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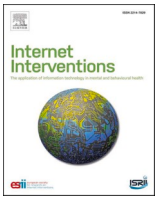

A blended intervention for adjustment disorder: Study protocol for a feasibility trial

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ABSTRACT

Introduction: Adjustment disorder (AjD) is a maladaptive response to one or more psychosocial stressors. In many cases, the symptomatology of this disorder disappears once the stressor or its consequences are no longer present. However, in some cases, if left untreated, the symptoms may worsen and develop into a more severe mental disorder. In this regard, different authors propose that a low-intensity intervention may be suitable for this disorder. Previous studies with other mental disorders and with patients with AjD found that blended interventions can be a viable and effective option. The aim of this study is to analyze the feasibility (the participants' expectations and preferences, the satisfaction and acceptance, the appropriateness of different methods of recruitment and data collection, and the reasons for dropping out) of a blended cognitive-behavioral intervention (CBT) for AjD that combines the use of a self-applied Internet-based program with videoconference sessions with a therapist. As a secondary objective, the potential efficacy of this intervention will be tested.

Method and analysis: A feasibility trial with a single-group and open-trial design will be conducted. A total of 41 participants will be assigned to the single treatment group. All the participants will be assessed for eligibility and respond at four measurement points: pre-treatment, post-treatment, and 3- and 12-month follow-ups. The treatment combines the use of an Internet-based intervention through a web platform with videoconference sessions with a therapist every 10–12 days. The intervention contains seven modules and is based on CBT. The main outcome measures are related to the feasibility of the intervention (adherence, treatment satisfaction and expectations, participants' opinions, preferences, therapeutic alliance, and usability). Clinical measures will also be assessed.

Discussion: To the best of our knowledge, this is the first study to test a blended intervention for AjD in the Spanish language. We expect this intervention to be feasible, and that a future Randomized Controlled Trial will be able to show its efficacy. Potential limitations include difficulties in recruiting the sample, failures in the computer systems, or a high dropout rate. Measures have been taken to try to reduce the impact of these limitations. This study received the approval of the Ethics committee of Universitat Jaume I in March 2022 (CD/42/2022).

Trial registration: ClinicalTrials.gov Identifier: NCT05464121. Registered 19 July 2022, https://clinicaltrials.gov/ct2/show/NCT05464121.

1. Introduction

Adjustment disorder (AjD) is a stress-related disorder defined as a maladaptive response to one or more identifiable psychosocial stressors. Its definition and diagnostic criteria are included in two of the most widely used diagnostic manuals: the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) of the American Psychiatric Association (APA, 2013) and the International Classification of Diseases (ICD-11) of

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the World Health Organization (WHO, 2018). However, the DSM-5 and previous versions of the ICD have received multiple criticisms that have led to this disorder being under-researched (Zelviene and Kazlauskas, 2018). In its latest version, the ICD-11 attempted to overcome the barriers observed in the DSM and previous versions of the ICD by incorporating a new definition of AjD with specific symptom criteria.

The ICD-11 diagnostic criteria for AjD include: (a) Presence of an identifiable psychosocial stressor or multiple stressors, (b) symptoms of worry related to the stressful event or the implications of the stressor, (c) a failure to adapt to the stressor causing significant impairment, (d) symptoms usually emerge within one month of the stressor and resolve within 6 months, unless the stressor persists for a longer period, and (e) AjD cannot be diagnosed if criteria for any other mental disorder are met.

One important aspect to consider is the high prevalence of this disorder (Zelviene and Kazlauskas, 2018), which is especially serious due to the lack of accessibility to psychological treatments for mental disorders in general. More than 60 % of people in need of psychological help cannot access treatment (Wang et al., 2005). Therefore, it seems urgent to develop new ways to deliver treatments that can increase their accessibility (Kazdin, 2017).

In the specific case of AjD, some authors suggest that despite being a frequent diagnosis, patients with AjD yet often remain untreated (Bachem and Maercker, 2016). One reason for this is that, due to the lack of clarity so far in diagnostic criteria, there is little clinical research focused on analyzing the treatment of this disorder (Bachem and Casey, 2018; O'Donnell et al., 2019). Literature reviews that focused on studying psychological treatments for AjD comprehensively, suggest that among the variety of interventions, Cognitive Behavioral Therapy (CBT) stands out as one of the most widely used (Constantin et al., 2020; Domhardt and Baumeister, 2018; O'Donnell et al., 2018). However, the study by O'Donnell et al. (2018), which is the only one that included a formal quality assessment, highlighted the low quality of the studies conducted so far. All other reviews agree on the need for further research on this issue.

