Programa de doctorado en Psicología

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Desarrollo y validación de un programa de tratamiento online para los trastornos adaptativos

Development and validation of an online treatment program for adjustment disorders

Memoria presentada por Iryna Rachyla para optar al grado de doctora por la Universitat Jaume I

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- Ojalá nada de esto hubiera ocurrido.

- Eso desean quienes viven estos tiempos, pero no les toca a ellos decidir. Lo único que podemos decidir es qué hacer con el tiempo que se nos ha dado.

El Señor de los Anillos

- I wish none of this had happened.

- So do all who live to see such times, but that is not for them to decide. All we have to decide is what to do with the time that is given to us.

The Lord of the Rings

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Presentation

The present doctoral dissertation is presented as a compendium of five publications; two of them have already been published in two different indexed journals. The thesis also includes two additional sections. First, *General introduction section* aimed at presenting the research topic, brief overview of the existing evidence and gaps in the knowledge which justify the importance of the conducted research. Study aims and hypotheses are also defined. The second additional section is devoted to the *General discussion of the results*. This section summarizes the main findings of the research work.

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

Abstract

Adjustment disorder (AjD) is one of the most common mental disorders. Besides causing significant distress, AjD also leads to an important functional impairment. In fact, it is among the most prevalent causes of sickness absence. And, despite the fact that it is considered a transient condition with a generally good prognosis, AjD is associated with high risk of suicide. Likewise, evidence suggests that it is an important problem which is worthy of professional attention. Nevertheless, since its first inclusion in DSM and ICD classifications of mental disorders, AjD has been poorly investigated. The lack of research led to an important scarcity of evidence based assessment instruments and psychological treatments.

Another current problem in the field of mental health is the access to psychotherapy, which is hampered by different barriers such as time constraints, waiting lists, stigma, or financial affordability. As a consequence, most people with mental disorders do not receive the assistance they need. The advent of internet and its widespread use have motivated the investigation into the potential of internet delivered intervention to improve the access to evidence-based treatments. Today, these

interventions are effectively used for the treatment of a wide range of mental disorders, producing similar effects as face-to-face therapy. However, despite their proven efficacy, internet delivered interventions have not yet been implemented in health care settings. The acceptability might be one key barrier.

The aim of the present thesis is to contribute to the assessment and treatment of AjD. The work is organized into five chapters. *Chapter 1* presents the first semi-structured diagnostic interview for AjD and reports the preliminary results on its validity and reliability properties. *Chapter 2* presents the results of the feasibility study conducted to assess the acceptability and usability of TAO, an internet-delivered intervention for AjD. The other three chapters are devoted to the randomized controlled trial (RCT) carried out to investigate the efficacy and acceptability of TAO: *Chapter 3* presents a detailed description of the study protocol; *Chapter 4* and *Chapter 5* report outcomes of the trial regarding the TAO efficacy and acceptability, respectively.

The results of the work represent an important advance in the field of AjD. First, it provides the preliminary evidence to support the use of the first semi-structured diagnostic interview in Spanish to assess and identify cases of AjD. Second, to the best of our knowledge, this is the first completed RCT on the efficacy and acceptability of an internet-delivered intervention for AjD. TAO was found to be well accepted and more effective than the mere passage of time in reducing distress among patients with AjD. The intervention also had additional benefits in terms of posttraumatic growth, positive affect, and quality of life. The evaluation of patients' opinion about the treatment revealed the important impact of intervention characteristics on treatment engagement.

General introduction

Mental disorders are highly prevalent worldwide and have a significant impact at all levels, as they are one of the leading causes of disability and mortality (Steel et al., 2014; WHO, 2013). In 2010, the economic costs associated with mental disorders in Europe were estimated at around €461 billion (Gustavsson et al., 2011) and at €46 billion in Spain (Parés-Badell et al., 2014). These costs result not only from the increased use of health system resources and medication, but also from other consequences of mental disorders, such as loss of productivity and sick leaves (Ruiz-Rodríguez et al., 2017).

From a large spectrum of mental disorders, adjustment disorder (AjD) is one of the most common conditions in clinical practice (Evans et al., 2013). Albeit with certain differences, two widely established systems for classifying mental disorders (DSM-5 and ICD-10) overlap in the definition of AjD as the development of clinically significant symptoms as a consequence of an important change or other stressful event (c). In order to ascertain this causal relationship, the onset of symptoms and stressful

event must be close in time, and if the stressor or its consequences are removed, the symptoms should be resolved within six months.

Despite some improvements were made in the classification of AjD from its first inclusion in DSM and ICD manuals, considerable uncertainties and difficulties still remained with regard to its diagnosis (Casey, 2014). Thus, the recently published ICD-11 represented a major change in the definition of AjD, since for the first time specific core symptoms were included (WHO, 2018): (1) excessive worry, recurrent and distressing thought, or constant rumination about the stressor and/or its implications; (2) failure to adapt to the stressor which leads to an important functional impairment. More evidence is still needed to provide enough support to this new conception of AjD (Kazlauskas, Zelviene, Lorenz, Quero, & Maercker, 2018). However, the ICD-11 proposal is without any doubt an important step forward that might promote greater interest in this disorder, which to date has received little attention from the research community.

Impact of AjD

According to literature, AjD is in between no disorder and other psychiatric disorders in terms of severity (Fernández et al., 2012; O'Donnell et al., 2016). Clinical symptoms of AjD are substantially more severe in patients diagnosed with AjD than in healthy population, but less severe than in other anxiety and affective disorders. However, although symptoms of AjD tend to be milder, they are severe enough to cause an important distress, functional impairment and low quality of life. In fact, AjD is one of the main causes of seek leaves and presents suicidality rates similar to those found in patients with Major Depressive Disorder (Calvo et al., 2009; Casey, Jabbar, O'Leary, & Doherty, 2015). Several studies have also found that AjD can lead to the development

of a more chronic condition (Yaseen, 2017). Providing intervention may prevent this chronicity and worsening of symptoms (Strain & Diefenbacher, 2008).

Assessment of AjD

Little research in the field of AjD led to the lack of valid and reliable assessment measures for this condition. Among the different structured diagnostic interviews, only the Schedule for Clinical Assessment in Neuropsychiatry (SCAN; Wing et al., 1974), the Structured Clinical Interview for DSM-IV (SCID; First, Spitzer, Gibbon, & Williams, 1999) and the Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) include a section for AjD. In all three instruments the AjD section is considered optional and it is used only when criteria for previously assessed disorders are not reached. Evidence suggests that this approach contributes to an important underestimation of AjD (Shear et al., 2000; Taggart et al., 2006), therefore, most experts agree that the diagnoses of this disorder should be based on the clinical judgment (Bachem & Casey, 2018).

Given this situation, a significant effort has been carried out to develop instruments to facilitate the detection of AjD. To date, two diagnostic interviews for AjD have been reported in the literature. The first one, is a structured *Diagnostic Interview for Adjustment Disorder* (DIAD) composed of 29 questions based on DSM-IV criteria for AjD (Cornelius, Brouwer, De Boer, Groothoff, & Van der Klink, 2014). Initial validation analyses have confirmed its content and construct validity, though further work on its reliability and other aspects of validity is needed.

The other interview was developed by our research group (Molés, Quero, Andreu-Mateu, Botella, & Baños, 2011). The interview presents a semi-structured format and it was used in several randomized controlled trials (RCT) on AjD as the

diagnostic instrument to detect and assess potential participants (Andreu-Mateu, 2011; Molés, 2016). However, no data on the validity or reliability of the interview have been reported yet. Therefore, one of the main objectives of the present thesis is the preliminary exploration of psychometric properties of the instrument.

As for self-report questionnaires developed specifically for AjD, only two instruments have been properly validated so far. The first one is the *Adjustment Disorder New Model* questionnaire (ADNM) which follows the new proposal of ICD-11 (Maercker et al., 2013). In order to screen for AjD, ADNM include a list of stressful life events and a list of symptoms. The aim of the instrument is to identify possible stressful events which might have taken place in the last two years and their accompanying symptoms. Validation studies revealed good psychometric properties for different available versions (Einsle, Köllner, Dannemann, & Maercker, 2010; Lorenz, Bachem, & Maercker, 2016). However, as it was mentioned previously, more evidence is still needed to provide support to the new conception of AjD.

The other self report questionnaire is the *Inventory of Stress and Loss* (ISL; Quero, Mor, Molés, Rachyla, Baños, & Botella, submitted). This is an adaptation of the *Inventory of Complicated Grief* (Prigerson et al., 1995) conducted by our research group. The adaptation involved replacing the reference to the "dead person" by other related to the "person or situation" which caused the distress symptoms. The aim was to assess the loss that triggers the stressful event in patients with AjD. Preliminary validation data showed excellent internal consistency and test-retest reliability (Quero, Molés, Mor, Baños, & Botella, 2014).

Treatment of AjD

Although no specific guidelines are available for the treatment of AjD, there is expert agreement that brief psychotherapy should be the treatment of choice (Strain & Diefenbacher, 2008). Pharmacotherapy, on the other hand, can be useful with patients who present severe depressive or anxiety symptoms (Hameed, Schwartz, Malhotra, West, & Bertone, 2011; Stein, 2015). However, pharmacotherapy aims to control clinical symptoms rather than to treat the disorder itself. Psychotherapy is required to reduce the impact of the stressful event by helping patients to eliminate the stressor, reframe the meaning of the stressor or develop coping skills (Strain, 1995). Following this idea, Botella, Baños, & Guillén (2008) developed an intervention protocol for AjD. The mentioned protocol combines cognitive behavioral therapy (CBT) and positive psychology in order to promote the reduction of distress symptoms, a change in the meaning of the stressful event, and the development of resilience. The *Book of Life* is one of the core components of the intervention, aimed to enable the evocation and the processing of the stressful event. The processing takes place throughout three stages: *Acceptance*, *Confrontation*, and *Change of Meaning*. A virtual reality system named *EMMA's world* was developed to facilitate this processing. However, the intervention can be used with or without this virtual reality system (Baños et al., 2011). The RCT performed on the efficacy of the protocol revealed that both formats were equally effective (Andreu-Mateu, 2011).

Other treatment approaches were also tested (Bachem & Casey, 2018). However, given the scarcity and methodological problems of the published studies, there is no "gold" standard treatment for patients with AjD.

Barriers to psychotherapy

According to WHO, in high-income countries between 35% and 50% of people with severe mental disorders do not receive a treatment for their problem (WHO, 2013). The percentage of unattended patients in low- and middle-income countries is even higher. Time constraints or transportation difficulties are among the most frequently reported barriers that hamper the access to psychotherapy (Mohr et al., 2006). Likewise, research shows that the use of health services decreases when geographical and temporal distance increases (López-Lara, Garrido-Cumbrera, & Díaz-Cuevas, 2012). Waiting lists are another important barrier. In most EU countries people wait for more than two months to access to psychotherapy (Barbato, Vallarino, Rapisarda, Lora, & Caldas de Almeida, 2016).

As for acceptability, several studies found that patients with depression preferred psychotherapy over antidepressants (Tompkins, Swift, Rousmaniere, & Whipple, 2017; Van Schaik et al., 2004). Nevertheless, certain attitudinal barriers, such as stigma, should be beard in mind. Despite the public understanding of mental illnesses seems to have increased in the last years (Schomerus, Schwahn, Holzinger, Pw, & Hj, 2012), the stigma remains one of the most important barriers to help-seeking, reported by more than 20% of patients (Clement et al., 2012; Clement, Schauman, Graham, Maggioni, & Bezborodovs, 2015).

These findings are consistent with those found in other study which detected that low perceived need for treatment is another important barrier, especially among patients with mild disorders (Mojtabai et al., 2012). Patients with more severe conditions, on the other side, report more attitudinal (e.g., perceived ineffectiveness, stigma and desire to

handle the problem on their own) and structural barriers (e.g., cost, lack of time, schedule change, or transportation difficulties).

Lastly, financial affordability is another important barrier to psychotherapy (Reisinger, Cummings, Hockenberry, & Druss, 2015). The cost factor is possibly more important in countries where private insurance is required to receive psychotherapy. However, long waiting lists and dissatisfaction with help received in public health care system may force people to search for assistance which is not covered by their insurance.

Internet-delivered interventions

Self-help technology based treatments, especially internet-delivered interventions, can help to overcome or sidestep some of the barriers to psychotherapy described above (Kazdin, 2017). Research on the potential of internet to contribute to the treatment of mental disorders started in the nineties (Andersson, Carlbring, Ljótsson, & Hedman, 2013). Since then, internet-delivered interventions were developed for a wide range of disorders and currently considerable evidence supports their effectiveness. Different meta-analyses reported effect sizes comparable to face-to-face interventions (Andersson, Cuijpers, Carlbring, Riper, & Hedman, 2014; Cunningham, Gulliver, Farrer, Bennett, & Carron-Arthur, 2014; Kumar, Sattar, Bseiso, Khan, & Rutkofsky, 2017). Guided interventions generally show better outcomes and lower dropout rates than totally unguided programs (Andersson et al., 2013; Castro et al., 2018).

Different advantages of the use of internet interventions have been highlighted (Griffiths, Lindenmeyer, Powell, Lowe, & Thorogood, 2006; Musiat & Tarrier, 2014). The first one involves their high reach. While face-to-face psychotherapy implies

treating only one patient or reduced group of patients at the same time, internet interventions provide help to hundreds and thousands of people at the same time, reducing exiting waiting lists. Flexibility with regard to time and location is another important advantage. Patients can access the intervention anytime, when their schedule allows it or when they need it most, without worrying about therapist availability. This flexibility offers the possibility to progress without pressure, according to one's own pace. Internet-delivered interventions can also be accessed from anywhere. Any person using Internet can have access to evidence-based treatments. Cost saving is another remarkable strength. Receiving psychotherapy online leads to the saving on transport expenses and also on the cost of the treatment, since these interventions are cheaper than face-to-face help. Internet-delivered interventions also generate important societal cost savings. In Spain, an internet-delivered intervention for depression showed a cost-saving of €169.50 per patient (Romero-Sanchiz et al., 2017). There is also an important cost-saving in terms of time. Internet-delivered interventions allow patients save time required to reach the hospital or other centre where they are receiving assistance. Finally, the use of internet-delivered interventions increases privacy and confidentiality. Therefore, these interventions might be especially attractive for people concerned about the stigma associated to mental illness.

Internet-delivered interventions for AjD

Evidence regarding the efficacy of self-help interventions for AjD is scarce but promising. Unguided use of bibliotherapy manual promoted the improvement in distress symptoms of AjD among burglary victims (Bachem & Maercker, 2016b). Comparison with a waiting list revealed greater reduction of clinical symptoms and higher proportion of patients showing reliable pre-post clinical change in the intervention group. As for internet-delivered interventions addressed to AjD symptoms, only one

provided preliminary data on its efficacy. Self-guided *Brief Adjustment Disorder Intervention* (BADI) produced significant decline of AjD symptoms, which was greater than that showed by participants from the waiting list (Eimontas, Rimsaite, Gegieckaite, Zelviene, & Kazlauskas, 2017).

Another two available interventions were also found during the literature review (Murphy et al., 2017; Servant et al., 2017), although both of them are currently undergoing validation and no data on their efficacy have been reported yet. Moreover, one of the interventions only targets cancer patients (Murphy et al., 2017) and the other focuses only on AjD with anxiety subtype (Servant et al., 2017), therefore, the use of these interventions is limited to specific subgroups of the population.

Given the high prevalence and impact of AjD, as well as the promising potential of internet-delivered interventions for reducing the burden of mental disorders in general and of AjD in particular, further research is required in order to contribute to the development of evidence-based interventions for AjD able to reach all people who may need them.

Aims of the thesis

Broad aims

The present doctoral thesis has two main objectives. The first one is to conduct the preliminary assessment of reliability and validity of a semi-structured diagnostic interview for AjD. The second aim is to conduct a RCT investigating the efficacy and acceptability of an internet-delivered CBT (ICBT) intervention for AjD. Given the lack of research in the field of AjD, it was decided to provide internet intervention along with brief weekly telephone support in order to, first, promote treatment adherence and, second, facilitate the detection of possible doubts and troubles that patients can have using a self-help of those characteristics. Thus, the broad aims of the thesis are, on the one hand, to contribute to the assessment and treatment of AjD and, on the other hand, to expand the knowledge about the implementation of internet-delivered interventions.

Specific aims

I. To evaluate the validity and reliability of the *Diagnostic Interview for Adjustment disorders*.

II. To test the efficacy of internet-delivered intervention combined with weekly telephone support in reducing distress and prompting positive change among patients with AjD.

III. To compare the intervention group with a control group (waiting list) that has not received any intervention in 7 weeks.

IV. To evaluate the maintenance of the acquired improvements in the follow-up periods (3, 6 and 12 months after finishing the intervention).

V. To assess the acceptability of the internet-delivered intervention in terms of take-up and drop-out rates, treatment expectations, satisfaction, usefulness, and opinion.

VI. To explore specific features of an internet-delivered intervention which might impact on users' satisfaction and adherence.

Hypotheses of the thesis

The hypotheses of the thesis are as follows:

I. The diagnostic interview will present good psychometric properties.

II. The Internet-delivered intervention will promote significant clinical change in all outcome measures.

III. The control group will also show clinical improvement.

IV. Participants from the intervention group will present larger improvement than participants from the waiting list.

V. The achieved improvements will be maintained over the follow-ups.

VI. The intervention will be well accepted among patients with AjD in terms of take-up rates and treatment expectations.

VII. The drop-out rate will be around 30%.

VIII. Those who complete the intervention will be satisfied with the intervention.

IX. Telephone support will be perceived as a factor promoting adherence.

Chapter

1 Diagnostic Interview for Adjustment Disorders: reliability and validity

This chapter has been submitted as:

Rachyla, I., Botella, C., Mor, S., Tur, C., López-Montoyo, A., & Quero, S. Diagnostic interview for adjustment disorders: reliability and validity.

Diagnostic Interview for Adjustment Disorders: reliability and validity

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ABSTRACT

Background: Although evidence suggests that Adjustment disorder (AjD) is one of the most common mental illnesses worldwide, there is an important lack of reliable and valid instruments for its diagnosis. The aim of the present work was to evaluate the validity and reliability of a semi-structured diagnostic interview for AjD.

Methods: Fifteen experts reviewed the content of the diagnostic interview and rated its relevance. The construct validity was estimated from the level of concordance between the interview and *Inventory of Stress and Loss* (ISL), on the one hand, and MINI, on the other. Seventy interviews have been recorded and later evaluated by another researcher, who was blind to the diagnoses made by the initial interviewer. Thirty-seven participants were interviewed twice with an interval of 7 weeks

Results: Experts' average score on opinion scale was 7.96 out of 10. The average content validity ratio was 0.26 for the whole scale and 0.78 when only the items which achieved the critical value were considered. Construct validity analysis revealed that the interview allowed to identify patients with and without AjD. Interrater agreement on the diagnosis and clinical severity was good and the agreement on AjD subtype was moderate. Test-retest reliability was moderate.

Conclusions: This is the first work in evaluating the validity and reliability of a semi-structured interview for AjD. The findings were positive and provided support to the potential of the interview as a diagnostic tool.

Keywords: adjustment disorder, diagnostic interview, reliability, validity, diagnosis.

INTRODUCTION

The two major classifications of mental disorders – DSM and ICD – include the diagnostic category Adjustment Disorder (AjD) to refer to the emotional and behavioral response which follows the onset of an identifiable stressful event and has an important impact on everyday functioning (APA, 2013; WHO, 1992). It is one of the most problematic categories. On the one hand, evidence suggests that it is highly prevalent in clinical practice (Evans et al., 2013). On the other hand, neither DSM nor ICD include a set of specific symptoms which might facilitate its diagnosis (Baumeister & Kufner, 2009; O'Donnell et al., 2016). Given its poor definition, it is not surprising the little attention that AjD has received from the research community, despite its high prevalence and the important impact (Jaimie L. Gradus, 2017). This scarce attention led to an important lack of valid and reliable instruments for the diagnosis of AjD.

Among the different structured diagnostic interviews, only the Schedule for Clinical Assessment in Neuropsychiatry (SCAN; Wing et al., 1974), the Structured Clinical Interview for DSM-IV (SCID; First, Spitzer, Gibbon, & Williams, 1999) and the Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) include a section for AjD. This section is optional in all three interviews, and it is administered only when patients do not reach criteria for a full threshold disorder assessed throughout previous sections. Several studies have found that the use of these structured interviews underestimated the prevalence of AjD (Shear et al., 2000; Taggart et al., 2006). For example, Taggart et al. (2006) found that AjD was more commonly diagnosed clinically (31.8%) than by SCID (7.8%). Many of patients with the clinical diagnosis of AjD have been classed as mild depression according to SCID.

The diagnostic label presents important treatment implications. Although there is currently no a treatment considered a 'treatment of choice' for AjD, brief psychotherapy

focused on the reframing of the stressful event and development of coping skills is considered as best practice (Bachem & Casey, 2018; James J. Strain & Diefenbacher, 2008). Antidepressants, commonly used in the treatment of depression, are effective in reducing depressed mood in patients with AjD (Hameed et al., 2011). However, pharmacotherapy aims to control clinical symptoms rather than to treat the disorder itself. There is an absence of evidence to suggest the efficacy of antidepressants for the treatment and relapse prevention in AjD (Ali, 2015; Bachem & Casey, 2018). Psychotherapy is required to enhance the coping strategies and the adaptation to the stressful event mentioned earlier.

Given the poor efficacy of the available measures to properly identify patients with AjD, most experts agree that the diagnosis of this disorder should be based on the clinical judgement. Nevertheless, there are not guidelines to help clinicians to verify the fulfillment of the already vague diagnostic features of AjD. In order to provide clinicians with a fast and standardized measure of AjD symptoms, *Adjustment Disorder New Model* questionnaire (ADNM) was developed. This questionnaire was developed according to the new diagnostic concept of AjD proposed for ICD-11 which suggests that AjD is characterized by two core symptoms – (1) preoccupation with the stressor or its consequences and (2) failure to adapt – and other symptoms considered accessory (avoidance, depressive mood, anxiety, and impulse disturbance) (Maercker et al., 2013; Maercker, Einsle, & Köllner, 2007). Validation studies revealed good psychometric properties for different available versions (Einsle et al., 2010; Lorenz et al., 2016). However, more evidence is still needed to provide enough support to the new conception of AjD, which is not shared by DSM (Zelviene & Kazlauskas, 2018).

Another instrument developed specifically for AjD is a structured *Diagnostic Interview for Adjustment Disorder* (DIAD) based on DSM-IV criteria for this disorder

(Cornelius et al., 2014). Although initial validation analyses have confirmed its content and construct validity, farther work on its reliability and other aspects of validity is needed. It also should be noted that DIAD does not assess if the criteria for other disorders are met. Therefore, this interview should be used together with other diagnostic instruments in order to guarantee a good differential diagnosis.

The aim of the present work was to evaluate the reliability and validity of the first semi-structured Spanish *Diagnostic Interview for Adjustment Disorders*. The interview was developed prior to the first publications on ADNM and DIAD. It was successfully used in different randomized controlled trials on AjD as the diagnostic instrument to identify suitable participants (Andreu-Mateu, 2011; Molés, 2016).

MATERIALS AND METHOD

Description of the Diagnostic Interview for Adjustment Disorders

This semi-structured diagnostic interview was developed by CB, RMB and SQ, taking into account the DSM-IV-TR (APA, 2000) and ICD-10 (WHO, 1992) criteria for diagnosing AjD, the Structured Clinical Interview for DSM-IV (SCID-CV; First, Spitzer, Gibbon, & Williams, 1996), and existing literature regarding this condition.

The interview consists of four parts: initial inquiry, symptom rating, severity and interference, and research.

Initial inquiry

This section explores the presence of stressful events using a list of 62 possible stressors related to: primary support group, social area, emigration, occupation, education, harassment, economic problems, legal system, and threat to personal safety. It also gathers information about the onset, duration and implication of each stressor. If

patients inform about distress triggered by the death of a loved one, the interview indicates the importance of assessing the symptoms of complex bereavement.

Symptom rating

This section assesses the severity, frequency, duration, latency time, and progress of the symptoms developed in response to the main stressor. This assessment is assisted by a list of 28 symptoms established by authors according to the literature and their experience treating patients with AjD. Patients are asked to rate the severity of each of these symptoms from 0 ("Not at all") to 8 ("Extremely severe"), and also their occurrence from 1 ("Never") to 6 ("Every day"). The inclusion of certain items detects the convenience of performing differential diagnosis with Post-traumatic Stress Disorder and Generalized Anxiety Disorder, and allows excluding that the symptoms are induced or aggravated by a medical condition or substance use.

Severity and interference

A 9-point scale is used to assess the severity of distress and impairment caused by the main stressor or its consequences. It was adapted from the Maladjustment Scale (Echeburúa, de Corral, & Fernández-Montalvo, 2000) and explores the impact of the stressor on the normal life in general as well as on each of the following areas: work/education, social life, leisure time, intimate relationship, and family.

Research

This section explores different aspects which might be useful for the intervention development. More specifically, patients are asked about: the factors that increase the severity of symptoms and distress related to the stressor; the way they have dealt with the problem until now; and if they experienced similar feelings or symptoms in the past.

Interviewers

The interviewers were predoctoral researchers with a Master degree, who also provided psychological assistance at the Emotional Disorder Clinic in Universitat Jaume I (Spain). Before participating in the study, interviewers were trained in the administration of the interview by a senior researcher, observing live and recorded interviews. It was decided that this training was enough, since all interviewers had experience in the application of validated diagnostic instruments. Once the study started, the performed interviews were monitored by professionals with extensive clinical experience and deep knowledge of the diagnostic interview. During these supervision sessions, information regarding the following points was assessed: (a) establishment of the current diagnosis, (b) differential diagnosis, (c) decision about the main stressor.

Content validity

Eleven expert psychologists and four expert psychiatrists from Spain (n=9), Argentina (n=5) and Mexico (n=1) participated in the study. All of the experts had more than ten years of experience in their field, and most of them (n=9) had twenty or more years of experience. All of them had an advanced experience in the treatment of AjD, and three also worked on the development and adaptation of assessment instruments and intervention programs for this disorder.

The experts were asked to assess the content of the interview. Two instruments were developed for this purpose. The first instrument consisted of a 15-item scale for assessing experts' opinion on the diagnostic interview which is object of overview in the present work. Each item was rated from 0 ("*Not at all*") to 10 ("*Completely*"), reflecting the level of agreement with every statement. The second instrument consisted of

classifying each item of the interview into three categories ("essential", "useful, but not essential", or "not necessary"), following the method proposed by Lawshe (1975).

Construct validity

First, the validity of the diagnostic interview was explored in relation to another AjD specific measure. Seventy-three participants aged between 18 and 58 years old (M=31.97, SD=10.41), fifty-six (76.7%) of whom were women, completed the *Inventory of Stress and Loss* (ISL; Quero, Mor, Molés, Rachyla, Baños, & Botella, submitted) after the diagnostic interview which was administered via telephone. The ISL was answered online, within the same week that the interview took place.

The ISL is a 17-item self report questionnaire that explores the symptoms related to AjD. It was adapted from the *Inventory of Complicated Grief* (Prigerson et al., 1995) replacing the reference to the "deceased person" by other related to the "person or situation" which caused the distress symptoms (e.g., "*I think about this person/situation so much that it's hard for me to do the things I normally do*"). Each statement is rated from 0 ("*Never*") to 4 ("*Always*"), where higher scores indicate a greater maladjustment. The validation of the instrument has recently been submitted for publication, revealing results similar to those presented earlier. These preliminary data showed high internal consistency (Chronbach's α 0.86 and 0.91 for AjD patients and non-clinical population respectively) and test-retest reliability (0.90) (Soledad Quero, Molés, Mor, Baños, & Botella, 2014).

On the other hand, the interview was compared with the measure of other constructs. Twenty-five patients were administered the *Diagnostic Interview for Adjustment Disorders* and MINI (sections corresponding to major depressive disorder, dysthymia, suicidality, manic/hypomanic episode, panic disorder, agoraphobia, social

phobia, obsessive-compulsive disorder, substance abuse/dependence, psychotic disorders, and generalized anxiety disorder) by two different interviewers. Again, the majority of the sample were women (68%) and the age ranged from 18 to 55 years (M=31.60, SD=10.74). Both interviews were administered via telephone within the same week but in different order. Regarding the order, in 16 cases interview for AjD was administered in the first place, in the other 9 cases, it was administered after MINI.

Interrater reliability

Seventy conducted interviews were recorded with patients' agreement and later evaluated by another professional of the team. Based on the information collected by the interviewers, and blind to their diagnosis, the raters (a) formulated a diagnostic hypothesis. Besides, if the diagnosis of AjD was made, interviewers (b) rated the level of distress-interference in functioning according to ADIS clinician's severity rating scale (Di Nardo, Brown, & Barlow, 1994), which ranges from 0 ("*Absent*") to 8 ("*Very severely disturbing/disabling*"), and (c) indicated the subtype of AjD ("with depressed mood", "with anxiety", "with mixed anxiety and depressed mood", "with disturbance of the conduct", "with mixed disturbance of emotions and conduct", "unspecified").

All interviews were performed via telephone. Forty-seven (67.1%) of interviewees were women and the age of the whole sample ranged from 18 to 61 years (M=30.30, SD=11.37).

Test-retest reliability

In order to examine the stability of the instrument, thirty-seven participants were interviewed twice with an interval of 7 weeks. Most of the participants were women (81.1%) and the age ranged from 18 to 55 years (M=18, SD=55). Before the retest

examination, raters checked that patients had not received any professional assistance for their problem and had not initiated or changed the pharmacological treatment.

Statistical analysis

All statistical analyses were performed with the software IBM SPSS Statistics version 22 for Windows.

Content validity

For the 15-item scale assessing experts' opinion on the *Diagnostic Interview for Adjustment Disorders*, descriptive statistics (mean, standard deviation, and range) have been computed for each item. The total mean score was calculated for the whole scale and interpreted adapting the acceptability ranges proposed for *System Usability Scale* (SUS) (Bangor, Kortum, & Miller, 2009). SUS is a fast and reliable scale used for assessing the usability of a given product or service. The instrument provides a score which can range from 0 to 100, higher scores indicate better usability (Bangor, Kortum, & Miller, 2008). Table 1.1 includes acceptability ranges proposed for SUS scores and their adaptation to interpret scores reported in the opinion scale used in the current study.

The essentiality of the items which compose the interview was measured computing the content validity ratio (CVR) for each item using Lawshe's formula which is CVR=(Ne - N/2) / (N/2), where Ne is the number of experts classifying an item as "essential" and N is the total number of experts. CVR is a direct linear transformation from the percentage of experts who considered an item to be "essential". CVR values range from -1 to 1, higher score indicating greater agreement among experts. Average CVR was computed for the whole scale.

Table 1.1 Acceptability ranges for *System Usability Scale* (SUS) and for experts' opinion scale

Acceptability ranges	**SUS**	**Experts' opinion scale**
Not acceptable	0 - 50	0 - 5
Marginal	50 - 70	5 - 7
Acceptable	70 - 100	7 - 10

Construct validity

To explore the expected link between the presence of AjD and the severity of stress and loss symptoms, a simple linear regression analysis was performed. The presence of AjD according to the interview and the sum score of the ISL were used as the independent and dependent variables respectively.

The agreement between MINI and the *Diagnostic Interview for Adjustment Disorders* was assessed using kappa coefficients. Since MINI was not screening for AjD, interviewers only reported if participants were ("*Yes*") or were not ("*No*") scoring for major depressive disorder, dysthymia, suicidality, manic/hypomanic episode, panic disorder, agoraphobia, social phobia, obsessive-compulsive disorder, substance abuse/dependence, psychotic disorders, and generalized anxiety disorder. On the other hand, the interviewers who administered the *Diagnostic Interview for Adjustment Disorder* reported if participants were ("*Yes*") or were not ("*No*") diagnosed with AjD according to the used interview.

Interrater reliability

The agreement between raters was estimated computing kappa coefficient for the following variables: (a) diagnoses of AjD (Yes/No), (b) AjD subtype ("with depressed mood", "with anxiety", "with mixed anxiety and depressed mood", "with disturbance of the conduct", "with mixed disturbance of emotions and conduct",

"unspecified"), and (c) symptom severity. Following the previous work assessing the reliability of ADIS-IV-L (Brown, Di Nardo, Lehman, & Campbell, 2001), it was considered that there was agreement regarding the symptom severity when the interrater difference was less than one point.

Test-retest reliability

Test-retest reliability was estimated using the kappa coefficient.

Ethics

The sample included in this study were participants assessed for their possible inclusion in a randomized controlled trial (ClinicalTrial.gov: NCT02758418) conducted at Universitat Jaume I and approved by the ethics committee of that university (October 2015). The participation was completely voluntary. Each participant provided their informed consent for their information to be used for research purposes.

RESULTS

Content validation

The experts' opinion on the content of the interview is presented in Table 1.2. The answers ranged from 6.27 (item "*The interview allows to discard other mental disorders and ensure that the symptoms expressed by patients are not merely an exacerbation of a preexisting mental disorder*") to 8.60 (item "*The interview covers all current DSM criteria for adjustment disorder*"). The total mean score for the whole scale was 7.96, indicating that the interview was generally assessed as acceptable.

