regalado et al., 2011) is a problem in psychological interventions. In this study, dropouts at post-treatment (26.45%) and follow-ups (41.57%) may be explained by attainment of expectations, motivation at group initiation, time availability, illness awareness, or active components of the program. These variables require further study.

To our knowledge, this is the first study to evaluate a skills training program for family members of people with BPD using an RCT design. FC has been studied in different parts of the world, but research studies based on this intervention have used other types of designs. In addition, it is also the first FC study to assess both family members and loved ones.

The differences between the groups in our study may be explained by several factors. First, although both groups consisted of an active treatment, FC has additional in-session exercises, such as role-playing, homework review, video viewing, and skills (active components), compared to TAU. However, although the means of the two groups of patients on the pretest showed no statistically significant differences, trends were observed in Cohen's d, where patients in the TAU group were more affected on the evaluation measures. Another factor could be that the FC family members had better scores on the pretest measures than the control group.

One of the limitations of our study is that family members in the FC group had a trend of higher pretest scores compared to the TAU group, and patients in the TAU group had worse results on measures before their family members started the program, compared to patients in the FC group. In addition, the measures were taken before and after the program. It would be advisable to carry out a process evaluation during treatment in future studies to control for significant events that may occur at the time of the posttreatment evaluation that could distort data collection. Another limitation in the results of the study was the large amount of sample loss in the patients' data and follow-ups, which makes it impossible to perform some statistical tests and generalize the results. Finally, another limitation is that the vast majority of the people with BPD were receiving treatment in clinical centers, which can affect patient outcomes. In addition, the collection of post-treatment assessment data from the patients was quite difficult because they did not receive the treatment directly (only family members participated), and they may not have felt as involved in completing the post-treatment or follow-up assessments.

New studies on FC with relatives of people with BPD and other pathologies should focus on more specific measurement instruments of the disorder and the specific skills taught in the program and consider the aforementioned limitations.

To ensure the implementation of the program in different mental health facilities in Spain, the official program manual was translated and adapted to Spanish, FC training courses have been held, the protocol and research results have been disseminated in different international and national congresses, and supervision has been provided for professionals from both clinical centers and associations of relatives of people with personality disorders.

CONCLUSIONS

In conclusion, our study contributes to the literature on FC by evaluating the efficacy of the program. The skills training offered by FC helps to improve coping and family climate. Future studies on this program should evaluate what factors are responsible for adherence to the program, more specific instruments for intervention skills, and adaptation of the program to family members of people with other mental disorders.

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CHAPTER 3

A smartphone application of “Family Connections” to increase the use of skills and the improving of psychological symptoms in relatives of people with borderline personality disorder: a study protocol for a randomized controlled trial.

This chapter has been accepted as:

Fernández-Felipe, I., Guillén, V., Castilla, D., Navarro-Haro, M. & García-Palacios, A. A smartphone application of “Family Connections” to increase the use of skills and improve psychological symptoms in relatives of people with borderline personality disorder: a protocol study for a randomized controlled trial. *Internet Interventions, 29*(3), 100546.

A smartphone application of “Family Connections” to increase the use of skills and the improving of psychological symptoms in relatives of people with borderline personality disorder: A study protocol for a randomized controlled trial.

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ABSTRACT

Background: The literature reveals that borderline personality disorder (BPD) is an important public mental health problem that affects both the patients and their families. Moreover, studies indicate a high prevalence of psychological symptoms and burden in relatives of people with BPD. Therefore, it is necessary to develop useful and accessible interventions specifically addressed to the caregivers. Smartphone interventions with Ecological Momentary Assessment (EMA) and Ecological Momentary Interventions (EMI) offer several potential advantages in this regard. The aims of our study are to test the effectiveness of a combined intervention supported by a smartphone app versus the same intervention supported by a paper-based manual, studying the feasibility and acceptance of both conditions and evaluating the perceptions and opinions of families about both interventions. This paper contains the study protocol. **Methods:** The design of this study protocol is a randomized controlled trial. A minimum of 116 relatives will be randomly assigned to two conditions: Treatment as usual (TAU) (N = 58) or Treatment as usual + EMI (TAU+EMI) (N = 58), with TAU being the Family Connection program. The primary outcome will be the Burden Assessment Scale. Secondary outcomes will include psychological symptoms, mastery and empowerment, and resilience. Outcomes will be assessed from pre-treatment to post-treatment (3 months). Statistical analyses will be performed using Student's t-tests, mixed models (ANCOVA) and intention-to-treat analysis. **Discussion:** The results of this study will provide a basis for future EMA- and EMI-based application interventions for family members of people with BPD and family members of people with other mental disorders who could benefit from the skills taught.

KEY WORDS: Borderline Personality Disorder, Relatives, Smartphone Application, Skills.

INTRODUCTION

Borderline personality disorder (BPD) stands out for the complexity and severity of its symptoms, which are characterized by high emotional intensity and instability, high impulsivity, identity disturbances, dissociation, and difficulties in interpersonal relationships (American Revised Manuscript Psychological Association, 2013). BPD has been related to low educational and occupational levels, deficits in social support, low life satisfaction, and very frequent use of services (Bohus et al., 2021). This high use of healthcare services including hospital admissions results in a large economic impact associated with the use of healthcare and the large number of healthcare professionals working in these devices (Amianto et al., 2011; Meuldijk et al., 2017; Sansone et al., 2011). In addition, high rates of self-harm and suicide are observed in 69-80% of people with BPD (Schneider et al., 2008). All these factors create an important public mental health problem that affects people with BPD and their families (Fruzzetti et al., 2005). BPD is frequently associated with general distress, depression, and anxiety in patients and their caregivers (Fruzzetti et al., 2005; Wilks et al., 2017). Family members of individuals with BPD develop psychological problems more easily, and the burden of the illness perceived by caregivers is one of its consequences (Hoffman et al., 1999; Hoffman & Fruzzetti, 2007). Research has shown that levels of burden and depression in family members increase due to lack of information about their loved one's diagnosis and about the evolution of BPD (Hoffman et al., 2003; Rajalin et al., 2009). However, other studies indicate that caregivers' involvement in the treatment of people with BPD reduces patients' relapse rates, they recover more easily, and their quality of life increases (Dixon et al., 2001; Rajalin et al., 2009).

Due to advancements in research and clinical work, psychological intervention programs for family members of people with BPD have shown good empirical evidence. The majority of these skill training programs are based on Dialectical Behavior Therapy (DBT) (Linehan, 1993) or its multiple adaptations (e.g., Guillén et al., 2020; Navarro-Haro et al., 2018). DBT is a psychological treatment that was developed for suicidal behavior, and it is the treatment with the most evidence for BPD (Stoffers et al., 2012; Storebo et al., 2020). DBT is a thirdgeneration therapy that uses a cognitive-behavioral approach and emphasizes context and function (Hayes et al., 2011). It consists of four weekly components: individual therapy, group skills training, therapist consultation team, and as-needed, between-session, telephone coaching. The skills training component of this treatment has been shown to be the key to treatment improvement (Linehan et al., 2015). Family Connections (FC) is a skills training program for family members of people with BPD that has received the strongest empirical support to date (Hoffman et al., 2005). It consists of six modules (12 sessions in all), each with specific objectives, in-session practical exercises, video viewing, and homework assignments. The modules are: introduction to BPD, family psychoeducation, relationship mindfulness skills, family environment skills, validation skills, and problem management skills.

This program has demonstrated its efficacy, thus far, through five uncontrolled trials across pre- and post-treatment measures and follow-ups (Ekdahl et al., 2014; Flynn et al., 2017; Hoffman et al., 2005; Hoffman & Fruzzetti, 2007; Liljedahl et al., 2019). Although this program is effective, it is not widely implemented. Mental health resources are limited, and psychological treatments do not reach everyone who could benefit from them (SalvadorCarulla et al., 2010). Thus, there is an urgent need to improve the delivery of mental health care by going beyond the traditional face-to-face approach (Kazdin, 2015). Accepted and accessible alternatives would be Internet-supported psychological interventions, which have been found to be effective and well-received (Andersson et al., 2019). In particular, in this study we are interested in the use of smartphone applications (apps) that can provide brief psychological interventions in real time to support psychotherapy. Some apps for people with BPD help to improve their symptomatology, generalize the skills learned to their daily context, keep daily records, and receive feedback from health professionals. Some examples are DBTCoach (Rizvi, 2011, 2016), EMOTEO (Prada, 2017), mDiary app (Helweg-Joergensen, 2019, 2020), B.RIGHT (Frías et al., 2020), Medtep DBT (Suñol, 2017), Pocket Skills (Schroeder, 2018), and CALMA (Rodante, 2020). However, to the best of our knowledge, there is no smartphone app specifically for family members of people with BPD.

Two specific approaches with very promising developments are Ecological Momentary Assessment (EMA) (Shiffman et al., 2008) and Ecological Momentary

Intervention (EMI) (Heron & Smyth, 2010). EMA is used for data collection in real time. Study participants receive scheduled alerts throughout the day, and they are invited to answer a series of questions via a mobile device such as a smartphone. These data consist of responses (e.g., thoughts, feelings, and behaviors) gathered at the moment participants are experiencing a specific symptom in their usual context, thus improving the ecological validity of the assessment questions and overcoming barriers related to memory deficits and recall bias (Shiffman et al., 2008). Another advantage is that EMA can not only collect information about symptoms and the context, but also about the temporal relationship between these variables, and this information provides greater insight into the momentary experiences of individuals (Torous et al., 2018; Van Os, 2013). Smartphones provide EMAs and EMIs that facilitate psychological interventions in a naturalistic context where the individual needs help at that moment (Balaskas et al. 2021). A study by Fuller-Tyszkiewicz et al. (2020) developed an EMI-based smartphone app intervention for caregivers of people with physical and/or mental disabilities. The results indicate that stress and depressive symptoms declined, and emotional well-being, optimism, self-esteem, support from family and significant other, and subjective well-being increased.

A large number of smartphone apps for people with psychological problems focus on providing instructions, adaptive self-help strategies, alerts, electronic diaries, or emotional state ratings. In this work, we propose The Family Connections app, which consists of a smartphone app built using EMAs and EMIs. The EMAs collect behavioral and emotional data in real time in a naturalistic environment and with multiple repeated measures (burden of illness, global family functioning, depression, anxiety, stress, validation, emotional regulation, and quality of life). The EMIs in our App are linked to these EMAs in that the software instructs the participant to perform one skill or another through alerts based on the EMA scores. These alerts are programmed daily for three months, and they allow the family member to perform the skill at the exact moment when the problem occurs in their environment. In addition, in the mobile application, family members have a virtual "Library" where they can visualize the material available for each skill without the need for an alert and, thus, apply the technique as needed. In conclusion, the FC program with the support of an app aims to train family members in DBT skills and, thus, promote a change in the symptomatology and attitudes towards the family climate in a naturalistic setting compared to FC with the support of a written manual with the contents of the program. To our knowledge, this is the first smartphone application developed using EMA and EMI for family members of BPD. The aims of our study are the following: (a) to test the effectiveness of a combined intervention supported by a smartphone app versus the same intervention supported by a paper-based manual; (b) to study the feasibility and acceptance of both conditions; and (c) to evaluate the families' perceptions and opinions about both interventions.

We hypothesize that: (a) the experimental condition will result in significant reductions in psychological symptoms and burden and significant improvements in family functioning and quality of life; and (b) the experimental condition will be significantly more accepted by the relatives due to its interactivity, its many more dynamic and updated contents, and the alert reminders that make it easier to remember to use it.

METHODS

Trial design and study setting

The study is a three-month, open-label, randomized, parallel-group trial carried out in centers specializing in personality disorders and family associations. It is designed to compare the efficacy of the FC program with the support of a smartphone application versus the usual treatment consisting of the FC application with a written manual with the contents of the program. Participants will be family members of people with borderline personality disorder. Our study will follow the SPIRIT statement guidelines for conducting clinical trials (Standard Protocol Items: Recommendations for Interventional Trials) (Chan et al., 2013; Chan et al., 2013) and the CONSORT statement (Consolidated Standards of Reporting Trials, http://www.consort-statement.org) (Moher et al., 2001; Moher et al., 2010).