It is suggested that low-intensity interventions, such as self-applied ones, may be more appropriate than traditional face-to-face treatment for AjD due to its transient nature (Bachem and Casey, 2018). Moreover, this format could help to increase the dissemination of psychological treatment and it could be as effective as face-to-face format, although further research is needed (e.g., Hedman-Lagerlöf et al., 2023).

This is supported by previous studies testing self-applied interventions for AjD that showed that this format is effective in reducing AjD symptomatology (e.g., Eimontas et al., 2018a; Eimontas et al., 2018b; Moser et al., 2019). In the study by Moser et al. (2019), it is important to mention that the reduction in AjD symptoms was not significantly different between the Care as Usual (CAU) control group and the intervention group (CAU + online treatment). However, the intervention group did report a significant improvement in some secondary measures (less depressive symptomatology and higher quality of life). Another example is the recent meta-analysis by Svärdman et al. (2022). It focused on investigating the efficacy of Internet-delivered CBT (ICBT) in adults with elevated perceived stress or stress-related disorders (including AjD) and showed the efficacy of these interventions in reducing symptomatology associated with these disorders.

Despite being an effective format, one of the disadvantages of Internet-delivered interventions is the high number of dropouts. A qualitative study focused on analyzing the experiences of some participants with emotional disorders who dropped out of an online transdiagnostic treatment showed that the lack of interaction with a therapist and the lack of personalization of the treatment were two of the main reasons for dropping out (Fernández-Álvarez et al., 2017).

In the case of AjD, an example of ICBT is described in the study of Rachyla et al. (2020). A Randomized Controlled Trial (RCT) was conducted with the aim of testing the efficacy of an ICBT called TAO compared to a waiting list control group. The results provided evidence for the efficacy of this intervention in reducing the impact of AjD. However, the dropout rate reported was around 23.5 %. Although this figure is lower than what has been observed in other studies (e.g., Eimontas et al., 2018a), it is still high. The authors suggest that incorporating therapeutic support through phone calls might have improved adherence to treatment. Nevertheless, it is necessary to continue to develop strategies to reduce the number of dropouts from these types of interventions.

One of the alternatives that can help to overcome these limitations is blended format, which is defined as the combination of self-applied interventions with face-to-face sessions with a therapist (Erbe et al., 2017). Some authors propose that sessions with the therapist do not necessarily have to be in person, but rather they can be delivered in other formats such as videoconferencing (e.g., Schuster et al., 2022). The possibility of delivering the entire intervention online could allow a larger number of people to access the treatment.

It is also suggested that blended format allows for greater therapist support and personalization of treatment which helps to reduce dropouts (Rasing et al., 2020). A recent literature review of computerized and blended treatments for depression, estimated that the dropout rate in unguided CBT ranged from 0 to 21 %, in guided CBT treatments it was around 17 %, and in blended CBT interventions it ranged from 0 to 13 % (Rasing et al., 2020).

Moreover, previous studies conducted with other mental disorders have shown that blended interventions are a well-accepted and effective option (e.g., Erbe et al., 2017; Schuster et al., 2018). Additionally, this format can also make treatment more cost-effective by reducing the time with the therapist and, therefore, the treatment costs (Erbe et al., 2017). Some authors, such as Díaz-García et al. (2021), suggest that this format may be suitable for participants who do not respond well to fully self-applied or fully guided treatments or prefer a format that combines these two.

To the best of our knowledge, only one blended treatment for AjD has been proposed so far. This CBT intervention was tested in an RCT and only included participants with the anxious subtype of AjD (Leterme et al., 2020). It combined a computer-based treatment consisting of five modules with face-to-face sessions with a professional. The results of this study showed that blended CBT was as effective as face-to-face format in reducing anxiety, depression, worry and perceived stress. However, in the secondary analysis blended CBT was slightly more effective in reducing some secondary outcomes related to anxiety and depression, compared to a face-to-face CBT group and a waiting list control group.

Therefore, the primary aim of this study is to analyze the feasibility of a CBT blended intervention for AjD as defined in the ICD-11. To this end, the use of a web platform will be combined with videoconference sessions with a therapist. The specific objectives are: (1) to explore participants' expectations and preferences, (2) to assess patients' satisfaction and acceptance of the treatment, (3) to study the appropriateness of different methods of recruitment and data collection (e.g., whether we can reach the target population, how broad or restrictive the eligibility criteria are, how willing patients are to participate, time needed to collect data), and (4) to explore participants' reasons for non-participation and dropping out of the treatment. Additionally, as a secondary objective, the potential efficacy of this intervention at post-treatment and follow-ups will be tested. For this purpose, intra-group changes in AjD related symptoms from baseline to post-treatment and follow-ups will be analyzed, with the main comparison being between baseline and post-treatment. The inclusion of the two follow-ups will serve to analyze their viability for a future RCT.