Table 1.2 Expert opinion (n=15) on the Diagnostic Interview for Adjustment Disorders

How strongly you agree:	**M (SD)**
1. The interview allows to decide whether the distress expressed by patients appeared in response to an identifiable stressful event	8.20 (1.21)
2. The interview allows to ensure that these emotional or behavior symptoms appeared within 3 months of the onset of the stressful event	8.27 (1.22)
3. The interview allows to indentify clinically significant symptoms	8.33 (1.29)
4. The interview allows to establish the level of impairment in different areas of functioning caused by clinical symptomatology	8.27 (1.33)
5. The interview allows to decide whether the distress expressed by patients is out of proportion to the severity or intensity of the stressful event	7.73 (1.16)
6. The interview allows to discard other mental disorders and ensure that the symptoms expressed by patients are not merely an exacerbation of a preexisting mental disorder	6.27 (1.91)
7. The interview allows to ensure that the symptoms expressed by patient do not represent normal bereavement	8.20 (1.32)
8. The interview allows to ensure that, once the stressor or its consequences have terminated, the symptoms do not persist for more than 6 months	7.73 (2.02)
9. The interview covers all current DSM criteria for adjustment disorder	8.60 (1.18)
10. The interview represents a useful tool for research	8.40 (1.84)
11. The interview represents a useful tool for clinical practice	7.73 (2.19)
12. The interview facilitates the diagnosis of adjustment disorder	8.40 (1.55)
13. The interview facilitates the rating of the severity of adjustment disorder	8.14 (1.66)
14. You would use the Diagnostic Interview for Adjustment Disorders if you had to attend patients with adjustment disorder	7.47 (2.10)
15. You would use the Diagnostic Interview for Adjustment Disorders to professionals who work with patients with adjustment disorder	7.60 (2.06)

M, mean; ***SD,*** standard deviation.

CVR results are presented in Table 1.3. CVR was negative for seven items (items 7, 11, 12, 17, 20, 21, and 22), indicating that fewer than half of the experts considered them "essential" for the diagnosis of AjD. In fact, all these seven items were included in the interview in order to gather important information for the treatment and not for the diagnosis. From those items which had positive CVR, i.e. items considered

"essential" by more than half of experts, nine obtained ratios higher than 0.49 (critical CVR), which is the minimum CVR value required for a sample of 15 experts. The nine items (items 1, 2, 3, 4, 5, 9, 10, 18, and 19) cover the current DSM criteria for AjD. The remaining six items (items 6, 8, 13, 14, 15, and 16) aim at facilitating differential diagnosis.

The average CVR was 0.26, indicating that approximately 63% of experts agreed that the items included in the interview were essential for the assessment of AjD. The average CVR was 0.78 when only items with values above the critical CVR were considered; indicating that approximately 89% of experts agreed that these nine items reflected the evaluated domain.

Table 1.3 Expert opinion (n=15) on content validity of the Diagnostic Interview for Adjustment Disorders

Items	N_e	N_e/N_t	CVR
1. Over the past few months, have you experienced any stressor in your life?	14	0.93	0.87*
2. How long ago did the stressor(s) take place? (specify date)	15	0.93	1.00*
3. Are any of the stressors still present today?	13	0.87	0.73*
4. Currently, and as a result of this stressor, do you have any type of emotional or behavioral symptom that is causing you distress or interfering with your life? For example, do you feel anxious, depressed, worried, incapable of moving forward, incapable of doing things …	15	1.00	1.00*
5. How distressing/severe is _____ (symptom from the list) since the _____ (main stressor) occurred/began? (rating scale from 0 to 8)	13	0.80	0.73*
6. Since the _____ (main stressor) occurred/began, how often have you experienced _____ (symptom from the list)? (rating scale from 1 to 6):	9	0.60	0.20
7. Predominance of symptoms (CLINICIAN'S JUDGMENT):	4	0.33	-0.47
8. After the event occurred, how soon did you start having these symptoms ?	7	0.53	-0.07
9. How long have you been experiencing these symptoms?	14	0.93	0.87*

10. Is the stressor or any of its consequences still present? (e.g., I still don't have any money, they still bully me at work, I am waiting for the trial …)	13	0.80	0.73*
11. Has there been any change in the severity of the symptoms related to the stressor? (e.g., Have the symptoms improved, got worse, or remained the same?)	7	0.40	-0.07
12. Besides this current/most recent time, have there been other separate periods of time in which you have experienced similar symptoms, either in relation to this or another stressor?	6	0.33	-0.20
13. Did you have these symptoms even before the stressor took place?	11	0.73	0.47
14. When did the stressor begin to be a problem in that it caused a lot of distress or interference with your life? (Note: attempt to ascertain more specific information, e.g., by linking onset to objective life events)	9	0.67	0.20
15. During the past 6 months, have you been continually worried or anxious about a number of events or activities in your daily life, in addition to those related to the stressor?	7	0.53	-0.07
16. Over this entire period of time when you have been having symptoms, have you been regularly taking any type of drug? (e.g., drugs of abuse, medication)	9	0.60	0.20
17. During this current period of time when you have been having symptoms, have you had any physical condition or illnesses? (e.g., pregnancy, hypothyroidism)	7	0.47	-0.07
18. Currently, how much distress is the stressor or the symptoms associated with it causing you? (rating scale from 0 to 8)	13	0.87	0.73*
19. Currently, how much the stressor or the symptoms associated with the stressor interfere in the following areas of your life? (rating scale from 0 to 8)	13	0.87	0.73*
20. Is there any situation, person, or image that seems to trigger or increase symptoms related to the stressor? [Inquire about internal (thoughts, images) and external (situations, people or objects related to the stressor) triggers]	5	0.33	-0.33
21. How do you handle the stressor and the symptoms related to the stressor?	6	0.13	-0.20
22. Did you ever experience similar feelings, perhaps milder, when you were a child?	2	0.20	-0.73

N_e: number of experts considering the item as "essential" for the diagnosis of adjustment disorder; **N_t**: total number of expert; **CVR**: Content Validity Ratio; ***** CVR above 0.49 which is the minimum CVR value required for a sample of 15 experts.

Construct validity

A statistically significant relationship was found between the presence or absence of AjD and the ISL score (R^2=0.187, β=0.45, ρ<.001). Participants with AjD scored higher (37.39±11.61) in ISL than participants without AjD (21.45±11.76). A standardized mean difference of d = 1.36 was found between AjD and non-AjD participants in ISL. Following Cohen's (1988) guidelines, d indices of around 0.20, 0.50, and 0.80 can be interpreted as reflecting low, moderate, and large clinical relevance. Therefore, a d index of 1.36 reflected a large difference between the two groups of participants.

The results of the comparison of the interview for AjD and MINI indicated that there were not agreement between the two instruments (κ= -0.46). In 92% of cases, patients diagnosed with one of the disorders explored by MINI did not have AjD according to the diagnostic interview for AjD and, conversely, patients diagnosed with AjD using the diagnostic interview for AjD did not scored at any of the MINI sections. Only two patients were diagnosed at the same time with AjD and major depressive episode.

Interrater reliability

Kappa value indicated a good interrater agreement (κ= 0.66, ρ<.000). In 82.8% both interviewers agreed in the presence/absence of AjD. Interrater agreement regarding the AjD subtype was of 71.8% (κ= 0.43, ρ<.001) and agreement on the clinical severity was of 81.3% (κ= 0.67, ρ<.000).

Test-retest reliability

Kappa value was 0.53, indicating moderate agreement between test and retest interviews.

DISCUSSION

The aim of the present work was to provide data regarding the reliability and validity of *Diagnostic Interview for Adjustment Disorders*, which is the first semi-structured Spanish interview developed specifically for AjD.

Regarding *content validation*, the interview was well accepted by experts. First, items aimed at checking the fulfillment of DSM criteria for the disorder presented agreement ratios above the critical CVR. Second, items included to rule out other possible causes for the symptoms were considered essential by more than half of the experts, though critical CVR value was not achieved. Finally, the seven items included in order to collect important information for the development and course of the treatment were considered essential by less than half of the experts. These findings are not surprising since the experts were asked to assess the items in terms of their relevance for the diagnostic decision. According to Lawshe's method (Lawshe, 1975), if a sample of 15 experts is used, at least 12 experts have to consider an item to be essential, otherwise it should be eliminated. At this point, it should be noted that CVR is usually computed for instruments such as questionnaires and scales and no works were found applying this method during the validation of an interview. However, we considered that the use of CVR could also provide support to the content validity of interviews. Furthermore, it was decided not to exclude the items which did not achieve critical CVR values, since we believe that they can provide additional advantages. In this line, literature points out the existence of symptom overlap between different common mental disorders which leads to important problems in distinguishing AjD from other disorders, such as depression or generalized anxiety disorder (Bachem & Casey, 2018). Thus, inclusion of items addressed to facilitate differential diagnosis may increase the accuracy of the diagnostic instrument. On the other hand, making a

diagnosis is not the only function of clinical interviews. Another main goal of clinical interviews is to provide a better understanding of the problem reported by the interviewed person in order to develop a treatment plan (Caballo, 2005). It was therefore decided to retain all interview items. In any case, the non-essential items might be skipped when the interview is used solely for diagnostic purposes, shortening the interview duration.

With regard to *construct validity*, a high agreement was found between interview-based diagnoses and the instrument measuring symptoms related to AjD. As it was expected, being diagnosed with AjD predicted a higher score on ISL. Between-group analyses revealed a large difference in ISL scores between participants with and without diagnoses of AjD. These results suggest good sensitivity of the interview to identify patients with AjD. On the other hand, the comparison with MINI-based diagnoses pointed out the good ability of the diagnostic interview to identify patients without AjD.

Finally, *interrater reliability* analyses revealed good interrater agreement regarding the diagnostic decision and clinical severity of the symptoms, and moderate agreement regarding AjD subtype. *Test-retest reliability* was moderate, indicating that, despite the fact that AjD is considered to be a transient condition (Yates, 2016), seven weeks later many patients, who did not receive any psychological treatment, still met diagnostic criteria for the disorder.

Limitations

The current work presents several limitations which should be addressed in future studies. The first limitation was the small number of participants, particularly in the analyses exploring test-retest reliability and the concordance between the diagnostic

interview and MINI. The small sample size might explain why higher kappa values were not obtained. Second, the number of non-psychiatric participants was not considered. Thus, the sample was divided into patients with and without AjD. This last group included both clinical and subclinical population. The third limitation was related to the instruments used for the estimation of construct validity. ISL used as a measure of AjD symptoms is a self-report with still little substantive support. As for MINI, the AjD section was not administered during the interview. Therefore, instruments enabling the diagnosis of AjD, such as ADNM questionnaire, should be used in future validation works. As it was mentioned, different works revealed that ADNM presents good psychometric properties (Einsle et al., 2010; Lorenz et al., 2016). Although the two core factor model of the AjD proposed by ADNM still requires further evidence support (Zelviene & Kazlauskas, 2018), the joint use of an instrument based on ICD-11 diagnostic criteria and another that follows DSM approach would allow to explore the concordance between these two classification systems, improving the current problems related to the assessment of AjD. On the other hand, given the lack of diagnostic instruments for AjD, analyses of concordance with the diagnoses made by an expert could also provide useful information.

CONCLUSIONS

Despite the above mentioned limitations, it must be noted that this is the first attempt to validate a semi-structured diagnostic interview for AjD. Overall, the findings were positive and provided support to the potential of the interview as a diagnostic tool for AjD. As it was mentioned previously, there is an important lack of reliable diagnostic instruments for this problem. Therefore, the current work represents a clear contribution to this under-researched field. Further studies are needed in order to improve the current detection of AjD cases in clinical settings. Valid and reliable

instruments will also contribute to the development of evidence based interventions for AjD, since they will enable the identification of diagnostically homogenous samples for clinical trials.

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Chapter

2 Feasibility study

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Web-based, self-help intervention for Adjustment Disorders: acceptance and usability

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ABSTRACT

Despite having proved their efficacy, Internet-based interventions (IBI) have not yet been implemented in health care settings. The acceptability of these interventions may be one key barrier. The present work aims to assess the acceptability and usability of a Web-based self-help intervention (TAO) for Adjustment disorders (AD) among 7 patients with AD and 15 clinicians. The intervention was well accepted and described as user-friendly by both samples. Furthermore, results of this work suggest that certain aspects should be considered during the development of IBI in order to promote adherence and achieve the desired changes. To our knowledge, this is the first work to explore specific features of an IBI that might impact on users' satisfaction and adherence.

Keywords: internet-based self-help interventions, acceptance, usability, adherence, adjustment disorders.

INTRODUCTION

Research has proven that Internet-based interventions (IBI) not only are an effective way to disseminate psychological interventions (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010), but they also provide advantages over traditional face-to-face therapy (Baños, Guillén, García-Palacios, Quero, & Botella, 2011). However, the low acceptability of IBI may be one of the reasons for the lack of implementation of these interventions in clinical settings (Musiat, Goldstone, & Tarrier, 2014). The present work assesses the acceptability and usability of a Web-based self-help intervention (TAO) for Adjustment disorders (AD) among patients and clinicians. AD is one of the most prevalent psychological disorders (Evans et al., 2013), which causes great suffering, including suicidal thoughts and behaviors (Casey, Jabbar, O'Leary, & Doherty, 2015). It is essential to develop evidence-based, well-accepted interventions, able to reach all who need them.

METHODS

Participants

Seven patients with AD (APA, 2013) and fifteen clinicians (12 clinical psychologists and 3 master students) voluntarily agreed to participate in the study and signed the informed consent form. The mean age of patients (4 men and 3 women) was 30.57 years (SD=11.18). The mean age of clinicians was 31.27 (SD=4.43). None of them were familiarized with TAO. However, five of the participants had wide experience in the development and use of internet-based interventions.

Measure

A survey to examine users' opinion on TAO was specifically designed for this pilot study. The survey was structured in three parts, each of them focused on different

aspects of the online-based intervention. In the first part 10-point Lickert scales were used to assess different characteristics and audiovisual resources included in TAO. Open answer questions were used in order to collect qualitative data. The second part included *System Usability Scale* (Brooke, 1986) to explore the user-friendliness of TAO. Finally, the third part explored users' attitude and opinion towards an internet-based, self-help intervention like TAO.

TAO: Adjustment Disorders Online

TAO is a self-applied online treatment program for AD structured in 7 modules and includes different multimedia resources: texts, videos, illustrations and interactive exercises. It is a computerized version of a CBT protocol including the following therapeutic components: psychoeducation, techniques to manage negative emotions, exposure, problem solving technique, acceptance and elaboration of the stressful event, positive psychology strategies, and relapse prevention. The system presents a simple interface which facilitates its use even to people who are not skilled in computers.

Procedure

Participants had approximately an hour to explore freely the module 3 of TAO program. Afterwards, they completed the survey described above.

RESULTS

Opinions on TAO module and the overall internet-based intervention for AD are shown in Tables 2.1 and 2.2, respectively. The intervention was well-received by both samples.

The usability of the system was scored with 88.93/100 (SD=5.37) by patients and 91.67/100 (SD=6.03) by clinicians. Finally, all participants highlighted the

inclusion of videos, clear and well-structured contents, simple terminology, and availability of examples as strengths of the intervention. Interactivity and the amount of written information were identified as aspects that could be improved.

Table 2.1 Means and standard deviations of participants' opinion on TAO module

		Patients	**Clinicians**
Usefulness of the program content	To help patients with AD	7.43 (1.40)	9.20 (1.01)
	To treat other psychological disorders	7.71 (1.25)	8.47 (1.69)
Characteristics of the program content	Logical	8.57 (0.79)	9.47 (0.52)
	Boring and/or difficult	2.86 (2.55)	2.33 (2.50)
	Pleasant and/or interesting	7.86 (1.07)	7.53 (1.51)
	Clear and/or understandable	8.14 (1.57)	8.93 (0.80)
	Need for professional assistance	2.00 (1.30)	3.93 (3.08)
Overall program rating	Module 3 of TAO program	8.00 (0.82)	8.67 (0.72)
	Multimedia contents	8.29 (1.38)	8.13 (0.99)
Usefulness of the included audiovisual resources	Texts	8.14 (1.46)	8.33 (1.11)
	Images	8.14 (1.07)	8.33 (1.40)
	Illustrations	7.71 (1.25)	8.47 (1.30)
	Videos	5.57 (1.40)	8.93 (1.03)

Table 2.2 Means and standard deviations of participants' opinion on TAO

	Patients	**Clinicians**
Helpful	7.86 (1.86)	8.53 (0.99)
Useful	8.00 (2.00)	8.13 (2.10)
Would use	7.71 (1.98)	8.13 (1.51)
Would recommend	-	8.80 (1.32)

DISCUSSION

TAO was well accepted and described as user-friendly by both, patients and clinicians. Different features of TAO were detected as adherence enhancers. Inclusion of relevant therapeutic contents does not seem to be enough to achieve the desired clinical changes. Therefore, certain aspects should be considered during the development of IBI.

To our knowledge, this is the first work to explore specific features of an IBI that might impact on users' satisfaction and adherence. Further study is needed in this field in order to be able to fully leverage the potential of IBI as a therapeutic tool.

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Chapter

3 Study protocol

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An internet-based intervention for adjustment disorder (TAO): study protocol for a randomized controlled trial

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ABSTRACT

Background: Adjustment Disorder (AjD) is a common and disabling mental health problem. The lack of research on this disorder has led to the absence of evidence-based interventions for its treatment. Moreover, because the available data indicate that a high percentage of people with mental illness are not treated, it is necessary to develop new ways to provide psychological assistance. The present study describes a Randomized Controlled Trial (RCT) aimed at assessing the effectiveness and acceptance of a linear internet-delivered cognitive-behavioral therapy (ICBT) intervention for AjD.

Methods: A two-armed RCT was designed to compare an intervention group to a waiting list control group. Participants from the intervention group will receive TAO, an internet-based program for AjD composed of seven modules. TAO combines CBT and Positive Psychology strategies in order to provide patients with complete support, reducing their clinical symptoms and enhancing their capacity to overcome everyday

adversity. Participants will also receive short weekly telephone support. Participants in the control group will be assessed before and after a seven-week waiting period, and then they will be offered the same intervention. Participants will be randomly assigned to one of the 2 groups. Measurements will be taken at five different moments: baseline, post-intervention, and three follow-up periods (3-, 6- and 12-month). BDI-II and BAI will be used as primary outcome measures. Secondary outcomes will be symptoms of AjD, posttraumatic growth, positive and negative affect, and quality of life.

Discussion: The development of ICBT programs like TAO responds to a need for evidence-based interventions that can reach most of the people who need them, reducing the burden and cost of mental disorders. More specifically, TAO targets AjD and will entail a step forward in the treatment of this prevalent but under-researched disorder. Finally, it should be noted that this is the first RCT focusing on an internet-based intervention for AjD in the Spanish population.

Trial registration: ClinicalTrial.gov: NCT02758418. Trial registration date 2 May 2016.

Keywords: adjustment disorder, internet-delivered cognitive-behavioral therapy, randomized control trial, effectiveness, acceptance.

BACKGROUND

Adjustment disorder (AjD) refers to the clinical symptomatology that appears in response to an identifiable stressful event, such as separation or divorce, job loss, diagnosis of a disease, or family conflicts. In order for the diagnosis of AjD to be made, symptoms must begin within 3 months after the stressor and disappear within a period of not more than 6 months once the stressor or its consequences have terminated. Because the presence of an identifiable stressor is the key characteristic of this disorder, in the DSM-5 (APA, 2013) AjD was classified under the new category of trauma and stress-related disorders. The same change has been proposed for the ICD-11, along with the proposal of a new diagnostic concept (Maercker et al., 2013). Despite these improvements, the category of AjD is not yet sufficiently clear (Casey, 2014) and a recent review study (Kazlauskas et al., 2017) revealed that there is still little support for the ICD-11 proposal of two symptom structure of AjD (preoccupation with a stressor or its consequences and failure to adapt).

According to the different studies carried out so far, AjD is a very common condition (Casey, 2014; Gradus, 2017; Yaseen, 2017). It is estimated to have an incidence of between 5% and 20% in mental health services, and about 50% in psychiatric consultation settings (APA, 2013). AjD is also one of the most frequent diagnoses in patients with organic diseases and surgical interventions (Baumschlager, Haas-Krammer, & Rothenhäusler, 2011; Courtwright et al., 2016; Hernández-Blázquez & Cruzado, 2016; Marinho, Marques, Esteves, Roma-Torres, & Braganca, 2016; Mitchell et al., 2011), and in cases of absenteeism and work disability (Lagerveld, Blonk, Brenninkmeijer, Wijngaards-de, & Schaufeli, 2012; Van der Klink, Blonk, Schene, & van Dijk, 2003). In addition to being a highly prevalent disorder, AjD causes considerable distress and marked impairment in different functional areas of patients'

lives (e.g., family, friendships, school/work, etc.), and it may increase the risk of suicidal thinking and behavior (Carta, Balestrieri, Murru, & Hardoy, 2009; Casey et al., 2015).

Despite these worrisome facts, little research has been conducted to identify and develop evidence-based interventions (EBI) for AjD. To the best of our knowledge, no specific EBI are available for AjD, just some suggestions and recommendations (Casey, 2014; Maercker, Bachem, Lorenz, Moser, & Berger, 2015). Furthermore, only a few interventions for AjD have been assessed in a randomized controlled trial (RCT) (Baños et al., 2011; Sundquist, Palmér, Johansson, & Sundquist, 2017; Van der Klink et al., 2003). Cognitive Behavioral Therapy (CBT) predominates in all of them, although other approaches are also included, such as the use of mindfulness.

In any case, the availability of an effective intervention does not guarantee that it reaches everyone who might need it. Internet-delivered cognitive-behavioral therapy (ICBT) might be a feasible solution for this problem. Currently, data on the efficacy of ICBT are available for a wide range of psychological disorders, including stress-related disorders (Andersson, 2016; Knaevelsrud & Maercker, 2007; Lewis et al., 2017; Wagner, Knaevelsrud, & Maercker, 2006; Zetterqvist, Maanmies, Strom, & Andersson, 2003). Some of the main advantages of these kinds of interventions are confidentiality, cost savings, flexibility because patients can access the treatment at any time and from anywhere, and the possibility of reaching patients who would otherwise never receive psychological assistance (Andrews, Newby, & Williams, 2015; R. Baños, Guillén, García-Palacios, Quero, & Botella, 2011).

Three brief computer-based interventions are available for the treatment of AjD symptoms. "iCanADAPT Early" is a transdiagnostic ICBT designed to treat depression

and anxiety disorders in cancer settings (Murphy et al., 2017). Although the program can be used for the treatment of AjD, it was not developed specifically for this condition. Moreover, the inclusion of cancer-specific CBT skills hinders the use of "iCanADAPT Early" with patients who suffer from AjD due to other stressful events. Seren@ctif is a stress management program based on CBT, developed to treat anxiety related to stress (Servant et al., 2017). The program focuses only on AjD with an anxiety subtype, and it is not yet accessible via the Internet. Patients have to go to the hospital and access the program on one of the computers available there. Finally, BADI is an online intervention for AjD that includes CBT, mindfulness, and body-mind practices (Skruibis et al., 2016). The program presents a modular format, giving users the possibility of choosing the content they want to work on. Preliminary positive findings were recently published for a BADI intervention (Eimontas et al., 2017). However, the high dropout rates were identified as the primary limitation of the intervention, and they were attributed to its modular and unguided format.

The only self-help intervention for AjD validated to date is a bibliotherapy manual developed by Bachem and Maercker (Bachem & Maercker, 2016a) for burglary victims. It is based on cognitive behavioral techniques that have been validated for the treatment of depressive, anxiety, or post-traumatic stress disorders, including behavioral activation, exposure, cognitive restructuring, and relaxation. The manual has been shown to be a feasible and effective solution for AjD symptoms. However, it has not been validated for AjD resulting from other stressors.

Given the impact and prevalence of AjD, we have developed TAO (*Trastornos Adaptativos Online*). TAO is the first online manualized intervention protocol for AjD developed for the Spanish-speaking population. The linear format of the program makes it possible to progressively start to solve the problematic situation. It is based on the

CBT intervention protocol developed by Botella, Baños, and Guillén (2008), which, to the best of our knowledge, is the first protocol specifically designed for AjD, showing efficacy in several studies (Baños et al., 2011; Quero et al., 2017). The aim of this study is to present the RCT that will be conducted to examine the effectiveness of TAO in reducing the distress and clinical symptoms of AjD, compared to a waiting list control group. Additionally, the level of patients' acceptance and satisfaction with the intervention will be assessed.

METHODS/DESIGN

Study design

The study is designed as a two-armed, single-blind, parallel group RCT. The trial was registered on the ClinicalTrial.gov database as NCT02758418, and it will be conducted following the Consolidated Standards of Reporting Trials (CONSORT) (Moher et al., 2010), the CONSORT extension for Electronic and mobile Health Applications and onLine TeleHealth interventions (CONSORT-EHELTH) (Eysenbach, 2011), and the SPIRIT guidelines (Standard Protocol Items: Recommendations for Intervention Trials) (Chan et al., 2013; Chan et al., 2013). All suitable participants for the trial will be randomly allocated to the intervention group (ICBT) or the Waiting List Control Group (WL). The online informed consent form will be signed before the randomization. Outcome measures will be assessed at baseline, post-intervention, and 3-, 6-, and 12-month follow-ups, in order to provide data on intervention effectiveness and maintenance of the improvements achieved. Figure 3.1 displays the flow chart of the study design.

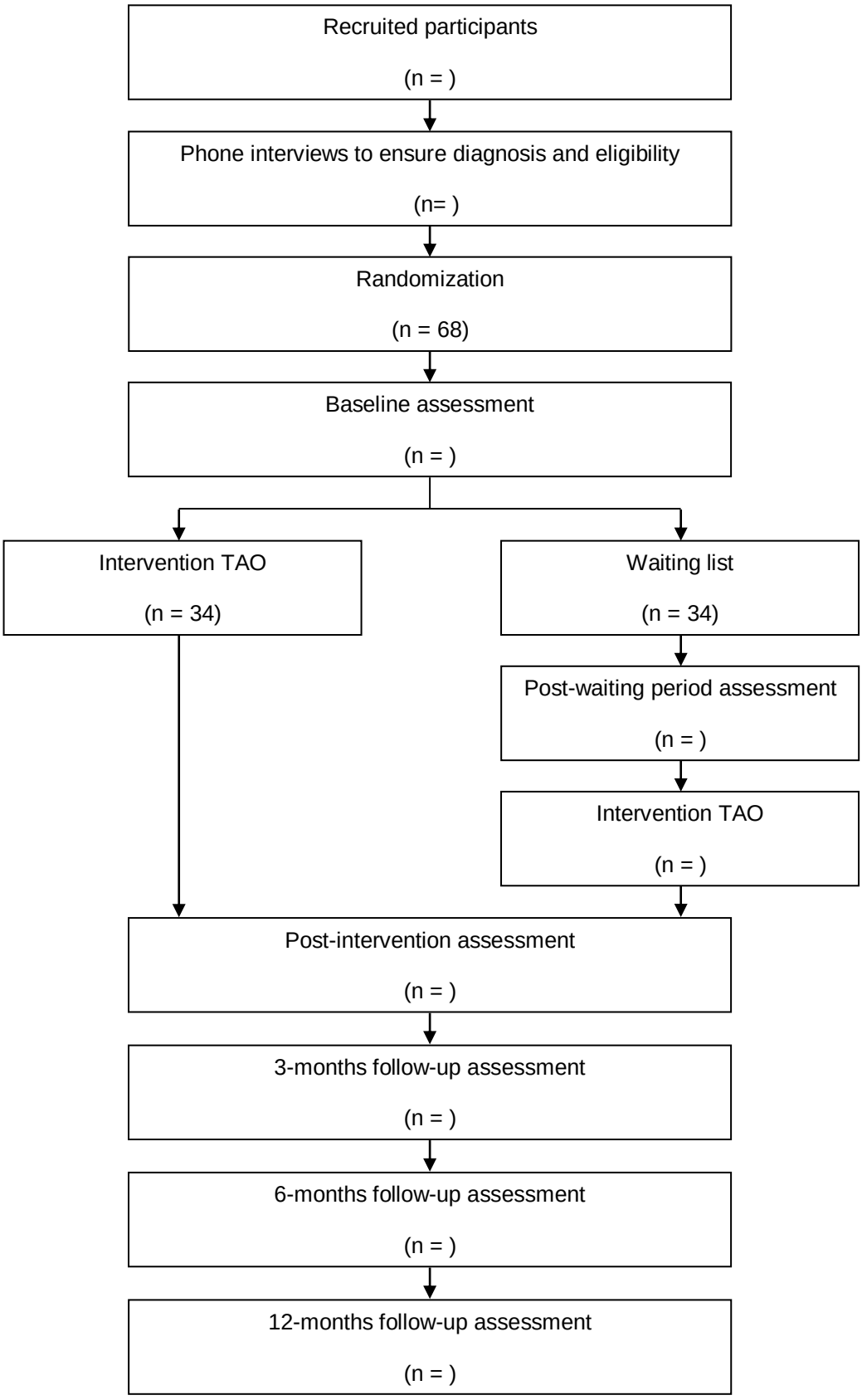

Figure 3.1 Flowchart of participants

Recruitment

The trial will be announced on local media (radio, TV, newspaper…) and the website of Universitat Jaume I, and disseminated through social networks (i.e., Facebook and Twitter). The advertisement will be published in newspapers, and information brochures will be placed on noticeboards at local universities (Universitat Jaume I and Universitat de València) and nearby towns.

People interested in the study will be encouraged to send an e-mail to tao@uji.es. The clinical team involved in the study will respond to all e-mails within 24 hours and arrange a telephone interview. The interview will last about 40-60 minutes, and its purpose will be to explain the terms of the clinical trial and check the fulfillment of eligibility criteria. The diagnostic interview will be administered to potential participants during this telephone call.

Eligibility criteria

In order to be included in the trial, participants must meet the following inclusion criteria: (1) be 18 years old or more; (2) meet DSM-5 (APA, 2013) criteria for AjD; (3) be able to understand and read Spanish; (4) be able to use a computer and have access to the Internet; (5) have an e-mail address. On the other hand, assessed participants who meet any of the following criteria will be excluded from the trial: (1) receiving another psychological treatment for AjD; (2) meet criteria for another severe mental disorder: alcohol or other substance abuse or dependence, psychotic disorder, dementia, or bipolar disorder; (3) meet criteria for a severe personality disorder or illness; (4) presence of risk of suicide or self-destructive behaviors. Undergoing pharmacological treatment is not an exclusion criterion during the study period, but any increase and/or

change in the medication during the study period will imply the participant's exclusion from subsequent analyses. A decrease in pharmacological treatment is accepted.

The decision about each participant's inclusion or non-inclusion will be made by the entire clinical team, ensuring a more objective and reliable diagnosis. The telephone interviews will also be recorded, with the patient's agreement, making independent inter-judge assessment possible.

Randomization and blinding

Participants included in the study will have to sign the participation agreement without having a priori knowledge about their group assignment. Study researchers will also be blind to the group to which the assessed participants will belong. Once the online informed consent has been signed, an independent researcher will perform a "blocked randomization", guaranteeing that the same number of participants are allocated to each condition (ICBT or WL). This allocation will be performed following a random number sequence generated by the Epidat 4.1 program.

Sample size

The sample size for the trial was calculated following the method described by Campbell, Julious, and Altman (1995), and Freiman, Chalmers, Smith, and Kuebler (1978). G*Power 3 software (Faul, Erdfelder, Buchner, & Lang, 2007) was used to facilitate power analysis.

Because there is no published research on the effectiveness of ICBT for the treatment of AjD, the sample size was calculated taking into account outcomes found in trials that used the BAI and BDI-II as measures of clinical change after an ICBT intervention in patients with clinical depression or anxiety disorder (Berger, Boettcher, & Caspar,

2014; Berger, Hämmerli, Gubser, Andersson, & Caspar, 2011; Ivarsson et al., 2014). After reviewing the literature and adopting a more conservative approach, an effect size of .70 was assumed in the present study. Considering a significance level of 5% and a power of 80%, 26 participants in each group would be enough to detect the assumed difference. However, because the literature reveals dropout rates from ICBTs of around 30% (van Ballegooijen et al., 2014), a sample of 68 participants will be recruited (34 per group).

Ethics

The protocol for this study has been approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain), and the study will be conducted in compliance with the Declaration of Helsinki and good clinical practice. Participation will be completely voluntary. Participants will also be informed that they may leave the study at any time.

The RCT will be carried out in accordance with current EU and Spanish legislation on privacy and data protection. In order to protect the privacy of the participants, all personally identifiable information will be replaced by a randomly assigned username and only made available to the researchers responsible for its supervision. All data from outcome measures and post-module assessments will be stored separately from the personal information and protected according to AES (*Advanced Encryptation Standard*).

