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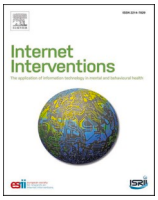

A smartphone application of "Family Connections" to increase the use of skills and improve psychological symptoms in relatives of people with borderline personality disorder: A study protocol for a randomized controlled trial

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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.

Method: 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.

1. 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 Psychiatric 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

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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 and 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; Storebø et al., 2020). DBT is a third-generation 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, 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 and 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 (Salvador-Carulla 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 DBT-Coach (Rizvi et al., 2011, 2016), EMOTEO (Prada et al., 2017), mDiary app (Helweg-Joergensen, 2019, 2020), B.RIGHT (Frías et al., 2021), Medtep DBT (Suñol et al., 2017), Pocket Skills (Schroeder et al., 2018), and CALMA (Rodante et al., 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 and 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.

2. Methods

2.1. 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., 2013a; Chan et al., 2013b) and the CONSORT statement (Consolidated Standards of Reporting Trials, http://www.consort-statement.org) (Moher et al., 2001; Moher et al., 2010).

2.2. 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.

2.3. 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 Fig. 1 (Moher et al., 2010).

2.4. 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 post-treatment 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 effect size 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 power of 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).

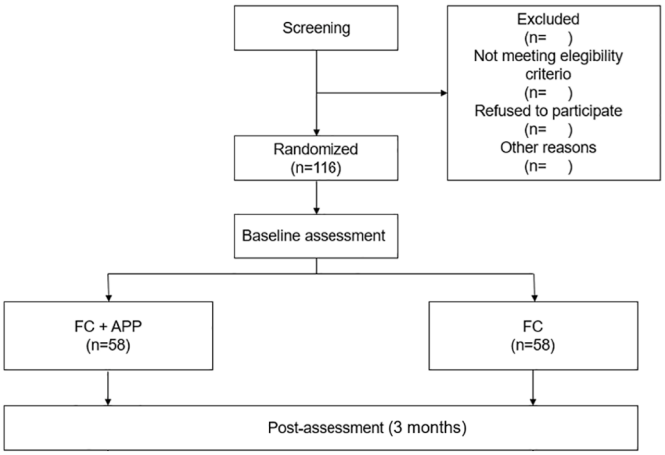

Fig. 1. Flowchart of the study.

2.5. 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.

2.6. 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.

2.6.1. 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.

2.6.2. 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.

2.7. 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 and 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 et al., 1994).

Depression, Anxiety and Stress (DASS-21; Lovibond and Lovibond, 1995). It contains 42 items about negative emotional symptoms (Lovibond and 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 ($\alpha = 0.94$), Anxiety ($\alpha = 0.87$), and Stress ($\alpha = 0.91$) (Antony et al., 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 et al., 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 et al., 1992).

Resilience (CD-RISC; Connor and 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 and Davidson, 2003). The CD-RISC authors reported accept test–retest reliability ($r = 0.87$) and strong internal consistency ($\alpha = 0.89$) (Connor and Davidson, 2003).

For the EMAs, we selected validated items from questionnaires measuring psychological aspects of family members, such as the Burden Assessment Scale (Horwitz and Reinhard, 1992), Global Family Functioning Scale (Epstein et al., 1983), Patient Health Questionnaire-9 (Kroenke et al., 2001), Depression, Anxiety and Stress (Lovibond and Lovibond, 1995), Generalized Anxiety Disorder-7 (Williams, 2014), Family Empowerment Scale (Koren et al., 1992), Difficulties in Emotion Regulation Scale (Hervás and Jódar, 2008), Connor-Davidson Resilience Scale (Connor and 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 (System 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.

2.8. 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.

2.9. 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 mixed-effects 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.

2.10. 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.

3. 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 and 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 to remember 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 et al., 2017; Rizvi et al., 2011, 2016; Rodante et al., 2020; Schroeder et al., 2018; Suñol et al., 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.

4. 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.

Declaration of competing interest

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

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