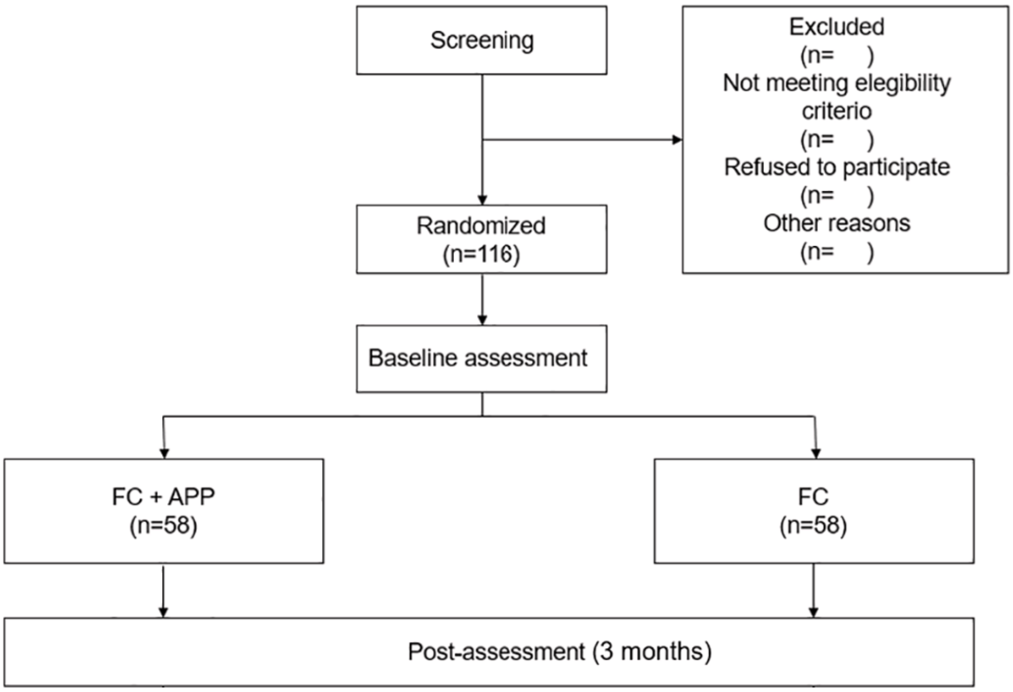
Eligibility criteria

Eligibility criteria will be as follows: (1) having a family member diagnosed with borderline personality disorder who may or may not live with his/her loved one, (2) being 18 years of age or older, (3) knowing and understanding the Spanish language, (4) having a smartphone with an Internet connection, and (5) signing the informed consent.

Recruitment timeline

Centers specializing in personality disorders and family associations receive a high number of patients each year, and so it is expected that many family members will be interested in the program. The therapist will provide a brochure with a brief description of the program and then invite family members to participate in the study. Family members who have met the inclusion criteria will participate in the skills training program after an initial interview, and they will be randomly assigned to one of the two conditions. The CONSORT flowchart for our study is shown in Figure 1 (Fig. 1) (Moher et al., 2010).

Fig.1 Flowchart of the study



Sample size

We conducted a literature search for interventions for family members of people with BPD to determine the sample size. Grenyer et al. (2019) conducted a controlled study of a group psychoeducational intervention for family members of people with

BPD. They measured dyadic adjustment (d = 0.78), family empowerment (d = 1.4), and burden (d = 0.45), with medium to large effect sizes. The results of this study showed significant improvements between posttreatment and 12-month follow-up. The effects found in this study are consistent with other studies that present psychological interventions for other mental disorders. Baruch et al. (2018) conducted a meta-analysis of psychological interventions for family members of people with bipolar disorder (Burden, g = -0.80). Based on this line of literature, we expect an effectsize of 0.60 because the design has two treatment conditions. The total sample size needed to reach this effect, taking into account an alpha of 0.05 and a statistical powerof 0.80 in a two-tailed t-test, is 90 participants (45 relatives per condition). Based on the literature on the possible loss of data during treatment, we expect a dropout rate of 29% (Flynn et al., 2017; Hoffman et al., 2005; Pearce et al., 2017; Rajalin et al., 2009; Regalado et al., 2011). Therefore, the final sample size will consist of 116 participants (58 relatives per condition). We used the G*Power software to perform these calculations (Faul et al., 2007).

Randomization

Family members who meet the inclusion criteria for this study will be randomly assigned to one of the two conditions: Treatment as usual (TAU) or Treatment as usual + EMI (TAU+EMI) in a 1:1 ratio after the initial interview has been conducted. Randomization of participants to each group will be performed by an investigator independent from the study using Excel random number software, and the investigator will provide the results to the research group. Randomization will be performed in permuted block sizes, so that there is a balance in each treatment condition. Neither family members, patients, therapists, nor study investigators will be provided with allocation information throughout this process. This is a double-blind design.

Interventions

Participants in both conditions will receive the FC program as Treatment as usual, as explained above. These are two active treatment conditions with the difference that the experimental condition is supported by a smartphone App and the other condition is supported by a written manual with the contents of the program. FC consists of 12 sessions grouped into six modules of two sessions each that combine up-to-date information on BPD, skills based on DBT strategies, practical exercises during the session, video viewing and homework. The content of the program consists of information about BPD and BPD-related issues, the role of the family, stigma, relationship mindfulness skills and emotional regulation strategies, radical acceptance, validation skills and coping skills within the nuclear family.

Smartphone application

Family members in the experimental group of this study will receive an ecological momentary intervention (EMI) derived from an ecological momentary assessment (EMA) via the Family Connections smartphone app. This app is to be used in real time in a naturalistic setting and with multiple repeated measures (illness burden, global family functioning, depression, anxiety, stress, validation, emotional regulation, and quality of life). The EMIs are linked to the EMAs because the application of the techniques depends on the cut-off point for each variable, which is decided by experts, and the software instructs the participant to perform one skill or another through alerts. The users will receive notifications twice a day reminding them to use the app. The notifications are programmed to occur twice a day, seven days a week, for three months. Moreover, the users can login at any time to answer the EMAs, thus allowing the family member to perform the skill at the exact moment when the problem occurs in their environment. All the assessment measures and data on whether or not they performed the skill will be recorded by an automatic alert at the end of the day, and adherence to the intervention will be monitored. In addition, in the mobile application, the family members have a virtual "Library" where they can visualize the material available for each skill without the need for an alert and, thus, apply the technique at the desired moment. The FC application will be available for free download from the Google Play store. For the time being, it will be available for Android devices (version 2.3 or higher), and, hopefully, we will be able to develop it for iOS in the future. However, Android is the most widely used operating system in Spain by more than 90% of the population (Kantar World Panel, 2018), and 85% in Europe (Gartner Inc., 2018). Before downloading the app, a brief description will be available that includes the name and contact details of the principal investigator, the purpose of the app, and a statement guaranteeing the confidentiality of the data.

Therapists and study investigators will receive specific training in the use of technologies and the mobile application.

Treatment as usual

Family members in this condition will receive the Family Connections manual, which contains all the information on the program sessions and skills training strategies in writing. This is the manual the therapists follow in each session to present the contents of the skills training.

Data collection

For data collection, all the investigators and therapists participating in the study will be provided with evaluation materials for family members' data and information on the use of data storage. In addition, a schedule of weekly meetings will be established to discuss issues related to the study.

In addition, demographic data will be collected from family members and their significant others, and clinical data will be analyzed in the efficacy study. Demographic data consist of gender, age, educational level, marital status, occupation, relationship to the patient, and psychiatric and psychological history. Clinical data will be measured with the following measures:

Burden Assessment Scale (BAS; Horwitz & Reinhard, 1992). It consists of 19 items and assesses the caregiver's objective and subjective burden within the past six months. Items are rated on a 4-point Likert scale ranging from 1(nothing) to 4 (a lot), and higher values indicate stronger burden. Internal reliability of the scale ranged from 0.89 to 0.91, and it has shown adequate validity (Reinhard, Gubman, Horwitz & Minsky, 1994).

Depression, Anxiety and Stress (DASS-21; Lovibond & Lovibond, 1995). It contains 42 items about negative emotional symptoms (Lovibond & Lovibond, 1995). Lovibond and Lovibond (1995) proposed a short version, creating a new questionnaire with 21 items in three subscales. Items are rated on a 4-point Likert scale ranging from 0 (It did not happen to me) to 3 (It happened to me a lot or most of the time), and higher scores indicate worse symptoms of depression, anxiety, or stress. The DASS-21 showed excellent factor structures. Regarding the internal consistency, Cronbach's alphas were excellent for the DASS-21 subscales: Depression (α = 0.94), Anxiety (α = 0.87), and Stress (α = 0.91) (Antony, Bieling, Cox, Enns & Swinson, 1998).

Family Empowerment (FES; Koren, DeChillo & Friesen, 1992). This scale consists of 34 items divided into three subscales: family, service system, and involvement in community, which refer to three types of empowerment, that is, attitudes, knowledge, and behaviors (Koren, DeChillo & Friesen, 1992). Items are rated on a scale from 1 (completely false) to 5 (completely true), and higher scores indicate a greater sense of empowerment. The psychometric properties are the following: regarding the internal consistency of the FES subscales, the coefficients range from 0.87 to 0.88, and validity and reliability are adequate (Koren, DeChillo & Friesen, 1992).

Resilience (CD-RISC; Connor & Davidson, 2003). This scale is a 25-item measure of resilience. Items are rated on a 5-point Likert scale ranging from 0 (absolutely not) to 4 (almost always), and the score is based on how the participant has felt in the past month. Higher scores indicate greater resilience (Connor & Davidson, 2003). The CD-RISC authors reported acceptable test–retest reliability (r = 0.87) and strong internal consistency (α = 0.89) (Connor & Davidson, 2003).

For the EMAs, we selected validated items from questionnaires measuring psychological aspects of family members, such as the Burden Assessment Scale (Horwitz & Reinhard, 1992), Global Family Functioning Scale (Epstein et al., 1983), Patient Health Questionnaire-9 (Kroenke et al., 2001), Depression, Anxiety and Stress (Lovibond & Lovibond, 1995), Generalized Anxiety Disorder-7 (Williams, 2014), Family Empowerment Scale (Koren et al., 1992), Difficulties in Emotion Regulation Scale (Hervás & Jódar, 2008), Connor-Davidson Resilience Scale (Connor & Davidson, 2003), Validation (built by our research team), and Quality of Life Index (Mezzich et al. 2000). The list of items can be found in Table 1. Regarding the usability and acceptability of the application, they will be evaluated using the System Usability Scale (Brooke, 2013), which consists of 10 items measured with a five-point Likert scale ranging from Strongly agree to Strongly disagree. We will measure usability and acceptability at the beginning of the use of the app and before the end of the study because continued app use can mask usability problems that occur at the beginning (Holzinger, 2005; Hornbæk, 2006). The list of items can be found in Table 2.

Table 1. EMA and EMI of the Family Connections App.

EMA	Response options	Alert (Cut-off point)	EMI
I have felt guilty for not doing enough to help my family member.	A	4	Video_Alternatives to Guilt
I am aware that I should set some limits for my family member, but I find it difficult to do so when the time comes.	B	1	Audio_Observing Limits
We find ways to solve everyday problems at home.	B	4	Video_”How” Skills, Video_DEAR MAN, Video_8 Steps of Problem Management
I have felt little interest or pleasure in doing things.	B	1	Video_Opposite_Action
I have felt down, depressed, or hopeless.	B	1	Video_Opposite_Action
I have felt that I can cope with all the things I have to do.	B	4	Video Awareness and/or Self-validation
I have successfully coped with small daily problems.	B	4	Video Awareness and/or Self-validation
I have felt nervous, anxious, or on edge.	B	1	Video_Opposite_Action
I have not been able to stop or control my worrying	B	1	Video_Opposite_Action
I argue a lot with others.	B	4	Video_Transactional Model
I know what to do when problems arise with my family members.	B	4	Video_”How” Skills
When I feel bad, I get angry at myself for feeling that way.	B	4	Audio_Identifying emotions
I experience my emotions as being out of control.	B	4	Audio_Identifying emotions
When I feel bad, I have difficulty concentrating.	B	4	Audio_Identifying emotions
I am aware of my emotions.	B	1	Audio_Identifying emotions
I have difficulty understanding my feelings.	B	4	Audio_Identifying emotions
I am proud of my accomplishments.	B	1	Image_Benign interpretation
I am bothered by certain attitudes of my family member but now is not the time to demand more things from him/her.	B	1	Video_Radical acceptance
When I have painful feelings, I tell myself that it is okay to feel this way.	B	1	Audio_Self-validation
I am learning a lot of skills. I am doing the best I can at the moment.	B	4	Video_Validation
I identify and communicate my understanding about what my family member is saying or feeling in a clear way.	B	4	Video_Validation
My quality of life (feeling satisfied and happy with my life in general) is...	C	2	Video_Caring for the Caregiver

A: 1=Not at all, 2=Somewhat, 3=Somewhat, 4=A lot; B: 1=Strongly agree, 2=Agree, 3=Disagree, 4=Strongly disagree; C: 1=Poor, 4=Regular, 7=Good, 10=Excellent.