Study groups

Adjustment Disorders Online (TAO)

Adjustment Disorders Online (TAO) is an ICBT based on a manualized protocol for the treatment of AjD, structured in a therapist handbook and a patient handbook. TAO

comprises the following therapeutic components: psychoeducation, techniques to manage negative emotions, exposure, problem-solving techniques, mindfulness, acceptance and elaboration of the stressful event, positive psychology strategies, and relapse prevention. It is the optimized version of the original intervention protocol for AjD developed by Botella et al. (2008). More specifically, TAO also includes behavioral activation for mood disturbance, problem-solving techniques to improve the capacity to deal with everyday challenges, and mindfulness to become aware of the thoughts and feelings related to the stressful event instead of trying to escape from them.

The intervention is easily accessible over the internet at https://www.psicologiaytecnologia.com/. In order to provide a more enjoyable experience, the program content is presented through texts, videos, pictures, vignettes, and interactive exercises. Different contents can also be downloaded as PDF files so that users can review them offline.

TAO is organized into seven sequential modules (see Table 3.1), and it takes about 7 to 10 weeks to complete it. Although users are encouraged to advance one module per week, some modules may require more time. Therefore, the program also emphasizes that everyone should progress at their own pace, dedicating enough time to understand the module contents and carry out the proposed activities.

Table 3.1 TAO content

Module	Aims of the module	Contents
0. Welcome module: starting this program.	- Providing information about TAO. - Promoting the adherence to the program. - Enhancing motivation for change.	- Information about the contents of each module. - Recommendations to get the maximum benefit from the program. - Meditation on reasons to change. - Goal setting.
1. Understanding emotional reactions.	- Providing information about AjD and common reactions to stressful events. - Learning of strategies to manage negative emotions.	- Psychoeducation. - Behavior activation. - Slow breathing technique.
2. Learning to deal with negative emotions.	- Facing avoided situations that contribute to the maintenance of the problem. - Improving the ability to deal with everyday challenges.	- Exposure. - Problem solving technique.
3. Accepting problems.	- Becoming aware of the personal experiences related to the stressful event. - Elaborating and processing the stressful event through the acceptance of the problematic situation.	- Mindfulness. - The Book of Life: Acceptance. - Elaboration of a metaphorical meaning for the stressful event.
4. Learning form problems.	- Starting to see problems as opportunities to grow and learn. - Elaborating and processing the stressful event through the confrontation of the problematic situation. - Promoting personal growth.	- Psychoeducation on the positive contribution of problems. - The Book of Life: Confrontation. - Development of personal strengths.

5. Changing the meaning of problems.	- Elaborating and processing the stressful event through the development of a new meaning for the problematic situation. - Developing a new attitude towards problems.	- Elaboration of a new metaphorical meaning for the stressful event. - The Book of Life: Change the meaning. - Letter of projection towards the future. - Choice of a personal life motto.
6. Relapse prevention.	- Assessing achievements accomplished so far. - Reviewing of leaned techniques. - Identifying problematic situations an developing a plan to deal with them.	- Review of the therapeutic achievements. - Action plan to deal with future problems.

All the modules present the same structure: 1) module agenda; 2) therapeutic contents of the module; 3) exercises and activities to put the psychological techniques learned in the module into practice; 4) assessment of the knowledge acquired during the module; 5) tasks to be completed before advancing to the next module; and 6) summary of the module. An effort was made to simplify the language used in TAO to make it easily understood by users, regardless of their socio-demographic features. Regarding the ease of use of TAO, preliminary results obtained in an acceptance and usability study performed with clinical psychologists and patients with AjD showed that the program interface is highly intuitive and user-friendly and does not require any previous training (Rachyla et al., 2017).

Waiting list control group

Participants on the waiting list group will be assessed before and after a period of 7 weeks. After completing a post-waiting period assessment, they will be offered the TAO program.

Support

Because the literature shows that guided ICBT provides better results than completely unguided interventions (Andersson & Titov, 2014), all the participants will receive weekly phone support. This support will consist of a short phone call (maximum 10 minutes) during the intervention stage. The aim of these phone calls will be: 1) to clarify doubts about the use and functioning of TAO; 2) to remind them of the importance of continuing to work on the program contents; and 3) to congratulate them for their effort and achievements. Patients will receive up to 10 telephone calls over a 7-10 week period, and so they will have a maximum of 100 min of therapeutic support. No additional clinical content will be provided during the phone calls.

The support will be provided by experienced psychologists who will have at least a Master's degree in Clinical Psychology. Before taking part in the trial, they will receive training in order to ensure that everyone provides the same support.

Assessment

Measurements will be taken at five different moments: baseline, post-intervention, and three follow-up periods (3-, 6- and 12-month). The diagnostic interviews will be administered by a trained clinician by phone. Moreover, all interviewers engaged in the assessment of potential participants will be supervised by a clinical team composed of mental health professionals with extensive experience in the diagnosis and treatment of stress-related disorders. Questionnaires will be self-administered online via the same virtual platform as the intervention program. Table 3.2 provides an overview of the measures used at each time point.

Table 3.2 Study measures and assessment times

Assessment moment	Telephone assessment performed by a therapist	Automatic online assessment
BL	Diagnostic Interview for Adjustment Disorders, ADIS-IV-L*	BDI, Suicide item, BAI, ISL, PTGI, PANAS, MQLI
Post-M	-	Post-module assessment scale, suicide item
Post-M1	-	Post-module assessment scale, suicide item, Expectation of treatment scale
Post-T	Diagnostic Interview for Adjustment Disorders	BDI, Suicide item, BAI, ISL, PTGI, PANAS, MQLI, Opinion of treatment scale
FU	Diagnostic Interview for Adjustment Disorders	BDI, Suicide item, BAI, ISL, PTGI, PANAS, MQLI

BL, Baseline; ***Post-M,*** post-module; ***Post-M1,*** post-module 1; ***Post-T,*** post-treatment; ***FU***, follow-ups; ***ADIS-IV-L,*** Anxiety Disorders Interview Schedule for DSM-IV: Lifetime Version; ***BDI,*** Beck Depression Inventory - Second Edition*;* ***BAI,*** Beck Anxiety Inventory; ***ISL,*** Inventory of Stress and Loss; ***PTGI,*** Posttraumatic Growth Inventory; ***PANAS,*** Positive and Negative Affect Scale; ***MQLI,*** Multidimensional Quality of Life Questionnaire; ***** used only when differential diagnosis is needed.

Diagnostic interviews

Diagnostic Interview for Adjustment Disorders. This interview will be used for the diagnosis of AjD and to check the fulfillment of inclusion/exclusion criteria. It is a semi-structured interview developed by our research group, taking into consideration the diagnostic criteria for AjD included in the DSM-IV-TR (APA, 2000), the ICD-10 (WHO, 1992), and the *Structured Clinical Interview for DSM-IV (SCID-CV;* First et al., 1996). The first part of the interview aims to explore the presence of a stressful event (current or past). In order to make the interview easier, a list of 46 possible stressors is included. The second part includes 28 symptoms related to AjD. The presence and

severity of these symptoms is rated on a 9-point scale (0=Not at all; 8=Very severe). The validation of this instrument is currently in process.

Anxiety Disorders Interview Schedule for DSM-IV: Lifetime Version (ADIS-IV-L; Di Nardo et al., 1994). This semi-structured interview will be used only when differential diagnoses with Generalized Anxiety Disorder and/or a Major Depressive Episode are needed. The ADIS-IV-L allows a reliable diagnosis of current and lifetime anxiety, mood, somatoform, and substance use disorders.

Primary outcome measures

Beck Depression Inventory - Second Edition (BDI-II) (Beck, Steer, & Brown, 1996), validated in the Spanish population (Sanz, Navarro, & Vázquez, 2003). The BDI-II is a widely used self-report inventory that measures characteristic attitudes and symptoms of depression. The total score is obtained by adding the scores on the 21 items that make up the instrument, with a maximum of 63 points. The instrument has good internal consistency (Cronbach's alpha of 0.76 to 0.95) and test-retest reliability of around 0.8.

Beck Anxiety Inventory (BAI) (Beck & Steer, 1990), validated in the Spanish population (Magán, Sanz, & García-Vera, 2008). The BAI measures the severity of both physiological and cognitive symptoms of anxiety. The 21 items are rated on a 4-point Likert-type scale (from 0 to 3), and the total score, which ranges between 0 and 63, is obtained after directly adding together the scores on all the items. Psychometric analyses carried out so far show excellent internal consistency (Cronbach's alpha $\geq$ 0.85).

Secondary outcome measures

Inventory of Stress and Loss (*ISL)*. This inventory is an adaptation of the Complicated Grief Inventory (Prigerson et al., 1995). It consists of 17 first-person statements about

the degree to which the lost person/situation interferes in the individual's life. There are 5 response options, ranging from 0 ("Never") to 4 ("Always"). The validation of the instrument is currently in process. However, preliminary validation data (Quero, Molés, et al., 2014) show excellent Cronbach coefficients in both general (0.91) and clinical AD (0.86) Spanish populations. Test-retest reliability was also excellent (0.90).

Posttraumatic Growth Inventory (PTGI) (Tadeschi & Calhoun, 1996). The PTGI is a 21-item instrument that assesses positive outcomes reported by individuals who have experienced traumatic events. A 6-point Likert response format is used, so that each statement is rated from "I did not experience this change as a result of my crisis" (scored 0), to "I experienced this change to a large degree as a result of my crisis" (scored 5). The instrument has excellent internal consistency (Cronbach's alpha of 0.90) and acceptable test-retest reliability of around 0.71.

Positive and Negative Affect Scale (PANAS) (Watson, Clark, & Tellegen, 1988). The PANAS consists of 20 items that evaluate two independent dimensions: positive affect (PA) and negative affect (NA). The range for each scale (10 items on each) is from 10 to 50. The Spanish version has demonstrated high internal consistency (0.89 to 0.91 for PA and NA, respectively, in women, and 0.87 and 0.89 for PA and NA, respectively, in men) in college students.

Multidimensional Quality of Life Questionnaire (MQLI) (Mezzich et al., 2000). This is a 10-item self-report instrument that assesses physical and emotional well-being, self-care, occupational and interpersonal functioning, community and services support, personal and spiritual fulfillment, and the overall perception of quality of life. Satisfaction in each of these areas is measured using a 10-point Likert rating scale. The MQLI is brief and easy to administer. It also presents good internal consistency (Cronbach's alpha of 0.79) and a test-retest reliability index of 0.89.

Opinion measures

Expectations and Treatment Opinion Scale (adapted from Borkovec & Nau, 1972). This self-report inventory measures patients' expectations before they start the treatment and their satisfaction when they complete the treatment. The 6 items are rated from 1 ("Not at all") to 10 ("Highly") and provide information about the extent to which: 1) the treatment is perceived as logical; 2) patients are satisfied with the treatment; 3) the treatment would be recommended to a friend with the same problem; 4) the treatment would be useful to treat other psychological problems; 5) patients perceive the treatment as useful for their particular problem; and 6) the treatment is perceived as aversive. Participants will answer the Expectations scale after the therapist explains the rationale for the treatment they will receive and before beginning the treatment. The Satisfaction scale will be completed once the treatment ends. This adaptation has been used in previous studies (Botella et al., 2009; Botella et al., 2016; Quero, Pérez-Ara, et al., 2014).

Opinion scale. This 8-item instrument was developed specifically for this trial in order to get more feedback about the participants' opinions about TAO. Four of the items are answered using an 11-point response scale, rating different statements from 0 ("Not at all") to 10 ("Very much"): (1) usefulness; (2) attractiveness; (3) convenience; (4) recommendation. Then, four short-answer questions are included to collect qualitative data about: (1) the most useful module; (2) positive features of the intervention; (3) negative features of the intervention; and (4) the overall opinion. This scale will be filled out at post-intervention.

Suicidal risk

The presence, frequency, and severity of suicidal thoughts will be assessed during the *Diagnostic Interview for Adjustment Disorders* administered by phone. The inclusion of a suicide item after each program module, at post-intervention, and at follow-up assessments will make it possible to detect participants who are at risk of suicide during the intervention and once the intervention is over.

Other Post-module measures recorded by the system

The post-module assessment will be performed using a short scale developed by the clinical team involved in the present trial. In addition to suicidal risk, the following variables will also be assessed: the general mood using a 7-point face rating scale, and the intensity of several emotions (joy, sadness, anger, hope, anxiety, relaxation, pride, and guilt) on a 7-point numeric scale. Finally, 10-point numeric scales will explore: (1) the feeling of self-efficacy to deal with the stressful event that caused the AjD; (2) acceptance of negative events; (3) openness to new experiences; and (4) satisfaction with the TAO module.

Data analyses

The statistical package IBM SPSS Statistics version 22.0 for Windows will be used for data analyses. Baseline differences between groups will be explored for continuous and categorical measures using both t-tests and chi-square tests. Repeated-measures ANOVAs will be used to assess within-group changes over time in primary and secondary outcome measures. Effect sizes will be estimated using Cohen's d. Linear regression models will be used to study the effect of different variables (e.g., gender, age, and treatment expectations) on adherence and response to the intervention. Any participants who do not complete the post-intervention assessment will be considered

drop-outs. On the other hand, the number of times each patient uses the program will be used as the measure of adherence.

Before analyzing the data, a review of state-of-the-art analytic methodology for RCT will be carried out in order to ensure the use of the most suitable statistical analyses. Finally, following SPIRIT and CONSORT guideline recommendations, both intention-to-treat and per-protocol analyses will be reported (Chan et al., 2013; Eysenbach, 2011).

DISCUSSION

According to the evidence, AjD is a common and disabling disorder. The lack of specific treatment guidelines for this disorder often results in the worsening of clinical symptoms because patients do not receive appropriate help. Although different psychological techniques have been found to be useful for its treatment, no EBI are yet available for AjD. In addition, evidence suggests that a large percentage of patients with mental disorders remain untreated, partly due to a lack of personal and primary health care resources, which indicates the need to research and develop new ways to deliver high quality interventions. Therefore, this study protocol describes a RCT to test the effectiveness of an ICBT for AjD (TAO), compared to a waiting list control group.

One of the main strengths of TAO is that it is based on a manualized intervention protocol that has already shown its efficacy in the traditional, face-to face format. The experience with this protocol provided the opportunity to optimize its effectiveness, focusing on active treatment components and adding techniques that clinicians and patients considered important. The TAO's linear approach allows the progressive acquisition of different skills needed to cope with distress in a gradual but effective way. Because the program was designed to be implemented in patients suffering from mild to severe symptoms, we think the linear structure may be more beneficial than a

modular system where patients can freely choose the contents they want to work on. TAO not only provides techniques for the management of distress caused by the stressful event, but it also emphasizes the importance of its reprocessing and gives it a new positive meaning. This reprocessing involves the exposure to thoughts, emotions, memories, and stimuli related to the event, and it can be highly stressful in some cases. Therefore, the use of linear programs like TAO ensures that patients have the resources they need for the successful completion of the task, thus reducing the number of dropouts.

Apart from testing the effectiveness of the web-based intervention for AjD, the RCT will also provide data about TAO's acceptability to patients and their satisfaction with it. This information will be crucial for the effective implementation of the program in health care settings because the barriers that currently prevent us from taking full advantage of these ICBTs, despite their demonstrated effectiveness, can be broken down.

Finally, personal growth achieved during the intervention period will also be assessed. According to WHO (1948), health is "A state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity". Huber et al. (Huber et al., 2011) also emphasize "the ability to adapt and to self-manage, in the face of social, physical and emotional challenges". Consequently, the reduction in clinical symptomatology might be insufficient to achieve an optimal state of health. Improvements in coping strategies, however, might increase the ability to successfully overcome future challenges, without developing a sense of helplessness and/or AjD. Therefore, the main goal of TAO is to provide strategies to deal with current and future difficult situations, whether or not they can be resolved.

However, the study has limitations. The main limitation is the lack of an active treatment control group for comparison. However, because AjD is considered a transient condition (Casey, 2014), it is useful to explore whether brief interventions like TAO can prevent the chronification of this disorder and the development of more severe symptomatology. Moreover, given the lack of EBI for AjD, the comparison with a waiting list control group could be the first step in the validation of psychological treatments for this condition. Another limitation is that the decision about whether to include participants or not is based on the AjD diagnosis made using the *Diagnostic Interview for Adjustment Disorders*, which is not a validated instrument. The use of other diagnostic tools, such as the Adjustment disorder new model questionnaire (ADNM-20) (Lorenz et al., 2016), would have helped to corroborate the diagnosis. Unfortunately, there are no diagnostic instruments for AjD adapted and validated in Spanish for the beginning of RCT.

On the other hand, one potential difficulty in implementing the study might be the dropout rates. According to the literature, around 30% of those who start an ICBT do not complete the program. Preliminary results on the engagement in the BADI modular intervention for AjD showed a dropout rate of more than 80% in the intervention condition (Eimontas et al., 2017). However, the inclusion of telephone support in the present study and the linear format of the TAO might improve the engagement of the patients who use it.

In sum, despite the limitations, the study represents an important attempt to improve access to an EBI that targets one of the most prevalent mental health problems. Showing the effectiveness of TAO might facilitate the inclusion of ICBT interventions within the National Health System, reducing the current waiting lists and improving the quality of the psychological care provided. As Kazdin (2015) points out, technology-based

interventions like TAO are designed to extend the reach of EBIs and, thus, reduce the burden of mental disorders.

ABBREVIATIONS

ADIS-IV-L: Anxiety Disorders Interview Schedule for DSM-IV, Lifetime version; AES: Advanced Encryptation Standard; AjD: Adjustment disorder; BAI: Beck Anxiety Inventory; BDI-II: Beck Depression Inventory, Second Edition; CBT: Cognitive Behavioral Therapy; CONSORT: Consolidated Standards of Reporting Trials; CONSORT-EHELTH: CONSORT extension for Electronic and mobile Health Applications and onLine TeleHealth interventions; DSM-5: Diagnostic and Statistical Manual of mental disorders, 5th edition; DSM-IV-TR: Diagnostic and Statistical Manual of mental disorders, 4th edition - text revision; EBI: Evidence Based Interventions; EU: European Union; ICBT: Internet-delivered Cognitive-Behavioral Therapy; ICD-10: International Classification of Diseases, 10th revision; ICD-11: International Classification of Diseases, 11th revision; ISL: Inventory of Stress and Loss; MQLI: Multidimensional Quality of Life Questionnaire; PANAS: Positive and Negative Affect Scale; PTGI: Posttraumatic Growth Inventory; RCT: Randomized Controlled Trial; SCID-CV: Structured Clinical Interview for DSM-IV, Clinician Version; SPIRIT: Standard Protocol Items - Recommendations for Intervention Trials; TAO: Adjustment Disorders Online, web-based intervention for Adjustment Disorders; WHO: World Health Organization; WL: Waiting List

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Availability of data and material

The study is currently in progress, in the stage of data recruitment. Consequently, it is not possible to share the data. Once available, the results of the trial will be presented at national and international conferences and in journal publications.

Authors' contributions

SQ, CB, MP-A, MM, DC, IR, and AM contributed to the planning of the RCT as well as the optimization of the intervention protocol and its adaptation to the web format. IR and SQ carried out all stages of the trial and drafted the manuscript. CB reviewed the manuscript and made valuable suggestions for improvements. All the authors have given their approval for the manuscript's publication.

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Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethical approval and consent to participate

The protocol for this study has been approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain) and follows the guidelines of the Declaration of Helsinki and current Spanish and European Union legislation on privacy and data protection. All participants are volunteers and have to sign an informed consent form in order to participate in the trial. Participants are provided with detailed information about the study and informed that they may leave the study at any time.

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Chapter

4 Effectiveness of TAO

This chapter has been submitted as:

Rachyla, I., Mor, S., Botella, C., & Quero, S. Guided internet-delivered intervention for adjustment disorders: results from a randomized controlled trial.

Guided internet-delivered intervention for adjustment disorders: results of a randomized controlled trial

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ABSTRACT

Background: Adjustment disorder (AjD) represents one of the most common mental health conditions. Lack of treatment can lead to more complex clinical problems and even to emergence of suicidal thoughts and behaviors. The scarce literature on AjD supports the effectiveness of low-threshold self-help interventions in reducing clinical distress symptoms. No internet-delivered CBT (ICBT) interventions are available for the treatment of AjD, despite their proven efficacy for treating other mental disorders and their potential to overcome the current barriers to face-to-face psychotherapy. The present randomized controlled trial (RCT) was aimed at exploring the effectiveness of TAO, the first disorder-specific ICBT intervention for AjD in Spanish.

Methods: Participants were randomly allocated to either an ICBT group (n=34) or a waiting list group (n=34). Brief weekly telephone support was provided during the intervention. Beck's inventories for depression and anxiety were used as primary outcomes while secondary outcomes included stress and loss symptoms, posttraumatic growth, positive and negative affect, and quality of life. All self-report questionnaires were completed via Internet.

Results: Only data from baseline and post-intervention assessments were analyzed. 76.5% of participants completed the whole intervention. Significant decrease in BDI, BAI, and ISL scores was observed in both groups, although patients from the intervention group also presented significant improvement in the others outcome measures (Cohen's *d* indices from .62 to 1.57). Between group comparison revealed greater improvement among patients who received ICBT, these group differences achieved significant level for depressive symptoms, posttraumatic growth, positive and negative affect, and quality of life, with effect sizes ranging from .44 to 1.16. Number of cases reaching clinically meaningful change was also significantly higher in ICBT group.

Conclusions: This is the first work reporting RCT results on the effectiveness of an ICBT intervention for AjD. Although the long-term durability of treatment gains is unclear, the current findings support the potential of TAO for reducing the clinical distress and promoting posttraumatic growth, positive affect, and quality of life among patients with AjD. Further research will contribute to improving the assistance provided to patients suffering from this underresearched condition.

Trial registration: ClinicalTrial.gov: NCT02758418. Trial registration date 2 May 2016.

Keywords: adjustment disorder, internet-delivered interventions, CBT, effectiveness, randomized controlled trial.

INTRODUCTION

Adjustment Disorder (AjD) is one of the most common psychiatric illnesses (Evans et al., 2013). It is characterized by the appearance of clinically significant emotional and behavioral symptoms in response to an identifiable stressful event (APA, 2013). It is considered a mild condition, situated between normalcy and pathology (Fernández et al., 2012; O'Donnell et al., 2016). However, although the clinical symptoms of AjD are milder than in other anxiety and affective disorders, they are severe enough to cause an important distress, functional impairment, low quality of life, and even suicidal ideation and behavior (Casey et al., 2015). Therefore, low-threshold interventions are recommended in order to prevent the chronicity and worsening of symptoms or the development of a more severe disorder (Bachem & Casey, 2018). The use of self-help interventions might be particularly useful for the treatment of AjD, given its often transient nature (Maercker et al., 2015).

Only one randomized control trial (RCT) has provided evidence on the effectiveness of a completely unguided self-help treatment for AjD. The bibliotherapy manual based on cognitive-behavioral therapy (CBT) improved distress symptoms of AjD among burglary victims, especially those related to the recurrent preoccupation with the stressor (Bachem & Maercker, 2016a). Cohen's *d* indices from 0.17 to 0.67 were found after comparing the intervention group with a waiting list (WL). The assessment of reliable change showed higher proportion of meaningful pre-post change in the intervention group than in the control group.

As for internet-delivered interventions aimed at AjD symptoms, three programs were found during the literature review. However, only one has provided preliminary data on its efficacy so far. *Brief Adjustment Disorder Intervention* (BADI) is a self-guided treatment program which integrates CBT, mindfulness, mind-body practices,

and other strategies addressed at improving social support (Skruibis et al., 2016). After 30 days of BADI use, participants reported a significant decline of AjD symptoms, with a within group effect size of 0.63. The comparison with a 30-days WL revealed a moderate between group effect size (Cohen's *d* index of 0.57) (Eimontas et al., 2017). The other two interventions are currently undergoing validation and no data on their efficacy have been reported yet (Murphy et al., 2017; Servant et al., 2017). Furthermore, both of these interventions present an important limitation since they can only be used with specific subgroups of the population. Thus, one of the interventions only targets cancer patients (Murphy et al., 2017) and the other focuses only on AjD with anxiety subtype (Servant et al., 2017).

This evidence, despite being scarce, provides support to the feasibility of internet-delivered interventions for the treatment of AjD. These interventions are already effectively used for the treatment of other mental disorders, such as depression or anxiety disorders (Andrews et al., 2018), producing similar effects as face-to-face therapy (Carlbring, Andersson, Cuijpers, Riperd, & Hedman-Lagerlöfh, 2018). Delivery of the psychological treatments over the Internet offers important advantages, especially in terms of reach, flexibility, cost saving, and confidentiality (Griffiths et al., 2006; P. Musiat & Tarrier, 2014). Different amount of therapist contact may be included. Guided interventions generally show better outcomes and lower dropout rates than totally unguided programs (Andersson et al., 2013).

Given the potential effectiveness of internet-delivered interventions for the treatment of mental disorders in general and of AjD in particular, TAO ("*Trastornos Adaptativos Online"*) program was developed. To our knowledge, TAO is the first internet-delivered disorder-specific intervention for AjD in Spanish. It is based on a manualized intervention protocol for AjD (Botella et al., 2008a) which showed efficacy

in several previous studies (Baños et al., 2011; Quero et al., 2017). Before its adaptation to online format, the protocol was reviewed and optimized including additional therapeutic techniques (Rachyla et al., 2018). The aim of the present work is to report the results of the RCT conducted to compare the efficacy of TAO (combined with a brief telephone support) with a WL control group.

METHODS

Study design

The study was a two-armed RCT that compared an intervention group, which received an internet-delivered cognitive-behavioral therapy (ICBT) intervention with weekly telephone support, to a 7-week WL control group. The allocation was performed by an independent researcher, who was not involved in the study, using Epidat software (version 4.1). Block randomization was used in order to maintain a balance among trial groups. The power analysis conducted with G*Power 3 software (Faul et al., 2007) before the beginning of the study revealed that a sample of 52 participants (26 per group) was needed to detect an effect size of 0.70 with power of 0.80 and one-tailed alpha of 0.05. Assuming a drop-out rate of 30% found in the literature on adherence to ICBT (van Ballegooijen et al., 2014), a sample of 68 participants (34 per group) was recruited. Assessments were conducted at baseline, post-intervention and three follow-up moments (3, 6 and 12 months). However, since more than half of study participants have not yet completed the follow-up assessments, only data from baseline and post-intervention are reported.

The protocol for the current RCT was approved by the Ethical Committee of Universitat Jaume I (October 2015) and registered on the ClinicalTrial.gov database as

NCT02758418. Further details regarding the development of TAO and the RCT designed to test its efficacy were published elsewhere (Rachyla et al., 2018).

Participants, recruitment and eligibility criteria

Participants were recruited through advertisements in the local media (radio, newspaper), social networks (Facebook, Instagram, Google+, online health forums), and on campus noticeboards and website. An informative e-mail was sent to all members of the university community of Universitat Jaume I and Universitat de València. Potential participants were also derived from the Emotional Disorder Clinic of Universitat Jaume I and other collaborating centers (Spanish Red Cross and Spanish Association Against Cancer).

Those interested in participating sent an e-mail to the indicated address or called to the provided number. All requests were answered within 24 hours. A telephone interview was arranged to explain the terms of the clinical trial and check the fulfillment of eligibility criteria (Table 4.1). People fulfilling the eligibility criteria had to sign an online informed consent before being randomly assigned to the intervention group (ICBT) or the control group (WL).

Table 4.1 Inclusion and exclusion criteria for participants

Inclusion criteria	Exclusion criteria
(1) Age ≥ 18 years	(1) Presence of risk of suicide or self-destructive behaviors
(2) Meeting DSM-5 criteria for AjD	(2) Receiving psychological treatment for AjD
(3) Ability to understand and read Spanish	(3) Presence of another severe mental disorder (substance abuse or dependence, psychotic disorder, dementia, or bipolar disorder)
(4) Ability to use a computer and having access to the Internet	(4) Presence of a severe personality disorder or illness
(5) Having an e-mail address	(5) An increase and/or change in the medication during the study period

Measures

During the RCT, no face-to-face contact was established with participants. All questionnaires were answered online and the diagnostic interview was administered via telephone or Skype call. The assessment measures included in the present study are recapitulated below. A more detailed description of each of these instruments can be found in the study protocol (Rachyla et al., 2018).

Diagnostic instrument: Diagnostic interview for Adjustment Disorders (Rachyla, Botella, Mor, Tur, López-Montoyo, & Quero, submitted); *Primary outcomes:* Beck Depression Inventory - Second Edition (BDI-II; Beck, Steer, & Brown, 1996) and Beck Anxiety Inventory (BAI; Beck & Steer, 1990); *Secondary outcomes:* Inventory of Stress and Loss (ISL; Quero, Mor, Molés, Rachyla, Baños & Botella, submitted), Posttraumatic Growth Inventory (PTGI; Tadeschi & Calhoun, 1996), Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1988), and Multidimensional Quality of Life Questionnaire (MQLI; Mezzich et al., 2000).

Treatment and therapists

Patients received an ICBT intervention based on a structured treatment protocol which combines CBT, positive psychology techniques and mindful awareness. The treatment protocol was called TAO and it consists of 7 sequential modules: "Starting the program", "Understanding emotional reactions", "Learning to deal with negative emotions", "Accepting problems", "Learning from problems", "Changing the meaning of problems", and "Relapse prevention".

The key objective of TAO is the emotional elaboration and processing of the stressful event which is achieved through acceptance, confrontation, and development of a new meaning for the problematic situation. The *Book of Life* is a therapeutic

activity focused on this objective. It is a sort of personal diary devoted to the stressful event and its impact on the life of the person who lived it. The Book of Life is a writing exercise, though it also includes the use of symbols, metaphors, pictures and even music. Apart of the elaboration component, TAO also includes motivation for change, psychoeducation on the common reactions to the stressful event and the positive contribution of problems, behavior activation, slow breathing technique, exposure, problem solving, mindfulness, development of personal strengths and optimism towards the future, and relapse prevention.

The content is presented through texts, videos, pictures, and vignettes (Figure 4.1). In order to facilitate the implementation of the learned skills, different practical activities are suggested, accompanied by illustrative examples and downloadable worksheets. A more detailed description of TAO can be found in the study protocol (Rachyla et al., 2018).

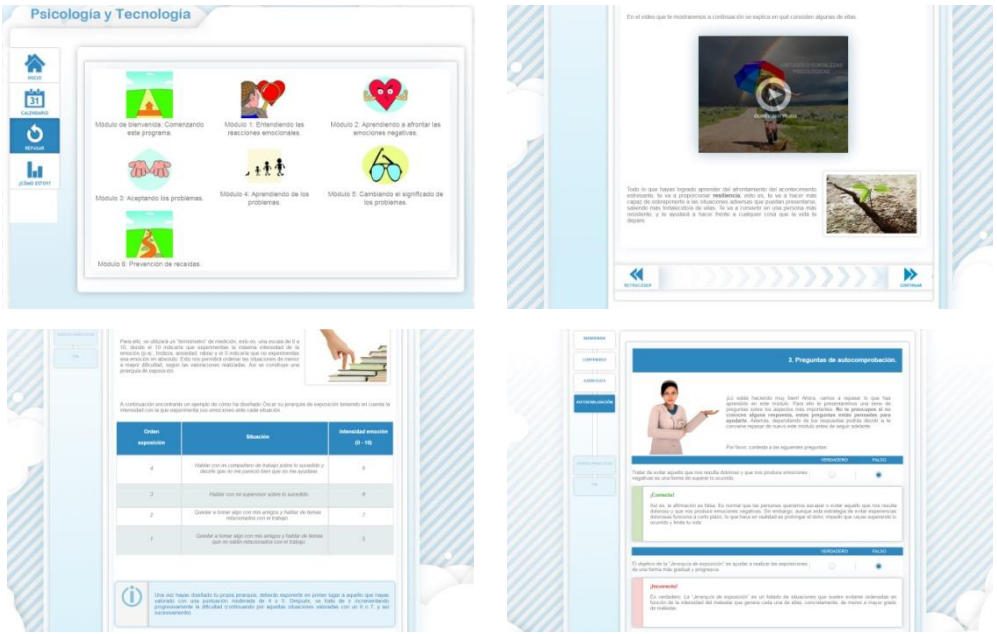

Figure 4.1 TAO screenshots

The treatment period lasted for about 7-10 weeks. During this time, participants received weekly telephone support. The support consisted of a short telephone call

(maximum 10 minutes) aimed at clarifying doubts, reinforcing for the accomplished work and encouraging patients to keep working. No additional clinical content or counseling was provided.

Only two therapists participated in the study. Both of them were PhD students with Master degree and clinical experience.

Statistical analyses

Baseline differences between study groups were examined using chi-square tests and independent sample t-tests for categorical and continuous data respectively.

Different metrics of adherence and use of the intervention were registered. The average session time was not registered since it was considered that the login duration was not a reliable indicator of time of intervention use. Instead, the number of logins was tracked. Since the post-intervention assessment was performed only when the last TAO module was completed, participants who had not finished the whole program were considered drop-outs.