2. Material and methods

2.1. Design

A feasibility trial with a single-group and open-trial design will be conducted. It will include four measurement points: baseline (pre-

treatment), immediately after the intervention (post-treatment), and at the 3- and 12-month follow-ups.

This work was registered in the Clinical Trials database (https://clinicaltrials.gov/) prior to its initiation (NCT05464121) and received the approval of the Ethics committee of the Universitat Jaume I (Castellón, Spain). The extension of the Consolidated Standards of Reporting Trials (CONSORT) statement for pilot and feasibility studies (Eldridge et al., 2016), the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth guidelines (Eysenbach, 2011), and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013a; Chan et al., 2013b) will be followed.

2.2. Study setting

This study will be conducted at the Emotional Disorders Clinical at the Universitat Jaume I in Castellón (Spain), although the entire intervention will be administered online.

2.3. Eligibility criteria

Participants will be included in the study if they meet the following criteria: (a) age > 18 years, (b) meeting diagnostic criteria for AjD based on the ICD-11 definition, (c) exceeding the cut-off point of 47.5 on the ADNM-20 questionnaire (Lorenz et al., 2016), (d) signing the informed consent, (e) being able to understand and read Spanish, (f) being able to use a computer and having access to the Internet, and (g) having an email address.

Reasons for exclusion include risk of suicide or self-destructive behaviors, diagnosis of another serious mental disorder (substance abuse or dependence, psychotic disorder, dementia, bipolar disorder, or personality disorder), receiving another psychological treatment during the study for AjD, or experiencing an increase and/or change in medication during the study period.

2.4. Intervention

2.4.1. Internet self-applied intervention and videoconference sessions

The blended intervention will combine a self-applied program administered through a web platform and videoconference sessions with