Table 2. Acceptance and usability (Systema Usability Service).

Item's number	Item
1	I think I would like to use this system frequently.
2	I found the system unnecessarily complex.
3	I thought the system was easy to use.
4	I think I would need the support of a technical person to be able to use this system.
5	I found that the various functions in this system were well integrated.
6	I thought there was too much inconsistency in this system.
7	I would imagine that most people would learn to use this system very quickly.
8	I found the system very cumbersome to use.
9	I felt very confident using the system.
10	I needed to learn a lot of things before I could get going with this system.

Data management, confidentiality, and access to data

First of all, the data sent through the Qualtrics platform will be stored in a secure and encrypted platform within the cloud, which will also be password protected. Personal data or any information that can identify study participants will be assigned a code to protect their privacy and the confidentiality of their personal data. These data will be retained for five years after the end of the study. Only the principal investigators of the study will have access to this information and will perform the statistical analysis of the data.

Statistical analysis

Two-way mixed-effects ANOVAs will be applied to test whether both groups are balanced on the dependent variables at pretest. In these analyses, the dependent variable will be the pretest scores, the fixed effects factor will be the type of treatment and the random effects factor, the family. To compare the efficacy of the two treatment conditions, two-way mixedeffects ANCOVAs will be applied. In these analyses, the dependent variable was the posttest scores, the covariate was the pretest scores, the fixed effects factor was the treatment type, and the random effects factor was the family. In addition, pretest-posttest change for each treatment group will be assessed by applying dependent samples t-tests. For data lost in the post-treatment collection, intention-to-treat analyses will be performed.

Ethics and informed consent

The investigators in the research group will inform the study participants about all the study details. In addition, they will explain the benefits of the skills training program and the commitment required to participate in a research study. The role of the investigators will be to ensure that the participants have understood this. Family members will be asked to sign the voluntary informed consent to participate in the program.

This study has been approved by the Ethics Committee of the University of Valencia (Spain). In addition, the trial was registered in Clinical Trials (clinicaltrials.gov) with identification number NCT05215392. It will be conducted in accordance with the Declaration of Helsinki Guidelines and the existing guidelines in Spain and the European Union to ensure the protection of participants in clinical trials.

DISCUSSION

As described, BPD has a significant impact on patients’ family members (Fruzzetti et al., 2005). Fortunately, empirically supported interventions for family members of people with BPD already exist and many of them are based on skills taught in DBT (Linehan, 1993) or its multiple adaptations (Guillén et al., 2020). FC is the most empirically supported intervention to date and several studies have proven its effectiveness (Ekdahl et al., 2014; Flynn et al., 2017; Hoffman et al., 2005; Hoffman & Fruzzetti, 2007; Liljedahl et al., 2019). However, sometimes the program does not reach everyone who needs it, or, once the intervention ends, participants may stop using it. Our "Family Connections App", based on EMA and EMI technologies, is designed to decrease the psychological symptoms and burden experienced by family members of people with BPD and increase their feelings of mastery, empowerment, and resilience. In addition, psychological interventions via mobile application allow for widespread administration to family members who have limited mobility, live in rural areas or attend centers that do not have the necessary equipment to carry out the psychological intervention.

Numerous applications have been developed for patients. However, there are few programs for family members, and so we think that administering FC in this format can be useful for reducing clinical symptomatology (and keeping it low over time.) and improving adherence to the program. In addition, it can provide greater clarity or ease in choosing the most appropriate skill for each situation and make it easier toremember how to apply the best strategy by using the video compared to the manual. We hypothesize that with the app, users feel more encouragement or support (from the notifications they receive) and greater satisfaction than with the manual, and they continue to use it over time due to its interactivity, its many more dynamic and updated contents, and the alert reminders that make it easier to remember to use it. Previous studies have shown that several apps for people with BPD can improve their symptomatology and generalize skills to their natural context (Frias et al., 2020; Helweg-Joergensen, 2019, 2020; Prada, 2017; Rizvi 2011, 2016; Rodante, 2020; Schroeder, 2018; Suñol, 2017). In addition, an EMA-based app for family members of people with physical and/or mental disabilities decreased stress and depressive symptoms and increased emotional well-being, optimism, self-esteem, support from family and significant others, and subjective well-being (Fuller-Tyszkiewicz et al., 2020).

For this reason, we believe that the Family Connections application developed for family members of people with BPD could improve psychological symptoms, illness burden, family climate, and quality of life. However, no intervention has been implemented for these family members using the FC application. Therefore, the purpose of this RCT is to test the effectiveness of a combined intervention supported by a smartphone app. The results of this study will provide a basis for future EMA- and EMI-based application interventions for family members of people with BPD and for family members of people with other mental disorders who could benefit from these skills.

In a recent systematic review, McKay et al. (2018) report that there are not enough data to evaluate the efficacy of mobile health applications. Therefore, numerous difficulties arise when carrying out efficacy studies in medical and clinical centers due to aspects related to the study design, such as randomization of the participants, program acceptance, compliance with the instruments, and user participation, as well as the blinding of researchers and health professionals and determining appropriate outcome measures (Neugebauer et al., 2017). Thus, we have designed this trial to increase scientific validity in future studies by addressing the difficulties mentioned above.

CONCLUSION

This RCT is the first study to investigate the use of a smartphone application using EMA and EMI technologies to reduce psychological symptoms, improve relationships within the family climate, and increase the empowerment and resilience of family members of people with borderline personality disorder. Standardized procedures will be used with robust scientific research methods. We believe that, through this study, we can determine whether this smartphone application is an effective intervention support that can be implemented in future studies.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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CHAPTER 4

"Family Connections", a DBT-based program for relatives of people with borderline personality disorder during the COVID-19 pandemic: a focus group study.

This chapter has been published as:

Fernández-Felipe, I., Díaz-García, A., Marco, H., García-Palacios, A. & Guillén, V. (2022). "Family Connections", a DBT-based program for relatives of people with borderline personality disorder during the COVID-19 pandemic: a focus group study. *International Journal of Environmental Research and Public Health*, 19, 79.

"Family Connections", a DBT-based program for relatives of people with borderline personality disorder during the COVID-19 pandemic: a focus group study.

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ABSTRACT

The COVID-19 pandemic has had a significant impact on the family environment due to the difficulties that have been generated by job losses, deaths, increase rates of family and domestic violence, poor mental health outcomes, and estrangement in personal relationships. “Family Connections” (FC) is an internationally renowned DBT-based program that supports the families and caregivers of people with borderline personality disorder. The study took place at a Specialized Health Centre in Spain. A focus group with seven participants was organized for people who had previously attended an FC group. The participants were asked about their experiences during the confinement periods that was caused by COVID-19 as well as their experiences and opinions on relatives, skills practiced, their need to and the advantages of attending the group, and satisfaction with the FC group. The qualitative research web program Dedoose was used for the thematic analysis of the data. The results showed that the participants experienced various experiences during confinement; validation and radical acceptance were determined to be the most useful skills; the importance of professionals and the content as well as the sincerity of attendees and having a safe space were determined to be the greatest benefits of the programs; and the participants all indicated great satisfaction of the program. This study allowed us to explore the experiences of family members of people with BPD with their loved ones during the confinement period caused by the COVID-19 pandemic. We evaluated the use of the FC program skills in the family environment during confinement, and we analyzed the acceptability and satisfaction with the FC program.

KEY WORDS: Borderline Personality Disorder, Family Connections, Relatives, DBT, Intervention, Caregivers.

INTRODUCTION

We are currently living in difficult times due to the global COVID-19 pandemic, a situation that has had a great impact on mental health due to the safety measures that have been implemented in order to prevent the spread of disease (physical and social isolation). These measures have resulted in loneliness and in a considerable reduction in social interactions, leading to risk factors for some mental disorders (e.g., schizophrenia and major depression). In addition, the uncertainty that surrounds the situation about the future as well as worries about health (one's own or that of loved ones), give rise to or intensify fear, depression, and anxiety. The prolongation of these psychological problems can lead to serious mental illnesses such as panic, obsessive-compulsive, stress, and trauma-related disorders (Fiorillo & Gorwood, 2020; Unützer et al. 2020). One of the areas on which this virus has a great impact is families. The experiences of different families throughout the pandemic differ because many factors influence the relationship between well-being and COVID-19, including physical and mental health, politics (Hsiang et al., 2020), race and/or ethnicity (Berkowitz et al., 2020; Van Dorn et al., 2020), economics (Dooley et al., 2020), individual and community resources (Berkowitz et al., 2020), and country of residence (CDC COVID-19 Response Team, 2020). Studies show that pandemics have a direct effect on people's well-being, creating problems such as illness, economic instability, and emotional isolation, among others (Pfefferbaum & North, 2020). To mitigate the spread of the pandemic, many countries, including Spain, were completely confined for more than two months. This great effort on the part of the population had a strong impact on stress, depression, fear, anger, boredom, and stigma (Brooks et al., 2020). In addition, a study by Vindegaard and Benros (2020) shows that psychological well-being in adults has declined compared to periods during the periods before the emergence of COVID-19.

The family environment is one of the areas that has been the most affected. The COVID-19 crisis has had a great impact on families because many of them have been fighting against health threats and difficult family situations such as family anddomestic violence. Unfortunately, many people have directly experienced the loss of family members, which has led to deep sadness, anxiety, and homesickness, among others (Weingarten & Worthern, 2018). In addition, there are also indirect effects of the pandemic that have arisen due to the set of limitations that have implemented in terms of interaction with the outside world and due to the intense moments that have been experienced in the family environment. Some of the most vital restrictions were those that were placed on physical and emotional contact, which in many countries limited to people living together. This restriction has had a significant impact, giving rise to strongly shared processes that provide many possibilities for both benefits and disadvantages (Minuchin, 1974). In addition, a study by McFarlane (2016) suggests that family difficulties arise for caregivers who have dealt with a family member with the help of others who are no longer present, as in the case of caregivers of people with mental disorders (Loukissa, 1994).

One of the most complex mental disorders is borderline personality disorder (BPD). It is characterized by high emotional intensity and instability as well as impulsivity and is associated with high rates of self-harm and suicide, with these two behaviors being seen in 69–80% of the BPD population (Schneider et al., 2008). In addition, this problem is associated with high rates of 24 h hospital intervention, recurrent use of health services and, consequently, high associated financial expenditure due to the use of these services (Bender et al., 2001; Meuldijk et al., 2017; Sansone et al., 2011; Soeteman et al., 2008), including the use of emergency services and multiple professionals (Amianto et al., 2011; Dimeff & Koerner, 2007; Meuldijk et al., 2017). It is a major public mental health problem that causes great distress to both patients and their loved ones (Fruzzetti et al., 2005).

BPD causes challenges among individuals and their families (Fruzzetti et al., 2005). Thus, it is important for both patients and families to receive specialized care and psychological treatments based on empirical evidence. Maladaptive family communication patterns play an important role in the etiology and maintenance of BPD. The family members of individuals with BPD are more likely to develop psychological problems (Hoffman & Fruzzetti, 2007; Noh & Turner, 1987), and one consequence is the perceived burden on caregivers (Hoffman et al., 1999; Links et al., 1988; Pope et al., 1983). On the one hand, some studies show that misinformation and uncertainty about their family member's diagnosis and the progression of the disorder increase levels of burden and depression (Hoffman et al., 2003; Rajalin et al., 2017). On the other hand, studies suggest that when family members are part of the treatment process for people with BPD, relapses are reduced, recovery is easier, and the quality of family life improves (Dixon et al., 2001; Rajalin et al., 2017).