Due to the often transient nature of AjD, the spontaneous remission of clinical symptoms was anticipated. However, following SPIRIT (Chan et al., 2013a; Chan et al., 2013b) and CONSORT (Eysenbach, 2011; Moher et al., 2010) guideline recommendations, both intent-to-treat and per-protocol analyses were conducted. Little's test was conducted to verify the random distribution of missing cases. The imputation of missing total scores for participants who did not complete the post-intervention or post-waiting period assessment was conducted using the Expectation Maximization (EM) algorithm. According to the literature, EM is an iterative regression-based procedure which provides excellent maximum likelihood estimates for missing data (Graham, 2009).

Repeated measures ANOVAs were conducted to explore the changes in outcome measures produced from baseline to post-intervention in both study groups. Assessment moment was used as within-group factor and experimental condition as between-group factor. The significance levels were corrected using Bonferroni adjustment in order to reduce type 1 error. Within- and between-group effect sizes were estimated computing Cohen's d indices (Cohen, 1988). The clinical significance of change observed in the scores of outcome measures from one assessment moment (baseline) to another (post-treatment) was determined calculating the Reliable Change Indexes (Jacobson & Truax, 1991).

All statistical analyses were conducted using statistical package IBM SPSS Statistics version 22.0 for Windows.

RESULTS

Baseline Characteristics

One hundred and sixty-four persons were recruited between May 2015 and March 2018. However, only 144 were assessed for eligibility criteria, and from them, only 68 were finally included in the study and randomized to one of the groups. Five participants from WL dropped out before completing the baseline assessment, thus only 63 participants were included in the analyses (see Figure 4.2). The final sample consisted of 47 women (74.6%) and 16 men (25.4%) aged between 18 and 58 years (M=32.81; SD=10.60), most of whom were single (54.0%, n=34). The majority of the participants were from Spain (81.0%, n=51), though also participated people from Argentina (4.8%, n=3), Brazil (3.2%, n=2), Colombia (3.2%, n=2), Chile (1.6%, n=1), Ecuador (1.6%, n=1), El Salvador (1.6%, n=1), Portugal (1.6%, n=1), and Romania

(1.5%, n=6). A high percentage of the sample were university students or people who had already completed their university education (74.6%, n=47).

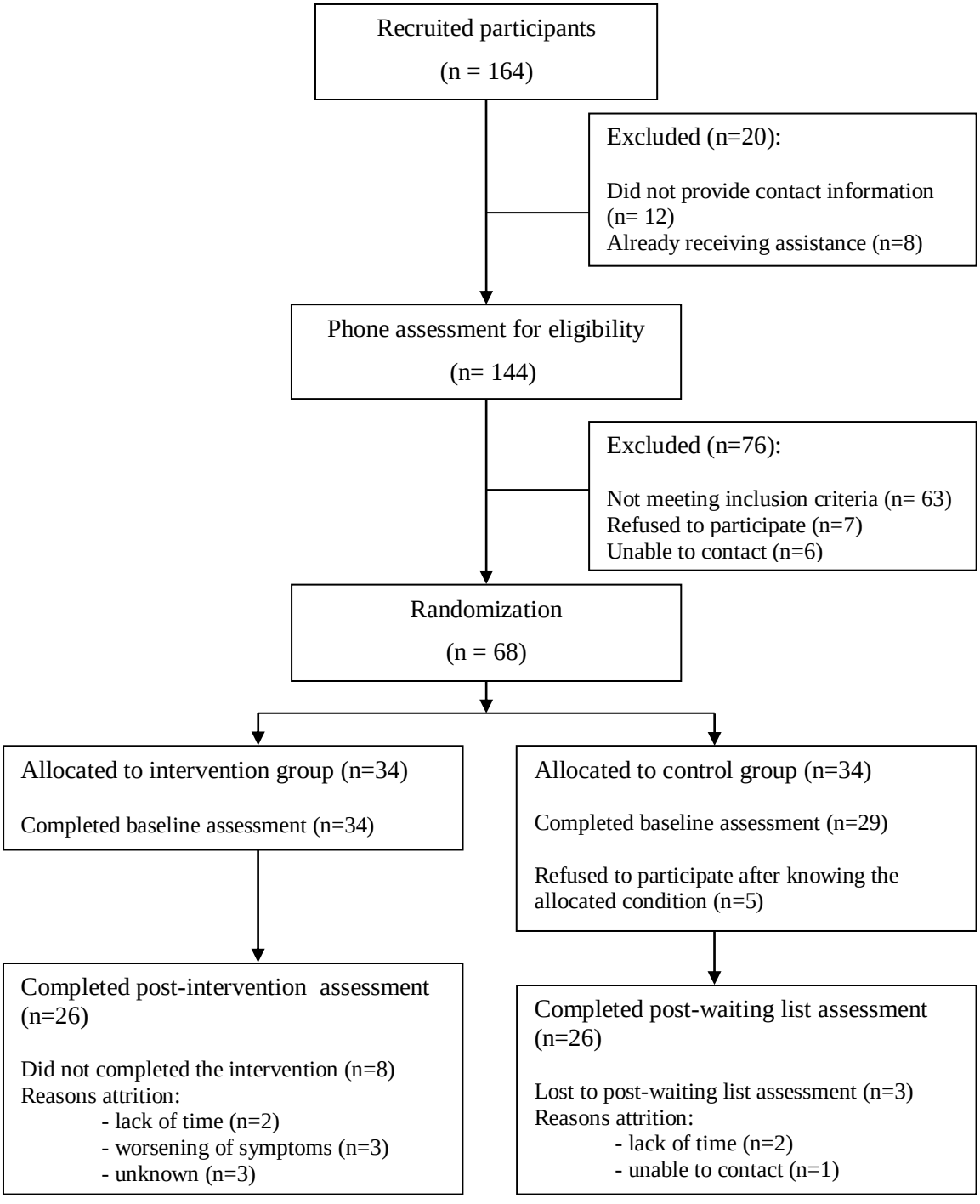

Figure 4.2 Flowchart of participants

In most cases, the distress symptoms had been presented for at least 6 months (49.2%, n=31), but only 8 participants were receiving medication at the moment of assessment (12.7%). Medication was monitored every week in order to detect any possible change, either in the drug or the dosage. AjD with mixed anxiety and depressive symptoms was the most prevalent subtype (69.8%, n=44). Break-up, separation or divorce was the most frequently reported stressor (30.2%, n=19), along with conflicts with family members (19.0%, n=12) and problems in the work or academic area (19.0%, n=12).

No baseline differences between groups were found for neither demographic nor clinical characteristics (Table 4.2).

Adherence and use

Out of 34 participants from the treatment condition, 26 (76.5%) completed all seven modules of TAO. Participants who did not complete all the modules were considered dropouts. From 8 participants considered dropouts, 1 (2.9%) completed only the first welcome module, 3 (8.8%) completed two modules, 3 (8.8%) completed three modules, and 1 (2.9%) completed five modules. Little's test confirmed the assumption that the data were missing completely at random (χ^2=6.28, ρ=.937).

Participants needed between 1 and 25 logins to complete a module, the total average was about 2 logins per module (M=2.28, SD=2.19). The average time between modules was 5.86 days (SD=4.14). The modules which took more time were the module 2 (M=12.40, SD=12.82), focused on exposure and problem solving technique, and the module 3 (M=12.22, SD=17.15), which included mindfulness practice and introduction to the *Book of Life*. Days with higher number of logins were Monday (M=3.68, SD=4.38), Tuesday (M=4.35, SD=3.93), and Wednesday (M=4.35, SD=4.01).

Table 4.2 Base-line characteristics of participants

	ICBT (n=34)	**WL** (n=29)	**Between group comparison**
Age mean (SD)	32.59 (10.40)	33.07 (11.01)	t (61) = 0.18, ρ=.859
Gender *n (%)*			
Female	24 (70.6%)	23 (79.3%)	χ^2 (1) = 0.63, ρ=.428
Male	10 (29.4%)	6 (20.7%)	
Marital status *n (%)*			
Single	17 (50.0%)	17 (58.6%)	χ^2 (4) = 4.47, ρ=.347
Unmarried couple	8 (23.5%)	4 (13.8%)	
Married	6 (17.6%)	2 (6.9%)	
Divorced/Separated	3 (8.8%)	5 (17.2%)	
Widowed	0 (0.0%)	1 (3.4%)	
Level of education *n (%)*			
Elementary education	3 (8.8%)	2 (6.9%)	χ^2 (2) = 0.65, ρ=.724
Secondary education	7 (20.6%)	4 (13.8%)	
Higher education	24 (76.5%)	23 (79.3%)	
Employment status *n (%)*			
Student	14 (41.2%)	14 (48.3%)	χ^2 (3) = 2.62, ρ=.454
Unemployed	6 (17.6%)	3 (10.3%)	
Employed/self-employed	12 (35.3%)	12 (41.4%)	
Work leave	2 (5.9%)	0 (0.0%)	
Medication *n (%)*			
Yes	6 (17.6%)	2 (6.9%)	χ^2 (1) = 1.63, ρ=.201
No	28 (82.4%)	27 (93.1%)	
Number of stressors *mean (SD)*	1.62 (0.70)	1.66 (0.72)	t (61) = 0.21, ρ=.835
Duration of symptoms related to the main stressor *n (%)*			
< 1 month	3 (8.8%)	2 (6.9%)	χ^2 (3) = 6.05, ρ=.109
1 - 3 months	8 (23.5%)	7 (24.1%)	
3 - 6 months	10 (29.4%)	2 (6.9%)	
> 6 months	13 (38.2%)	18 (62.1%)	
Distress/ interference severity *mean (SD)**	4.88 (1.15)	4.52 (1.18)	t (61) = 1.24, ρ=.220
Outcome measures *mean (SD)*			
BDI	26.68 (9.76)	24.72 (9.04)	t (61) = 0.82, ρ=.416
BAI	20.76 (12.62)	19.10 (9.09)	t (61) = 0.59, ρ=.557
ISL	35.88 (10.23)	37.07 (14.71)	t (61) = 0.38, ρ=.708
PTGI	39.44 (21.73)	37.62 (19.78)	t (61) = 0.35, ρ=.731
PANAS+	20.41 (8.12)	21.66 (8.01)	t (61) = 0.61, ρ=.545
PANAS-	29.47 (7.43)	27.21 (8.36)	t (61) = 1.14, ρ=.259
MQLI	4.83 (1.52)	5.28 (1.24)	t (61) = 1.29, ρ=.202

ICBT, Internet-delivered Cognitive-Behavioral Therapy; ***WL***, Waiting List; ***SD***, Standard Deviation; ***BDI***, Beck Depression Inventory; ***BAI***, Beck Anxiety Inventory; ***ISL***, Inventory of Stress and Loss; ***PTGI***, Posttraumatic Growth Inventory; ***PANAS+***, Positive and Negative Affect Scale - positive affect subscale; ***PANAS-***, Positive and Negative Affect Scale - negative affect subscale; ***MQLI***, Multidimensional Quality of Life Questionnaire; ***** according to the clinician's judgment

Treatment effectiveness at post-treatment (ITT analyses)

Table 4.3 shows intervention outcomes for ITT sample. The repeated measures ANOVA analyses, corrected using Bonferroni adjustments, revealed a significant main effect of time on all assessment measures: BDI [F(1, 61)=92.47, ρ=.000], BAI [F(1, 61)=29.03, ρ=.000], ISL [F(1, 61)=52.17, ρ=.000], PTGI [F(1, 61)=48.08, ρ=.000], PANAS [positive affect: F(1, 61)=42.45, ρ=.000; negative affect: F(1, 61)=31.70, ρ=.000], and MQLI [F(1, 61)=32.76, ρ=.000]. Within-group comparisons showed significant clinical improvement over time among participants of ICBT group in all considered measures, with pre-post effect sizes from 0.62 to 1.57. On the other hand, participants from control group only presented significant score change in BDI, BAI, and ISL. Within-group effect sizes in the control group ranged from 0.23 to 0.71.

Significant interaction effect between the moment of assessment (BL, post-intervention) and the experimental condition (ICBT, WL) was found, indicating a different pattern of change over time between groups on BDI [F(1, 61)=15.20, ρ=.000], PTGI [F(1, 61)=20.99, ρ=.000], PANAS [positive affect: F(1, 61)=17.40, ρ=.000; negative affect: F(1, 61)=11.37, ρ=.001], and MQLI [F(1, 61)=9.75, ρ=.003] scores. Compared with the control condition, the intervention group showed significantly greater improvement in all outcome measures (*d* indices from 0.44 to 1.16), except for BAI [F(1, 61)=3.81, ρ=.056; *d* index of 0.26) and ISL [F(1, 61)=3.96, ρ=.051; *d* index of 0.69].

Treatment effectiveness at post-treatment (completers analyses)

Results from completers-only analyses were similar to those found in ITT analyses (Table 4.4). Time effects were as follows: BDI [F(1, 50)=76.77, ρ=.000], BAI [F(1, 50)=22.03, ρ=.000], ISL [F(1, 50)=41.90, ρ=.000], PTGI [F(1, 50)=41.65,

ρ=.000], PANAS [positive affect: F(1, 50)=38.55, ρ=.000; negative affect: F(1, 50)=26.17, ρ=.000], and MQLI [F(1, 50)=27.08, ρ=.000]. As for interaction effect, ICBT group showed significantly greater improvement on BDI [F(1, 50)=18.23, ρ=.000], ISL [F(1, 50)=6.37, ρ=.015], PTGI [F(1, 50)=23.13, ρ=.000], PANAS [positive affect: F(1, 50)=21.29, ρ=.000; negative affect: F(1, 50)=13.98, ρ=.000], and MQLI [F(1, 50)=11.12, ρ=.002] than the WL group. In this case, only on BAI no significant differences between the two groups were found [F(1, 50)=3.48, ρ=.068].

Table 4.3 Means, standard deviations, within- and between-group effect sizes for primary and secondary outcomes at base-line and post-treatment (intention-to-treat sample)

	WL (n =29)			**ICBT** (n =34)			**Between-group Cohen *d*** [95%CI]
	BL M (SD)	**Post** M (SD)	**Within-group Cohen *d*** [95%CI]	**BL** M (SD)	**Post** M (SD)	**Within-group Cohen *d*** [95%CI]	
BDI	24.72 (9.04)	18.08 (10.65)	0.71 [0.30, 1.13]	26.68 (9.76)	10.97 (6.51)	1.57 [1.05, 2.09]	0.81 [0.30, 1.33]
BAI	19.10 (9.09)	15.35 (10.03)	0.40 [0.02, 0.78]	20.76 (12.62)	12.76 (9.78)	0.62 [0.25, 0.99]	0.26 [-0.24, 0.76]
SLI	37.07 (14.71)	28.04 (13.66)	0.60 [0.20, 1.00]	35.88 (10.23)	19.99 (9.52)	1.52 [1.01, 2.03]	0.69 [0.18, 1.19]
PTGI	37.62 (19.78)	42.95 (19.38)	0.26 [-0.64, 0.11]	39.44 (21.73)	65.51 (19.18)	1.18 [-1.63, -0.73,]	1.16 [-1.69, -0.62]
PANAS+	21.66 (8.01)	23.77 (7.78)	0.26 [-0.63, 0.12]	20.41 (8.12)	30.08 (7.47)	1.16 [-1.61, -0.72]	0.82 [-1.33, -0.30]
PANAS-	27.21 (8.36)	25.26 (8.93)	0.23 [-0.15, 0.60]	29.47 (7.43)	21.72 (5.81)	1.02 [0.59, 1.44]	0.47 [-0.03, 0.97]
MQLI	5.28 (1.24)	5.76 (1.59)	0.38 [-0.76, 0.01]	4.83 (1.52)	6.43 (1.44)	1.03 [-1.45, -0.60]	0.44 [-0.94, 0.06]

WL, Waiting List; ***ICBT***, Internet-delivered Cognitive-Behavioral Therapy; ***BL***, Base-Line; *Post*, Post-intervention; ***M***, Mean; ***SD***, Standard Deviation; ***CI***, Confidence Interval; ***BDI***, Beck Depression Inventory; ***BAI***, Beck Anxiety Inventory; ***ISL***, Inventory of Stress and Loss; ***PTGI***, Posttraumatic Growth Inventory; ***PANAS+***, Positive and Negative Affect Scale - positive affect subscale; ***PANAS-***, Positive and Negative Affect Scale - negative affect subscale; ***MQLI***, Multidimensional Quality of Life Questionnaire

Table 4.4 Means, standard deviations, within- and between-group effect sizes for primary and secondary outcomes at base-line and post-treatment (completers)

	WL (n =26)			**ICBT** (n =26)			**Between-group Cohen *d*** [95%CI]
	BL M (SD)	**Post** M (SD)	**Within-group Cohen *d*** [95%CI]	**BL** M (SD)	**Post** M (SD)	**Within-group Cohen *d*** [95%CI]	
BDI	24.15 (9.33)	18.35 (11.24)	0.60 [0.18, 1.03]	26.73 (9.75)	9.88 (6.64)	1.68 [1.05, 2.30]	0.90 [0.33, 1.47]
BAI	18.96 (9.29)	15.46 (10.59)	0.37 [-0.04, 0.77]	19.92 (10.45)	11.80 (9.23)	0.75 [0.31, 1.20]	0.36 [-0.19, 0.91]
SLI	37.77 (14.29)	28.04 (14.33)	0.52 [0.11, 0.94]	36.62 (10.20)	19.00 (10.49)	1.68 [1.05, 2.30]	0.71 [0.15, 1.27]
PTGI	37.69 (20.55)	41.81 (20.02)	0.19 [-0.59, 0.20]	40.42 (21.76)	68.62 (18.27)	1.26 [-1.79, -0.72]	1.38 [-1.98, -0.77]
PANAS+	21.85 (8.42)	23.46 (8.14)	0.19 [-0.58, 0.21]	19.73 (7.96)	30.69 (7.96)	1.34 [-1.88, -0.79]	0.88 [-1.45, -0.31]
PANAS-	27.21 (8.36)	25.15 (9.21)	0.16 [-0.23, 0.55]	29.47 (7.43)	21.00 (6.21)	1.11 [0.60, 1.61]	0.50 [-0.05, 1.05]
MQLI	5.29 (1.27)	5.68 (1.66)	0.30 [-0.70, 0.10]	4.80 (1.63)	6.59 (1.53)	1.06 [-1.56, -0.57]	0.56 [-1.12, -0.01]

WL, Waiting List; ***ICBT***, Internet-delivered Cognitive-Behavioral Therapy; ***BL***, Base-Line; *Post*, Post-intervention; ***M***, Mean; ***SD***, Standard Deviation; ***CI***, Confidence Interval; ***BDI***, Beck Depression Inventory; ***BAI***, Beck Anxiety Inventory; ***ISL***, Inventory of Stress and Loss; ***PTGI***, Posttraumatic Growth Inventory; ***PANAS+***, Positive and Negative Affect Scale - positive affect subscale; ***PANAS-***, Positive and Negative Affect Scale - negative affect subscale; ***MQLI***, Multidimensional Quality of Life Questionnaire

Improvement and deterioration

Table 4.5 shows percentages of completer participants who showed clinically meaningful change from baseline to post-intervention in the outcome measures used in the current study, and also percentages of participants who, besides showing clinically relevant change, achieved the status of recovery (i.e., obtained scores outside the range of dysfunctional population). These percentages were higher in the intervention condition. Moreover, the found differences resulted to be significant for all measures, except for ISL.

Table 4.5 Percentages of participants in each condition showing reliable change and achieving the status of recovery at post-treatment

	ICBT (n=26)		**WL** (n=26)		**Between group differences**
	Reliable change proportion n (%)	**"Recovery" category** n (%)	**Reliable change proportion** n (%)	**"Recovery" category** n (%)	
BDI	20 (76.9%)	18 (69.2%)	9 (34.6%)	6 (23.1%)	$\chi^2 = 13.75$, $\rho = .003$*
BAI	9 (34.6%)	8 (30.8%)	2 (7.6%)	1 (3.8%)	$\chi^2 = 6.64$, $\rho = .036$*
SLI	19 (73.0%)	18 (69.2%)	11 (42.3%)	10 (38.5%)	$\chi^2 = 5.49$, $\rho = .139$
PTGI	9 (34.6%)	9 (34.6%)	2 (7.6%)	1 (3.8%)	$\chi^2 = 9.30$, $\rho = .026$*
PANAS+	15 (57.7%)	12 (46.2%)	3 (11.5%)	2 (7.7%)	$\chi^2 = 12.38$, $\rho = .002$*
PANAS-	11 (42.3%)	9 (34.6%)	1 (3.8%)	1 (3.8%)	$\chi^2 = 10.90$, $\rho = .004$*
MQLI	16 (61.6%)	10 (38.5%)	5 (19.2%)	2 (7.7%)	$\chi^2 = 10.24$, $\rho = .017$*

ICBT, Internet-delivered Cognitive-Behavioral Therapy; ***WL***, Waiting List; ***BDI***, Beck Depression Inventory; ***BAI***, Beck Anxiety Inventory; ***ISL***, Inventory of Stress and Loss; ***PTGI***, Posttraumatic Growth Inventory; ***PANAS+***, Positive and Negative Affect Scale - positive affect subscale; ***PANAS-***, Positive and Negative Affect Scale - negative affect subscale; ***MQLI***, Multidimensional Quality of Life Questionnaire; ***** statistical significance

DISCUSSION

The present study aimed at investigating the effectiveness of an ICBT intervention for AjD combined with brief weekly telephone support. The results showed that TAO was effective in reducing negative affect as well as depressive, anxiety, and AjD symptoms related to stress and loss. The intervention also promoted increase of posttraumatic growth, positive affect, and quality of life.

Since AjD is considered to be a transitional, self-resolving condition (Bachem & Casey, 2018), the reduction of clinical symptoms was also expected in control participants. As it was expected, the control group showed significant improvement but only on the outcomes measuring depression (BDI), anxiety (BAI), and stress and loss symptoms (ISL). Moreover, the effect sizes found in the control group were smaller than those found in the intervention group. These results suggest that the impact of the stressful event diminished over time. However, the use of TAO not only promoted better adaptation to the stressful situation, reducing clinical symptoms triggered by the stressor, but also facilitated posttraumatic growth, positive affect, and quality of life.

Comparison with the WL revealed significant differences between both groups. According to ITT analyses, the intervention group presented significantly larger improvement in all outcome measures, except on BAI and ISL. When only completer sample was included in the analyses, the results again showed significant between-group differences in all instruments, including ISL. Only on BAI no significant differences were found. In addition, the proportion of participants showing reliable change was also significantly higher in the ICBT group. These results suggest that the intervention allowed achieving a health status which is closer to WHO definition of mental health and which states that mental health is more than just the absence of psychopathology. Instead, mental health represents "a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community" (WHO, 2001).

Adherence rate was 76.47%, similar to that reported for other ICBT interventions combined with therapist support for adult depression and anxiety disorders (Andrews et al., 2018; Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010). The

analyses of dropouts showed that abandonments were completely random. Moreover, in line with previous research, the dropouts occurred over the course of the treatment, rather than at the beginning (Van Ballegooijen et al., 2014). According to these authors, this gradual dropout pattern is not necessarily due to a lack of intervention acceptability, but might be explained by other factors, such as the feeling that the intervention is no longer needed. Nevertheless, further research is needed to draw firmer conclusions on adherence to ICBT for AjD.

Regarding TAO use, following program instructions, participants dedicated approximately one week to each module. However, modules aimed at stressor confrontation required more time. This greater time requirement should be taken into account in the development of treatment programs for AjD. Patients should also be encouraged to progress at their own pace and devote more time to these core therapeutic components, which might be more challenging. On the other hand, relatively low login frequency was observed. However, it was not surprising since most of the participants reported working offline using the downloadable files containing module summaries and activities. This preference for offline work suggests the convenience of including downloadable worksheets in order to facilitate the review and the performance of assigned activities. Finally, greater use of TAO was registered in the days before weekly calls aimed at providing therapist support. Since no psychological assistance was provided during telephone calls, the weekly support seems to have played a more motivating role. This finding is consistent with the literature on the role of therapist support as an important facilitator of adherence (Castro et al., 2018; Hilvert-Bruce, Rossouw, Wong, Sunderland, & Andrews, 2012).

The study has several limitations. First, most of participants were recruited as volunteers who showed interest in an online intervention. It is unclear if this willingness

to receive internet-delivered intervention affected adherence and treatment outcomes. On the other hand, the found interest is also encouraging and it is in line with existing literature. In a recent study, 25.0% of participants reported willingness to use self-help e-mental health services and 33.8% indicated intention to use therapist-assisted e-mental health programs (March et al., 2018). Another study found out that the intention to use online mental health programs ranged between 40% and 71% (Batterham & Calear, 2017). Thus, internet interventions seem to represent an accepted treatment alternative by at least part of the population.

The second limitation concerns the measures of change in clinical symptoms. Only ISL represented a specific measure of AjD symptoms. Although this instrument has already been validated, showing good psychometric properties (Quero et al., submitted), inclusion of other disorder-specific measures, such as *Adjustment Disorders New Model* questionnaire (Maercker et al., 2013) would have provided more conclusive results. However, no validated instruments for assessment of AjD were available at the beginning of the RCT. As for primary outcome measures, while previous works support the utility of BDI to detect potential cases of AjD (Ruiz, Silva, & Miranda, 2001), little is known about the utility of BAI. According to literature, BAI is a measure of panic rather than of anxiety in general (Leyfer, Ruberg, & Woodruff-Borden, 2006). Thus, although higher scores suggest the presence of pathological anxiety, people without a diagnosis of any anxiety disorder can also score high in the instrument. In our study, no significant differences were observed in the reduction of BAI scores between intervention and control groups. However, it does not necessarily imply that participants did not improve or that they still presented pathological anxiety. In fact, proportion of participants showing reliable change was significantly higher in the intervention group. Furthermore, anxiety reported at post-intervention might be qualitatively different from

baseline intervention. Thus, most participants at post-intervention interview indicated feeling more anxiety because they were facing the stressor, instead of avoiding it. In any case, further research on sensitivity of BAI to clinical change in AjD is needed. Moreover, it should be noted that participants of both groups completed self-report questionnaires via online. In this regard, different studies have found that internet administration of questionnaires did not affect their psychometric properties or treatment outcomes of ICBT interventions for depression and anxiety disorders (Carlbring et al., 2007; Mason & Andrews, 2014). However, it is not clear whether automated administration of instruments can affect the assessment of AjD.

Finally, as it was mentioned previously, data from follow-up assessment periods are not available yet, so no conclusions on durability of gains achieved with the ICBT delivered in the present study can be made.

In conclusion, results of the present work support the efficacy of TAO for the treatment of AjD. TAO was more effective than the mere passage of time and conferred additional benefits in terms of posttraumatic growth, positive affect, and quality of life. The study represents an important contribution to the field of AjD, which has received little attention over all these years. Although lack of follow-up data hinders the knowledge about long-term treatment gains, clinical changes observed from baseline to post-intervention are encouraging. More research is needed in order to improve the quality of assistance provided to patients with AjD. Meanwhile, TAO represents an effective and accessible evidence-based treatment option for those who might need it.

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Chapter

5 Acceptability of TAO

This chapter has been submitted as:

Rachyla, I., Mor, S., Botella, C., & Quero, S. Acceptability of an internet-delivered intervention for adjustment disorders and its role as predictor of efficacy.

Acceptability of an Internet-delivered intervention for adjustment disorders and its role as predictor of efficacy

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ABSTRACT

Background: Research on internet-delivered CBT interventions (ICBT) revealed their efficacy and feasibility to reduce the current burden of mental disorders. Nevertheless, internet interventions are scarcely implemented in clinical practice. Evidence suggests that patients prefer face-to-face interventions and most of those who start an internet intervention drop-out before finishing it. Certain disorders, such as adjustment disorder (AjD), might be an especially suitable target for ICBT. The aim of the present work was to explore the acceptability of TAO, an ICBT for AjD with therapist support, and its impact on treatment outcomes.

Method: The acceptability was estimated from the acceptance to participate in the randomized controlled trial addressed to explore TAO effectiveness. Other indicators of acceptability were treatment adherence, expectations, satisfaction, and opinion reported by 34 patients who received TAO.

Results: Results revealed good acceptance to receive ICBT. Participants showed positive expectations towards TAO and 76.5% completed the whole intervention. Less positive expectations did not reduce treatment effectiveness but they might have led to

treatment abandonment. Generally, participants were satisfied with TAO. Greater satisfaction with overall intervention and treatment modules aimed at promoting identification with treatment goals, relapse prevention, and change in the meaning of the stressor predicted greater posttraumatic growth and improvement in positive affect and quality of life. Participants also reported positive opinion about TAO and the use of ICBT, but indicated that it required considerable motivation. Therapeutic support was perceived as an adherence facilitator; other ways of improving treatment engagement were also suggested.

Conclusion: TAO was well accepted among patients with AjD. However, further research is needed in order to discover factors that could promote acceptability and engagement with internet interventions. The implementation of ICBT requires the development of treatment programs which are both effective and also attractive for patients.

Keywords: internet-delivered CBT, adjustment disorder, acceptability, expectations, satisfaction, adherence.

INTRODUCTION

Since their appearance in the late 90s, Internet-delivered interventions have been widely investigated and accumulated a strong empirical support. Different meta-analyses pointed out that the efficacy of these interventions was comparable to the efficacy of face-to-face psychotherapy (Andrews et al., 2018; Carlbring, Andersson, Cuijpers, Riperd, & Hedman-Lagerlöfh, 2018). Albeit more research is needed to establish this equivalence, internet-delivered interventions might be a feasible solution to the current treatment gap, which refers to the difference between the prevalence of mental disorders and the proportion of people affected by mental disorders who receive treatment (Kohn, Saxena, Levav, & Sraceno, 2004).

According to World Health Organization, between 35% and 50% of people with mental health problems do not receive help in high-income countries (WHO, 2013). This rate is even higher in low- and middle-income countries. The quality of the received treatment is another important problem. An epidemiological survey conducted across 21 countries revealed that only 27.6% of people meeting criteria for an anxiety disorder have received some treatment, though only about 9.8% received a possibly adequate treatment (Alonso et al., 2018). New ways of disseminating evidence-based psychological interventions (EBPIs) are needed since individual, face-to-face treatments do not reach all people in need (Kazdin, 2017).

Internet-delivered interventions can help to overcome or sidestep some of the current barriers to psychotherapy. Among the main advantages of internet-delivered interventions are accessibility, flexibility, affordability, confidentiality, and their wide reach (Griffiths et al., 2006; Peter Musiat, Goldstone, & Tarrier, 2014). However, these advantages are not enough to consider internet-delivered interventions as a feasible alternative to face-to-face psychotherapy. Despite demonstrated effectiveness, the

implementation of a certain treatment represents a significant challenge if patients are not willing to use it. Thus, evidence suggests that there is a direct link between treatment acceptability, adherence, and clinical outcomes (Swift & Callahan, 2009). Notwithstanding this evidence, little attention has been paid to the assessment of the variables related to the acceptability of internet-delivered interventions.

The acceptability is usually estimated from take-up and drop-out rates, or from patients' satisfaction, collecting information about positive and negative aspects of the received treatment (Kaltenthaler et al., 2008). Treatment preferences, expectations, or ease of use have been also reported as indicators of acceptability (Botella et al., 2016; Mohr et al., 2010). Overall, the existing evidence indicates that internet-delivered interventions are a less preferred treatment option than the face-to-face therapy (Batterham & Calear, 2017; Gun, Titov, & Andrews, 2011; Kayrouz et al., 2015; Mohr et al., 2010; Wallin, Mattsson, & Olsson, 2016) and are usually associated with higher rates of attrition (Castro et al., 2018; Donker et al., 2013). Although contrary results were also found, indicating that adherence to internet-delivered interventions was comparable to other forms of psychotherapy, including face-to-face therapy (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Van Ballegooijen et al., 2014). In addition, despite a greater preference for face-to-face interventions, people also express interest in internet-delivered interventions (March et al., 2018), indicating that these interventions result attractive and, therefore, can be a feasible and effective treatment alternative. The high satisfaction among patients who complete the intervention (Andrews et al., 2018; Botella et al., 2016; Campos et al., 2018; Richards et al., 2016) also supports the clinical potential of internet-delivered interventions for treating mental disorders.

On the other hand, according to the clinical guidelines of National Institute for Health and Care Excellence (NICE), computerized cognitive behavioral therapy

programs delivered via internet, are more recommended for treating mild or severe symptoms, rather than for more severe conditions (NICE, 2006). Therefore, internet-delivered interventions might be specially suitable for certain disorders, such as Adjustment Disorder (AjD) (Maercker, Bachem, Lorenz, Moser, & Berger, 2015).