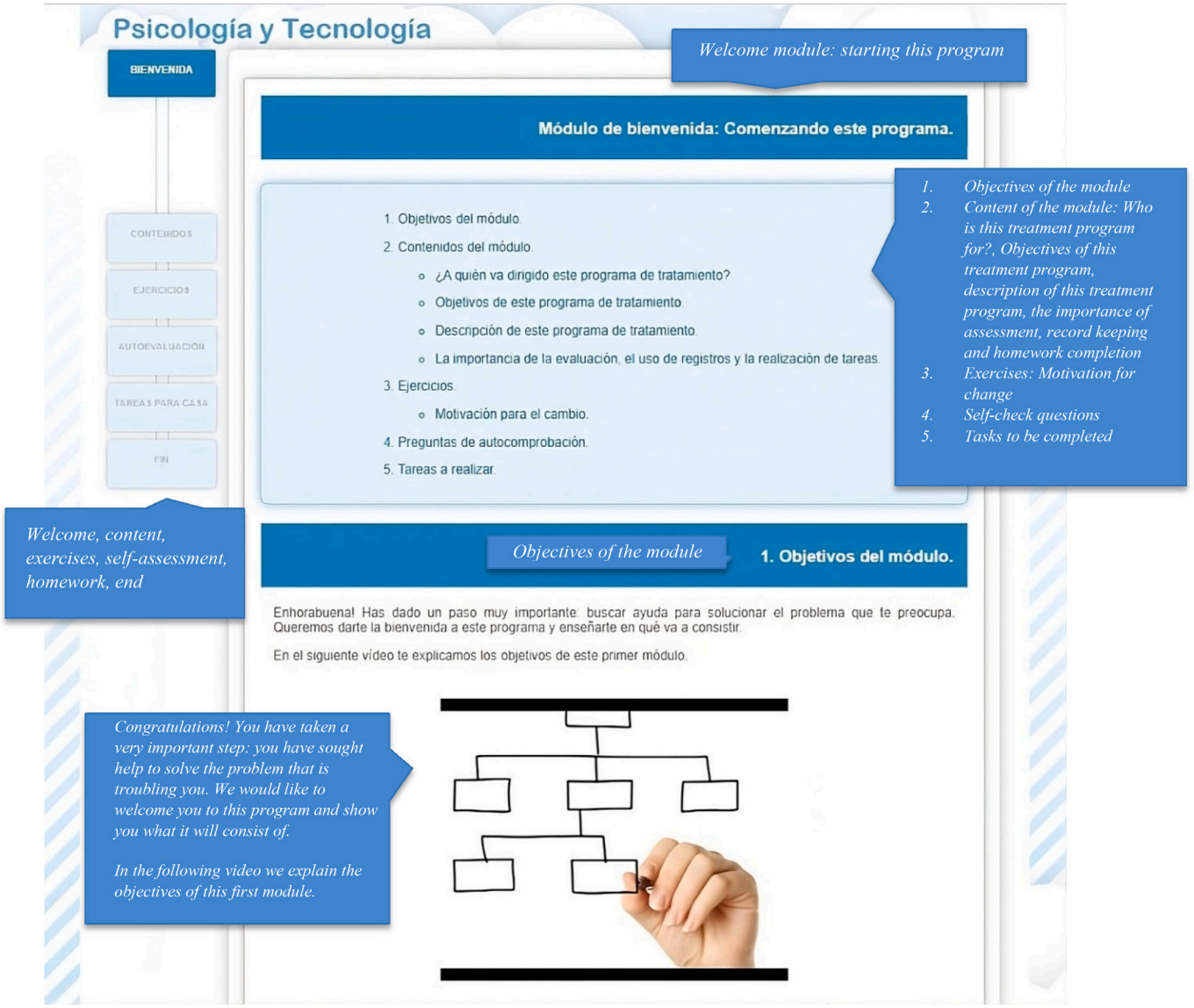

Fig. 1. Image of the treatment web platform.

a therapist using Google Meet software.

The TAO self-applied program (Adjustment Disorder Online) is accessible online through the Psychology and Technology website. Data security and protection issues can be found in the Ethics and dissemination section. All participants will have their own username and password that will give them access to the platform at any time. The platform contains text, downloadable PDFs, and various multimedia contents such as images and videos. It also offers the possibility of reviewing previously viewed treatment content, and it includes a calendar and graphs with clinical measures that allow participants to monitor their progress after treatment and during the follow-ups. To ensure the safety of the participants, the platform includes alarms that alert the clinician when a participant may be at risk of suicide. A screenshot of the treatment platform can be seen in Fig. 1.

The content of the program is organized in seven sequentially accessible modules, each lasting approximately 60 min. The estimated duration of the intervention is 12 weeks. Thus, participants will complete one module of the treatment every 10–12 days, in addition to having an individual videoconference session with a therapist (lasting approximately 30 min). The aim of these sessions will be to present the main contents of the module to be worked on online in the next few days, resolve doubts, and motivate the patients to continue with the therapy.

To improve adherence to the intervention during treatment and follow-ups, participants will receive reminder emails. Criteria for discontinuing the intervention will be a change in the dosage of the psychotropic drug, the explicit request of the participant, or a worsening of the mental disorder. A participant will be considered a treatment dropout when, after meeting the eligibility criteria and signing the informed consent, they explicitly declare that they do not want to continue with treatment or when they have not responded to reminders for videoconference sessions or access to the platform for 1 month.

The therapists who will participate in the study, during both the assessment and treatment process, will be trained clinicians with at least a master's degree and training in CBT protocols.

2.4.2. *Therapeutic components*

This treatment is the optimized version of the original intervention protocol for AjD developed by Botella et al. (2008) and subsequently updated by Rachyla et al. (2020). It is based on CBT and includes different components of positive psychology and exercises adapted from Neimeyer's (2000) reconstruction of meaning approach to grief therapy. A detailed description of the treatment content can be found in Table 1.

Table 1
Videoconference sessions, modules, and objectives.

Session	Videoconference session	Module	Objectives
S0	10 min: - Introduction of the therapist - Explain how the blended format works - Recall with the patient the reason for the consultation and the therapeutic objectives 20 min: - Presentation of M0 - Explain the importance of motivation and fluctuations in motivation as a normal part of the therapy process. Ambivalence - Emphasize the importance of the use of homework	M0. Starting this program	- Presentation of the treatment - Learn about the ambivalence of motivation for change
S1	10 min: - Presentation of the agenda - Resolving doubts and questions about M0 - Emphasize the importance of homework 20 min: - Presentation of M1	M1. Understanding emotional reactions	- Learn about the nature of AjD - Learn strategies for managing emotional reactions: behavioral activation and slow breathing
S2	10 min: - Presentation of the agenda - Resolving doubts and questions about M1 - Emphasize the importance of homework 20 min: - Presentation of M2	M2. Learning to cope with negative emotions	- Learn the exposure technique to help cope with negative emotions - Learn how to solve problems by using the problem-solving technique
S3	10 min: - Presentation of the agenda - Resolving doubts and questions about M2 - Emphasize the importance of homework 20 min: - Presentation of M3	M3. Accepting the problems	- Learn the logic of elaboration - Practice elaboration by becoming aware of emotions, thoughts, images, memories, etc. in order to learn to accept them - Reflect on the new meaning that problems can have

(*continued on next page*)

2.5. *Outcome measures*

The assessment will take place at four time points: pre-treatment, post-intervention, at the 3-month and 12-month follow-ups (see a detailed description of the assessment procedure in Table 2).