Fortunately, group intervention and skills training programs for the family members of people with BPD exist and are empirically supported. Almost all family skills training programs are based on Dialectical Behavior Therapy (DBT) or DBT adaptations (Guillén et al., 2020). DBT (Linehan, 1993) is a specific psychological treatment for people with borderline personality disorder that addresses the symptoms of behavioral and emotional dysregulation that often materialize as suicide and parasuicide. DBT belongs to the group of so-called third generation therapies and incorporates the cognitive and behavioral approach, emphasizing the context and function (Hayes et al., 2011). The program for the family members of people with BPD that has the most empirical support is Family Connections (FC) (Hoffman et al., 2005). FC consists of six modules that are divided into two sessions each, and each module has specific aims and practical exercises. The modules are the following: introduction, family education, relationship mindfulness skills, family environment skills, validation skills, and problem management skills.

Five uncontrolled clinical trials with pre- and post-treatment and follow-up assessments (Ekdahl et al., 2014; Flynn et al., 2017; Hoffman et al., 2005; Hoffman & Fruzzetti, 2007; Liljedahl et al., 2019) have been conducted to date. The results of this program have been replicated, and the results were consistent and maintained or improved over a 3- or 6-month follow-up period. Studies show significant decreases in burden, grief, anxiety, and depression, and significant increases in the participants' subjective experiences of mastery, empowerment, well-being variables, and family functioning (Guillén et al., 2020). These encouraging results for family climate and functioning may be explained by program content that validates the patients' coping behaviors, decreases their psychological symptoms, improves well-being and relationships between family members and patients, leads to a greater understanding of the problem, works to reduce the stigma of the disorder, and increases family empowerment (Liljedahl et al., 2019).

Qualitative studies are an interesting method that can be used for collecting and analyzing non-numerical data to understand concepts, opinions, or experiences. A qualitative study with eight family members of people with BPD by Dunne and Rogers (2013) showed that these family members are poorly served or not served at all by mental health services and that they need support from professionals to improve their well-being. Another qualitative study of 19 family members of people with BPD used open questionnaires and group interviews. The results determined that the relatives are continually afraid that something bad might happen, and they try to keep the family atmosphere as bearable as possible in addition to feeling guilt and lifelong grief about their relative with BPD. In terms of mental health services, the family members of people with BPD feel left out and abandoned, and they have lost confidence in mental health professionals (Ekdahl et al., 2011). Kay, Poggenpoel, Myburgh, and Downing (2018) conducted a qualitative, exploratory, descriptive, and contextual study with eight family members of people with BPD, and the results showed that these relatives have a lack of knowledge about the disorder, which produces feelings of disempowerment. Finally, another qualitative study on the experiences of family members of people with BPD with self-injurious behavior and attempted suicide was carried out with four family members (Giffin, 2008). The results showed that these relatives suffer from chronic and traumatic stress as well as a strain on the family climate and between the relatives and mental health services. These results indicate the need for an approach that considers family members in a meaningful way in treatment as well as in their relationships with mental health services (Giffin, 2008).

These results suggest that qualitative research allows us to acquire more detailed and richer information in the form of descriptions and to observe the context and social meaning and how they affect individuals. In addition, communication takes place in a more horizontal way through the use of different tools that allow for unexpected discoveries to be made during the research process. Qualitative research also makes it possible to study individual experiences in greater depth. Given the findings from other qualitative studies with family members of people with BPD, it is important to explore the views and experiences of these people in the extraordinary situation of the COVID-19 pandemic.

This research has several objectives. The first objective was to assess the experiences that the family members of individuals with BPD have had with their loved ones during the confinement period caused by the COVID-19 pandemic. The second objective was to evaluate the use of the FC program skills (validation, radical acceptance, emotion regulation, problem management, and mindfulness of relationships) in the family environment during confinement. The third objective was to evaluate the acceptability and satisfaction with the FC program.

METHODS

Participants and Recruitment

The participants were recruited from a group that received FC prior to and during COVID-19 confinement. These groups were previously formed by randomizing a sample of relatives of people with BPD who had been recruited for another efficacy study. They received the FC program for three months, and the follow-up coincided after the confinement, which is when we conducted this qualitative study. The selected family members received a phone call from our research group, inviting them to participate in the focus group if they had no contact with a person who was positive for COVID-19, had no symptoms, and were not waiting for the results of a diagnostic test for COVID-19. This group consisted of nine family members: four mothers, two fathers, a partner, and two children. In all, there were four families. All of theparticipants attended over 80% of the program sessions, but only seven of them attended the focus group after confinement.

Four families composed of seven family members of people with BPD were selected. They stated that they complied with the established rules, and they presented their motivation for participating in the focus group discussions. Prior to the focus group, the family members were asked to sign a consent form allowing the researchers to write down the content of the discourse in the focus group discussions and to publish the information that was collected. They were informed that the presentation of the data would be confidential and that no statement would be able to be traced to a particular participant.

Description of “Family Connections”

Family Connections is an intervention program that is based on DBT strategies. It is composed of six modules that are divided into two sessions each, and it was created to improve family attitudes and to reduce family exhaustion (Hoffman et al., 2005). The modules are (a) Introduction, which provides information about the aims of the program, the criteria and symptoms of BPD, and the role of emotion regulation; (b) Family Education, which provides information about treatment programs for BPD, comorbid disorders, the biosocial model, and the transactional model of the development of BPD; (c) Relationship Mindfulness Skills, which presents states of mind, emotion regulation skills, and mindfulness of the relationship; (d) Family Environment Skills, which explains radical acceptance, and the aim is to understand the relationship between the individual and the family’s welfare and the importance of maladaptive ways of thinking that are related to blame; (e) Validation Skills, which presents validation and self-validation skills as well as learning how to set clear limits and how to achieve self-respect; and (f) Problem Management Skills, which focuses on interpersonal efficacy, defining problems and solutions, and problem management skills. Each module has specific objectives and practical exercises as well as videos with examples of people with BPD and their relatives.

Data Collect and Procedure

A qualitative method was used in this study. A focus group with seven participants was organized in July 2020 for people who had previously attended a FC group. The participants simultaneously participated in a single two-hour session with the researcher, and they completed a questionnaire with open and closed questions. The discussions in this focus group took place in a large and safe place that allowed all the COVID-19 security measures to be respected and was located in a Spanish center that is specialized in personality disorders. The organization of this focus group was motivated by the fact that this would allow contact after the COVID-19 pandemic confinement among the relatives who attended the FC group. Before and during the pandemic, a face-to-face skills group was conducted with the relatives of people with BPD, which also used the FC program, where they learned DBT-based strategies. One researcher (IF-F) asked all of the study questions during the session and moderated the discussion. The participants responded to the questions that were asked, interacted with each other, and listened to other the responses of other participants. The focus groups were held face-to-face in the clinic and lasted two hours. The focus groups were carried out by two researchers (IF-F and AD-G) and were transcribed verbatim by the first author.

Ethical Considerations

The guidelines of the Declaration Helsinki and existing guidelines in Spain and the European Union for the protection of patients in clinical trials were followed in this study. The Ethics Committee of the University of Valencia (Valencia, Spain) approved this study. The trial was registered at ClinicalTrial.gov under trial number NCT04160871.

Measures

Interview Protocol

A semi-structured interview with open-ended questions was designed that focused on (a) the experiences that caregivers had during confinement with their relatives; (b) the skills that they learned during the program, which skills were the most useful to them, and which skills they used during the confinement; (c) their needs before attending the therapy group, the advantages of attending it, and adherence to the group; and (d) satisfaction with and acceptance of the FC group. For this interview, the construction process included an initial discussion among the team members. Second, the questions were elaborated by two research team members separately. Finally, agreement was reached by comparing the two lists of questions, trying to balance the greatest number of topics with the least number of questions.

Examples of questions that were addressed in the focus groups are provided in Table 1.

Table 1. Questions 1 addressed in the focus group.

How was the confinement and what experiences did you have with your family member in this period?
What skills used in the program have you learned, and which have been most useful to you?
What skills have you used the most during confinement?
Why did you come to the FC group?

What experiences have you had with the group?
What do you think is essential for a group like this to work?
What advantages have you found in attending this group compared to your usual treatment?
Why do you think it is necessary for family members to adhere more to this group?

[1] Translated from Spanish into English.

Opinion of treatment scale by modules (OTSM). The Opinion of Treatment Scale by Modules is an instrument that was developed by our research team and that was adapted from Borkovec and Nau (1972). This questionnaire evaluated opinions that participants have about and acceptance of the program using numerical scales and open questions as well as their acceptance towards any changes made to the six therapeutic modules. The questions are related to the logic of the treatment, the degree of satisfaction with the program, whether they would recommend the program, and the usefulness and expectations of the program. In addition, they assessed the learning and usefulness of the skills that had been taught in the module on a scale from 0 (none) to 10 (high).

Data Analysis

The qualitative analysis of the focus group was conducted using a qualitative research web program called Dedoose, which is a qualitative research program that contains tools to manage and analyze data that have been obtained from qualitative information. First, a separate set of codes was created in coding themes by an expert from the research team with expertise in qualitative studies. We used the Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong et al., 2007) for the coding of the focus group transcript and for the analysis of these data. To perform the content analysis, we relied on the research literature in this field, and this resulted in the themes that appeared in the coding process (Elo & Kyngäs, 2008). Induction and deduction methods were used for the data coding process. A double-blind design was used to conduct the coding by two researchers independently. This analysis addressed one of the main points of the focus group: the experiences of family members of people with borderline personality disorder during the confinement period that was induced by COVID-19 and the use of the skills that were learned in the Family Connections skills training program.

RESULTS

Characteristics of the Relatives and Patients

Seven family members participated in the focus group. The participants were three mothers, two fathers, a daughter, and a husband of a person with borderline personality disorder. None of the participants were in any type of ongoing therapeutic program at the time of the qualitative study. The sociodemographic characteristics of the relatives and the patients are shown in Table 2. All of the fragments of the interactions between the relatives were in Spanish and have been translated into English.

Table 2. Characteristics of the relatives and patients.

Participant	Characteristics	Mean (SD)
Caregiver	**Age (years)**	53,43 (27 to 68)
		n (%)
	Sex	
	Female	5 (71,4)
	Male	2 (28,6)
	Relationship with the patient	
	Mother	3 (42,9)
	Father	2 (28,6)
	Husband	1 (14,3)
	Daughter	1 (14,3)
Patient	**Age (years)**	36 (22 to 57)
		n (%)
	Sex	
	Female	4 (100)
	Mental disorder diagnosis	
	BPD	1 (25)
	BPD and Major Depressive Disorder	1 (25)
	BPD and Bipolar Disorder	1 (25)
	BPD and Anorexia Nervosa Disorder	1 (25)

Family 1

The family members in Family 1 consisted of the patient’s partner and daughter. These two relatives had been given multiple diagnoses during their relative’s journey through the health system, and they had never learned management skills that could be used with their relative or had received psychoeducation about BPD. The patient was a 57-year-old woman who was on leave from work. She had a diagnosis of bipolar disorder and BPD. She had been suffering from the disorder for more than 30 years, with numerous hospital admissions and two suicide attempts. She was in a state of high impulsivity.

Family 2

Family 2 consisted of the patient's father and mother. Because the patient's diagnosis was recent when they started the program, these relatives had never received treatment or had been informed about the persons diagnosis. The patient was a 28-year-old woman who studied and worked at the same time. She had a diagnosis of BPD. She had been admitted to hospital because of a suicide attempt. The characteristics of this patient were high emotional and behavioral dysregulation. She had learned to regulate these areas, and she was in an advanced stage of treatment, meaning that she had completed the DBT program twice and was no longer receiving treatment.