AjD is the diagnostic category for the distress triggered by an identifiable stressful event (APA, 2013). According to the literature, AjD is a highly prevalent condition (Evans et al., 2013; Yaseen, 2017), usually associated with a favorable prognosis (Carta et al., 2009; Yates, 2016). In fact, AjD is considered a transient condition (Zelviene & Kazlauskas, 2018), which may be resolved spontaneously. However, AjD involves significant distress, important reduction of quality of life, and severe interference in daily activities (Fernández et al., 2012; Gradus, 2017). Furthermore, sometimes AjD can become chronic, lead to more severe conditions and increase suicide risk (Casey et al., 2015; O'Donnell et al., 2016). Evidence also points out that there are different vulnerability factors for the development of AjD. More specifically, AjD was associated with greater neuroticism, less extraversion, and more maladaptive coping styles (Vallejo-Sánchez & Pérez-García, 2017). Thus, despite its sometimes transient nature, AjD symptom can reappear in response to new stressors if an appropriate treatment is not provided. Previous research revealed that AjD is one of the main causes of recurrent sickness absence (Koopmans et al., 2011; van der Klink, Blonk, Schene, & van Dijk, 2003). Therefore, a treatment should be considered in order to alleviate the distress and prevent the aggravation or recurrence of the disorder, among other reasons (Bachem & Casey, 2018).

Despite the absence of specific guidelines for the treatment of AjD, brief psychotherapies are considered to be the most appropriate (Casey & Bailey, 2011). Self-help interventions showed to be a promising treatment alternative in terms of efficacy

(Bachem & Maercker, 2016; Eimontas, Rimsaite, Gegieckaite, Zelviene, & Kazlauskas, 2017; Kazlauskas et al., 2017). Very few studies researching acceptability issues of these self-help interventions for AjD are available. Acceptability of bibliotherapy among burglary victims with clinical or subclinical AjD symptoms was reported in terms of satisfaction and treatment engagement (Bachem & Maercker, 2016b). The results showed that the majority of participants were satisfied with the followed intervention and 24.5% reported having read the whole manual. Another study examined engagement into a self-guided modular intervention for AjD (Eimontas et al., 2017). In this case, about half of participants did not engaged in the intervention and only 13.5% of participants completed the 30-day follow-up assessment.

The aim of the present work was to explore the acceptability of an Internet-delivered Cognitive Behavioral Therapy (ICBT) intervention for AjD and its impact on the clinical change. Acceptability was estimated from take-up and drop-out rates, treatment expectations, satisfaction, usefulness, and opinion.

METHOD

Research design

The acceptability was assessed among participants of a randomized controlled trial (RCT) aimed at developing and validating an ICBT for AjD (Rachyla et al., 2018). Participants were randomly allocated to either intervention or waiting list control group. In this work only data from the intervention group were used. The assessment was conducted online at five different moments: baseline, post-intervention, 3-, 6-, and 12-month follow-up. A brief post-module assessment was also included. Patients' expectations about the treatment were assessed after the first module, which included

detailed information about the intervention program. Due to the project time limits the follow-up assessments could not be completed and, therefore, are not reported.

The study protocol was approved by the Ethics Commitee of Universitat Jaume I and registered at https://www.clinicaltrials.gov as NCT02758418. The participation was voluntary. Patients' informed consent was obtained before their inclusion in the trial. The agreement to join the study was provided by clicking the "Accept" button and answering a brief socio-demographic survey.

Sample characteristics

In the present work, only participants from the intervention group were included. Therefore, the sample consisted of 34 participants between the ages of 18 and 58 (M=32.59, SD=10.40), the majority of whom were women (n=24, 70.6%). Twenty-seven (79.4%) of the participants were from Spain, two (5.9%) from Argentina, two (5.9%) from Colombia, one (2.9%) from Brazil, one (2.9%) from El Salvador, and one (2.9%) from Portugal. Twenty-four (70.6%) participants have completed university education or were university students. Regarding the clinical characteristics of the sample, twenty-five (73.5%) presented AjD with mixed anxiety and depressive symptoms, six (17.6%) presented AjD with anxiety, and three (8.8%) met criteria for AjD with depressed mood. Only six (17.6%) participants were taking medication. Drug name and dosage were registered at baseline and then monitored throughout the intervention. More detailed sample description can be seen in the Table 5.1.

Table 5.1 Base-line characteristics of participants

	Total sample (n = 34)
Gender *n (%)*	
Female	24 (70.6%)
Male	10 (29.4%)
Marital status *n (%)*	
Single	17 (50.0%)
Unmarried couple	8 (23.5%)
Married	6 (17.6%)
Divorced/Separated	3 (8.8%)
Level of education *n (%)*	
Lower secondary education (compulsory)	3 (8.8%)
Upper secondary education (post-16)	5 (14.7%)
Higher education	26 (76.5%)
Employment status *n (%)*	
Student	14 (41.2%)
Unemployed	6 (17.6%)
Employed/self-employed	12 (35.3%)
Work leave	2 (5.9%)
Computer proficiency *n (%)*	
Basic	4 (11.8%)
Medium	15 (44.1%)
Advanced	13 (38.2%)
Expert	2 (5.9%)
Number of stressors *mean (SD)*	1.62 (0.70)
Duration of symptoms related to the main stressor *n (%)*	
< 1 month	3 (8.8%)
1 - 3 months	8 (23.5%)
3 - 6 months	10 (29.4%)
> 6 months	13 (38.2%)
Distress/ interference severity *mean (SD)*[a]	4.88 (1.15)
Distress severity *mean (SD)*[b]	6.70 (1.31)
Interference severity *mean (SD)*[b]	6.06 (1.54)
Outcome measures *mean (SD)*	
BDI	26.68 (9.76)
BAI	20.76 (12.62)
ISL	35.88 (10.23)
PTGI	39.44 (21.73)
PANAS+	20.41 (8.12)
PANAS-	29.47 (7.43)
MQLI	4.83 (1.52)

ICBT, Internet-delivered Cognitive-Behavioral Therapy; ***WL***, Waiting List; ***SD***, Standard Deviation; ***BDI***, Beck Depression Inventory; ***BAI***, Beck Anxiety Inventory; ***ISL***, Inventory of Stress and Loss; ***PTGI***, Posttraumatic Growth Inventory; ***PANAS+***, Positive and Negative Affect Scale - positive affect subscale; ***PANAS-***, Positive and Negative Affect Scale - negative affect subscale; ***MQLI***, Multidimensional Quality of Life Questionnaire; [a] according to the clinician's judgment (range 0-8); [b] according to the patient's judgment (range 0-8)

Recruitment and procedure

The sample for the trial was recruited via printed advertisements and announcements on internet, radio and newspaper. Collaborating centers informed about the trial when detected possible cases of AjD. Those interested in participating contacted the research team by email or telephone. A telephone interview was arranged to provide more detailed information about the trial and conduct the *Diagnostic Interview for Adjustment Disorders* (Rachyla et al., in preparation). Participants who fulfilled the inclusion criteria and provided their informed consent were included in the study. The block randomization was conducted by an independent researcher, who was not involved in the RCT, and the assigned group was communicated by telephone. The baseline assessment was completed after the randomization. The intervention group had access to the ICBT 24 hours after completing the assessment. The treatment lasted from 7 to 10 weeks. During the intervention period patients received weekly support. The support consisted in a voice call (maximum 10 minutes) aimed at clarifying doubts, reminding the importance of moving forward, and congratulating for their effort. When the intervention was finished, participants completed the assessment online and the diagnostic and opinion interviews were conducted by telephone.

Inclusion and exclusion criteria

Apart from meeting DSM-5 (APA, 2013) criteria for AjD, participants had to be at least 18 years old, understand and be able to read Spanish, and have an email address, access to internet, and basic knowledge about how to use a computer. Participants were excluded if they were already receiving psychological assistance, met diagnostic criteria for another severe mental disorder (including personality disorder and substance abuse or dependence) or presented high risk of suicide or self-destructive behaviors. The

medication was monitored over the course of the trial. A change in the medication or an increase in the dosage was considered an exclusion criterion.

Measures

Diagnostic Interview

Diagnostic Interview for Adjustment Disorders (Rachyla et al., in preparation) was used to identify participants who were fulfilling eligibility criteria for the RCT. It is a semi-structured interview which lasts approximately 60 minutes and provides information about the main stressor, clinical symptoms developed as a consequence of this stressor and its impact on the person's normal life and functioning. ADIS clinician's severity rating scale (Di Nardo et al., 1994) was completed by the interviewers at the end of each interview in order to indicate the level of distress-interference in functioning (from 0/"Absent" to 8/"Very severely disturbing/disabling").

Patients' expectations about the treatment

A 6-item scale was adapted from the *Credibility/Expectancy questionnaire* (Borkovec & Nau, 1972): (1) "How logical does the treatment seem to you?"; (2) "How satisfied are you with the treatment you are going to receive?"; (3) "To what extent would you recommend this intervention to a friend of yours with the same problem?"; (4) "How useful do you feel this treatment would be in treating other psychological problems?"; (5) "To what extent do you feel this treatment is going to be useful for you?"; (6) "How aversive do you feel this treatment will be?". Each item was rated from 1 ("Not at all") to 10 ("Very much").

Patients' satisfaction with the treatment

Patients' satisfaction after completing the intervention was assessed using the same scale than for expectations, but the items were slightly modified: (1) "How logical did the treatment seem to you?"; (2) "How satisfied are you with the received treatment?"; (3) "To what extent would you recommend this intervention to a friend of yours with the same problem?"; (4) "How useful do you feel this treatment would be in treating other psychological problems?"; (5) " To what extent do you feel this treatment helped you?"; (6) "How aversive did you find this treatment?".

Patient's opinion about the treatment modules

Before starting a new module participants rated from 0 ("Not at all") to 10 ("Very much") the following statements referring to the previous module: (1) "To what extent did you like the module?", and (2) "To what extent did you find useful the module?".

Patient's opinion about the treatment and the received support

A short opinion questionnaire was developed specifically for the RCT. Participants were asked to rate from 0 ("Not at all") to 10 ("Very much") the following statements: (1) "To what extent did you find the internet intervention useful?"; (2) "To what extent do you feel that the internet intervention is an attractive way to receive psychological assistance?"; (3) "To what extent do you feel that the internet intervention is an comfortable way to receive psychological assistance?". Qualitative data were also collected asking participants about positive and negative features of the intervention. Two questions were developed to assess participants' opinion on weekly support: (1) "To what extent did you like to receive the weekly call from a therapist?"; (2) "To what extent did you find useful the weekly call from a therapist?". Participants were asked to

rate each of these statements from 0 ("Not at all") to 10 ("Very much") and justify their answer.

Treatment efficacy

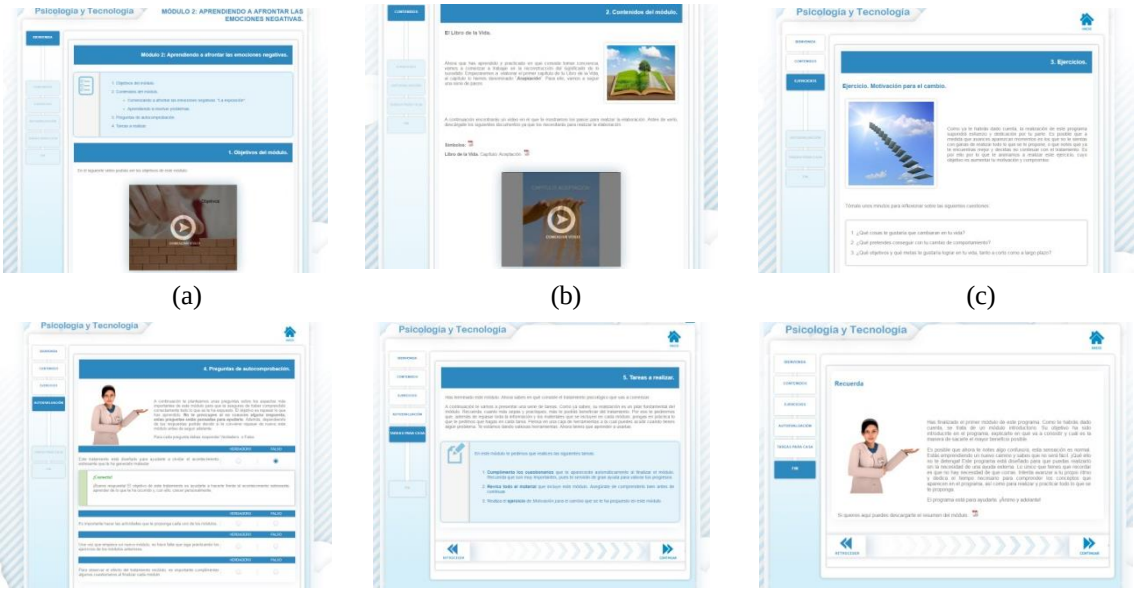
Treatment efficacy was estimated from a battery of self-report questionnaires which included: Beck Depression Inventory - Second Edition (BDI-II), Beck Anxiety Inventory (BAI), Inventory of Stress and Loss (ISL), Posttraumatic Growth Inventory (PTGI), Positive and Negative Affect Scales (PANAS), and Multidimensional Quality of Life Questionnaire (MQLI). For more detail see the study protocol (Rachyla et al., 2018).

Intervention

The received intervention was TAO, the Spanish acronym for Adjustment Disorders Online. It is a seven-module ICBT, accessible at https://www.psicologiaytecnologia.com/. Participants log in with a user name randomly generated during registration, thus protecting their privacy. The modules are activated sequentially (one after the other). Participants were advised to progress at their own pace but not more than one module per week, so it took them between 7 and 10 weeks to complete the intervention.

The program presents a linear navigation, so participants can only go forward or backward, following the usual structure of a CBT session (Figure 5.1): setting agenda; working on agenda (giving periodic summaries and proposing activities intended to put into practice the learned psychological techniques); assigning tasks to do before the next session; checking if patients have understood the contents which have been covered during the session; summarizing the session. Each module follows the same structure and combines texts, videos, pictures, vignettes, interactive exercises, and downloadable

pdf files. This format was used in order to, first, make the program more user-friendly and, second, to help participants realize that each module is tailored towards specific treatment goals.



(a) (b) (c)

(d) (e) (f)

Figure 5.1 TAO module structure: (a) agenda and therapeutic goals; (b) therapeutic contents; (c) proposal of activities; (d) self-assessment questions; (e) tasks assignment; (f) summary.

As for therapeutic contents, TAO includes the following components: (1) psychoeducation on AjD and common reactions to stressful events; (2) behavioral activation and slow breathing technique to manage negative emotions; (3) exposure to avoided situations which contribute to the maintenance of the problem; (4)problem-solving technique to improve the ability to deal with everyday challenges; (5) mindfulness to become aware of the personal experiences(feelings, thoughts, emotions); (6) elaboration and processing of the stressful event through the acceptance, confrontation, and development of a new meaning for the problematic situation; (7) positive psychology strategies to promote personal growth and a new attitude towards problems; and (8) relapse prevention. The first module is introductory and aims at providing information about how the intervention works and the contents of each

module, recommendations to get the maximum benefit from the program, and enhancing the motivation for change. Content of each module is shown in the Table 5.2.

Table 5.2 TAO content

Module	Contents	Activities
Module 0 Welcome module: starting this program	- Who TAO is aimed at - Treatment goals - TAO overview - Importance of assigned tasks	- Meditation on reasons to change - Goal setting
Module 1 Understanding emotional reactions	- The impact of stressful events - Common reactions to stressful events - Development and maintenance of adjustment disorders - Management of negative emotion through behavioral activation and slow breathing exercises	- My reaction to the stressful event - Development and maintenance of distress according to my own experience
Module 2 Learning to deal with negative emotions	- Confrontation of negative emotions and avoided situations - Learning how to handle effectively everyday challenges	- Exposure - Practicing problem solving
Module 3 Accepting problems	- Introduction to elaboration - Development of a metaphorical meaning for the stressful event - Mindfulness - Practicing elaboration: acceptance of the problematic situation - Role of problems	- Development of metaphorical meaning - Becoming aware of personal experiences related to the stressful event - Book of Life: Acceptance - Problems over the course of my life
Module 4 Learning from problems	- Learning from problems - Practicing elaboration: confrontation of the stressful situation - Concept of personal strengths	- Book of Life: Confrontation - Development of personal strengths
Module 5 Changing the meaning of problems	- Development of a new metaphorical meaning for the problematic situation - Practicing elaboration: development of a new meaning for the problematic situation - Development of a new attitude towards problems	- Development of a new metaphorical meaning - Book of Life: Change of meaning - Letter of projection towards the future - Choice of personal life motto
Module 6 Relapse prevention	- Review of achieved changes - Overview of acquired skills - Lapse versus relapse - Risk and signs of relapse - Practicing a relapse	- My achievements - Usefulness of practiced skills - Action plan to deal with future problems

Participants received a brief telephone call every week during the time that the intervention lasted. At the beginning of the intervention participants were assigned a therapist who was responsible for these weekly calls. Only two therapists participated in the study. Both had Master degree in Clinical Psychology and experience providing psychological assistance at the Emotional Disorder Clinic in Universitat Jaume I (Spain). Before the commencement of the RCT, therapists were trained in order to provide the same kind and level of support. More detailed description of TAO can be found in Rachyla et al. (2018).

Statistical analyses

Means and standard deviations were also computed for treatment expectations, satisfaction, and opinion, on one hand, and for satisfaction with and perceived usefulness of intervention modules and the received telephonic support, on the other. Treatment efficacy was estimated using reliable change indexes (Jacobson & Truax, 1991), which were calculated for BDI, BAI, ISL, PANAS positive affect subscale, PANAS negative affect subscale, and MQLI. Stepwise regression analyses were conducted to assess whether the clinical reliable change was predicted by patients' expectations, treatment satisfaction, or perceived intervention modules usefulness and satisfaction. Qualitative information was grouped according to common themes.

RESULTS

Acceptance of participation

As it is shown in the Figure 5.2, seventy-eight of the 144 assessed people fulfilled the inclusion criteria for the trial; forty-four contacted because they were interested in an online intervention and thirty-four were derived from the Emotional Disorders Clinic of Universitat Jaume I or by their family doctor, but were initially

interested in a face-to-face therapy. Sixty-eight participants signed the informed consent and were finally included in the RCT (34 were assigned to the intervention group and 34 to the control group). Four of the patients derived from the Emotional Disorders Clinic refused to participate in the study and preferred face-to-face treatment. Finally, six participants did not participate because they were unable to be contacted. Three of these participants were initially interested in an online intervention and three in a face-to-face therapy.

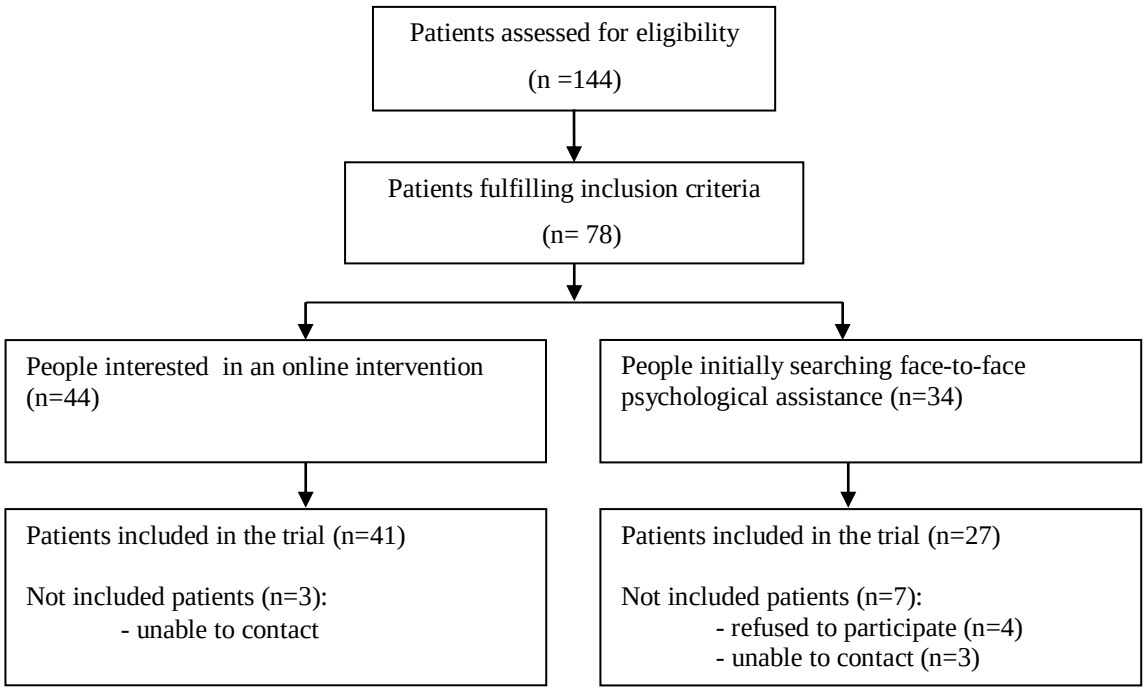


Figure 5.2 Flowchart of participants

Adherence

Out of 34 participants included in the TAO condition, eight participants dropped out from the intervention group before they completed the ICBT program. The reasons for dropping out were: time constraints (n=2), feeling that the intervention did not match their needs (n=2), worsening of clinical symptoms and feeling that a professional

help was needed to manage them (n=2). Two participants did not answer the phone or the email, so their reasons for dropping out are unknown.

Patients' expectations about the treatment

The results of the participants' expectations, differentiating between completers and dropouts, are presented in Table 5.3. Completers scored higher on the scale, as well as on each of the items, except for the item referring to aversiveness. Results of the regression analyses exploring the impact of the expectations on the clinically reliable change at post-intervention are shown in Table 5.4. As can be observed, item 6 of the Treatment expectation scale ("How aversive do you feel this treatment will be?") predicted 13.6% and 14.8% of change in depression and stress and loss symptoms respectively. Those who expected the treatment to be more aversive showed greater reduction on BDI and ISL scores. On the other hand, items 1 ("How logical does the treatment seem to you?") and 4 ("How useful do you feel this treatment would be in treating other psychological problems?") predicted 26.4% of variance on PANAS positive affect subscale from baseline to post-intervention.

Table 5.3 Means and standard deviations on *Treatment Expectation Scale* for dropouts and completers

	Completers (n=26) Mean (SD)	Dropouts (n=8) Mean (SD)
Logic	8.12 (1.93)	7.88 (2.64)
Satisfaction	8.00 (1.92)	6.88 (2.42)
Recommendation to others	8.27 (2.27)	8.13 (3.00)
Usefulness for other problems	7.42 (2.50)	6.75 (3.11)
Usefulness for their problem	7.50 (1.82)	6.38 (2.92)
Aversiveness	2.50 (2.35)	3.63 (1.92)
Overall expectations	47.81 (10.15)	43.38 (13.17)

Table 5.4 Results of stepwise regression analyses predicting the variance of clinically reliable change attributable to patients' expectations about the treatment

		R^2	β	t	ρ
BDI	Item 6: aversiveness	.136	-0.41	-2.22	.036
BAI	-	-	-	-	-
ISL	Item 6: aversiveness	.148	-0.43	-2.31	.030
PTGI	-	-	-	-	-
PANAS+	Item 4: usefullness for other problems	.264	0.88	3.26	.003
	Item 1: logic		-0.57	-2.13	.044
PANAS-	-	-	-	-	-
MQLI	-	-	-	-	-

BDI Beck Depressed Inventory, *BAI* Beck Anxiety Inventory, *ISL* Inventory of Stress and Loss, *PTGI* Posttraumatic Growth Inventory, *PANAS+* Positive and Negative Affect Scale - positive affect subscale, *PANAS-* Positive and Negative Affect Scale - negative affect subscale, *MQLI* Multidimensional Quality of Life Questionnaire

Patients' satisfaction with the treatment

Participants' scores on *Treatment Satisfaction Scale* are presented in Table 5.5. Results of the regression analyses exploring the impact of the satisfaction on the clinically reliable change at post-intervention are shown in Table 5.6. Patients' perceived benefit from the treatment was a significant predictor of posttraumatic growth, explaining 17.7% of the variance. The overall satisfaction with the received treatment contributed to the clinically significant change on positive affect (35.7%). Item 3 ("To what extent would you recommend this intervention to a friend of yours with the same problem?") predicted 20.0% of variance on MQLI.

Table 5.5 Means and standard deviations on *Treatment Satisfaction Scale*

	Mean (SD)
Logic	7.60 (2.10)
Satisfaction	7.56 (2.16)
Recommendation to others	8.12 (2.32)
Usefulness for other problems	7.76 (2.74)
Usefulness for their problem	7.76 (2.30)
Aversiveness	2.42 (2.12)
Overall satisfaction	47.04 (11.52)

Table 5.6 Results of stepwise regression analyses predicting the variance of clinically reliable change attributable to patients' satisfaction with the received treatment

		R^2	β	t	ρ
BDI	-	-	-	-	-
BAI	-	-	-	-	-
ISL	-	-	-	-	-
PTGI	Item 5: usefulness for their problem	.177	0.46	2.48	.021
PANAS+	Satisfaction with the treatment (total score)	.357	0.62	3.79	.001
PANAS-	-	-	-	-	-
MQLI	Item 3: recommendation to others	.200	0.48	2.64	.014

BDI Beck Depression Inventory, *BAI* Beck Anxiety Inventory, *ISL* Inventory of Stress and Loss, *PTGI* Posttraumatic Growth Inventory, *PANAS+* Positive and Negative Affect Scale - positive affect subscale, *PANAS-* Positive and Negative Affect Scale - negative affect subscale, *MQLI* Multidimensional Quality of Life Questionnaire

Program modules: perceived satisfaction and usefulness

Satisfaction with and perceived usefulness of intervention modules are reported in Table 5.7. Module 6 was the module with higher satisfaction (M=7.76, SD=1.92) and usefulness (M=7.76, SD=1.92) score. Regression analyses showed that satisfaction with module 0 was a significant predictor of posttraumatic growth from baseline to post-intervention (R^2=.171, β=.45, t=2.44, ρ=.023), while satisfaction with module 6 predicted change in positive affect (R^2=.300, β=.57, t=3.36, ρ=.003) and satisfaction with module 5 predicted change in perceived quality of life (R^2=.166, β=.45, t=2.40, ρ=.022). Finally, perceived usefulness of module 6 was predictor of change in positive affect (R^2=.286, β=.56, t=3.26, ρ=.003) and quality of life (R^2=.126, β=.40, t=2.12, ρ=.045).

Table 5.7 Satisfaction with the intervention modules and their perceived usefulness

	Satisfaction Mean (SD)	**Usefulness** Mean (SD)
Module 0	6.44 (2.51)	5.85 (2.71)
Module 1	7.52 (2.59)	6.97 (2.65)
Module 2	7.10 (2.12)	7.10 (2.34)
Module 3	7.63 (1.57)	7.44 (1.83)
Module 4	7.12 (2.49)	7.15 (2.43)
Module 5	7.40 (2.48)	7.24 (2.47)
Module 6	7.76 (1.92)	7.76 (1.92)

Patients' opinion about the treatment

The program was perceived as useful (M=8.00, SD=1.48), comfortable (M=8.91, SD=1.44), and an attractive (M=7.77, SD=1.77) way of receiving psychological assistance. Results concerning qualitative opinion about the received treatment are presented in Table 5.8.

Telephone support

Participants reported that they did not just liked the weekly calls (M=9.41, SD=1.10), but also found them useful (M=8.82, SD=1.37). Reasons for the positive evaluation of the telephone support were: promotes the adherence (motivates to move forward), opportunity to solve doubts (even if you do not have any), knowing that you are not alone (a specialist behind the machine who is monitoring your progress).

Table 5.8 Qualitative opinion about the internet-delivered intervention for adjustment disorders

	Strengths	Aspects to improve
Content characteristics	- techniques that work and can be generalized to other problems/situations - useful, practical, and attractive exercises - examples of how to put into practice what you are learning - case reports of people with adjustment disorder: useful for realizing that you are not alone0	- chance of accessing additional modules (e.g., assertiveness, self-esteem, sleep disturbance) - more examples
Formal characteristics	- intuitive and easy to use - clear and simple language - well-structured and organized contents - brief modules	- option to continue where you left it - more customizable (e.g., adding alarms, to-do list) - more notifications and reminders (e.g., the importance of using the program, techniques learned in previous modules) - greater interactivity: different actions depending on user's response - "Help" button - less sequential format: opportunity to chose the content to view/work
Format characteristics	- combines different multimedia resources (less monotonous than only reading) - videos: useful when you are tired or unmotivated, require less effort - downloadable PDF files: accessible when you need them, do not require internet connection	- downloadable video narratives
Other characteristics	- privacy: specially attractive for people who do not feel comfortable sharing personal experiences - accessibility: whenever and wherever you need it - convenience: without leaving home, suits your schedule/needs, allows to progress at your own pace - chance to repeat wished/needed parts - autonomy: you achieve your goals on your own	- requires considerable motivation, commitment, and determination (difficult when you are tired or busy)

DISCUSSION

The aim of the present work was to assess the acceptability of an ICBT intervention for AjD in terms of take-up rates, adherence, as well as treatment expectations, satisfaction, and usefulness. Impact of acceptability on treatment efficacy was also investigated. Another objective was to explore if the ICBT was considered as an attractive and comfortable way of receiving psychological assistance among patients with AjD. Finally, positive and negative program features were analyzed.

Results for *take-up rates* showed that only four out of seventy-eight participants fulfilling eligibility criteria for the RCT rejected to participate, being all of them initially interested in face-to-face therapy. This result supports the findings reported by Mohr et al. (2010) who pointed out that those patients who were more interested in receiving psychological intervention showed greater preference for face-to-face interventions. However, the other thirty referred patients who were seeking psychological assistance accepted to participate and forty-four people contacted because they were interested in an online intervention. These findings suggest that patients with AjD perceived an internet-delivered intervention as a feasible alternative to face-to-face therapy.

With regard to *adherence*, out of thirty-four participants, 76.5% completed the ICBT. The dropout rate in the intervention group was 23.5%, slightly below 30% reported in literature on adherence to ICBT with included support (Andrews et al., 2018; Van Ballegooijen et al., 2014). To the best of our knowledge, TAO is the only therapist-supported ICBT for AjD, the other two self-help interventions do not provide any therapist guidance (Bachem & Maercker, 2016b; Eimontas et al., 2017). In the RCT assessing efficacy of bibliotherapy for the treatment of AjD the percentage of people who completed the whole bibliotherapy manual was 24.5% (Bachem & Maercker,

2016b), suggesting that the providence of guidance might elevate patients' motivation and consequent treatment engagement. No comparison can be made with the only internet-delivered intervention available for AjD, since authors estimated adherence in terms of number of completed exercises (Eimontas et al., 2017).

On the other hand, time constriction was one of the reasons behind treatment dropout. The worsening of symptoms was another reason which might be in line with previous research (Johansson, Michel, Andersson, & Paxling, 2015) where patients who dropped out from ICBT reported that treatment demands exceeded their capabilities. In our study, the feeling of being completely overwhelmed by the situation prompted two participants to seek greater therapeutic support. In fact, both participants initiated face-to-face intervention after leaving the project. The third reason for dropping out was the feeling that the intervention did not match their needs.

As for *expectations* with regard to ICBT for AjD, results were similar to those found in the literature for other disorders, such as depression (Botella et al., 2016) or specific phobia (Campos et al., 2018). Treatment expectations were lower among dropouts than among completers, supporting somehow the assumption that treatment expectations are associated with treatment adherence (Swift & Callahan, 2009). However, due to the small sample size of dropouts in the present study it could not be explored whether the observed between group differences were statistically significant, therefore further study is needed in order to draw firmer conclusions in this regard. Regression analyses revealed that expectations predicted treatment efficacy. More specifically, patients who anticipated that the treatment would be more aversive showed greater reduction in the severity of depressive and stress and loss symptoms related to the stressful event. On this matter, the expected aversiveness might be related to the anticipated confrontation of the stressor. Thus, people who found it particularly difficult

to face the stressor perceived greater benefit in terms of distress reduction. However, it does not mean that other patients did not improve, only that they showed a minor change.

Perceiving TAO as a useful intervention program not only for AjD but also for treating other psychological problems showed greater increase in positive affect. This finding suggests that interventions for AjD should not focus uniquely on symptoms directly related to the stressor, but also address other domains. This approach was already adapted for treating women recently exposed to conflict (Khan et al., 2017). Khan et al. (2017) used a transdiagnostic intervention PM+ developed by WHO for treatment of common mental health problems (Dawson et al., 2015). The aim of PM+ was to reduce symptoms related to depression, anxiety, and stress, but also to promote physical and psychosocial functioning. PM+ was highly accepted, though data on its efficacy have not been reported yet. Different studies conducted to compare transdiagnostic and disorder-specific ICBTs, found no differences in terms of efficacy (Dear et al., 2015, 2016; Titov et al., 2015) or acceptability (Fogliati et al., 2016). However, transdiagnostic approach could promote changes in other domains, such as positive affect. Feeling that the intervention could be used for other purposes, beyond the distress caused by the stressor, might lead patients to implement the learned techniques in other areas of their lives, thus improving their wellbeing and experience of positive emotions.

On the other hand, patients who perceived TAO as less logic for treating their problem experienced greater increase in positive emotions. This finding is encouraging since it suggests that even patients with less positive initial expectations benefited from the intervention. However, poor expectation might result in treatment abandonment. As it was mentioned above, patients who dropped out showed lower scores on *Treatment*

expectations scale and at least two patients dropped out because they felt that TAO did not suit their needs. Since a previous study reported that the providence of information about an internet-delivered intervention influenced positively treatment acceptance among depressed patients (Ebert et al., 2015), this strategy could also be used to encourage patients to continue to use the ICBT intervention, even if it does not seem to meet their demands. It also should be reminded that treatment results are not immediate, in order to prevent patients from getting discouraged and dropping out.