2.5.1. *Sociodemographic data, screening and diagnostic measures*

First, a brief structured telephone interview and a semi-structured videoconference interview developed for this research team will be used to check the inclusion/exclusion criteria. The age, gender, educational level, occupation, marital status, and place of residence of all participants will be assessed.

For the diagnosis of AjD following the ICD-11 criteria, the ADNM-20 (Einsle et al., 2010) will be administered by a clinician via videoconference. It consists of a first part that includes a list of stressful events that participants may have experienced in the past 2 years. In the second part, patients' symptomatology is evaluated in reference to the most stressful event. The response scale ranges from 1 (never) to 4 (frequently). A cut-off point of 47.5 is required to differentiate between people with low and high risk of AjD (Lorenz et al., 2016). Previous studies showed the good psychometric properties of this questionnaire (Einsle et al., 2010).

Table 1 (*continued*)

Session	Videoconference session	Module	Objectives
S4	10 min: - Presentation of the agenda - Resolving doubts and questions about M3 - Emphasize the importance of the homework 20 min: - Presentation of M4	M4. Learning from problems	- Reflect on what we can learn from problems - Practice elaboration - Understand the importance of identifying your own psychological strengths
S5	10 min: - Presentation of the agenda - Resolving doubts and questions about M4 - Emphasize the importance of homework 20 min: - Presentation of M5	M5. Changing the meaning of the problems	- Elaborate a new meaning of the stressful event in the present moment and how it could be in the future - Promote a new attitude to cope with the difficulties. Letter of projection into the future and choice of a personal motto for life
S6	10 min: - Presentation of the agenda - Resolving doubts and questions about M5 - Emphasize the importance of homework 20 min: - Presentation of M6	M6. Relapse prevention	- Evaluate progress made with treatment - Review skills learned - Learn how to deal with future problems - Understand the need to keep working on our own improvement

Additionally, to ensure that the exclusion criteria are met and make a differential diagnosis, the corresponding modules of the Structured Clinical Interview for the DSM-IV (SCID-I; First et al., 1996) will be used mainly to rule out the diagnosis of major depression or posttraumatic stress disorder and the modules of Anxiety Disorders Interview Schedule (ADIS-IV; Brown et al., 1988) will be used mainly to rule out generalized anxiety disorder or other anxiety disorders.

2.5.2. Primary outcomes: feasibility assessment

2.5.2.1. Adherence. The number of modules completed by participants, the number of times participants enter the treatment, the total time spent in the treatment, whether they review the treatment contents, and the dropout rates will be recorded. The reasons for dropping out will be assessed using a qualitative interview designed by the clinical team of the study. This will include a list of reasons from which the person can choose why they dropped out of treatment (they can also add any that are not on the list), and questions about what they would have liked to have been different, whether they would have continued in the program if that had been different, what were the main barriers/limitations to treatment, and whether they can think of any strategies to improve adherence.

2.5.2.2. The expectations and satisfaction questionnaire adapted from Borkovec and Nau (1972). It includes two different scales containing 6 items each (rated from 0 to 10). One refers to expectations about the treatment before the intervention begins. The other scale is used to assess satisfaction with the treatment once it is over.

2.5.2.3. The intervention opinion questionnaire. This opinion assessment tool was developed for this study. First, participants' preferences before and after the blended intervention will be assessed. Second, at post-treatment, participants will answer questions related to the satisfaction (0−10) and usefulness (0–10) of each component of the treatment, the different aspects of the intervention (e.g., text, videos, images), the videoconference sessions with a therapist every 10–12 days, and the blended format. Participants will be asked about the reasons for their scores, and the presence of adverse or unexpected events during treatment will be reported. Finally, the satisfaction and usefulness of each treatment module and the participants' opinions after each videoconference session with the therapist will also be evaluated using a response scale from 0 to 10.

2.5.2.4. The Working Alliance Inventory for guided Internet Interventions (WAI-I; Gómez-Penedo et al., 2020). The WAI-I evaluates the components of the therapeutic alliance according to Bordin (1979), using 12 items assessed from 1 to 7.

2.5.2.5. The Usability System Scale (SUS; Bangor et al., 2008; Brooke, 1996; Castilla et al., 2023). This instrument will be used to evaluate the usability of the TAO web platform. It has 10 items (rated from 1 to 5) and assesses the usability of a service or product and its acceptance by the users.