Family 3

Family 3 consisted of one mother. This mother had attended several therapeutic groups for family members and had received psychological treatment. She had accompanied her daughter during the psychiatric and therapeutic process for 20 years. The patient was a 37-year-old female university student. She had a diagnosis of BPD and Anorexia Nervosa. She had had multiple hospital admissions due to three suicide attempts, one of which had a high risk of lethality resulting in irreversible physical injury. She had sequelae from that autolytic attempt and was in intensive psychological treatment.

Family 4

Family 4 consisted of a mother and a father. Due to the patient's recent experience in the healthcare system, these relatives came to the group confused about the diagnosis. They had never participated in a group of relatives or received psychological treatment. The patient was a 22-year-old female university student. She had a diagnosis of BPD and Major Depressive Disorder. She had never had any hospital admissions or suicide attempts. The main characteristics of this patient were a low mood, emotional dysregulation, and identity dysregulation.

Qualitative Results

The results that are shown are from the experiences of four families (Family 1, Family 2, Family 3, and Family 4) during the confinement period that was implemented due to COVID-19. The responses could be divided into five themes.

Theme 1: The Impact of COVID-19 Confinement on People with BPD

Spain is one of the countries that has been the most affected by the COVID-19 pandemic (Instituto Nacional de Estadística, 2020). One of the restrictions that had the greatest impact is the total confinement of the population for more than two months. All of the relatives in this study live with people with BPD. Therefore, all of the experiences in this section refer to having spent the confinement period together. The experiences of these four families were very different due to where each patient was in their treatment process, among other factors.

Positive Experiences

Family 1 reported good experiences during the confinement period, and the daughter said:

"In general, we were afraid to be at home to see what could happen because we of course didn't know how we would react, and they are much more sensitive […], so there has been a little bit of tension and nervousness in that area, like a punching bag… and I tell her, but Dad is taking it personally, she has a disorder, and when she's up here she lashes out at the person closest to her, which is you, because you're stuck with her 24 h a day. But she was fine with us, with everything that was happening. I believe she has acted very well, was strong, and helped me in everything; she has been incredibly positive."

Family 2 also had a good experience, and the father commented:

"We've been amazed. Wonderful, very surprising, we could not believe it. I had a hard time because my wife got the coronavirus. Then, the whole family was followed up

with, and they did the diagnostic test, the serology on all of us, and the only one who had really gone through it is her, not us. One day she was overwhelmed, and she said to her brother "please, I want to rest, I am studying". She was studying non-stop every day; she has signed up for a lot of online courses, and she has done everything. She is very happy. And there is more. Two weeks ago, suddenly she became independent".

Neutral Experiences

In contrast, the mother from Family 3 commented that it was *"Strange, a very strange thing, I don't know,"* because neither she nor her relative assimilated to what was happening, and they were very irritable about any little thing.

Negative Experiences

Finally, Family 4 did not have a good experience with their daughter during the confinement, although, as the mother said, it was not all negative:

"I don't even feel like saying anything. Because everybody is good… and we are not. We had improved a lot just a few weeks ago, and we have gone backwards. During the confinement, it has been… uf. Sometimes, it's hard for us to even know about allowing yourself to lose control because I don't know if I allow myself to or if I lose it without permission because I'm tired; I'm very tired. You are more dependent than you were before the confinement. We have achieved something good because we also have to say something good, and that is that the social isolation she had is gone because now she stays with her friends".

Theme 2: Learning and Knowing What Is Going on with Their Relatives

The family members learned DBT skills in FC in order to know about and accept the problem their loved one has, empower themselves, improve the family climate, and enhance their quality of life. The partner in Family 1 opened the topic by saying *"We have learned things that we may not have known how to manage"* because none of the participants had previously participated in a skills group for family members of people with borderline personality disorder. The daughter in this family summarized what she learned in terms of both psychoeducation and skills:

“I think that the most important thing we have learned is to know what our family member suffers. I think none of us knew because we could not understand why they behaved as they did. Learning about their problem and putting into practice all the methods to improve our coexistence with them has been positive because there came a time when we could not live with that person.”

Regarding Family 2, the father commented that he had learned to set limits, something he did not do before attending the group for fear of triggering a crisis:
“Look, one of the things we have learned is that I overprotected my daughter out of fear that a crisis would occur. But there came a moment, when I came here to the group, that I said, “this is as far as I go”. I was doing it for her sake, but then I realized that I was being very selfish, and I felt guilty, and I have learned all that here, not that I didn’t know it, but to say, “it’s not just me who is thinking it, it’s that they are telling me”. In short, I have now learned to say “No.”

The mother in this family referenced one of the objectives of the program:
“It is like the famous statement: “let’s take care of the caregiver”. If we don’t take care of the caregiver, they won’t be able to take care of you because you are sick, you can’t take care of them because you don’t know how.”

Finally, the mother in Family 4 referred to all of the participants in the group and their motivation for coming to learn how to manage the relationship with their loved one:
“It seems to me that here we all worry a lot, you with your mother, you with your wife, you with your daughter, and you are of course and another relative who is not here today. I think that we have come here because we are eager to learn and to know what is going on with our relative. We have taken in everything to learn.”

Theme 3: Validation and Radical Acceptance Were the Most Used and Useful DBT Skills during Confinement Due to COVID-19

The participants were asked about the DBT-based skills that they learned during the FC program and that they had to perform during the confinement period. These questions were categorized into (a) most useful skills and (b) the skills that were the most used during the confinement period.

Most Useful Skills

Of all the skills that the FC program teaches, all of the family members responded that the most useful ones were validation and radical acceptance:

On the one hand, the partner in Family 1 said, "I think acceptance has been the most important thing because it helps you realize what you have and what you must accept, and that's how it is. Not hitting the wall."

On the other hand, the mother in Family 4 commented that "Validating her feelings, her sensations, and all that has seemed very important to me. Knowing how to say, "I understand that you are like this…"

In addition, the psychoeducation prior to the skills seen in the program helped them to understand their relatives' diagnosis.

Most Used Skills during the Confinement

As for the skill that was the most used during confinement, all of the family members responded that it was validation. This is one of the skills that surprised them the most during the program, and along with the multimedia material, they integrated this concept very well. In addition, they saw significant changes when they started using it. The daughter of one of the patients stated that due to the large amount of time they spent at home because of the COVID-19 restrictions, she had many aspects to validate. The skills that were used the most often by the family members can be seen in Table 3.

Table 3. Skill scores on the OTSM questionnaire.

	Family 1		**Family 2**		**Family 3**	**Family 4**	
	Couple	**Daughter**	**Mother**	**Father**	**Mother**	**Mother**	**Father**
Knowledge about BPD	8	9	8	7	8	9	8
Identification and management of emotions	7	8	7	6	7	9	7
Awareness of your family member's emotions	8	8	7	8	6	9	7

Usefulness of Acceptance skills	10	9	10	10	9	10	10
Usefulness of Validation skills	9	9	10	10	8	10	9
Ability to validate your family member	9	8	9	9	9	9	9
Usefulness of Management of problems	9	10	10	10	9	10	9
Ability to manage problems with your family member	7	8	9	8	7	8	9

Theme 4: Professionals, the Content of the Program, the Sincerity of All the Attendees, and Having a Safe Space

One of the problems that arises during the psychological treatment of people with mental disorders is that the caregiver of the family member with BPD is often neglected. The participants in this group commented that they had beenaccompanying their family member to therapy for many years, but they had never hadthe opportunity to be part of a family-to-family support group and receive clear and comprehensive information about the problem their family member was having and skills for dealing with it. When asked why they came to the group, the answers were the following:
“To learn, learn how to handle the situation”(mother in Family 3); “To know how to act because we did not know how to act on many occasions”(father in Family 2); “We are in a situation that is a borderline situation, and I have to find a way to cope with it” (partner in Family 1); “I think that it’s a good thing that we all came here with an empty glass, with a blank slate, and that we all came here to fill it up” (father in Family 4); “We came here to learn”(mother in Family 3); and “Because we were lost” (mother in Family 2).

Many times, in therapeutic groups, there are participants who do not start the group or who drop out. All of the participants who attended the focus group attended more than 80% of the sessions. However, as participants in a therapeutic group, they were asked why it is necessary for members to join the group.

The most frequent responses were the education that was received from the professionals who created the group and the help they provided, the content of the

program, the sincerity of all of the attendees, and having a safe space to express their concerns and worries. The mother in Family 4 said:
“Knowing that we are not the only ones and that, as you said before, we are not doing so badly… Because all of us here, I imagine, have been told so many diagnoses for our relative and so many strange things that now it turns out that there is a diagnosis that fits well “.

That is, the group is necessary to provide clear and concrete information about the problem and to form a support network among equals where they feel listened to and supported. The father in Family 4 said *“…that we have seen that we share many things in common with others, and one very important thing I think is that they listen to you and help you and support you and each other and you listen to others”.*

Relatives of people with BPD suffer, among other things, from the burden of their family member. The father in Family 4 added:
“It is common that we have someone very close to us who causes conflict. Knowing that he or she is not alone in the world relieves you of a lot of weight. It frees you from the burden, and then the capacity that each one has to transform it or to be able to contribute to that family member, that is already inside of you, but to be able to communicate and to be able to say it in public”. The mother in this family interacted with him, adding *“It’s just, who do you tell your problems to? No one, you can’t,” and the father in Family 2 replied, “Because people don’t seem to understand you”.*

In addition, the father in Family 4 mentioned one of the benefits of the group’s privacy and sincerity:
“And another thing that I think is good, I don’t know if any of you have thought about it, but what I have thought about is the fact that here everyone belongs to different places and backgrounds and outside of here we don’t have any relationship, none, and that’s positive. Why? Because when you and I come here, I come to tell you about my daughter’s problems and my problems with her, but they stay here; they do not leave here. Therefore, I can see them around the city one day, and I will say hello to them. Moreover, for me that is fundamental, the fact that you come to a group of people that you do not know, and you are willing to come. I was in another city today, and you

have to come from work and leave your work and come here. You share intimate things, and they stay here, in the sense that if I, for example, knew you from before, it would be more difficult. I would not be so open.”

Finally, another advantage that the group provides is the increase in hope about their loved one. The mother in Family 4 said:
“We’re going to leave with hope because when we came here, we didn’t have any, at least not us”.

Theme 5: Great Satisfaction with and Acceptance of the FC Group

As for the satisfaction with the program and the support from the group, all of the participants responded that it was great. In addition, they said that the lack of knowledge about their relative’s diagnosis and the lack of tools and skills made them feel lost. The daughter in Family 1 commented:
“It has been very good for us because we were lost, and it has helped us to realize that it is something that affects many people, and that the reactions of our relatives are similar.”

In addition, the fact that it was a safe environment where they could interact with each other gave them a lot of satisfaction. The mother in Family 4 said:
“Then we come here, and we have something in common, we share. I also find it very enriching that we can talk to each other. A member of the group could have seen something that works that I may not have seen.”

The partner in Family 1 replied:
“The first time I came here, I was a little reluctant because had to expose my problems and speak in public, but as the sessions went on, I thought “I’m looking forward to it, because I want to express this, and I want them to know it”.

In addition, the mother in Family 4 commented:
“You feel sheltered.”

Finally, the father in Family 4 said:

"This is like you go and say things that in other places we can't. You open, you tell, and it is a good experience. It is therapy for the caregiver. It is learning how to take care of ourselves so that we can take care of them later."

The satisfaction with and acceptance of the FC program bythe family members can be seen in Table 4.

Table 4. Satisfaction and acceptance of FC on the OTSM questionnaire.

	Family 1		Family 2		Family 3	Family 4	
	Couple	**Daughter**	**Mother**	**Father**	**Mother**	**Mother**	**Father**
Program is logical	9	10	8	8	10	10	10
Satisfaction with the program	10	10	9	9	9	10	9
You would recommend the program	10	10	10	10	10	7	9
Usefulness of program and expectations	9	9	9	9	10	10	10

DISCUSSION

The aim of this study was to explore the experiences of family members of people with BPD with their loved ones during confinement period that was implemented due to the COVID-19 pandemic. Furthermore, we evaluated the use of the FC program skills in the family environment during confinement, and we analyzed the acceptability and satisfaction with the FC program. Five relevant themes emerged: (a) various experiences of family members of people with BPD during confinement due to COVID-19; (b) learning and knowing about the experiences of their relatives; (c) validation and radical acceptance were the most used and the most useful DBT skills during confinement due to COVID-19; (d) professionals, the content of the program, the sincerity of all the attendees, and having a safe space were considered to besignificant benefits of the program; and (e) the participants demonstrated a great level of satisfaction and acceptance of the FC program. Although these issues are linked to ideas from previous studies (Dunne & Rogers, 2013; Ekdahl et al., 2011; Giffin, 2008; Kay et al., 2018), this is the first study to describe the experiences of family members of people with BPD and to explore the use of the FC program during confinement due to COVID-19 as well as analyzing the satisfaction with and the acceptance of the FC program.