Participants expressed moderate *satisfaction* with their treatment. Regression analyses showed that treatment satisfaction did not predict distress reduction. Patients who were less satisfied with TAO reported clinical change on BDI, BAI, ISL, and PANAS negative affect subscale similar to that reported by more satisfied participants. Therefore, it seems that the ICBT was equally effective in all patients. However, the satisfaction predicted posttraumatic growth and increase in positive affect and quality of life. The analyses of the impact of each treatment module revealed, on one hand, that satisfaction with modules 0, 5, and 6 predicted clinically significant change in posttraumatic growth, quality of life, and positive affect respectively. On the other, perceived usefulness of module 6 predicted clinically significant change in positive affect and quality of life. Module 0 was aimed at helping patients to give name to their problem and propose a way to manage it. Feeling more identified with TAO target population and agreeing with the proposed way to approach the problem might lead to higher satisfaction, greater treatment engagement, and consequent posttraumatic growth. On the other hand, the module 6 was aimed at raising awareness about the progress made since the beginning of the intervention, summarizing learned skills, preparing patients for recurrence of some symptoms and identifying warning signs of relapse. Seeing the program as an integrated whole, where every module was focused

on treating different parts of the same problem, might help patients to feel more empowered to handle the problem situation. In addition, the relapse prevention component was aimed at promoting the sense of achievement, which also might explain greater improvement in positive affect and quality of life. Finally, the impact of module 5 on the quality of life was an encouraging finding since that module had as objective to change the way of approaching the stressful situation.

Finally, the general *opinion* of participants was that TAO represented a useful, comfortable and attractive way of receiving psychological assistance. As positive aspects of TAO participants highlighted its contents (inclusion of effective techniques, examples, practical and attractive exercises), form (structure, intuitive interface, easy understandable language, and brief modules) and format (combination of different multimedia resources, inclusion of videos and downloadable PDF files). Regarding the advantages of ICBT interventions, participants highlighted confidentiality, accessibility from any place and at any time, comfort of working on your wellbeing from home, without need for transportation or changing your schedule, chance to progress at your own way, reviewing or dedicating more time to certain parts of the intervention, and perceived self-efficacy. However, participants indicated that ICBT required considerable motivation, commitment, and determination. Therapist support was seen as an important resource to overcome this barrier. Despite telephone calls did not include additional clinical content, participants felt that they had someone to help them. This finding is consistent with previous research which found out that support provided in ICBT was effective even when it was provided by a person without clinical experience (Baumeister, Reichler, Munzinger, & Lin, 2014). Thus, if the main function of therapist call is to increase motivation (Schröder, Berger, Westermann, Klein, & Moritz, 2016), it might be replaced by other type of automated support. For example, Titov et al. (2013)

found that automated emails promoted both adherence and clinical improvement. Participants from TAO indicated that a more customizable and interactive interface would also enhance ICBT use.

Limitations

The generalization of present findings could be compromised by several study limitations which should be addressed in future research. First, the sample size was too small to allow definitive conclusions on acceptability of ICBT interventions for treatment of AjD. Second, 73.5% of the sample was people who contacted because they were interested in ICBT intervention. This initial interest could have affected the results. Third, the majority of the sample were women and most had relatively high education level, factors which were found to be associated with greater willingness to use internet-delivered interventions (Batterham & Calear, 2017).

Conclusions

In sum, the present work showed that ICBT with clinical support was well accepted among patients with AjD. Expectations towards the treatment were positive. The results suggest that treatment expectations were related to adherence. However, treatment outcomes were not significantly affected, indicating that those with more negative expectation also improved with treatment. The drop-out rates were lower than it was expected. Satisfaction with the treatment was good and it was predictor of posttraumatic growth and increase in positive affect and quality of life. Three intervention modules were related to satisfaction: introductory module which provided information about the ICBT, relapse prevention module, and also the module aimed at changing the way of perceiving the stressful event. This suggests the advisability of incorporating these components into treatment protocols for AjD. Therapist support

promoted treatment adherence. However, adherence might be also achieved through certain system functions as well as including contents aimed at facilitating engagement, and not only clinical change.

To the best of our knowledge, this is the first study exploring the acceptability of an ICBT intervention for AjD, so it represents a significant step forward in this field. Further research is required since it will allow revealing more about both acceptability and engagement related factors. Development of treatment programs which are effective and also attractive for patients will lead to increased exploitation of all potential offered by internet-delivered interventions.

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General discussion

The board aim of the present thesis was to contribute to the advance in the assessment and treatment of AjD. More specifically, the main objectives of the work were, firstly, to provide preliminary data regarding the validity and reliability of a semi-structured diagnostic interview for AjD (*Chapter 1*). To the best of our knowledge, this is the first interview of these characteristics available for the assessment of this disorder. In fact, the lack of well validated diagnostic and assessment instruments is one of the main challenges in the research on AjD. Structured diagnostic interviews such as SCID or MINI, albeit being widely used for screening of other mental disorders, were found to underestimate the prevalence of AjD (Shear et al., 2000; Taggart et al., 2006). As for specific instruments for AjD, only two were reported in the literature so far (DIAD and ADNM) but both of them still require further empirical evidence (Bachem & Casey, 2018). Besides, none of these instruments have been neither translated into Spanish nor validated in Spanish population. In view of that situation, our group developed the diagnostic interview which is one of the focus points of the present thesis. Although the interview was successfully used in different RCTs on AjD, its reliability and validity had not been evaluated yet. Therefore, the *validation study* was conducted exploring

content and construct validity, on one hand, and interrater and test-retest reliability, on the other. Overall, the findings were positive and provided support to the potential of the interview as a diagnostic tool.

The second main objective of the thesis was to investigate the efficacy and acceptability of an ICBT for AjD (TAO) combined with brief weekly telephone support. Nevertheless, given the scarcity of research on the use of ICBT for the treatment of AjD, a *feasibility study* aimed at assessing the acceptability and usability of the intervention was conducted prior to the initiation of the RCT (*Chapter 2*). The results showed that TAO was well accepted and described as user-friendly by both, patients and clinicians. In addition, a qualitative exploration revealed that the inclusion of videos, clear and well-structured contents, simple terminology, and availability of examples were perceived as adherence enhancers. On the other hand, the interactivity and the amount of written information were considered as aspects that could be improved. These findings were consistent with the acceptability results from the RCT carried out later, indicating that the features of the internet-delivered intervention may have an impact on users' satisfaction and consequent adherence. This could explain, at least partly, the dropout rates observed among people using ICBT interventions, even when they are administered with therapist support.

Once preliminary feasibility was tested, we proceeded with the *RCT* (*Chapter 3*). The results from the *efficacy study* (*Chapter 4*) showed that participants from the intervention group presented significant clinical improvement in all outcome measures, with moderate to large effect sizes, supporting our initial hypothesis. As it was expected, control group also improved over seven weeks of waiting list. However, also in line with our initial hypotheses, participants from the intervention group presented significantly larger improvement and higher rates of reliable change. In addition, control

group only showed decrease in distress symptoms, whereas TAO also promoted posttraumatic growth, positive affect, and quality of life. Thus, the results of this thesis support the potential effectiveness of ICBT interventions for the treatment of AjD and it is therefore in line with the little evidence on this topic published to date (Bachem & Maercker, 2016a; Eimontas et al., 2017). Furthermore, the results also highlighted additional benefits of providing an intervention like TAO. The use of a treatment program led to a better adjustment to the stressful situation and promoted positive changes, which did not take place when the intervention was not provided.

Finally, the *acceptability study* was conducted (*Chapter 5*). The acceptability was estimated in terms of acceptance to participate and treatment adherence, expectations, satisfaction, and opinion. The results showed that the ICBT was well accepted among patients with AjD.

First, the *take-up* of TAO was high. Sixty-eight participants, out of seventy-eight, accepted to participate in the trial. Only four patients explicitly refused to receive an internet-delivered intervention, expressing preference for face-to-face assistance. Although most of the participants (60.29%) were people who contacted because they were interested in the trial, 39.71% of participants were patients who were actively searching for face-to-face assistance but accepted to participate when they were offered TAO.

Second, the *adherence* to the intervention was good, 76.47% of participants completed the whole program. The randomness of the abandonments found in our trial supports the assumption that the treatment dropout might be due to reasons other than the lack of acceptability, such as the feeling that the intervention is no longer needed (Van Ballegooijen et al., 2014). In this sense, AjD is considered to be a transient

condition and spontaneous recovery was expected (Patra & Sarkar, 2013). However, participants from our RCT also indicated other factors that can lead to dropout. The use of an internet-delivered intervention requires considerable motivation, commitment, and determination, which are difficult when you feel tired or have plenty of things to do. This finding is consistent with previous research. Thus, Johansson, Michel, Andersson, & Paxling (2015) found out that if the treatment represents a significant workload, it can lead to the non-adherence. TAO users expressed that the weekly telephone calls from the therapist motivated them to keep using the intervention. Indeed, greater use of the program was registered in the days before weekly calls. This explains why completely unguided interventions are associated with higher dropout rates (Castro et al., 2018). However, it should be noted that no clinical content was provided during the phone calls. So, as Baumeister, Reichler, Munzinger, & Lin (2014) pointed out previously, it suggests that this support can also be provided by people who are not mental health professionals or can even be replaced by other type of automated support. Thus, participants indicated that a more customizable and interactive interface would also enhance ICBT use.

Third, *expectations* with regard to TAO were positive. In line with previous research (Swift & Callahan, 2009), treatment expectations were lower among dropouts than among completers, suggesting positive relationship with treatment adherence. However, it was also found that participants with less positive initial expectations also benefited from the intervention. Thus, patients who anticipated that the treatment would be more aversive showed greater reduction in the severity of depressive and stress and loss symptoms related to the stressful event, and patients who perceived TAO as less logic for treating their problem experienced greater increase in positive emotions.

Fourthly, *satisfaction* with the treatment was moderate. Encouragingly, it was found that lower satisfaction did not impact the reduction of distress symptoms. Nevertheless, it did predicted posttraumatic growth and increase of positive affect and quality of life. Three intervention modules were related to satisfaction: introductory module which provided information about the ICBT, relapse prevention module, and also the module aimed at changing the way of perceiving the stressful event. This suggests the importance and advisability of these components as part of treatment protocols for AjD.

Lastly, exploration of *opinion* about TAO showed that patients perceived the ICBT as a useful and attractive way of receiving psychological assistance. As advantages of using an intervention like this, participants highlighted the privacy, accessibility, convenience, autonomy, and chance to repeat the wished or needed parts. Certain aspects of the program were seen as its strengths, such as attractive exercises, combination of different multimedia resources, intuitive and easy to use interface, etc. (for further details, see *Chapter 5*). However, participants also suggested some improvements which, in their opinion, might enhance the experience of using TAO, such as inclusion of transdiagnostic modules, possibility of adding notifications and reminders, greater interactivity, etc. These findings suggest that the inclusion of relevant therapeutic contents is not enough to achieve the desired clinical changes or treatment adherence. It is not surprising since it also applies to face-to-face psychotherapy. Thus, therapeutic alliance was found to be an important factor influencing the outcome of the psychotherapeutic process (Ardito & Rabellino, 2011). In the case of ICBTs, the presence of a therapist is lower, or even inexistent, and consequently other aspects of the intervention may become more relevant. Therefore, during the development of internet delivered-interventions target population should be taken into consideration in

order to create programs which are effective but also attractive for them. Users have to feel that the intervention meets their needs and does not represent an additional burden of work.

Strengths

The present thesis has several strengths:

- All the reported results were drawn from a RCT which included a control group. The protocol for the trial was approved by the Ethics Committee of Universitat Jaume I and registered on ClinicalTrial.gov database as NCT02758418. The study protocol was also reviewed by Ministry of Economy and Competitiveness (Spain), who positively assessed the quality, relevance, and feasibility of the project.

- The trial was conducted following the Consolidated Standards of Reporting Trials (CONSORT), the CONSORT extension for Electronic and mobile Health Applications and onLine TeleHealth interventions (CONSORT-E-HEALTH), the SPIRIT guidelines (Standard Protocol Items: Recommendations for Intervention Trials), and in compliance with the Declaration of Helsinki and good clinical practice.

- The study protocol was published in *BMC Psychiatry* to prove the transparency of the research process.

- The sample size was calculated prior to the beginning of the RCT to assure an adequate power to detect statistical significance. In order to compensate the anticipated sample loss, the current dropout rates from ICBTs (Andrews et al., 2018; van Ballegooijen et al., 2014) were taken into account.

- Both intention-to-treat and per-protocol analyses were conducted, thus providing a more unbiased estimation of treatment effect. Expectation Maximization algorithm was chosen as the method to impute missing values, since it is based on strong statistical traditions (Graham, 2009).

- Following the literature (Sullivan & Feinn, 2012), the study results were reported in terms of statistical significance but also in terms of effect size (Cohen's d), thus providing an estimation of the magnitude of the treatment effect.

- Clinical meaningfulness of treatment outcomes was inferred using the widely accepted reliable change index, proposed by Jacobson & Truax (1991).

- The efficacy of the ICBT was explored at the same time as its acceptability, providing important information on how to improve the implementation of these interventions in actual clinical practice.

- TAO, the ICBT intervention for AjD which is the main point of the present thesis, is based on a manualized protocol that has already shown its efficacy in the traditional, face-to-face format. The previous experience with the protocol provided the opportunity to optimize its effectiveness, focusing on active treatment components and adding techniques that clinicians and patients considered important. In addition, according to literature the use of manual-based interventions ensures the use of empirically supported treatments, a fact which increases patients' chance of responding positively to psychotherapy (Mansfield & Addis, 2001).

- TAO's linear approach might have had an impact on treatment engagement. The linear structure can be especially suitable for patients suffering from mild to severe

symptoms, since it allows the progressive acquisition of different skills needed to cope with distress in a gradual but effective way.

- Particular attention was paid to the positive growth following the stressful life event. Thus, the efficacy of the intervention was considered in terms of its potential to promote the complete health status, and not only the reduction in clinical symptomatology (WHO, 2001).

Limitations

Two main limitations of the work are due to the research topic itself. Thus, as the first limitation it should be highlighted the lack of diagnostic and assessment instruments for AjD. The *Diagnostic Interview for Adjustment Disorders* and *Inventory of Stress and Loss* used in the RCT have shown good psychometric properties, although further research is still needed to confirm their validity and reliability. The use of other diagnostic tools, such as ADNM, could have provided more conclusive results. Unfortunately, no specific instrument for AjD adapted and validated in Spanish was available at the moment the present study was initiated. Perhaps the recently published ICD-11 will promote greater interest in AjD and consequent development of empirically supported assessment instruments for this disorder.

The second limitation, which is common to all ICBT interventions, concerns the dropout rates. The dropout rate in the present RCT was 23.5%, slightly below 30% reported in the literature on adherence to ICBT with included therapist support (Andrews et al., 2018; Van Ballegooijen et al., 2014). The acceptability study, reported in the Chapter 5 of the present thesis, provided important information about factors that can lead to adherence or non-adherence to an ICBT intervention. More research is needed on the acceptability of ICBT interventions and not only on their efficacy. Only

by developing treatment programs which are attractive for patients, it will be possible to reduce the current dropout rates.

Nevertheless, certain limitations are also due to the trial methodology. First, the characteristics of the sample could have affected the results of the trial. Thus, 60.29% of the sample was people who contacted because they were interested in an ICBT intervention. Moreover, the majority of the sample were women and most had relatively high education level, factors which were found to be associated with greater willingness to use internet-delivered interventions (Batterham & Calear, 2017). The found interest in ICBT is encouraging. However, the main relevance of internet-delivered interventions lies on their possibility to reach a larger number of people in need of psychological assistance, thus reducing the burden of mental disorders. Therefore, the next step might be to offer TAO to patients in clinical settings who are currently on a waiting list to be attended by a specialist.

Second, all assessment was conducted online. Literature on this subject suggests equivalence between online questionnaires and their respective paper-and-pencil versions (Rutherford et al., 2016; Wouter van Ballegooijen, Riper, Cuijpers, van Oppen, & Smit, 2016), some works however indicate that these conclusions cannot be generalized to all questionnaires (Alfonsson, Maathz, & Hursti, 2014; Noyes & Garland, 2008). No works were found investigating the reliability of assessment of AjD conducted online, so it is unknown whether the mode of administration of self-report questionnaires somehow affected the patient-reported outcomes.

Third, participants completed questionnaires after they were informed about the results of the randomization assignment. The knowledge of the randomization

assignment may have an impact on patients' willingness to complete the baseline assessment and also on their scores on the questionnaires (Brooks et al., 1998).

Another limitation is that it was not explored whether sociodemographic, clinical, or personality characteristics of the sample influenced the response or adherence to the treatment. Likewise, the lack of an active treatment control group might represent another study limitation. However, given the scarcity of evidence-based interventions for AjD, the comparison with a waiting list control group could be the first step in the validation of psychological treatments for this disorder. In addition, since AjD is considered a transient condition, it is especially useful to explore whether brief interventions like TAO can prevent the chronification of this disorder and the development of more severe symptomatology.

Finally, without any doubt, the non-availability of follow-ups is the main limitation of the thesis. Follow-ups provide important information about the magnitude of the intervention effect (Llewellyn-Bennett, Bowman, & Bulbulia, 2016), therefore this information will be published as soon as it is available.

Future lines of research

As it was mentioned before, AjD is a highly underresearched disorder - particularly when compared with other disorders, such as depression. Further research is required to improve the understanding of AjD, as well as its assessment and treatment.

The results of the present thesis indicate that brief interventions can promote important positive changes in terms of posttraumatic growth and increase in positive affect and perceived quality of life. In the future, it would be highly interesting to explore, first, the long-term maintenance of these changes and, second, their impact on coping with future adversities. In this line, previous works found out negative

relationships between variables such as subjective happiness, satisfaction with life, and coping strategies and the severity of clinical symptoms in patients with AjD (Reyes-Torres, Rachyla, Fuentes-Cerda, Molés, & Quero, 2018; Tur, Rachyla, López-Montoyo, & Quero, 2018). Literature also highlights the buffering effect of positive affect on the emotional response to a stressful event (Fredrickson, 2009; Vazquez, Hervas, Rahona, & Gomez, 2009). Given the apparent importance of these variables, major research on protective factors against AjD would allow to reduce the burden of this prevalent disorder. First, it could help to develop prevention programs to reduce the incidence of AjD. Second, it could help to improve the current intervention protocols in order to avoid future relapses.

The development of ICBTs is another important field to explore. As for internet delivered intervention in general, an important effort should be done to promote their use and acceptability among patients with mental disorders, reducing the current dropout rates. The results of the thesis suggest that greater attention should be paid to the form and format of ICBTs. In addition, it should be considered the study of sociodemographic and/or clinical differences between those who agree to use ICBT interventions and those who do not. Thus, further research in this field will allow developing interventions which are both effective and attractive.

As for TAO, it was found to be an effective and feasible treatment alternative for AjD. Nevertheless, the results might be influenced by the fact that weekly telephone support was provided during the intervention. In the future, it should be explored whether the intervention is equally effective without any therapist support. Moreover, given the scarce but promising evidence for the use of ICBTs for the treatment of AjD, the comparison with an active treatment group should be considered. For example, since AjD is most commonly seen in primary care setting (Carta et al., 2009), the comparison

of effects achieved with ICBT and those achieved with the treatment as usual would greatly contribute to improve the current assistance provided to patients with this pathology and bridging the gap between research and clinical practice

Finally, one of the study limitations mentioned previously indicated that the sample characteristics might have influenced the reported results. As it was mentioned, it would be interesting to investigate the efficacy of the intervention in people who do not show particular interest in ICBTs. However, in order to avoid the possible influence of a greater preference for a face-to-face intervention, TAO could be offered to patients who do not receive any intervention due to the existence of a waiting list. Thus, TAO would not be an alternative to the treatment as usual, but an alternative to the waiting list.

Conclusions

The conclusions of the thesis are as follows:

- The semi-structured *Diagnostic Interview for Adjustment Disorders* used in the present thesis showed good preliminary psychometric properties in terms of content and construct validity, on the one hand, and interrater and test-retest reliability, on the other.

- The RCT conducted to investigate the effectiveness of TAO, an ICBT for AjD, showed that participant who received the intervention presented significant reduction in the symptoms of depression and anxiety, as well as in the symptoms of stress and loss that were triggered by the stressful event.

- Participants who used TAO also reported significant increase in posttraumatic growth, positive affect, and perceived quality of life.

- Waiting list control group was used as the comparator in the conducted effectiveness study. Participants from this group also presented significant improvement in the symptoms of depression, anxiety, and stress and loss, although to a lesser extent than participants from the intervention group. Besides, no significant change was observed in posttraumatic growth, positive affect, or quality of life.

- The between-group comparison revealed that TAO was more effective than a waiting list of seven weeks. The proportion of participants showing reliable change was significantly higher in the intervention group. Thus, the results suggest that TAO not only facilitated a better adaptation to the stressful situation, reducing clinical symptoms triggered by the stressor, but also conferred additional benefits in terms of posttraumatic growth, positive affect, and quality of life.

- TAO was well accepted among patients with AjD. The take-up rate was high, 87.2% of patients accepted to receive the internet-delivered intervention and only 5.1% preferred a face-to-face assistance.

- The dropout rate was 23.5%, slightly below 30% reported in the literature on adherence to ICBT with included therapist support.

- Overall expectations towards the treatment were positive. Less positive expectations did not interfere with treatment outcomes but may have influenced treatment adherence.

- Satisfaction with the treatment was good and it was predictor of posttraumatic growth and increase in positive affect and quality of life.

- TAO was seen as a useful, comfortable and attractive way of receiving psychological assistance. However, the features of the internet-delivered intervention may have an impact on users' satisfaction and adherence.

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Annexes:

Ethical approval

UNIVERSITAT JAUME·I

5 October 2015

To Whom It May Concern

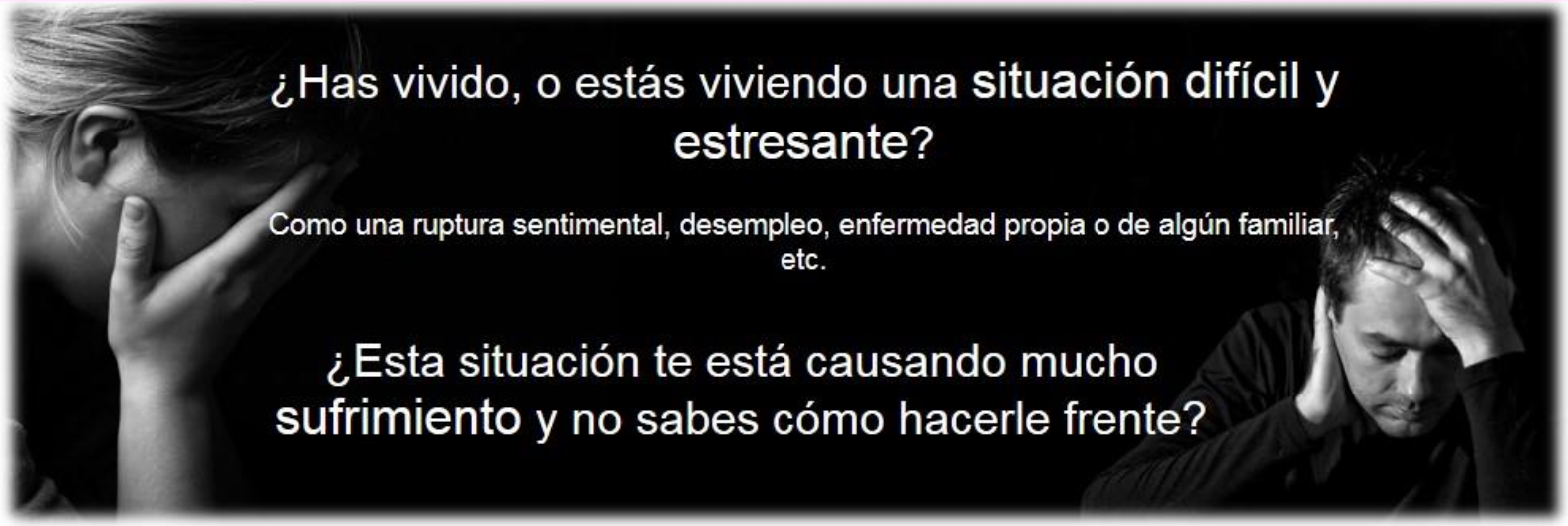
This is to certify that the Professional Ethics Committee of the Universitat Jaume I has issued a favourable report on the project "Development and Validation of an Online Treatment Program for Adjustment Disorders", whose principal investigator is Soledad Quero Castellano, after considering that the project meets all the regulations concerning professional ethics.

UNIVERSITAT JAUME·I

Beatriz Tomás Mallén
Secretary of the Professional Ethics Committee
Universitat Jaume I
Castelló de la Plana, Spain

Annexes:

Sample recruitment



Desde la Universitat Jaume I (Castellón, España) ofrecemos **AYUDA GRATUITA** que podrás recibir desde la comodidad de tu casa a través de **INTERNET**.

Si tienes más de 18 años y estás interesado, contacta con nosotros enviando un correo a **tao@uji.es**

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¿Estás viviendo una situación que te está causando mucho sufrimiento?

Aprende a superar las dificultades y fomenta tu **crecimiento personal**.

Te ofrecemos **AYUDA** psicológica **GRATUITA** que podrás recibir desde la comodidad de tu casa a través de **INTERNET**.

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QUIÉNES SOMOS

En el Laboratorio de Psicología y Tecnologia (LabPsiTec), de la Universidad Jaume I de Castellón y de la Universidad de Valencia, estamos más de 15 años investigando las posibilidades que las Nuevas Tecnologías de la Información y la Comunicación (TICs) (como la Realidad Virtual, la Realidad Aumentada, Internet, los sistemas móviles, etc.) pueden ofrecer a la Psicología Clínica, como herramientas de evaluación y de tratamiento, así como el estudio de los procesos psicológicos básicos.

Para más información, visita nuestra página web:

www.labpsitec.es

Este programa ha sido desarrollado dentro de un proyecto Nacional gracias a la colaboración de:

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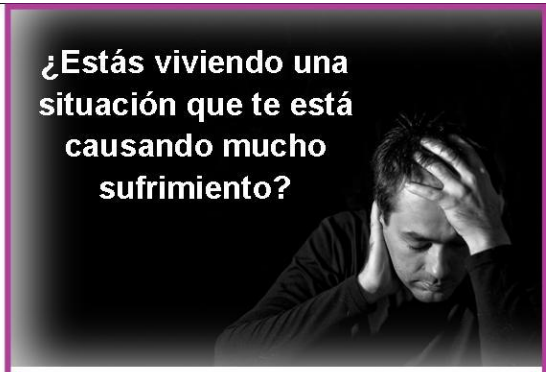
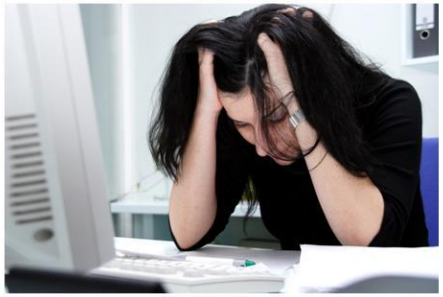


Desde la Universitat Jaume I ofrecemos

AYUDA GRATUITA

que podrás recibir desde la comodidad de tu casa.



La vida está llena de cambios y de múltiples problemas. Las personas somos capaces de responder a la mayoría de estas complicaciones.

Sin embargo, a veces surgen **dificultades** importantes que no sabemos muy bien cómo afrontar, como una ruptura sentimental, divorcio, enfermedad grave, pérdida de trabajo, etc.

Otras veces se producen **cambios** que aparentemente parecen sencillos de manejar pero pueden convertirse en algo muy estresante para la persona, como cambiar de trabajo o lugar de residencia, casarse, tener un hijo, jubilarse, etc.

Incluso, hay momentos en la vida en los que es posible sentirse completamente **desbordado** por los acontecimientos y se hace muy difícil poder seguir con nuestras tareas cotidianas.

¿TE SIENTES IDENTIFICADO?

Si es así, ahora tienes la oportunidad de acceder a un programa psicológico **GRATUITO**, que podrás realizar desde tu casa, totalmente auto-aplicado a través de **Internet**.

Este programa incluye estrategias psicológicas que han demostrado ser eficaces para ayudar a personas que han tenido que afrontar distintas dificultades o situaciones estresantes.

El objetivo no sólo consiste en **superar el acontecimiento** estresante vivido, sino **aprender de lo sucedido**, fomentar el desarrollo y **crecimiento personal** y, de esta forma, salir fortalecido de la experiencia.

Si tienes más de 18 años y

estás interesado,

contacta con nosotros

enviando un correo a

tao@uji.es

o llamando al

964 38 76 43

Annexes:

Terms of the study

GUION SCREENING TELEFÓNICO

¡

Este guion es la garantía de que vamos a tratar a todos los participantes de igual manera.

Las palabras exactas pueden variar, cada cual tiene su ritmo y sus preferencias al expresarse, pero es muy conveniente que hagamos llegar la información de la misma manera a todos los participantes.

!

1.- Saludar.

2.- Asegurarse de que hablamos con la persona correcta.

SI NO ES EL CASO o si a la persona le resulta imposible atendernos en este momento, indicaremos que nos volveremos a poner en contacto con ella más tarde. Preguntar por su disponibilidad horaria.

"Mi nombre es……. Te llamo de parte del equipo de investigación Labpsitec, de la Universitat Jaume I de Castellón. Recientemente te habías puesto en contacto con nosotros indicando que estás atravesando una situación difícil, que te está provocando sufrimiento. ¿Es así?"

"En nuestro grupo de investigación estamos llevando a cabo un estudio que consiste en ofrecer ayuda psicológica gratuita online a todas las personas que han tenido que afrontar distintas dificultades o situaciones estresantes. El objetivo de esta llamada es explicarte en qué consiste el estudio y si estás interesado/a, valorar si puedes participar en el mismo. ¿Estás interesado/a en que te explique el estudio?"

"La participación en el estudio implica el acceso al programa Trastornos Adaptativos Online, nosotros lo llamamos TAO. Este programa tiene una duración aproximada de 7 a 10 semanas y ha sido diseñado para poder ser realizado desde casa, de una forma completamente auto-aplicada a través de Internet. Su objetivo es ayudar a las personas que lo utilicen a superar los acontecimientos estresantes que han tenido lugar en sus vidas, que aprendan de lo sucedido y que salgan fortalecidas de la experiencia, fomentando su desarrollo y crecimiento personal.

GUION SCREENING TELEFÓNICO

TAO consta de 7 módulos. En cada módulo se aprenden diferentes técnicas muy potentes que ayudan a hacer frente al malestar y adaptarse de manera más flexible a las situaciones complicadas que puedan aparecer en nuestro día a día.

En el estudio habrá tres grupos. El primer grupo accederá a los módulos del programa TAO a través de una plataforma virtual denominada Psicología y Tecnología en los próximos días, el segundo grupo recibirá los mismos módulos en formato PDF en su dirección de correo electrónico, también en los próximos días. En ambos casos el contenido será el mismo, sólo variará el formato en el que se presente. Finalmente, el tercer grupo recibirá el tratamiento dentro de 10 semanas, aproximadamente el tiempo que dura la intervención en los otros dos grupos. Después de 10 semanas de espera, a los participantes de este grupo de espera se les comunicará en qué formato recibirán la intervención.

La asignación a cada uno de los grupos será aleatoria. Te informaremos por teléfono a qué grupo has sido asignado.

Entendemos que la idea de no recibir ayuda hasta dentro de 10 semanas puede desagradaros, sin embargo, es la única forma que existe para realizar un estudio científico riguroso."

"Además, antes de empezar la intervención se te pedirá que cumplimentes una serie de cuestionarios y te pediremos que los vuelvas a contestar al finalizar la intervención. Esto necesario para conocer en qué medida te has beneficiado de la intervención recibida. Por último, te pediremos que vuelvas a contestar los mismos instrumentos a los 3, 6 y 12 meses de haber finalizado la intervención. De esta forma sabremos si los cambios producidos durante la intervención se mantienen en el tiempo. Estas evaluaciones se realizarán a través de Internet y por teléfono, por lo que en ningún momento se requerirá tu desplazamiento."

"Ahora que sabes en qué consiste la ayuda que ofrecemos y las condiciones que implica, ¿continúas interesado/a en recibirla y así participar en nuestro estudio?"

Dejar que la persona decida. Si no lo tiene claro, dejarle la posibilidad de que nos lo comunique más tarde por e-mail. (**tao@uji.es**)

SI LA PERSONA NO SABE SI QUIERE PARTICIPAR

"No te preocupes, entendemos que puedas necesitar tiempo para tomar la decisión. Si quieres, no hace falta que tomes la decisión ahora. Puedes pensártelo y hacernos llegar

GUION SCREENING TELEFÓNICO

tu decisión a través del correo electrónico. Eso sí, te pedimos que nos lo notifiques en el transcurso de los próximos 7 días.