2.5.3. Secondary outcomes: preliminary efficacy assessment

The AjD symptomatology will be assessed using the *Adjustment Disorder New Module-20* (*ADNM-20*; Einsle et al., 2010). The intensity with which a situation or a person lost as a result of the stressful event interferes with the participant's life will be evaluated with the *Loss and Stress Inventory* (*IEP*; Quero et al., 2019a). The *Positive and Negative Affect Scale* (*PANAS trait*; Díaz-García et al., 2020; Watson et al., 1988) will be used to assess two dimensions of mood (positive and negative affect). The *Posttraumatic Growth Inventory* (*PTGI*; Tedeschi and Calhoun, 1996; Weiss and Berger, 2006) assess positive psychological change after an adverse or traumatic experience. Finally, the *Overall Anxiety Severity and Impairment Scale* (*OASIS*; González-Robles et al., 2018; Norman et al., 2006) and the *Overall Depression Severity and Impairment Scale* (*ODSIS*; Bentley et al., 2014; Mira et al., 2019) will be used to assess the frequency and severity of anxiety and depression symptoms, as well as the degree of avoidance and interference. In the case of the ODSIS, an additional item was included to evaluate the presence of suicidal ideation symptoms.

2.5.4. Other outcomes

The change in efficacy measures after each treatment module will be assessed using questions related to the following aspects: mood at this time and changes in mood after the module, perceived self-efficacy in dealing with the stressful event, and acceptance and openness to future experiences. Additionally, the *Purpose-in-Life Test-10 Items* (*PIL-10*; Crumbaugh and Maholick, 1964; García-Alandete et al., 2013) and the *Quality of Life Inventory* (*QLI*; Frisch et al., 1992; Mezzich et al., 2000) will be used to assess different aspects of meaning in life and patients' quality of life in different areas and overall, respectively.

2.6. Sample size

Because this study is a feasibility trial, a formal sample size calculation is not required. However, for the potential efficacy objective, the sample size is determined by considering the changes in AjD symptoms between pre-test and post-test as the main outcome. To this end, a significance level of 5 % was assumed, with a statistical power of 80, a

Table 2
Measures, times, and tools for assessment.

	STUDY PERIOD					TOOLS
	Enrolment	Post-allocation			Close out	
TIMEPOINT		*Pre-treatment*	*Post-treatment*	*3-month follow-up*	*12-month follow-up*	
ENROLMENT:						
Pre-screening interview	X					Phone call
Sociodemographic data and screening interview	X					Videoconference
Adjustment Disorder New Module-20	X					Videoconference
Informed consent	X					Qualtrics
INTERVENTIONS:						
Blended intervention for AjD		◆——	——◆			Psychology and Technology website
ASSESSMENTS:						
Adherence measures		◆——	——◆			Psychology and Technology website
➢ **Reasons for dropping out**					X	Phone call
Expectations and Satisfaction questionnaire		X	X	X	X	Psychology and Technology website
Opinion Questionnaire about the intervention			X			Qualtrics
➢ **Preferences**		X	X			Qualtrics
Working Alliance Inventory-I			X			Psychology and Technology website
Usability System Scale			X			Psychology and Technology website
Adjustment Disorder New Module-20 (self-applied form)		X	X	X	X	Qualtrics
Inventory of Stress and Loss		X	X	X	X	Psychology and Technology website
Positive and Negative Affect Scale		X	X	X	X	Psychology and Technology website
Posttraumatic Growth Inventory		X	X	X	X	Psychology and Technology website
Overall Depression Severity and Impairment Scale		X	X	X	X	Psychology and Technology website
Overall Anxiety Severity and Impairment Scale		X	X	X	X	Psychology and Technology website
Purpose-in-Life Test-10 Items		X	X	X	X	Psychology and Technology website
Quality of Life Inventory		X	X	X	X	Psychology and Technology website
Post-module efficacy measures		After each treatment module				Psychology and Technology website

bilateral contrast, and an effect size of moderate magnitude (d = 0.50), according to Cohen's (1988) guideline for standardized mean differences. The resulting sample size was 34 participants. However, following a strict criterion an expected dropout rate of 17 % was considered (Rasing et al., 2020), resulting in a sample size of 41 participants.

2.7. Recruitment

Several social networks (e.g., Whatsapp, Instagram, Facebook, and Linkedin), informative posters placed on the Universitat Jaume I and Universitat de València campuses, the university websites, and traditional media (e.g., local newspapers and radio) will be used for recruitment. In addition, patients who seek psychological treatment at Universitat Jaume I Emotional Disorders Clinic will be recruited. Recruitment for this study is already ongoing. An example of the flowchart is shown in Fig. 2.