The family members of people with BPD needed to talk about their experiences during confinement due to COVID-19. There were positive, neutral, and negative experiences with their relatives. Some of them mentioned how surprised they were that everything was going well in their family and how well they were coping with these difficult and uncertain times. However, others commented on how difficult it was for them to live with this family member and the setback in the symptoms that was seen during the confinement. Studies suggest that when family members are part of the treatment process for people with BPD, relapses are reduced, recovery is easier, and the quality of family life improves (Dixon et al., 2001; Rajalin et al., 2017). Sharing these experiences and interacting with other family members with similar problems and with professionals provides a network of support and a feeling that they are not alone.

One of the most important things that the family members learned during the program was what the family member diagnosis means and helped them to understand their behavior was well as how to practice the tools that could be used to increase family functioning. In addition, an important aspect that they verbalized repeatedly is that they were now aware that the caregiver must take care of him or herself in order to provide good care for their family member. This agrees with the line of results found in other studies that have suggested that misinformation and uncertainty about their family member’s diagnosis and the progression of the disorder increases relatives’ levels of burden and depression (Hoffman et al., 2003; Rajalin et al., 2017).

As for the skills that were provided by the FC program, during the confinement, validation was the skill that was used the most often. This is one of the skills that surprised them the most during the program, and along with the multimedia material, they integrated this concept very well. In addition, they saw significant changes when they started using it. Another skill that they found quite useful was acceptance because it helped them to release the burden and grief related to having a family member with BPD and allowed them to stop becoming frustrated about something that was not under their control. In line with the literature, creating or maintaining a safe and validating family environment in which all family members are accepted can be very difficult when one or more family members are persistently distressed by the possibility of their loved one committing suicide (Linehan, 1993). One of the reasons for the creation of FC was to improve validation and acceptance skills to create and maintain a validating family environment in the face of crises (Hoffman et al., 2005).

One problem that arises during the psychological treatment of people with mental disorders is that the family member is often neglected. The participants in this group gave a lot of importance to the training of the professional who oversaw the group, the content of the program, the sincerity of all those attending the group, and having a safe space where they could transmit their concerns and doubts. In one study, Hoffman et al. (2005) described the “surplus stigma” that the family members of people with BPD experience due to a lack of understanding and prejudice towards people diagnosed with this personality disorder. They point out that these attitudes are not only related to society, but they also stem from the healthcare system. This was also reflected in our study, where the participants mentioned the importance of feeling safe in a non-judgmental space where they could talk about complicated issues without fear of prejudice and stigma about this disorder.

The families who participated in this focus group mentioned that they were very satisfied with the FC program and that the information about their family member’s diagnosis and the skills that they learned made them feel safe. In addition, belonging to a group whose members have something in common and who have lived through similar family experiences made them feel that they were not alone, that they could be hopeful, and that they were listened to. We can conclude that the FC program is satisfactory for family members of people with BPD and that it generates security due to the availability of updated information about the diagnosis of their loved one and the learning of different skills that can be used to manage the family situation. Furthermore, we conclude that it generates an emotional support network where family members feel listened to by others and makes them more hopeful.

Practical Implications

This study suggests that FC is a good skills program for family members of people with BPD. In addition, it shows that it is crucial for family members to acquireknowledge about their relative's diagnosis and to create a support network of people with similar problems where they can interact and listen to others. Unfortunately, the family members of individuals with BPD are very affected, and they often experience high levels of anxiety, stress, burden, and hopelessness (Hoffman et al., 35). Therefore, family members need to be supported by both professionals and other family members, and this support and recognition should be promoted in the mental health network and in campaigns. Some international scientific associations have issued statements on how to accommodate the consequences of the pandemic. Stewart and Appelbaum (2020) state that a COVID-19 diagnostic test should be performed on those patients presenting with symptoms and, if positive, they should beisolated in specialized patient units. However, such isolation cannot violate human rights or neglect the patient's treatment needs. In addition, they must be attended to virtually and, if this is not possible, all public health protocols must be carried out in person.

Another practical implication is that FC can help families with a BPD relative to cope, not only with life in general, but also with extraordinary events, such as being confined at home due to a pandemic. It is worth exploring whether the skills that were learned during the FC could also help other families with relatives with other psychological or physical problems to cope better with stressful events.

Strengths and Limitations

This qualitative study allowed us to acquire detailed information about these caregivers' experiences with their family members with BPD during confinement due to COVID-19 through the descriptions that they provided of their experiences from a more social context that allows us to understand how these experiences have affected them. In addition, thanks to more horizontal communication, interactions and responses emerged during the focus group that were not premeditated and thus provided very rich information during the research. Another strength of this study was the contribution to research in this population using a qualitative method, which is still very scarce in relatives of people with BPD.

This study has some limitations. The main limitation of the study was the small sample that we were able to obtain after the COVID-19 period. Larger samples are more representative of results. Another limitation was that only one focus group was conducted and that people with BPD did not participate, giving us other valuable information. In addition, the fact that the study was only conducted in a health care setting in Spain limits the generalizability to other parts of Spain and internationally. Another possible limitation is that this study only really captures the experiences of families who are still in good relationships with the person with BPD and not those of people who are the relatives of an individual with BPD who is no longer receiving support. The contents of the results depend on the willingness of the family members to disclose this information as well as the ability of the interviewer, one of the key points in qualitative studies (Knox & Burkard, 2009). Another limitation could be that one of the participants in the FC program did not participate in the focus group and could have provided relevant information for this research. Despite these limitations, this is the first study to describe the experiences of family members of people with BPD and to explore the use of the skills that were learned from the FC program during the confinement period that was implemented due to COVID-19 in addition to analyzing the satisfaction with and acceptance of the FC program, which could be useful in designing and implementing interventions for family members. The focus group was a safe space for these family members to discuss their experiences and to express themselves, allowing them to ask questions to the professional and to interact with other family members.

However, we hope that future generations of family members will have greater access to the FC program and that they will be able to enjoy and take advantage of the possibilities that are offered by this skills program. It is fairly limited in terms of the costs that are involved in accessing the program due to the lack of economical and human resources in the Spanish public sanitary system. It is recommended that this program become more accessible through the reduction of those barriers.

CONCLUSIONS

We can conclude that Family Connections is a skills training program for family members of people with BPD that has both clinical and family environment benefits. Although there have been several studies on the effectiveness of the program, it is necessary to listen to family members and to consider how they live their daily lives with their loved ones. In addition, we know that skills practice is often complex, even more so when living in a context of confinement due to a global pandemic. It is necessary for health professionals to be trained in skills training programs, as this cost can be offset by the improvement in the well-being of families as well as in the reduction of psychological symptoms and the burden on the family environment. Finally, further research with this population and the implementation of these highly accessible family groups is needed to reach as much of the population as possible.

FUNDING

This research was funded by (R + D + I) Conserjeria de Innovación, Universidades, Ciencia y Sociedad Digital: Subsidies for Consolidable Research Groups of the Valencian Community, Spain (Grants for Consolidable Research Groups)—AICO/2021 and also by PhD grant has been awarded to I.F-F from the Ministry of Education, Culture and Sport (FPU) (FPU17/ 04210) to produce a doctoral thesis.

INSTITUTIONAL REVIEW BOARD STATEMENT

The study was conducted according to the guidelines of the Declaration ofHelsinki, and approved by the Ethics Committee of the University of Valencia (Valencia, Spain). It was approved by the Human Research Ethics Committee at the meeting held on 12 April 2018, with procedure number H1520331909767.

INFORMED CONSENT STATEMENT

Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patient(s) to publish this paper.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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GENERAL DISCUSSION

In the past few decades, many studies have been carried out on BPD. However, interest in the study of family members of people with BPD has grown in recent years. Caregivers are a central component of the lives of people with psychological problems, and vice versa, given that BPD has a strong impact on family members (Fruzzetti et al., 2005). Therefore, it is important to know the difficulties that arise in the family experience and the demands that underlie family members' lack of resources and tools, in order to better understand the family functioning between family members and people with BPD and open up new avenues of psychological treatment and skills training for them.

The general objective of this doctoral thesis was to extend our knowledge about FC to relatives of people with BPD in Spain. To do so, we provided a global perspective of the results of our studies, considering four different temporal developments: (a) designing the study, adapting the materials to Spanish, and training the therapists, (b) collecting information in the extraordinarily vital moment of the COVID-19 pandemic, (c) testing of efficacy of the FC program in the Spanish population, and (d) designing a mobile application as a medium for the FC program.

In this chapter, we will begin by describing the main findings of this doctoral thesis, which will follow the line of the research questions presented in the introduction. In addition, the limitations of this research study will be stated, and directions for future research will be presented. Finally, the conclusions of this dissertation will be developed.

Key findings

The present doctoral thesis considered the formulation of three main research questions. The different studies aimed to provide theoretical and methodological evidence to justify the approach adopted throughout this research and answer each of the questions posed in the introduction, using as a reference the four chapters the thesis contains (**Chapter 1**, **Chapter 2**, **Chapter 3,** and **Chapter 4**).

Comparison of FC versus TAU

Is FC superior to TAU while retaining the same results as other studies, and will the results be maintained or improved at 6-month follow-up? Do the changes observed in family members have any relationship with the clinical evolution of their loved ones with BPD?

Today, BPD can be considered a growing public mental health problem that causes considerable distress, not only in the people who develop it, but also in their family environment (Fruzzetti et al., 2005). Several research studies indicate that family members of people with BPD have high levels of psychological distress (Hoffman & Fruzzetti, 2007; Noh & Turner, 1987) and suffer from illness burden (Bradley, 1979; Hoffman et al., 1999; Links et al., 1988; Pope et al., 1983). In addition, the literature shows that the etiology and maintenance of this disorder are related to maladaptive patterns of family communication (Hoffman et al., 1999; Links, 1990). Another problem arises due to the scarce information available about BPD and the limited understanding of the problem by family members, which can produce depressive and burden symptomatology in family members (Hoffman et al., 2003; Rajalin et al., 2009). In contrast, other studies show that the participation of family members in the treatment of people with BPD leads to better recovery and family well-being (Dixon et al., 2001; Rajalin et al., 2009).

First, the RCT was conducted with a group of family members who participated in the FC program, compared to another group of family members who performed TAU. The results of the interaction between the two groups showed that FC is effective in improving burden, family mastery and empowerment, and emotional attention, compared to the control group. There were no significant differences between the two groups in family functioning, symptoms of depression, anxiety and stress, quality of life, or resilience.

Second, analyses were performed for each group separately, comparing post-treatment to baseline. Family members in the FC group showed significant improvements in burden, depressive symptoms, anxiety and stress, family domain and empowerment, and emotional regulation. No significant improvements were obtained in global family functioning, quality of life, or resilience. With regard to the TAU group, significant improvements were obtained in quality of life and the communication/policy variable of family mastery and empowerment. There were clinically relevant effects on symptoms of depression, anxiety and stress, family empowerment and mastery, and emotional regulation, although these effects were not statistically significant.

Overall, our study demonstrated that having up-to-date information about BPD and greater understanding, providing training in skills based on DBT strategies through content and practical exercises, and creating an emotional support network with other family members with similar problems foster psychological well-being and increase family mastery and empowerment and emotion regulation. Consistent with previous studies (Ekdahl et al., 2014; Flynn et al., 2017; Hoffman et al., 2005; Hoffman & Fruzzetti, 2007; Liljedahl et al., 2019) where the FC program generated significant relief of family burden and anxiety and depression symptoms and significant increases in family empowerment, well-being, and overall family functioning, our results show a significant improvement in emotion regulation. That is, our results are congruent with previous literature showing the efficacy of FC in relatives of people with BPD. Furthermore, it would be relevant to test this program in relatives of people with other diagnoses where emotion dysregulation may exist, such as suicidal behaviors, eating disorders, or other personality disorders.