De todas formas, ¿podrías responderme ahora a una serie de preguntas para valorar así si nuestro programa se adapta a tus necesidades y si puede ser de utilidad en tu caso?"

SI LA PERSONA NO QUIERE, nos despedimos amablemente y le recordamos que puede ponerse en contacto con nosotros cuando quiera a través del correo electrónico y pedimos que nos haga llegar su decisión durante los próximos 7 días.

SI LA PERSONA SIGUE INTERESADA,

"Gracias por tu interés en participar en nuestro estudio. Ahora necesito hacerte una serie de preguntas para valorar si nuestro programa se adapta a tus necesidades y si puede ser de utilidad en tu caso. Responder a las preguntas nos puede llevar entre 30 y 50 minutos. ¿Dispones ahora de este tiempo o prefieres que te llame en otro momento?"

Si la persona **NO puede** ahora, le damos cita telefónica para otro momento y nos despedimos.

Si la persona **SÍ puede,** se realiza la Entrevista Diagnóstica para los TA y la Entrevista Biográfica parte 2 (Variables biográficas).

"Como te he comentado, el programa de intervención que ofrecemos está dirigido a personas que han vivido o están viviendo una situación difícil y estresante que les genera mucho sufrimiento. En los últimos meses, ¿has sufrido tú algún acontecimiento negativo o estresante? (…)"

"Muy bien, esto es todo. Ahora tenemos que valorar con el resto del equipo clínico si nuestro programa se adapta a tus necesidades. Me pondré en contacto contigo en los próximos días para comunicarte si puedes participar en el estudio y, de ser así, la condición que te ha sido asignada y los pasos a seguir. Mientras tanto, recibirás en tu correo electrónico un e-mail con toda la descripción del estudio así como el Consentimiento informado que tendrás que firmar para participar en el estudio. Para firmar el Consentimiento informado simplemente tendrás que contestar diez preguntas que recogen información personal de los participantes.

GUION SCREENING TELEFÓNICO

No te preocupes, la página web que utilizamos cumple con la Ley de Protección de datos y la información se tratará respetando en todo momento la confidencialidad de los participantes.

Por mi parte esto es todo. ¿Tienes alguna duda?"

Si la persona **NO** tiene dudas:

"Gracias por tu tiempo y necesitas hacer cualquier consulta, no dudes en contactar con nosotros enviando un e-mail a tao@uji.es

Que tengas un buen día."

Annexes:

Informed consent

TAO: Trastornos Adaptativos Online

Estimado/a participante del programa Trastornos Adaptativos Online (TAO). A través de este correo podrás responder al cuestionario online del que te hablamos. El motivo por el que este correo es tan largo es porque tiene la función de informarte de las condiciones con las que se lleva a cabo el estudio en el que has mostrado interés. De esta manera, si decides continuar adelante e implicarte, solamente tendrás que acceder al enlace del cuestionario y responderlo. Si, por el contrario, quisieras no continuar con el estudio, solamente tendrías que acceder al enlace que aparece al final de este correo.

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

Tu participación en el estudio implica el acceso al programa *Trastornos Adaptativos Online (TAO)*. Este programa ha sido diseñado para poder ser realizado desde casa, de una forma completamente auto-aplicada a través de Internet. Su objetivo es ayudar a las personas que lo utilicen a superar los acontecimientos estresantes que han tenido lugar en sus vidas, que aprendan de lo sucedido y que salgan fortalecidas de la experiencia, fomentando su desarrollo y crecimiento personal. TAO consta de 6 módulos. En cada módulo se aprenden diferentes técnicas muy potentes que ayudan a hacer frente al malestar y adaptarse de manera más flexible a las situaciones complicadas que puedan aparecer en nuestro día a día.

En el estudio habrá tres grupos. El primer grupo accederá a los módulos del programa TAO a través de una plataforma virtual denominada Psicología y Tecnología en los próximos días, el segundo grupo recibirá los mismos módulos en formato PDF en su dirección de correo electrónico, también en los próximos días. En ambos casos el contenido será el mismo, sólo variará el formato en el que se presente. Finalmente, el tercer grupo recibirá el tratamiento dentro de 10 semanas. La asignación a cada uno de los grupos será aleatoria. Te informaremos por teléfono a qué grupo has sido asignado.

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

Acepto de manera libre mi participación en el estudio de TAO. Entiendo la naturaleza y el propósito de los procedimientos que entraña el presente estudio y que se me han comunicado previamente. Entiendo que la investigación está diseñada para promover el conocimiento científico y que la Universitat Jaume I de Castellón usará los datos que yo le proporcione sólo y exclusivamente para esta investigación. Entiendo que los datos que proporciono serán considerados como confidenciales. Mi nombre o cualquier otra información no se harán públicos en ninguna presentación o publicación de la investigación. El procesamiento y uso de mis datos anónimos se llevará a cabo y se almacenará en papel y en formato electrónico durante 15 años. Entiendo que puedo retirarme del estudio en cualquier momento, sin dar ningún tipo de explicación y sin ningún tipo de inconveniente para mí. Entiendo que la Universitat Jaume I de Castellón puede usar los datos recogidos en este proyecto para un proyecto de investigación posterior pero que las condiciones bajo las cuales he proporcionado la información seguirán siendo las mismas.

Si has decidido que quieres responder a los cuestionarios online y **formar parte del estudio**, este es el enlace al que tienes que ir:

Comenzar el cuestionario

Por favor, contesta las siguientes preguntas que recogen información personal de los participantes.

Te recordamos que esta información únicamente se utilizará para fines científicos y no se utilizará en ningún tipo de presentación y publicación de la investigación. Sin embargo, si no estás conforme y/o deseas realzar cualquier tipo de consulta o comentario, no dudes en contactar con nosotros enviando un correo a tao@uji.es

E-mail: _____

Edad: _____ Fecha de nacimiento: _____

Sexo:
- ☐ Masculino
- ☐ Femenino
- ☐ Otro (especifique): _____

Nacionalidad: _____

Estado Civil:
- ☐ Soltero/a
- ☐ Casado/a
- ☐ En pareja
- ☐ Separado/a
- ☐ Divorciado/a
- ☐ Viudo/a
- ☐ Otro (especifique): _____

Nivel de estudios:
- ☐ Ninguno
- ☐ Básicos (Graduado escolar)
- ☐ Medios (BUP, Bachillerato, COU, PREU, FP II)
- ☐ Superiores
- ☐ Otro (especifique): _____

Situación laboral:
- ☐ Trabaja
- ☐ En desempleo
- ☐ Estudiante
- ☐ De baja temporal
- ☐ Baja por larga enfermedad
- ☐ Jubilado/a

☐ Otro (especifique): _____

Convivencia:

☐ Domicilio propio solo/a
☐ Domicilio propio con la pareja
☐ Domicilio propio con la pareja y/o hijos
☐ Domicilio de familiares
☐ Domicilio de vecinos o amigos
☐ Residencia
☐ Otro (especifique): _____

Acontecimiento estresante:

☐ Ruptura/Divorcio y problemas derivados
☐ Problemática familiar
☐ Problemas laborales y *mobbing*
☐ Enfermedad propia o de algún familiar
☐ Otro (especifique): _____

¿Cuál dirías es tu nivel de dominio de las nuevas tecnologías?

☐ Nulo
☐ Básico
☐ Medio
☐ Avanzado
☐ Experto
☐ Otro (especifique): _____

Annexes:

Diagnostic interview

DIAGNOSTIC INTERVIEW FOR ADJUSTMENT DISORDERS

(English version)

Name ..... Code/ID number .....

Age ..... Date of birth ..... Sex ❑ Woman ❑ Man

Interviewer .....

Diagnosis ..... Date .....

I. INITIAL INQUIRY

1- Over the past few months, have you experienced any stressor in your life?

YES ____ NO ____

TYPE OF STRESSOR	Yes/No	Duration in months/years
***RELATED TO THE PRIMARY SUPPORT GROUP*:**		
-break-up, separation/divorce		
-partner's infidelity		
-conflicts/problems with other family members		
-reconciliation		
-marriage		
-new marriage of a family member		
-death of a relative [1]		
-pregnancy/birth of a child		
-children leaving home (empty-nest)		
-incorporation of a family member		
-a family member leaving		
-moving house		
-health problems of a family member		
-your own health problems		
-abuse from partner/parents		
-abandonment		
RELATED TO THE SOCIAL AREA:		
-death of a friend [1]		
-loss of social support		
-prolonged loneliness		
-housing problems		
-change in place of residence		
-discrimination		
-a major life change (e.g., retirement, leaving home…)		

[1] If YES, consider evaluating COMPLICATED GRIEF

-problems with a social agent: doctor, social worker…		
EMMIGRATION:		
-emigration		
- refugee resettlement		
-difficulty adapting to a new culture		
-discrimination		
-lack of access to basic/public services (e.g., education, health, social services, employment...)		
-housing difficulties/living in precarious conditions		
-financial instability		
-difficulties due to language barriers		
WORK AREA:		
-unemployment		
-being fired		
-retirement		
-promotion		
-job change		
-dissatisfaction with work		
-conflicts with the boss/coworkers		
-stressful job		
-difficult work conditions		
-work-related failures		
ACADEMIC AREA		
-beginning/end of a stage		
-problems with classmates		
-changing school/high school/faculty (department)		
-problems with studies		
-academic failures		
PROBLEMS WITH BULLYING/ABUSE		
-mobbing		
-bullying		
-others		
ECONOMIC PROBLEMS		
-beginning/end of a business/bankruptcy		
-economic problems		
-earning/winning a large amount of money		
PROBLEMS WITH THE LEGAL SYSTEM OR DELINQUENCY		
-arrest		
-being put in jail		
-trial		
-victim of a criminal act		
THREAT TO PERSONAL SAFETY		

-accident		
-natural catastrophes/disasters		
-physical/sexual aggression		
-serious illness		
-threat or danger to someone else		

2- How long ago did the stressor(s) take place? (specify date)

Stressor 1:.....
Stressor 2:.....

Stressor 3:.....

3- Are any of the stressors still present today?

Stressor 1:.....
Stressor 2:.....

Stressor 3:.....

4- Currently, and as a result of this stressor, do you have any type of emotional or behavioral symptom that is causing you distress or interfering with your life? For example, do you feel anxious, depressed, worried, incapable of moving forward, incapable of doing things …

YES ____ NO ____

II. SYMPTOM RATING

In this section rate the severity, the frequency and the onset of symptoms triggered by the main stressor using the scales and suggested queries below. Do not record symptoms that are not associated with the stressor (e.g., if patients report they have always had low self-esteem, specify how much the stressor is affecting their self-esteem). Ask about the frequency and the onset only if the symptom was rated 5 or higher.

5- How distressing/severe is _____ (symptom from the list below) since the _____ (main stressor) occurred/began?

0	1	2	3	4	5	6	7	8
Not at all		**Slight**		**Moderate**		**Severe**		**Extremely severe**

Inquiry ONLY FOR THOSE SYMPTOMS WHICH WERE RATED 5 OR HIGHER:

6- Since the _____ (main stressor) occurred/began, how often have you experienced _____ (symptom from the list below)?:

1	2	3	4	5	6
Never	**A few days a month**	**Several days each month**	**Once a week**	**A few days a week**	**Every day**

7- After the event occurred, how soon did you begin to experience _____ (symptom from the list below)?:

SYMPTOMS	Severity (0-8)	Frequency (1-6)	When did it start?[2]
Sadness			
Rage/anger			
Guilt			
Anxiety/fear			
Motor restlessness, inability to sit still			
Confusion/uncertainty			
Feelings of hopelessness			
Crying			
Feelings of worthlessness			
Low self-esteem			
Thoughts of death			
Muscle tension			
Difficulty falling/staying asleep or sleeping too much			
Poor appetite or overeating			
Restlessness/nervousness			
Fatigue			
Difficulty concentrating			
Irritability			
Difficulties relating to others			
Social withdrawal or isolation			
Difficulty accepting what happened			
Avoidance of thoughts, people, or situations associated with the stressor			
Feeling of detachment or estrangement from others			
Physiological response (sweating, shaking) at exposure to cues related to the stressor			

[2] Specify whether the symptom is presented since the stressor began or it appeared later.

Emotional numbing [3]			
Recurrent or intrusive dreams or memories [3]			
Feelings of reliving the experience [3]			
Constant worry about different topics [4]			
Others			

Comments: .....
.....
.....

8- Predominance of symptoms (CLINICIAN'S JUDGMENT):

Anxious	**-3**	**-2**	**-1**	**0**	**1**	**2**	**3**	**Depressive**

9- After the event occurred, how soon did you start having these symptoms ?

Within the first month	**Within 1 - 3 months**	**> 3 months later**

10- How long have you been experiencing these symptoms?

Less than 1 month	**Between 1 and 3 months**	**Between 3 and 6 months**	**More than 6 months**

11- Is the stressor or any of its consequences still present? (e.g., I still don't have any money, they still bully me at work, I am waiting for the trial …)

YES ____ NO ____

Specify .....
.....
.....

12- Has there been any change in the severity of the symptoms related to the stressor? (e.g., Have the symptoms improved, got worse, or remained the same?)

-3	**-2**	**-1**	**0**	**1**	**2**	**3**
Very much worse	**Much worse**	**Minimally worse**	**No change**	**Minimally improved**	**Much improved**	**Very much improved**

[3] If the symptom is too severe and distressing, consider evaluating Post-traumatic stress disorder
[4] If the symptom was highly frequent and distressing even before the onset of the stressor, consider evaluating Generalized Anxiety Disorder.

13- Besides this current/most recent time, have there been other separate periods of time in which you have experienced similar symptoms, either in relation to this or another stressor?

YES ____ NO ____

Specify .....
.....
.....

14- Did you have these symptoms even before the stressor took place?

YES ____ NO ____

Specify .....
.....
.....

15- When did the stressor begin to be a problem in that it caused a lot of distress or interference with your life? (Note: attempt to ascertain more specific information, e.g., by linking onset to objective life events)

Date:.....

Comments: .....
.....
.....

16- During the past 6 months, have you been continually worried or anxious about a number of events or activities in your daily life, in addition to those related to the stressor?

YES ____ NO ____

17- Over this entire period of time when you have been having symptoms, have you been regularly taking any type of drug? (e.g., drugs of abuse, medication)

YES ____ NO ____

Specify (type; amount; dates of use) .....
.....
.....

18- During this current period of time when you have been having symptoms, have you had any physical condition or illnesses? (e.g., pregnancy, hypothyroidism)

YES ____ NO ____

Specify (type and date of onset/remission) .....
.....
.....

III. SEVERITY AND INTERFERENCE

19- Currently, how much distress is the stressor or the symptoms associated with it causing you?

0	1	2	3	4	5	6	7	8
No distress		**Mild distress**		**Moderate distress**		**Severe distress**		**Extreme distress**

20- Currently, how much the stressor or the symptoms associated with the stressor interfere in the following areas of your life?

WORK/SCHOOL. In your functioning at work/school.

0	1	2	3	4	5	6	7	8
Not at all		**A little**		**Somewhat**		**A lot**		**Extremely**

SOCIAL LIFE. In your social relationships/friendships with other people.

0	1	2	3	4	5	6	7	8
Not at all		**A little**		**Somewhat**		**A lot**		**Extremely**

LEISURE TIME. In your leisure activities (going out, excursions, trips, sport practice …).

0	1	2	3	4	5	6	7	8
Not at all		**A little**		**Somewhat**		**A lot**		**Extremely**

INTIMATE RELATIONSHIP. In your relationship with your partner or the possibility of having one.

0	1	2	3	4	5	6	7	8
Not at all		**A little**		**Somewhat**		**A lot**		**Extremely**

FAMILY. In your family relationships.

0	1	2	3	4	5	6	7	8
Not at all		**A little**		**Somewhat**		**A lot**		**Extremely**

OVERALL SCALE. In your normal life in general.

0	1	2	3	4	5	6	7	8
Not at all		**A little**		**Somewhat**		**A lot**		**Extremely**

IV. RESEARCH

21- Is there any situation, person, or image that seems to trigger or increase symptoms related to the stressor? [Inquire about internal (thoughts, images) and external (situations, people or objects related to the stressor) triggers]

Specify .....
.....
.....

22- How do you handle the stressor and the symptoms related to the stressor?

Specify .....
.....
.....

23- Did you ever experience similar feelings, perhaps milder, when you were a child?

YES ____ NO ____

If YES, specify dates and nature (situations, frequency, symptoms) of those experiences
.....
.....

ENTREVISTA DIAGNÓSTICA PARA TRASTORNOS ADAPTATIVOS

(Spanish version)

Nombre ..... Código/DNI .....

Edad ..... Fecha de nacimiento ..... Sexo ❑ Mujer ❑ Hombre

Entrevistador .....

Diagnosis ..... Fecha .....

INFORMACIÓN INICIAL

1- ¿Has experimentado algún factor estresante en tu vida en los últimos meses?

SI ____ NO ____

TIPO DE FACTOR ESTRESANTE	Si/No	Duración en meses/años
RELACIONADO CON EL GRUPO DE APOYO PRIMARIO:		
-ruptura, separación / divorcio		
-infidelidad de la pareja		
-conflictos / problemas con otros miembros de la familia		
-reconciliación		
-matrimonio		
- nuevo matrimonio de algún miembro de la familia		
-muerte de un familiar [5]		
-embarazo / nacimiento de un hijo		
- independización de los hijos		
-incorporación de un miembro de la familia		
- marcha de algún miembro de la familia		
- cambio de hogar		
-problemas de salud de un miembro de la familia		
-problemas de salud propios		
-malos tratos por parte de la pareja / padres		
-abandono		
RELACIONADO CON EL ÁMBITO SOCIAL:		
-muerte de un amigo [1]		
-pérdida de apoyo social		
-soledad prolongada		
-problemas de vivienda		
-cambio de lugar de residencia		
-discriminación		

[5] Si la respuesta es SI, considérese evaluar DUELO COMPLICADO

-cambio vital (p.ej. jubilación, irse de casa…)		
-problemas con un agente social: médico, trabajador social…		
EMIGRACIÓN:		
-emigración		
-reasentamiento de refugiados		
-dificultad para adaptarse a una nueva cultura		
-discriminación		
-falta de acceso a servicios públicos / básicos (p.ej. educación, salud, servicios sociales, empleo…)		
-dificultades en la vivienda / condiciones precarias de vida		
-inestabilidad financiera		
-dificultades debido a las barreras del idioma		
ÁMBITO LABORAL:		
-desempleo		
-despido		
-jubilación		
-ascenso		
-cambio de trabajo		
-insatisfacción en el trabajo		
-problemas con el jefe / compañeros		
-trabajo estresante		
-condiciones de trabajo difíciles		
-fracasos laborales		
ÁMBITO ACADÉMICO		
-inicio / fin de una etapa		
-problemas con los compañeros		
-cambio de colegio / instituto / facultad (departamento)		
-problemas con los estudios		
-fracasos académicos		
PROBLEMAS CON EL ACOSO/ABUSO		
-“mobbing”		
-“bullying”		
-otros		
PROBLEMAS ECONÓMICOS		
-comienzo / fin de un negocio / quiebra		
- problemas económicos		
-ganancia de una gran cantidad de dinero		
PROBLEMAS LEGALES O DELINCUENCIA		
-arresto		
-encarcelamiento		

-juicio		
-víctima de un acto delictivo		
AMENAZA A LA SEGURIDAD PERSONAL		
-accidente		
-catástrofes naturales / desastres		
-agresión física / sexual		
-enfermedad grave		
-amenaza o peligro para otra persona		

2- ¿Cuánto hace que el/los acontecimiento/s estresante/s tuvo/tuvieron lugar? (Especificar la fecha)

Acontecimiento 1:.....
Acontecimiento 2:.....

Acontecimiento 3:.....

3- ¿Alguno de los acontecimiento estresantes está todavía presente hoy en día?

Acontecimiento 1:.....
Acontecimiento 2:.....

Acontecimiento 3:.....

4- En la actualidad, y como consecuencia de este acontecimiento estresante, ¿tienes algún tipo de síntoma emocional o de comportamiento que te cause malestar o interfiera en tu vida? Por ejemplo, ¿te sientes ansioso, deprimido, preocupado, incapaz de seguir adelante, incapaz de hacer cosas…?

SI ____ NO ____

V. VALORACIÓN DE LOS SÍNTOMAS

En esta sección evalúe la gravedad, frecuencia y el inicio de los síntomas desencadenados por el principal acontecimiento estresante usando las escalas y preguntas que hay a continuación. No registre síntomas que no estén relacionados con el acontecimiento estresante (p.ej., si los pacientes informan que siempre han tenido baja autoestima, especifique en qué medida el acontecimiento estresante está afectando a su autoestima). Pregunte por la frecuencia y la aparición solamente si el síntoma fue valorado con 5 o más.

5- ¿Hasta qué punto_____ (el síntoma de la lista de abajo) es angustiante / intenso desde que_____ (el detonante) sucedió/empezó?

0	1	2	3	4	5	6	7	8
Nada		**Leve**		**Moderado**		**Grave**		**Extremadamente Grave**

Pregunta solamente sobre aquellos síntomas que han sido valorados con 5 o más:

6- Desde que _____ (el acontecimiento estresante) sucedió/empezó, ¿con qué frecuencia has experimentado _____(síntoma de la lista de abajo)?:

1	2	3	4	5	6
Nunca	**Algunos días al mes**	**Varios días al mes**	**Una vez a la semana**	**Varios días a la semana**	**Todos los días**

7- Después de que ocurriera el detonante, ¿cuándo empezaste a experimentar _____ (síntoma de la lista de abajo)?:

SYMPTOMS	Severity (0-8)	Frequency (1-6)	When did it start?[6]
Tristeza			
Rabia / enfado			
Culpa			
Ansiedad / miedo			
Inquietud, incapacidad de estar quieto			
Confusión/ incertidumbre			
Sentimientos de desesperanza			
Llanto			
Sentimientos de inutilidad			
Baja autoestima			
Ideas de muerte			
Tensión muscular			
Dificultad para dormir / quedarse dormido o dormir demasiado			
Poco apetito o comer en exceso			
Inquietud / Nerviosismo			
Fatiga			
Dificultad para concentrarse			
Irritabilidad			
Dificultades para relacionarse con los demás			
Retirada o aislamiento social			
Dificultad al aceptar lo ocurrido			
Evitación de pensamientos, personas o situaciones relacionadas con el acontecimiento estresante			
Sensación de desapego o extrañamiento respecto los			

[6] Especificar si el síntoma está presente desde que comenzó el estresor o apareció más tarde.

demás			
Respuesta fisiológica (sudor, temblor) ante estímulos relacionados con el acontecimiento estresante			
Embotamiento afectivo [7]			
Sueños o recuerdos recurrentes o intrusivos [3]			
Sensación de revivir la experiencia [3]			
Preocupación constante sobre diferentes temas[8]			
Otros			

Comentarios: .....
.....
.....

8- Predominio de síntomas (SEGÚN EL JUICIO DEL CLÍNICO):

Ansioso	**-3**	**-2**	**-1**	**0**	**1**	**2**	**3**	**Depresivo**

9- Después de que ocurriera el acontecimiento, ¿cuándo empezaste a tener estos síntomas?

En el primer mes	**Entre el mes 1 y 3**	**A partir del mes 3**

10- ¿Durante cuánto tiempo has experimentado estos síntomas?

Menos de 1 mes	**Entre 1 y 3 meses**	**Entre 3 y 6 meses**	**Más de 6 meses**

11- El acontecimiento estresante o alguna de sus consecuencias, ¿está aún latente? (p. ej. Aún no tengo dinero, me siguen molestando en el trabajo, estoy esperando el juicio…)

SI ____ NO ____

Especifica .....
.....
.....
.....
.....

[7] Si el síntoma es demasiado grave y doloroso, considera evaluar el trastorno de estrés postraumático.
[8] Si el síntoma era bastante frecuente y doloroso incluso antes de la aparición del desencadenante, considera evaluar el Trastorno de Ansiedad Generalizada.

12- ¿Ha habido algún cambio en la gravedad de los síntomas relacionados con el detonante? (p.ej., ¿Los síntomas han mejorado, empeorado, o están igual?)

-3	-2	-1	0	1	2	3
Muchísimo peor	Mucho peor	Minimamente peor	Sin cambio	Minimamente mejor	Mucho mejor	Muchísimo mejor

13- Además del momento más presente / actual, ¿ha habido otros periodos de tiempo separados en los que hayas experimentado síntomas similares, o bien en relación a este o a otro factor desencadenante?

SI ____ NO ____

Especifica .....
.....
.....
.....
.....

14- ¿Sufriste estos síntomas incluso antes de que el desencadenante sucediera?

YES ____ NO ____

Especifica.....
.....
.....
.....
.....

15- ¿Cuándo empezó el desencadenante a representar un problema al causar mucha angustia o interferencias en tu vida? (Fíjate: intenta determinar información más específica, p. ej., vinculando el inicio con eventos objetivos de la vida)

Fecha:.....

Comentarios: .....
.....
.....

16- En los últimos 6 meses, ¿has estado constantemente preocupado o ansioso por una cantidad de acontecimientos o actividades en tu vida diaria, aparte de los que están relacionados con el detonante?

SI ____ NO ____

17- Durante todo este periodo de tiempo en el que has estado teniendo síntomas, ¿has tomado de manera regular, algún tipo de sustancia? (p.ej., droga, medicamento)

SI ____ NO ____

Especifica (tipo; cantidad; fechas de uso) .....
.....
.....

18- Durante este periodo de tiempo actual en el que has estado teniendo síntomas, ¿has tenido algún tipo de condición física o enfermedad? (p.ej., embarazo, hipotiroidismo).

YES ____ NO ____

Especifica (tipo y fecha de inicio / remisión).....
.....
.....

VI. GRAVEDAD E INTERFERENCIA

1- Actualmente, ¿cuánto malestar te está provocando el acontecimiento estresante o los síntomas asociados con él?

0	1	2	3	4	5	6	7	8
Ningún malestar		**Malestar leve**		**Malestar moderado**		**Malestar grave**		**Malestar muy grave**

2- Actualmente, ¿cuánto interfiere el acontecimiento estresante o los síntomas asociados a él en las siguientes áreas de tu vida?

TRABAJO/ESTUDIOS. En tu funcionamiento en el trabajo / colegio.

0	1	2	3	4	5	6	7	8
Nada		**Poco**		**Bastante**		**Mucho**		**Muchísimo**

VIDA SOCIAL. En tus relaciones sociales / amistad con otras personas.

0	1	2	3	4	5	6	7	8
Nada		**Poco**		**Bastante**		**Mucho**		**Muchísimo**

TIEMPO LIBRE. En tus actividades de ocio (salidas, excursiones, viajes, deportes…).

0	1	2	3	4	5	6	7	8
Nada		**Poco**		**Bastante**		**Mucho**		**Muchísimo**

RELACIONES ÍNTIMAS. En la relación con tu pareja o en la posibilidad de tener una.

0	1	2	3	4	5	6	7	8
	Nada		**Poco**		**Bastante**		**Mucho**	**Muchísimo**

FAMILIA. En tus relaciones con tu familia.

0	1	2	3	4	5	6	7	8
	Nada		**Poco**		**Bastante**		**Mucho**	**Muchísimo**

ESCALA GLOBAL. En tu vida normal en general.

0	1	2	3	4	5	6	7	8
	Nada		**Poco**		**Bastante**		**Mucho**	**Muchísimo**

VII. INVESTIGACIÓN

1- ¿Existe alguna situación, persona, o imagen que parece desencadenar o aumentar los síntomas relacionados con el acontecimiento estresante? [Pregunta por desencadenantes internos (pensamientos, imágenes) y externos (situaciones, personas, objetos relacionados con el acontecimiento estresante)]

Especifica.....
.....
.....
.....
.....

2- ¿Cómo manejas el acontecimiento estresante y los síntomas relacionados con éste?

Especifica.....
.....
.....
.....
.....

3- ¿Tuviste sentimientos parecidos, quizás más leves, cuando eras niño/a?

SI ____ NO ____

Si la respuesta es SI, especificar fechas y naturaleza (situaciones, frecuencia, síntomas) de dichas experiencias.

.....
.....

Annexes:

Assessment protocol

Cumplimentar por el paciente

Beck Depression Inventory (BDI-II)

(Beck, Steer y Brown, 1996)

Nombre: **Fecha:**

INSTRUCCIONES: Este cuestionario consiste en 21 grupos de afirmaciones. Por favor, lee con atención cada uno de ellos y, a continuación, señala cuál de las afirmaciones de cada grupo describe mejor el modo en el que te has sentido **durante las dos últimas semanas, incluyendo el día de hoy**. Rodea con un círculo el número que se encuentre escrito a la izquierda de la afirmación que hayas elegido. Si dentro del mismo grupo, hay más de una afirmación que consideres igualmente aplicable a tu caso, señálala también. **Asegúrate de leer todas las afirmaciones dentro de cada grupo antes de efectuar la elección**.

1. Tristeza	**6. Sentimientos de castigo**
0 No me siento triste habitualmente	0 No siento que esté siendo castigado
1 Me siento triste gran parte del tiempo	1 Siento que puedo ser castigado
2 Me siento triste continuamente	2 Espero ser castigado
3 Me siento tan triste o tan desgraciado que no puedo soportarlo	3 Siento que estoy siendo castigado
2. Pesimismo	**7. Insatisfacción con uno mismo**
0 No estoy desanimado sobre mi futuro	0 Siento lo mismo que antes sobre mí mismo
1 Me siento más desanimado sobre mi futuro que antes	1 He perdido confianza en mí mismo
2 No espero que las cosas mejoren	2 Estoy decepcionado conmigo mismo
3 Siento que mi futuro es desesperanzador y que las cosas sólo empeorarán	3 No me gusto
3. Sentimientos de fracaso	**8. Auto-críticas**
0 No me siento fracasado	0 No me critico o me culpo más que antes
1 He fracasado más de lo que debería	1 Soy más crítico conmigo mismo de lo que solía ser
2 Cuando miro atrás, veo fracaso tras fracaso	2 Critico todos mis defectos
3 Me siento una persona totalmente fracasda	3 Me culpo por todo lo malo que sucede
4. Pérdida de placer	**9. Pensamientos o deseos de suicidio**
0 Disfruto de las cosas que me gustan tanto como antes	0 No tengo ningún pensamiento de sucidio
1 No disfruto de las cosas tanto como antes	1 Tengo pensamientos de suicidio, pero no los llevaría a cabo
2 Obtengo muy poco placer de las cosas con las que antes disfrutaba	2 Me gustaría suicidarme
3 No obtengo ningún placer de las cosas con las que antes disfrutaba	3 Me suicidaría si tuviese la oportunidad
5. Sentimientos de culpa	**10. Llanto**
0 No me sietno especialmente culpable	0 No lloro más de lo que solía hacerlo
1 Me siento culpable por muchas cosas que he hecho o debería haber hecho	1 Lloro más de lo que solía hacerlo
2 Me siento culpable la mayor parte del tiempo	2 Lloro por cualquier cosa
3 Me siento culpable constantemente	3 Tengo ganas de llorar continuamente, pero no puedo

CONTINÚA EN LA PÁGINA SIGUIENTE

11. Agitación	17. Irritabilidad
0 No estoy más inquieto o agitado que de costumbre	0 No estoy más irritable de lo habitual
1 Me sietno más inquieto o agitado que de costumbre	1 Estoy más irritable de lo habitual
2 Estoy tan inquieto o agitado que me cuesta estarme quieto	2 Estoy mucho más irritable de lo habitual
3 Estoy tan inquieto o agitado que tengo que estar continuamente moviéndome o haciendo algo	3 Estoy irritable continuamente
12. Pérdida de interés	**18. Cambios en el apetito**
0 No he perdido el interés por otras personas o actividades	0 No he experimentado ningún cambio en mi apetito
1 Estoy menos interesado que antes por otras personas o actividades	1a Mi apetito es algo menor de lo habitual 1b Mi apetito es algo mayor de lo habitual
2 He perdido la mayor parte de mi interés por los demás o por las cosas	2a Mi apetito es mucho menor que antes 2b Mi apetito es mucho mayor de lo habitual
3 Me resulta difícil interesarme por algo	2a He perdido completamente el apetito 2b Tengo ganas de comer continuamente
13. Indecisión	**19. Dificultades de concentración**
0 Tomo decisiones más o menos como siempre	0 Puedo concentrarme tan bien como siempre
1 Tomar decisiones me resulta más difícil que de costumbre	1 No puedo concentrarme tan bien como habitualmente
2 Tengo mucha más dificultad en tomar decisiones que de costumbre	2 Me cuesta mantenerme concentrado en algo durante mucho tiempo
3 Tengo problemas para tomar cualquier decisión	3 No puedo concentrarme en nada
14. Inutilidad	**20. Cansancio o fatiga**
0 No me siento inútil	0 No estoy más cansado o fatigado que de costumbre
1 No me considero tan valioso y útil como solía ser	1 Me canso o fatigo más fácilmente que de costumbre
2 Me siento inútil en comparación con otras personas	2 Estoy demasiado conasado o fatigado para hacer muchas cosas que antes solía hacer
3 Me siento completamente inútil	3 Estoy demasiado cansado o fatigado para hacer la mayoría de las cosas que antes solía hacer
15. Pérdida de energía	**21. Pérdida de interés en el sexo**
0 Tengo tanta energía como siempre	0 No he notado ningún cambio reciente en mi interés por el sexo
1 Tengo menos energía de la que solía tener	1 Estoy menos interesado por el sexo de lo que solía estar
2 No tengo suficiente energía para hacer muchas cosas	2 Estoy mucho menos interesado por el sexo ahora
3 No tengo suficiente energía para hacer nada	3 He perdido completemente el interés por el sexo
16. Cambios en el patrón de sueño	
0 No he experimentado ningún cambio en mi patrón de sueño	
1a Duermo algo más de lo habitual 1b Duermo algo menos de lo habitual	
2a Duermo mucho más de lo habitual 2b Duermo mucho menos de lo habitual	
3a Duermo la mayor parte del día 3b Me despierto 1 o 2 horas más temprano y no puedo volver a dormirme	

Ítem de suicidio

Nombre: **Fecha:**

Durante la última semana, ¿con qué frecuencia has tenido pensamientos sobre suicidio?