2.8. Data collection procedure

People interested in participating could contact the study by e-mail or telephone. The clinical team will respond to emails or calls within 24 h and set up an initial interview. After completing this first pre-screening interview by telephone, two assessment sessions will be held to confirm that the eligibility criteria are met. The Adjustment Disorder New Module-20 scale (ADNM-20; Einsle et al., 2010) will be used for the diagnosis of AjD according to the ICD-11. These sessions will be conducted via videoconference by a trained therapist. In addition, participants will be asked about their psychotropic medication and monitored for changes in dosage or type of medication during the treatment and

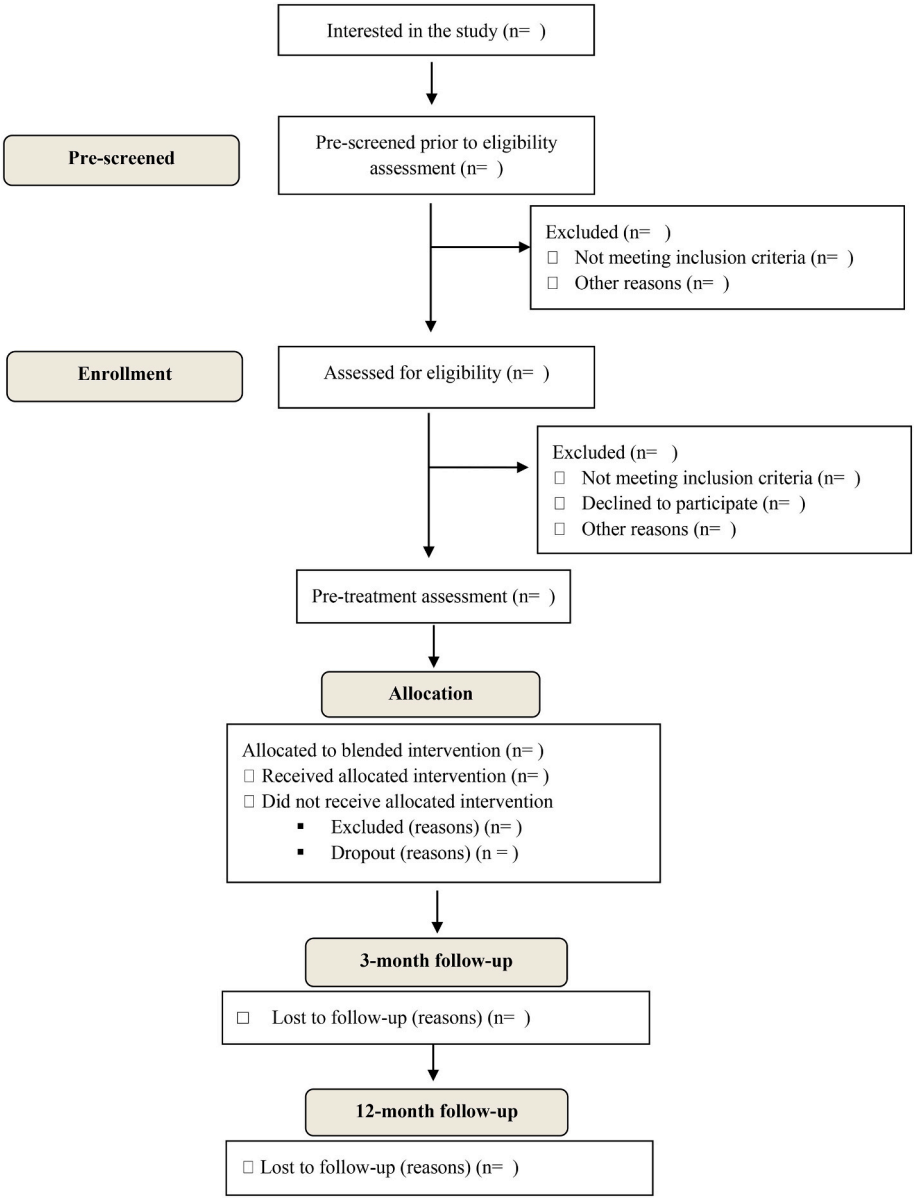

Fig. 2. Flowchart of participants.

follow-ups.

After participants have been informed of the characteristics of the intervention, they will sign an informed consent form and begin treatment. All of them will respond to assessments at four time points.

For participants who do not complete the intervention, they will still be encouraged to respond to T2, T3, and T4 assessments. Additionally, they will be asked to respond to the qualitative dropout interview.

2.9. Data analysis plan

The main data will be reported narratively for the primary feasibility objective, illustrated with descriptive statistics, and reported in accordance with the CONSORT 2010 declaration (Eldridge et al., 2016). Missing data will be used to determine dropout rates. Adherence will be evaluated based on the frequency with which each patient uses the program. Means (SD) and/or frequencies (%) will be used to portray the data in a descriptive manner.