Regarding the results of the six-month follow-up, the analyses of the two groups were performed separately. On the one hand, in the FC group, statistically significant improvements were observed in all variables. On the other hand, in the TAU group, significant improvements were observed in disease burden, symptoms of depression, anxiety and stress, quality of life, and emotional regulation. However, the results of these comparisons are based on follow-up completers,and there was a high rate of data loss. Therefore, the results should be interpreted with extreme caution due to possible bias in the estimates of the effects of the loss. Another reason for this great loss in follow-up may have been reflected in the impact of the COVID-19 pandemic, which has affected the results in recent years. In addition, the comparison of the results in the Spanish population and the US results during a pandemic in two very different health systems increases the difficulty in generalizing the results. The dropout rate, at 6 months follow-up, is significant and, as such, the value of some of the statistical analyses with small numbers is less useful.

Regarding the results for the patients’ change from the beginning of their relatives’ program to the end, it can be observed that those patients whose relatives participated in the FC group obtained statistically significant differences in depression, anxiety and stress, emotional interference, and validation. No statistically significant differences were found in global family functioning, emotion regulation, or parental emotional availability. On these variables, clinically relevant effects were obtained in global family functioning and emotional regulation, although there was not enough statistical power to indicate a statistically significant result. On the other hand, with regard to the patients whose relatives participated in the TAU group, a statistically significant result was observed for emotional rejection. Clinically relevant effects were obtained for all the variables, except parental emotional availability, although there was not enough statistical power to indicate a statistically significant result.

However, it was not possible to perform interaction analyses between the two groups that would allow us to draw conclusions about the improvement in people with BPD depending on the training received by their relatives, due to the large sample loss in the post-treatment data collection.

Design of a mobile App for family members of people with BPD and design of a randomized clinical trial to test the utility of the App

Will the support of the mobile app in conjunction with the FC program result in significant reductions in symptoms and psychological burden and significant improvements in family functioning and quality of life? Will the mobile app be significantly more acceptable and satisfying to family members than a paper manual?

FC is the most empirically supported skills training program for people with BPD to date for improving interference with caregivers' psychological health and family life. However, this program has been studied only in its face-to-face format with trained professionals and/or family members, and the use of new technologies as a medium for this intervention has received less attention.

Currently, an increasing number of mobile applications for people with BPD show beneficial effects in improving the symptomatology of the disorder and the generalization of strategies to their natural contexts (Frias et al., 2020; Helweg-Joergensen, 2019, 2020; Prada, 2017; Rizvi 2011, 2016; Rodante, 2020; Schroeder, 2018; Suñol, 2017). However, to our knowledge, the literature on mobile apps for family members of people with BPD is nonexistent. Only one study with family members of people with physical and/or mental disabilities showed results of decreased stress and depressive symptoms and increased emotional well-being, optimism, self-esteem, support from family and significant others, and subjective well-being (Fuller-Tyszkiewicz et al., 2020).

In addition, the use of mobile applications has certain advantages over face-to-face psychological interventions, such as the economic cost to individuals. The use of this mobile application can be generalized to family members who have limited mobility, live in rural areas, or attend centers that do not have the necessary equipment to carry out psychological interventions. In addition, the great advantage of EMI is the possibility of practicing the skills learned in the FC program in the natural context and customizing the skills based on the EMA, offering the family member a specific strategy depending on his/her psychological state at a given time.

In this doctoral thesis, we present the design of the App and the design of a randomized controlled trial to test its efficacy and acceptability. In a next study, we will conduct this trial.

In line with previous literature, our results could support using FC for improving associated symptomatology in caregivers, reducing burden, and improving family functioning.

The design and proof of efficacy of these results would lay the groundwork for the application of new technologies along with the FC program for family members who could benefit from using the skills at the time they need them within their natural context. In addition, it could also be useful for family members of people with other mental disorders and improve the access to resources for this population.

Experiences during the COVID-19 confinement after participating in the FC program

What experiences have family members of people with BPD had with their loved ones during the period of confinement caused by the COVID-19 pandemic? What FC program skills (validation, radical acceptance, emotion regulation, problem management, and relationship mindfulness) did family members use during confinement? What is the degree of acceptability and satisfaction with the FC program?

Since the emergence of the COVID-19 pandemic, we have seen a direct focus on research studies on this topic and the wealth of data this has provided. However, qualitative studies provide great scientific insight, and listening to family members generates heuristics that can supplement the data. The literature suggests that when family members are part of the treatment process for people with BPD, the patients show a lower rate of relapse, greater ease in recovery, and improved family well-being (Dixon et al., 2001; Rajalin et al., 2017). Sharing their own experiences and interacting with relatives of people with the same problems as their loved ones, along with the work of professionals, creates a very important emotional support network.

The results of our study indicated that, during confinement, family members experienced positive, neutral, and negative experiences with their loved ones that involved both good coping in difficult times and worsening of symptoms due to social isolation. Another result obtained was that family members had a better understanding of their relative's diagnosis and behavior. In addition, they were aware of the need to take care of themselves in order to provide better care for their relatives. These results are consistent with other studies that find that misinformation and uncertainty about the diagnosis are factors that increase relatives' levels of burden and depression (Hoffman et al., 2003; Rajalin et al., 2017).

In addition, our results indicated that validation was the skill family members used the most during confinement. They also mentioned that acceptance was very helpful due to the release of burden and pain related to the disorder. Linehan (1993) indicates that creating or maintaining a safe and validating family environment where all family members are accepted can be very difficult when one or more family members are persistently distressed about the possibility of their loved one committing suicide.

Finally, the results showed that family members were very satisfied with the FC program, and that the information about their family member's diagnosis and the skills they learned made them feel confident. In addition, creating a support network with other family members made them feel less alone and more hopeful and understood.

LIMITATIONS

The results of the two studies presented in this doctoral thesis are interpreted taking into account some limitations listed in the following section. Limitations of **Chapter 1** and **Chapter 3** will not be presented because they consist of two study protocols.

Comparison of FC versus TAU

In **Chapter 2**, we conducted an RCT to test the efficacy of FC compared to an active condition in Spanish caregivers of people with BPD. Although very interesting results were found, some limitations of this study should be considered.

1. We found that, in the baseline measures, the family members of the group in the experimental condition (FC), on average, had more favourable scores than the control group. Regarding the patients in the control group (TAU), worse results were observed on the measures before their family members started the program. Therefore, the strategy used in the analyses was to use the pretest measures as a covariate.
2. The outcome measures were obtained in the timeline before and after the program was carried out, without obtaining more information about significant

events that could arise at the time of the post-treatment evaluation, which could distort the data collection. Therefore, future studies should obtain process evaluation measures during the intervention.

3. The vast majority of people with BPD were treated in clinical centers, and this can affect patient outcomes. In addition, it was quite difficult to collect post-treatment assessment data from the patients because they did not receive the treatment directly (only family members participated), and so sometimes they did not feel as involved in completing the post-treatment or follow-up assessments
4. Finally, there was a large sample loss in the patients' data and follow-ups, which makes it difficult to generalize the results through some statistical tests.

Experiences during the COVID-19 confinement after participating in the FC program

In **Chapter 4**, we explored the experiences of a relatives' group during the COVID-19 confinement after completing the FC program. The limitations of this qualitative study are the following:

1. The focus group for this qualitative study consisted of a very small sample of a total of seven family members who agreed to participate right after confinement. Because of this, it is difficult to generalize the results, given that larger samples are more representative.
2. The group of participants were only family members, who are the people for whom the intervention program is intended. However, the fact that BPD patients did not participate in the group meant that we could not obtain information that could be very valuable.
3. The study sample was obtained from three private clinics in a Spanish autonomous community; therefore, the results could be limited to other community settings such as associations of people with mental disorders or other geographical areas of the country.
4. In addition, the loved ones of the family members in the group were receiving psychological and specialized treatment at the time their caregivers participated in the program. Therefore, the results cannot be generalized to relatives of

people with BPD who are not receiving any kind of support.

FUTURE LINES OF RESEARCH

The studies that are part of the present doctoral thesis, despite the limitations mentioned above, are the basis for very important future research lines:

Dissemination and implementation of *Family Connections*

After translating and adapting the FC program into Spanish, one of the future directions is to publish this manual so that it can be available to mental health professionals. This will make it possible to disseminate the program in Spanish clinics, family associations, or public health units where such cases are treated. In addition, another objective, in line with the philosophy of the authors of the program, is to carry out face-to-face and online training courses for other professionals. Finally, for greater dissemination of the program, another objective is to present the results of the research in national or international publications and national and international congresses.

Furthermore, taking into account that the FC program skills are based on DBT strategies, which are transdiagnostic, another future direction for the dissemination of the program would be to design and validate other FC programs for family members of people with other mental disorders, such as eating disorders or suicidal behaviors.

Promoting the use of ICT

The literature indicates that FC is the most empirically supported program for family members of people with BPD (Hoffman et al., 2005), and it is led by health professionals and/or trained family members who train the participants in family management skills. However, after completing the program, family members only have a manual describing the skills to consult. For this reason, the design and development of a mobile app for these relatives as a support after the intervention could be very useful and beneficial for them because these devices have the advantage of intervening in the natural context of the family and/or providing information about the skills through multimedia content.

The study protocol included in this thesis is the first step before carrying out a randomized controlled trial to test the efficacy and acceptability of an App to support FC. We will initiate this study in the coming year.
In addition, the development of this mobile app lays the groundwork for future studies with relatives of people with other mental disorders, due to the possibility of providing the skills in another population.

Exploring relevant variables in family members and patients

After finding very relevant results in the studies presented in this doctoral thesis, it would be interesting to explore the variables that could not be analyzed due to sample loss, as well as other relevant variables of interest. In addition, it would be advisable to use more specific measurement instruments for the specific skills taught in the program, in order to observe the results with these new forms of assessment, such as the capacity for validation and self-validation, the development of mindfulness, or acceptance. It would be very interesting to carry out moderation and mediation studies to explain which mechanisms or processes produce certain effects and when, or the situations where they occur. Finally, it would also be important to include longer-term follow-ups to find out whether the results obtained are maintained.

Another future line would be to obtain data not only from family members, but also from patients, given that this was not possible in our research study due to sample loss. In addition, involving the patients at some points in the program or in the post-treatment evaluation in both experimental and qualitative studies could be very valuable when collecting and contrasting the information with the relatives.

Finally, process evaluation studies are becoming increasingly important in order to explore how changes are produced during the implementation of the program, rather than basing the results only on the post-treatment data collection.

CONCLUSIONS

The studies included in the present dissertation contribute scientifically to the field of interventions with family members of people with BPD, and, in particular, they extend our knowledge about the FC program and the use of ICT to support interventions for family members. The results of several studies (Ekdahl et al., 2014; Flynn et al., 2017; Hoffman et al., 2005; Hoffman & Fruzzetti, 2007; Liljedahl et al., 2019) indicated an improvement in anxiety symptoms and depression in family members and a significant decrease in disease burden, and the FC program enhanced empowerment and family functioning. The results obtained in this doctoral dissertation are not only consistent with the literature, but they also add new findings, such as increased resilience, emotional regulation, and quality of life.

In addition, we add valuable information to the research studies conducted so far, such as the patients' participation in the evaluation measures, qualitative results after the completion of the program, and the design of a mobile app as an adjunct to FC.

Despite some limitations found in the studies described above, this doctoral dissertation expands our knowledge about family members of people with BPD and the skills training the FC program provides, and it highlights the need to care for caregivers. The results obtained highlight the importance of including the family in the treatment when there are serious psychological problems, and they show us how often this is not done. Therefore, it is extremely important to offer help to all those who need it.

Finally, this thesis provides a basis for future research, mainly directed to enhancing this program with ICT and disseminating FC not only in relatives of people with BPD, but also in other populations that might benefit from it.