0	**Nada.** No he tenido pensamientos de suicidio.
1	**Infrecuente.** En alguna ocasión he tenido pensamientos de suicidio, pero de forma esporádica.
2	**Ocasional.** Algunas veces he tenido pensamientos de suicidio.
3	**Frecuente.** En muchas ocasiones he tenido pensamientos de suicidio.
4	**Todo el tiempo.** Casi la mayor parte del tiempo he tenido pensamientos de suicidio.

Beck Anxiety Inventory (BAI)

(Beck y Steer, 1993; adaptación española: Sanz y Navarro, 2003)

Nombre: **Fecha:**

A continuación hay una lista de síntomas comunes de ansiedad. Por favor, lee cuidadosamente cada uno de los ítems. Indica el grado en que te has visto afectado por cada uno de ellos **durante la última semana y en el momento actual**. Elige de entre las siguientes opciones la que mejor se corresponda:

0	1	2	3
En absoluto	**Levemente**: no me molesta mucho	**Moderadamente**: fue muy desagradable, pero podía soportarlo	**Severamente**: casi no podía soportarlo

Durante la pasada semana y hoy, siento o he sentido…

Durante la pasada semana y hoy, siento o he sentido…	**En absoluto**	**Levemente**	**Moderadamente**	**Severamente**
1. Hormigueo o entumecimiento	0	1	2	3
2. Sensación de calor	0	1	2	3
3. Debilidad en las piernas	0	1	2	3
4. Incapacidad para relajarme	0	1	2	3
5. Miedo a que suceda lo peor	0	1	2	3
6. Mareos o vértigos	0	1	2	3
7. Palpitaciones o taquicardia	0	1	2	3
8. Sensación de inestabilidad	0	1	2	3
9. Sensación de estar aterrorizado	0	1	2	3
10. Nerviosismo	0	1	2	3
11. Sensación de ahogo	0	1	2	3
12. Temblor de manos	0	1	2	3
13. Temblor generalizado	0	1	2	3
14. Miedo a perder el control	0	1	2	3
15. Dificultad para respirar	0	1	2	3
16. Miedo a morir	0	1	2	3
17. Estar asustado	0	1	2	3
18. Indigestión o molestia abdominal	0	1	2	3
19. Sensación de desmayarse	0	1	2	3
20. Rubor facial	0	1	2	3
21. Sudoración (no debida al calor)	0	1	2	3

Inventario de Estrés y Pérdida (IEP)

(Adaptado de Prigerson et al., 1995)

Nombre: **Fecha:**

Por favor, marca con una cruz la respuesta que mejor describa cómo te sientes **en este momento** con respecto a la pérdida de la persona (p.ej., una pareja) o de la situación (p.ej., un trabajo, la salud) como resultado del acontecimiento estresante que te ha sucedido.

	Nunca	Raramente	A veces	A menudo	Siempre
1. Pienso tanto en esa persona/situación que me resulta difícil hacer las cosas que normalmente hago.	0	1	2	3	4
2. Los recuerdos sobre la persona/ situación me producen malestar.	0	1	2	3	4
3. Siento que no puedo aceptar la pérdida de esa persona/situación.	0	1	2	3	4
4. Siento mucha nostalgia por la persona/ situación que he perdido.	0	1	2	3	4
5. Me siento atraído por lugares y cosas asociadas a la persona/situación.	0	1	2	3	4
6. No puedo evitar sentirme enfadado/a sobre la pérdida de esa persona/ situación.	0	1	2	3	4
7. Siento incredulidad acerca de lo que ocurrió.	0	1	2	3	4
8. Me siento aturdido respecto a lo que ocurrió.	0	1	2	3	4
9. Desde que perdí a esa persona/ situación me resulta difícil confiar en los demás.	0	1	2	3	4
10. Desde que perdí a esa persona/ situación, siento como si ya no me importase nadie más o como si me sintiera distante de aquellos que me importan.	0	1	2	3	4
11. Siento dolores u otros síntomas que me producen malestar desde que se produjo la pérdida.	0	1	2	3	4
12. Abandono ciertas situaciones para evitar las cosas que me recuerdan a la persona/ situación.	0	1	2	3	4
13. Siento que la vida está vacía sin esa persona/situación.	0	1	2	3	4
14. Siento que es injusto que yo viva después de sufrir esta pérdida.	0	1	2	3	4
15. Siento amargura respecto a la pérdida de la persona/situación.	0	1	2	3	4
16. Siento envidia de otras personas que no han sufrido una pérdida.	0	1	2	3	4
17. Me siento solo/a gran parte del tiempo desde que perdí a esa persona/situación.	0	1	2	3	4

Inventario de Crecimiento Postraumático (PTGI)

(Tedeschi y Calhoun, 1996)

Nombre: **Fecha:**

A veces las crisis personales suponen cambios importantes en la propia vida. Por favor, indica para cada una de las cuestiones señaladas más abajo **si el cambio descrito se ha producido en tu vida**. No hay respuestas correctas ni incorrectas. No olvides completar todas las cuestiones. Para responder a cada cuestión debe utilizar la siguiente escala y rodear el número que se ajuste mejor a tu caso:

0	No experimenté este cambio como resultado de la crisis.
1	Experimenté este cambio en una medida muy pequeña como resultado de la crisis.
2	Experimenté este cambio en una medida pequeña como resultado de la crisis.
3	Experimenté este cambio en un grado medio como resultado de la crisis.
4	Experimenté este cambio en una gran medida como resultado de la crisis.
5	Experimenté este cambio en medida muy grande como resultado de la crisis.

	Sin cambio	Muy Pequeño	Pequeño	Medio	Grande	Muy grande
1. He cambiado mis prioridades sobre lo que es importante en la vida.	0	1	2	3	4	5
2. Aprecio más el valor de mi propia vida	0	1	2	3	4	5
3. He desarrollado nuevos intereses	0	1	2	3	4	5
4. Tengo un sentimiento más fuerte de confianza en mí mismo	0	1	2	3	4	5
5. Tengo una mejor comprensión de algunas cuestiones espirituales	0	1	2	3	4	5
6. Veo de manera más clara que puedo contar con la gente en momentos de crisis	0	1	2	3	4	5
7. He establecido un nuevo rumbo en mi vida	0	1	2	3	4	5
8. Tengo una mayor sensación de cercanía hacia los demás	0	1	2	3	4	5
9. Estoy más dispuesto a expresar mis sentimientos	0	1	2	3	4	5
10. Ahora sé mejor que puedo enfrentarme a los problemas	0	1	2	3	4	5
11. Creo que puedo hacer cosas mejores con mi vida	0	1	2	3	4	5
12. Puedo aceptar mejor las cosas tal como vienen	0	1	2	3	4	5
13. Puedo valorar mejor el día a día	0	1	2	3	4	5
14. Han aparecido nuevas oportunidades que, de no haber pasado esto, no habrían sucedido.	0	1	2	3	4	5
15. Tengo más sentimientos de compasión hacia los demás	0	1	2	3	4	5
16. Pongo más energía en mis relaciones personales	0	1	2	3	4	5
17. Ahora intento más cambiar aquellas cosas que deben de cambiarse	0	1	2	3	4	5
18. Tengo una fe religiosa más fuerte	0	1	2	3	4	5
19. Descubrí que era más fuerte de lo que en realidad pensaba	0	1	2	3	4	5
20. Aprendí mucho sobre lo extraordinaria que llega a ser la gente	0	1	2	3	4	5
21. Acepto mejor que necesito a los demás	0	1	2	3	4	5

Escala de afecto positivo y negativo (PANAS)

(Watson, Clark y Tellegen, 1988; LabPsiTec 2010)

Nombre: **Fecha:**

A continuación se indican una serie de palabras que describen sentimientos y emociones. Lee cada una de ellas y contesta hasta qué punto sueles sentirse **habitualmente** de la forma que indica cada expresión.

Generalmente me siento…	Nada o casi nada	Un poco	Bastante	Mucho	Muchísimo
1. Interesado/a por las cosas	1	2	3	4	5
2. Estresado/, tenso/a	1	2	3	4	5
3. Emocionado/a, ilusionado/a	1	2	3	4	5
4. Disgustado/a, molesto/a	1	2	3	4	5
5. Con energía, con vitalidad	1	2	3	4	5
6. Culpable	1	2	3	4	5
7. Asustado/a	1	2	3	4	5
8. Hostil	1	2	3	4	5
9. Entusiasmado/a	1	2	3	4	5
10. Orgulloso/a (de algo), satisfecho/a conmigo mismo/a	1	2	3	4	5
11. Irritable, malhumorado/a	1	2	3	4	5
12. Despejado/a, despierto/a	1	2	3	4	5
13. Avergonzado/a	1	2	3	4	5
14. Inspirado/a	1	2	3	4	5
15. Nervioso/a	1	2	3	4	5
16. Decidido/a	1	2	3	4	5
17. Atento/a (a las cosas), concentrado/a	1	2	3	4	5
18. Intranquilo/a, inquieto/a	1	2	3	4	5
19. Activo/a	1	2	3	4	5
20. Con miedo, miedoso/a	1	2	3	4	5

COMPRUEBA SI HAS CONTESTADO A TODAS LAS FRASES CON UNA SOLA RESPUESTA

Afecto Positivo =

Afecto Negativo =

Índice de calidad de vida (QLI)

(Mezzich, Cohen y Ruipérez, 2011)

Nombre: **Fecha:**

Por favor, indica cuál es tu nivel de salud y calidad de vida en la actualidad en las escalas siguientes.

1. **Bienestar físico** (sentirse con energía, sin dolores ni problemas físicos).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

2. **Bienestar psicológico/emocional** (sentirse bien y satisfecho consigo mismo).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

3. **Autocuidado y funcionamiento independiente** (cuida bien de su persona, toma sus propias decisiones).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

4. **Funcionamiento ocupacional** (capaz de realizar trabajo remunerado, tareas escolares, y tareas domésticas).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

5. **Funcionamiento interpersonal** (capaz de responder y relacionarse bien con su familia, amigos y grupos).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

CONTINÚA EN LA PÁGINA SIGUIENTE

6. **Apoyo social-emocional** (disponibilidad de personas en quien puede confiar y de personas que le proporcionen ayuda y apoyo emocional).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

7. **Apoyo comunitario y de servicios** (buen vecindario, disponibilidad de recursos financieros y de otros servicios).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

8. **Plenitud personal** (sentido de equilibrio personal, de autogobierno, de solidaridad, y de disfrute sexual y estético).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

9. **Plenitud espiritual** (experimentar una elevada filosofía de vida, religiosidad y trascendencia más allá de una vida).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

10. **Percepción global de Calidad de vida** (sentirse satisfecho y feliz con su vida en general).

1	2	3	4	5	6	7	8	9	10
Malo			Regular			Bueno			Excelente

Escala de Expectativas sobre el Tratamiento

(Adaptado de Nau y Borkovec, 1972)

Nombre: **Fecha:**

Después de haber explicado en qué va a consistir el tratamiento que va a recibir, nos gustaría saber tu opinión sobre el mismo. Por favor, contesta a las siguientes preguntas.

1. ¿En qué medida te parece **lógico** este tratamiento?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

2. ¿En qué medida te **satisface** el tratamiento que vas a recibir?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

3. ¿En qué medida le **recomendarías** este tratamiento a un amigo que tuviera tu mismo problema?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

4. ¿En qué medida crees que este tratamiento podría ser **útil para tratar otros problemas** psicológicos?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

5. ¿En qué medida crees que el tratamiento va a resultar **útil en tu caso**?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

6. ¿En qué medida este tratamiento te resulta **aversivo**?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

Escala de Opinión sobre el Tratamiento

(Adaptado de Nau y Borkovec, 1972)

Nombre: **Fecha:**

Después de haber recibido el tratamiento, nos gustaría saber tu opinión sobre el mismo. Por favor, contesta a las siguientes preguntas.

1. ¿En qué medida te ha parecido **lógico** este tratamiento?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

2. ¿En qué medida te ha **satisfecho** el tratamiento que has recibido?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

3. ¿En qué medida le **recomendarías** este tratamiento a un amigo que tuviera tu mismo problema?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

4. ¿En qué medida crees que este tratamiento podría ser **útil para tratar otros problemas** psicológicos?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

5. ¿En qué medida crees que el tratamiento te ha resultado **útil en tu caso**?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

6. ¿En qué medida este tratamiento te ha resultado **aversivo**?

1	2	3	4	5	6	7	8	9	10
Nada									Muchísimo

Nombre: **Fecha:**

Condición:

Escala de Opinión sobre el Programa

1. ¿En qué medida consideras que el programa TAO ha sido una herramienta **útil** para ti?

0	1	2	3	4	5	6	7	8	9	10
Nada		**Poco**		**Algo**		**Bastante**		**Mucho**		**Muchísmo**

¿Por qué?

2. ¿En qué medida TAO te parece una forma **atractiva** de recibir ayuda psicológica?

0	1	2	3	4	5	6	7	8	9	10
Nada		**Poco**		**Algo**		**Bastante**		**Mucho**		**Muchísmo**

¿Por qué?

3. ¿En qué medida TAO te parece una forma **cómoda** de recibir ayuda psicológica?

0	1	2	3	4	5	6	7	8	9	10
Nada		**Poco**		**Algo**		**Bastante**		**Mucho**		**Muchísmo**

¿Por qué?

4. ¿En qué medida **recomendarías** TAO a un amigo o familiar que esté sufriendo un problema psicológico parecido al tuyo?

0	1	2	3	4	5	6	7	8	9	10
Nada		**Poco**		**Algo**		**Bastante**		**Mucho**		**Muchísmo**

¿Por qué?

5. ¿Cuál ha sido el **módulo** que te ha parecido más **útil**?

6. ¿Qué es lo que más te ha gustado del programa de auto-ayuda? ¿Qué destacarías?

7. ¿Qué es lo que menos te ha gustado del programa?

8. Opinión general sobre el programa de intervención recibido a través de Internet y aspectos a mejorar.

Escala de Opinión sobre la Guía y Apoyo Concedido

1. ¿En qué medida te ha **gustado** recibir una breve llamada telefónica (máximo diez minutos) de apoyo semanal por parte de un terapeuta?

0	1	2	3	4	5	6	7	8	9	10
Nada		**Poco**		**Algo**		**Bastante**		**Mucho**		**Muchísmo**

¿Por qué?

2. ¿En qué medida consideras que te ha **ayudado** recibir esa breve llamada telefónica de apoyo semanal?

0	1	2	3	4	5	6	7	8	9	10
Nada		**Poco**		**Algo**		**Bastante**		**Mucho**		**Muchísmo**

¿Por qué?

Cumplimentar por el terapeuta

ESCALA DE VALORACIÓN DEL CLÍNICO

(Adaptación de la Clinician´s ratings del ADIS-IV, Di Nardo, Brown y Barlow, 1994)

Nombre ..... Código/DNI .....

Edad ..... Fecha de nacimiento ..... Género ❑ Mujer ❑ Hombre

Entrevistador ..... Condición ..... Número sesiones .....

Diagnóstico ..... Fecha .....

Teniendo en cuenta la información recabada en la evaluación, evaluaría la gravedad de este paciente como:

0	1	2	3	4	5	6	7	8
Ausente: ninguna sintomatología		**Leve**: ligeramente perturbadora/no realmente incapacitante		**Moderada**: sintomatología definitivamente perturbadora/incapacitante		**Grave**: sintomatología marcadamente perturbadora/incapacitante		**Muy grave**: sintomatología muy gravemente perturbadora/incapacitante

***Nota importante:** Para valorar esto es importante que el terapeuta tenga información sobre diagnóstico multiaxial, anamnesis y entrevista biográfica. Por lo tanto, la valoración de la gravedad del paciente se hará transcurridas unas cuantas sesiones y habiendo recabado información suficiente.

Referencia:

Di Nardo, P.A., Brown, T.A., & Barlow, D.H. (1994). *Anxiety disorders interview schedule for DSM-IV: Lifetime version (ADIS-IV-L)*. New York: Graywind Publications.

Evaluación post-módulo

Protocolo de evaluación post-módulo TAO

1) Estado de ánimo:

Marca la cara que mejor refleje cómo te sientes en este momento.

1 2 3 4 5 6 7

A continuación encontrarás una serie de palabras que expresan una emoción. Indica en qué medida sientes cada una de estas emociones EN ESTE MOMENTO, teniendo en cuenta la siguiente escala:

1	2	3	4	5	6	7
Nada en absoluto	Muy poco	Poco	Algo	Bastante	Mucho	Totalmente

Alegría	1	2	3	4	5	6	7
Tristeza	1	2	3	4	5	6	7
Enfado/ Rabia	1	2	3	4	5	6	7
Esperanza	1	2	3	4	5	6	7
Ansiedad	1	2	3	4	5	6	7
Relajación/ Tranquilidad	1	2	3	4	5	6	7
Orgullo	1	2	3	4	5	6	7
Culpabilidad	1	2	3	4	5	6	7

En comparación a cómo te sentías antes de empezar este módulo, ¿Cómo te encuentras AHORA?

Mucho peor	Peor	Algo peor	Igual	Algo mejor	Mejor	Mucho mejor

Durante la última semana, ¿Con qué frecuencia has tenido pensamientos sobre suicidio?

0: Nada. No he tenido pensamientos de suicidio.

1: Infrecuente. En alguna ocasión he tenido pensamientos de suicidio, pero de forma esporádica.

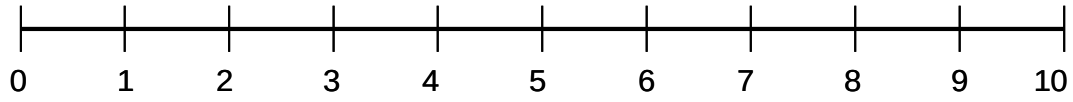
2: Ocasional. Algunas veces he tenido pensamientos de suicidio.

3: Frecuente. En muchas ocasiones he tenido pensamientos de suicidio.

4: Todo el tiempo. Casi la mayor parte del tiempo he tenido pensamientos de suicidio.

2) Autoeficacia:

Señala el número que mejor describa en qué medida en este momento te sientes CAPAZ de afrontar con EFICACIA el problema que has sufrido. Siendo 0 "no me siento capaz en absoluto" y 10 "me siento totalmente capaz".



No me siento capaz en absoluto.

Me siento totalmente capaz.

Si comparas tu capacidad de hacer frente con EFICACIA al problema que has sufrido antes y después de completado este módulo, ¿Cómo te sientes AHORA?

Mucho menos capaz	Menos capaz	Algo menos capaz	Igual capacidad	Algo más capaz	Más capaz	Mucho más capaz

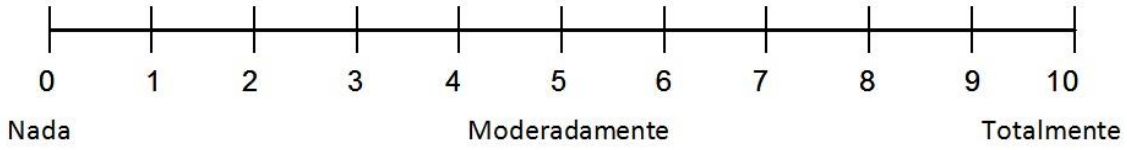
3) Aceptación:

¿En qué medida crees en este momento que estás aceptando los "acontecimientos negativos"?

Nada Moderadamente Totalmente

4) Apertura:

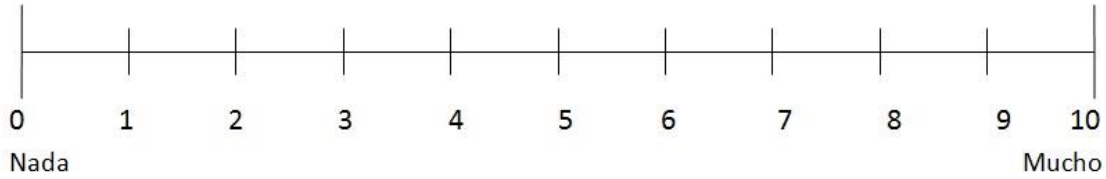
En estos momentos, ¿en qué medida estás abierto/a a nuevas experiencias que te puede deparar el futuro?



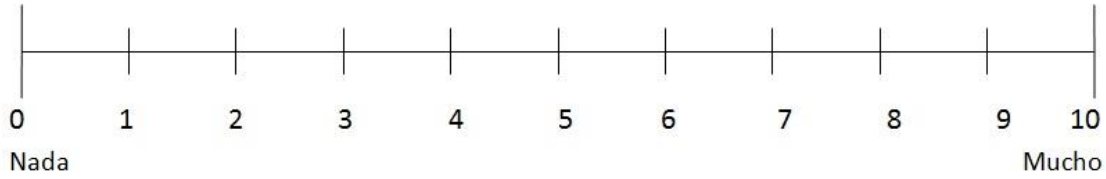
5) Satisfacción:

Evalúa en una escala de 0 a 10 cada una de las preguntas que se muestran a continuación. Siendo 0 nada y 10 mucho.

¿En qué medida te ha gustado este módulo?



¿En qué medida crees que este módulo te ha sido útil o beneficioso?



Annexes:

TAO user manual

MANUAL DE USO DE

PSICOLOGÍA Y TECNOLOGÍA

Contenidos del manual.

1.- El acceso al tratamiento online.

- **Crear un usuario.**

Una vez que estés dado de alta en el Programa, recibirás un correo con tu enlace.

Al acceder al enlace, se te pedirá que generes una contraseña. La contraseña deberá tener un mínimo de 8 caracteres. Recuerda que es privada, no se la des a nadie. Nosotros nunca te la pediremos

En esta misma pantalla verás tu usuario (ejemplo: LoginXXX).

Podrás acceder al programa desde la página principal de Psicología y Tecnología (*http://www.psicologiaytecnologia.com*).

- **Navegar por el programa.**

El manejo del programa es idéntico al de la mayoría de las páginas Web. No tienes que preocuparte por nada más que leer con atención todo lo que el protocolo te va a ir mostrando y guiando acerca de lo que hay que hacer. En cada página te indicará las acciones que puedes llevar a cabo y te mostrará claramente cómo hacerlo.

Desde el ordenador de tu casa podrás acceder sin problemas al protocolo de tratamiento que te ha sido asignado mediante los principales navegadores de Internet. El programa está adaptado para funcionar con cualquier navegador, aunque los más recomendados son Google Chrome, Mozilla Firefox o Microsoft Explorer.

Si no puedes acceder o visualizar correctamente los diferentes contenidos del programa, te recomendamos que cambies el navegador. Si el problema persiste, ponte en contacto con nosotros (tao@uji.es) y te ayudaremos a resolverlo.

2.- ¿Qué vas a encontrar en el protocolo de tratamiento?

- **La estructura del programa.**

La primera vez que accedas al programa con tu usuario y contraseña, se te presentará un módulo de bienvenida. En este módulo de bienvenida se te explicará en qué consiste una intervención psicológica aplicada a través de Internet y qué puedes hacer para sacarle el máximo provecho.

Al terminar, se te activará automáticamente el siguiente módulo, el módulo de evaluación. El módulo de evaluación se compone de diferentes cuestionarios pensados para obtener información útil acerca del problema específico que puedes tener. Al contestar los cuestionarios recuerda que no existen respuestas correctas ni incorrectas. Simplemente se trata de que en cada pregunta elijas la opción que mejor te describa a ti o la situación que estás viviendo.

Una vez terminada la evaluación inicial, debes esperar por lo menos 24 horas para poder volver a entrar en la Web (*por ejemplo, si la evaluación la terminaste a las 16:43h del lunes, podrás volver a entrar a partir de las 16:43h del martes*). Esto será así en esta única ocasión, a partir de ese momento, podrás entrar en la Web cada vez que lo desees.

Transcurridas las 24 horas de espera, ya podrás acceder al primer módulo de tratamiento.

Cuando transcurran 10 semanas desde el inicio del tratamiento, te pediremos que vuelvas a realizar la misma evaluación. El objetivo de esta evaluación será conocer hasta qué punto te ha ayudado el protocolo de tratamiento. Además, lo que esperamos es que los cambios que realices y los beneficios que obtengas no sean algo pasajero, por eso es muy importante que pasado un tiempo después de acabar el programa realices de nuevo la evaluación. Así que a los 3, 6 y 12 meses después de terminar el programa, recibirás un e-mail que te pedirá que realices las evaluaciones de seguimiento.

- **Módulos del protocolo de tratamiento.**

Los protocolos de tratamiento constan de diferentes módulos y los podrás revisar tantas veces como quieras.

Para facilitar el uso de la plataforma y la comprensión de los distintos contenidos, todos los módulos presentan la misma estructura.

Cada módulo tiene un apartado introductorio en el que se explica qué es lo que vas a aprender.

Después, en el apartado de *Contenidos* se aprenden diferentes técnicas y herramientas psicológicas, que se presentan por medio de textos, viñetas y vídeos.

Al acabar el apartado de contenidos, encontrarás diferentes *ejercicios* o actividades que te ayudarán a reforzar lo que se ha trabajado en el módulo, profundizar en sus contenidos y/o practicar las estrategias aprendidas. Se explicará cómo se realiza cada uno de estos ejercicios y verás cómo lo han hecho otras personas con problemas similares al tuyo.

En el apartado de *Autoevaluación* hay una serie de preguntas que te ayudarán a repasar lo aprendido y ver si te conviene repasar mejor algún apartado.

En el apartado de *Tareas para casa* el programa te indicará qué tareas deberás realizar antes de continuar con el siguiente módulo.

La realización de estos ejercicios y tareas para casa es un aspecto fundamental del protocolo de tratamiento, por lo que nuestro consejo es que los pongas en práctica tantas veces como te sea posible y que los sigas practicando durante todo el tratamiento y también cuando éste acabe. Se trata de valiosas herramientas que te ayudarán a conseguir el cambio.

Antes de empezar un módulo se revisará si has realizado las tareas que se te habían propuesto en el módulo anterior. Estas preguntas de comprobación sólo aparecerán la primera vez que accedas al nuevo módulo.

Por último, encontrarás un resumen que te permitirá repasar lo que has visto en el módulo.

3.- Protocolo de tratamiento para los Trastornos Adaptativos.

El programa de tratamiento para los Trastornos Adaptativos que estás a punto de comenzar consta de 7 módulos. Estos módulos se activarán con frecuencia semanal. Es decir, cada semana tendrás acceso a un nuevo módulo. Este procedimiento se utiliza para evitar que realices todo el tratamiento en un día, pues no te aportará beneficio alguno.

Nuestra recomendación es que realices un módulo por semana. No obstante, es posible que puedas necesitar más tiempo en algunos módulos, por lo que podría resultarte útil dedicarle dos semanas a aquellos que consideres necesario.

Intenta reservar algún momento cada semana para entrar con tranquilidad y comprender todo lo que te presenta el programa. Es importante entrar al menos una vez a la semana.

4.- Cuestiones importantes.

Te recomendamos que te impliques a fondo en el programa, que no seas un espectador pasivo. Recuerda, para adquirir las nuevas habilidades es necesario que practiques todo lo que puedas.

Podrás ver y repetir tantas veces como quieras los contenidos de los módulos. Asegúrate de comprender bien lo que te explican. Es muy importante para poder beneficiarte del programa.

Otro aspecto importante es que avances a tu propio ritmo y que planifiques tu uso del protocolo de tratamiento.

No quieras correr antes que andar. Recuerda que para que las estrategias que te propone este programa de tratamiento se conviertan en habilidades es muy importante que vayas realizando las tareas y practiques mucho. No ganarás nada por ver y hacer todo el programa en un fin de semana. Sé paciente y asegúrate de realizar las actividades que se te propongan en cada módulo antes de pasar al siguiente.

Recuerda que tienes un correo de contacto por si encuentras problemas con alguna parte de la web: tao@uji.es.

5. - Preguntas frecuentes

- ✓ **No he recibido el correo electrónico de confirmación, ni los datos para entrar en la Web del Protocolo de Tratamiento online.**

Una vez registrado/a, recibirás un correo electrónico en el que se te indicarán los pasos a seguir para poder acceder a la Web.

En caso de no recibirlo, por favor, revisa la carpeta "Spam" de tu correo electrónico y/o ponte en contacto con tao@uji.es para indicarnos que no lo has recibido.

- ✓ **No puedo registrarme en la Web y solicitar mi contraseña.**

La Web funciona correctamente a través de los principales navegadores (*Mozilla-Firefox, Explorer, Google Chrome*). Sin embargo, es muy importante acceder a la Web a través de un PC u ordenador portátil y no a través de los navegadores de los teléfonos móviles o tabletas, ya que en estos dispositivos el sistema podría no funcionar correctamente.

- ✓ **No puedo entrar en la Web de Psicología y Tecnología.**

- Asegúrate de introducir tu nombre de usuario correctamente (*por ejemplo: "LoginXXX"*).
- Asegúrate de introducir tu contraseña correctamente.
- Asegúrate de presionar el botón "Entrar" y no el botón "Registrarse".

- ✓ **Al entrar en la Web, me pide registrarme nuevamente.**

- Asegúrate de que te encuentras en la página principal de acceso (https://www.psicologiaytecnologia.com) y no en la Web de registro.
- Asegúrate de que después de poner tu usuario y contraseña has seleccionado el botón "Entrar" y no el botón "Registrarse".

- ✓ **No recuerdo mi contraseña o me dice que no estoy introduciendo la contraseña correcta.**

Puedes generar una nueva contraseña a través del botón "Recordar Contraseña" de la Web de Psicología y Tecnología. Se te enviará por correo electrónico el link para restablecer tu contraseña.

Pasos a seguir para generar una nueva contraseña:

Por favor, realiza los siguientes pasos:

1. Ve a la página principal del sistema www.psicologiaytecnologia.com

2. Haz clic donde dice "Recordar contraseña".

3. Introduce el email con el que te has dado de alta en el sistema.

4. Recibirás un email con un enlace. Al pinchar en él podrás ingresar una nueva contraseña.

(Debes ingresar a cambiar la contraseña dentro de las siguientes 48 horas de haber recibido el email. Si no puedes ingresar en ese tiempo, debes volver a realizar estos pasos).

Por favor, si continuas con la dificultad, avísanos enviándonos un email a tao@uji.es.

- ✓ **He terminado la evaluación inicial, pero no puedo entrar en la Web del Protocolo de tratamiento.**

Recuerda que una vez terminada la evaluación inicial, debes esperar por lo menos 24 horas para poder volver entrar en la Web (*por ejemplo, si la evaluación la terminaste a las 16:43h del lunes, podrás volver a entrar a partir de las 16:43h del martes*). Esto será así en esta única ocasión, a partir de ese momento, podrás entrar en la Web cada vez que lo desees.

- ✓ **No puedo visualizar los videos o éstos se cortan.**

Es posible que tu navegador no tenga los plugins o códecs necesarios. No te preocupes, para poder visualizar los videos, descarga el software que la misma Web te recomienda instalar para poder visualizarlos.

La señal de Internet también influye en el buen funcionamiento del programa. Si durante la reproducción el vídeo se interrumpe constantemente, páralo y deja que se cargue antes de volver a reproducirlo.

- ✓ **No tengo muy claro cómo usar la Web de Psicología y Tecnología.**

- Lee las instrucciones que se te presentan en cada uno de los módulos y los videos de ejemplo.
- Envía tus dudas por correo electrónico a: tao@uji.es

- ✓ **No tengo muy claro lo que tengo que hacer en los ejercicios.**

En la Web encontrarás diferentes videos de ayuda que te explicarán lo que tienes que hacer en cada uno de los ejercicios. Así mismo, encontrarás diversos ejemplos de cómo realizarlos.

- ✓ **No tengo impresora para imprimir los ejercicios**

No te preocupes, puedes hacer los ejercicios en un folio, libreta o cuaderno siguiendo el modelo de los PDF.

- ✓ **He dejado unos minutos sin utilizar la Web de Psicología y Tecnología y luego no puedo seguir trabajando.**

No te preocupes, esto es totalmente normal, ya que cuando la Web detecta que ha pasado un tiempo sin que haya actividad, por seguridad y confidencialidad, se cierra. Solo tienes que volver a entrar con tu usuario y contraseña.