For the secondary aim, mixed-effects models will be used to assess the treatment's potential efficacy of the treatment, as it allows intention-to-treat analyses. The pre-test, post-test, and two follow-ups (at 3 and 12 months) will be considered as measurement occasions. The effect sizes and associated 95 % confidence intervals (CI) for the intra-group changes will also be calculated. Both the completers and the intention-to-treat data will be subject to statistical analysis. SPSS version 28.0 will be used for all data analyses.

3. Ethics and dissemination

This study received the approval of the Ethics committee of the Universitat Jaume I in Castellón, Spain (file number CD/42/2022, March 2022). All the participants who will take part in the trial will receive a prior explanation of what the study will consist of and how the treatment works. After the explanation and before starting the intervention, all participants will sign an informed consent form that presents the study information in a detailed and clear manner. Patients will always participate on a voluntary basis and may leave the study at any time. The principles of the Declaration of Helsinki shall be fully respected throughout the trial. The treatment web platform, the software for videoconferencing, and the data collection-oriented web pages comply with the European Union data protection law. Participants will

be provided with a personal username and password known only to them. The databases will use codes to protect sensitive data such as personal information, and personal data will be separated from clinical data. Only members of the study clinical team will have access to these data.

4. Discussion

The main aim of this study is to analyze the feasibility of a CBT blended intervention for AjD, as defined in the ICD-11, that combines a self-applied Internet intervention and videoconference sessions with a therapist.

Blended interventions are a growing field due to their many advantages. As mentioned above, it is difficult to access psychological treatments, not only for AjD, but for most mental disorders (Wang et al., 2005). Some authors have proposed that the incorporation of technologies into psychological treatments could improve their dissemination (Fairburn and Patel, 2017; Kazdin, 2017). One example is Internet-based treatments.

However, the lack of adherence to these interventions has led to the emergence of other alternatives, such as the blended format tested in this study. Previous studies conducted with other mental disorders have shown that blended interventions can be a viable, well-accepted and an effective alternative for many patients (Erbe et al., 2017; Schuster et al., 2018). In addition, this format can also make treatment more cost-effective reducing intervention costs (Erbe et al., 2017). However, in the case of AjD, as far as we know, only one study has tested a blended intervention (Leterme et al., 2020). Furthermore, it should be noted that, in this particular study, the face-to-face part was conducted by a nurse rather than a therapist. In addition, the computer-based component was performed in the same office, and not in an online format. Despite these differences, this study showed that an intervention using this format could also be effective in reducing the symptomatology of participants with AjD.

The intervention presented in this study protocol is based on evidence-based CBT components for AjD, and it includes different components of positive psychology and exercises adapted from Neiyemer's (2000) reconstruction of meaning approach to grief therapy. This treatment has already been tested in both face-to-face (Quero et al., 2019b) and self-applied formats (Rachyla et al., 2020), showing promising results.

To the best of our knowledge, this study presents the first blended intervention for AjD that combines a self-applied intervention via a web platform with videoconference sessions with a clinician every 10–12 days. In addition, it will be the first blended intervention for AjD in the Spanish language, which could bring this psychological treatment closer to all Spanish speakers.

We expect to show the feasibility of this blended intervention, in order to conduct a future RCT to determine the efficacy of an intervention with these characteristics for the treatment of adults with AjD.

4.1. Limitations

The main limitation of this study refers to the lack of randomization of participants. In this line, studies with a control group would be advisable in order to improve the design and methodology of a future RCT. Other limitations that may arise during the trial could have to do with difficulties in recruiting the sample, failures in the computer systems, or a high dropout rate. First, it is suggested that social media, posters and traditional media may not be sufficient to reach the estimated sample size. If it is necessary to increase the number of participants, we will also recruit by advertising in different universities or patient associations. Problems with computer systems will be taken care of by an engineer from the research team. Finally, regarding the dropout rate, we have adopted a strict criterion and contemplated a 17 % dropout rate in the sample size calculation.

5. Conclusion

The results of this study will provide valuable data about the feasibility and acceptability of a blended intervention for AjD. In addition, participants' use of the intervention and their feedback, expectations, and preferences will allow us to better understand their needs and adjust the design of future studies that test interventions for this disorder.

Consent for publication

Not applicable.

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CRediT authorship contribution statement

SFB wrote the manuscript on the study protocol. SQ, SFB, JG, MP, and ADG collaborated in the study design. PC and SQ supervised and reviewed the writing of the article. All the authors read and approved the final manuscript.

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.

Data availability

Because this study is still in the recruitment phase, data cannot yet be shared.

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