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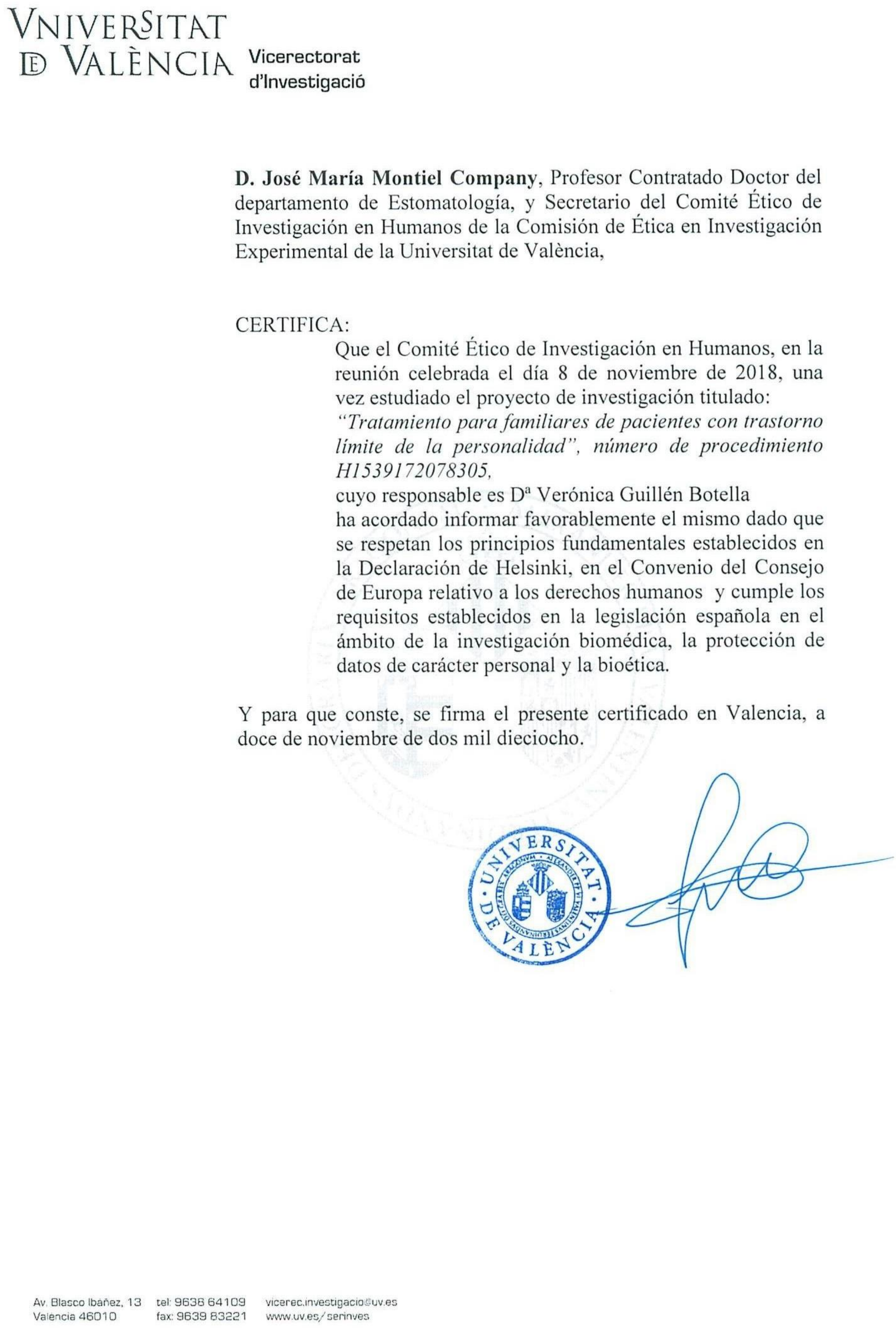
ANNEXES

Ethical approval



VNIVERSITAT DE VALÈNCIA
Vicerectorat d'Investigació

D. José María Montiel Company, Profesor Contratado Doctor del departamento de Estomatología, y Secretario del Comité Ético de Investigación en Humanos de la Comisión de Ética en Investigación Experimental de la Universitat de València,

CERTIFICA:

Que el Comité Ético de Investigación en Humanos, en la reunión celebrada el día 8 de noviembre de 2018, una vez estudiado el proyecto de investigación titulado: *"Tratamiento para familiares de pacientes con trastorno límite de la personalidad", número de procedimiento H1539172078305,*
cuyo responsable es Dª Verónica Guillén Botella
ha acordado informar favorablemente el mismo dado que se respetan los principios fundamentales establecidos en la Declaración de Helsinki, en el Convenio del Consejo de Europa relativo a los derechos humanos y cumple los requisitos establecidos en la legislación española en el ámbito de la investigación biomédica, la protección de datos de carácter personal y la bioética.

Y para que conste, se firma el presente certificado en Valencia, a doce de noviembre de dos mil dieciocho.

Av. Blasco Ibáñez, 13
Valencia 46010
tel: 9636 64109
fax: 9639 83221
vicerec.investigacio@uv.es
www.uv.es/serinves

Informed consent

HOJA DE CONSENTIMIENTO INFORMADO

1. INFORMACIÓN AL PARTICIPANTE.

Ha mostrado interés en participar en el estudio **"Family Connections: Un programa para familiares de personas con TLP",** desarrollado por la Universitat de València. A continuación, le pediremos que nos proporcione su consentimiento, de forma escrita, para participar en este estudio. Por favor, lea el siguiente texto con detenimiento y no dude en hacer cualquier pregunta.

La información básica que debe conocer es la siguiente:

a. Los resultados de este proyecto de investigación pueden contribuir a la mayor comprensión de los procesos que contribuyen a mejorar la calidad de vida de los familiares de pacientes con trastorno límite de personalidad.

b. De acuerdo con el conocimiento existente, el protocolo de evaluación en este estudio no implica un riesgo para su salud.

c. La participación en este proyecto de investigación es voluntaria y puede cancelarse en cualquier momento. Si rechaza participar, no habrá consecuencias negativas para usted. Si se retira del proyecto, puede decidir si los datos utilizados hasta ese momento, deben borrarse o si se pueden seguir utilizando tras haberlos convertido en anónimos (p. ej., eliminando los datos de la información identificativa, incluido el código, para que resulte imposible volver a identificarlos). Puede solicitar a los investigadores que le proporcionen los datos almacenados en el registro y que corrijan los errores en ellos en cualquier momento.

Las autorizaciones concedidas en este documento podrán ser revocadas mediante la presentación del oportuno escrito.

d. Los datos que se deriven de la participación pueden ser utilizados con fines de investigación, estudio y publicación, salvaguardando siempre el derecho a la intimidad y el anonimato.

e. El proyecto se realizará siguiendo los criterios éticos internacionales recogidos en la Declaración de Helsinki.

Si necesita cualquier aclaración, puede contactar con la investigadora del proyecto, Verónica Guillén (veronica.guillen@uv.es)

2. COMPROMISO DE CONFIDENCIALIDAD.

2.1. Datos personales.

Consiento en el tratamiento de mis datos personales, en el marco del Trabajo de Investigación **"Family Connections: Un programa para familiares de personas con TLP"**. La información objeto de tratamiento será utilizada para el desarrollo de funciones docentes y académicas propias de la Universitat de València como:

- La investigación.
- La creación, desarrollo, transmisión y crítica de la ciencia, de la técnica y de la cultura.
- La difusión, la valorización y la transferencia del conocimiento.

La Universitat de València se compromete a que cualquier divulgación pública de los resultados obtenidos con motivo de la investigación, se realizará anonimizando debidamente los datos utilizados, de modo que los sujetos de la investigación no resultarán identificados o identificables.

2.2. Publicación.

Los resultados del Trabajo de Investigación son susceptibles de publicación. En caso de tal utilización, se asegurará que Vd. nunca sea identificado por su nombre apellidos, ni mediante información alguna que le haga identificable.

Los datos serán tratados de forma confidencial, siguiendo para ello las medidas y niveles de seguridad de protección de los datos personales exigidos por la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal y su normativa de desarrollo.

3. CONSENTIMIENTO.

Don/Doña____,

mayor de edad, titular del DNI:____________________________, por el presente documento manifiesto que:

He sido informado/a de las características del Proyecto de Investigación titulado: **"Family Connections: Un programa para familiares de personas con TLP"**.

He leído tanto el apartado 1 del presente documento titulado "información al participante", como el apartado 2 titulado "compromiso de confidencialidad", y he podido formular las dudas que me han surgido al respecto. Considero que he entendido dicha información.

Consiento el tratamiento de mis datos personales, en el marco del Trabajo de Investigación **"Family Connections: Un programa para familiares de personas con TLP"**.

Estoy informado/a de la posibilidad de retirarme en cualquier momento del estudio.

En virtud de tales condiciones, acepto libre y voluntariamente participar en este estudio y cumplimentar los cuestionarios que se me indiquen.

Y en prueba de conformidad, firmo el presente documento en el lugar y fecha que se indican a continuación.

_____________,____________de___________________de 2019.

Nombre y apellidos del / de la participante: Firma:	*Nombre y apellidos del investigador responsable*: Firma:

Co-authors agreements

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Azucena García Palacios, como coautor/ coautora doy mi **autorización** a Isabel Fernández Felipe para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Fernández-Felipe, I., Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302. https://doi.org/10.1186/s12888-020-02708-8.
- Fernández-Felipe, I., García-Palacios, A., Marco, H., & Guillén, V. (2022). "Family Connections", a Program for Relatives of People with Borderline Personality Disorder, Versus Treatment As Usual in Specialized Care: A randomized controlled trial. *Submitted to Acta Psychiatrica Scandinavica*.
- Fernández-Felipe, I., Guillén, V., Castilla, D., Navarro-Haro, M. & García-Palacios, A. A smartphone application of "Family Connections" to increase the use of skills and the improving of psychological symptoms in relatives of people with borderline personality disorder: a study protocol for a randomized controlled trial. *Internet Interventions, 29*(3), 100546. https://doi.org/10.1016/j.invent.2022.100546.
- Fernández-Felipe, I., Díaz-García, A., Marco, H., García-Palacios, A. & Guillén, V. (2022). "Family Connections", a DBT-based program for relatives of people with borderline personality disorder during the COVID-19 pandemic: a focus group study. *International Journal of Environmental Research and Public Health, 19*, 79. . https://doi.org/10.3390/ijerph19010079.

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Verónica Guillén Botella, como coautor/ coautora doy mi **autorización** a Isabel Fernández Felipe para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Fernández-Felipe, I., Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302. https://doi.org/10.1186/s12888-020-02708-8.
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Relación de publicaciones:

- Fernández-Felipe, I., Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of “Family Connections”, a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302. https://doi.org/10.1186/s12888-020-02708-8.
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Rosa M. Baños, como coautor/ coautora doy mi **autorización** a Isabel Fernández Felipe para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Fernández-Felipe, I., Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302. https://doi.org/10.1186/s12888-020-02708-8.

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Relación de publicaciones:

- Fernández-Felipe, I., Guillén, V., Castilla, D., Navarro-Haro, M. & García-Palacios, A. A smartphone application of "Family Connections" to increase the use of skills and the improving of psychological symptoms in relatives of people with borderline personality disorder: a study protocol for a randomized controlled trial. *Internet Interventions, 29*(3), 100546. https://doi.org/10.1016/j.invent.2022.100546.

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Relación de publicaciones:

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Cristina Botella Arbona, como coautor/ coautora doy mi **autorización**
a Isabel Fernández Felipe para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Fernández-Felipe, I., Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302. https://doi.org/10.1186/s12888-020-02708-8.

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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.

Mercedes Jorquera, como coautor/ coautora doy mi **autorización** a Isabel Fernández Felipe para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Fernández-Felipe, I., Guillén, V., Marco, H., Díaz-García, A., Botella, C., Jorquera, M., Baños, R. & García-Palacios, A. (2020). Efficacy of "Family Connections", a program for relatives of people with borderline personality disorder, in the Spanish population: study protocol for a randomized controlled trial. *BMC Psychiatry, 20*(1), 302. https://doi.org/10.1186/s12888-020-02708-8.

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

Y para que conste firmo el presente documento,

Valencia, 22 de junio 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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