FACULTAD DE CIENCIAS DE LA SALUD
DEPARTAMENTO DE PSICOLOGÍA BÁSICA, CLÍNICA Y PSICOBIOLOGÍA

LA EFICACIA DE UN TRATAMIENTO COMPUTARIZADO APLICADO A TRAVÉS DE INTERNET PARA EL TRATAMIENTO DE LA FOBIA A VOLAR: UN ESTUDIO CONTROLADO

EFFICACY OF A COMPUTERIZED TREATMENT DELIVERED VIA THE INTERNET FOR FLYING PHOBIA: A RANDOMIZED CONTROL TRIAL

TESIS DOCTORAL

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A mis padres
A Paola

Los locos abren caminos que
después recorren los sabios
(Carlos Dossi)

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(Jorge Drexler, Bailar en la cueva)

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Presentación

La presente tesis doctoral adquiere un formato por compendio de publicaciones, incluyendo artículos indexados en reconocidas revistas de impacto y publicaciones científicas internacionales. En el momento de la redacción de esta tesis dos artículos estaban publicados y otros dos trabajos habían sido enviados a revistas de relevancia científica para su revisión y posterior aceptación. La tesis doctoral que se presenta se compone de cuatro capítulos que recoge cada uno de los artículos mencionados (Table 1). Aunque todos los capítulos están orientados al objetivo principal, cada uno de ellos cuenta con entidad propia, pudiendo ser leídos de manera independiente. Los coautores han manifestado su aceptación para que el doctorando presente el trabajo como tesis, así como su renuncia expresa de presentarlo como parte de otra tesis doctoral.

De acuerdo con la normativa de estudios de doctorado regulados por el RD 99/2011 (que modifica el Real Decreto 1393/2007 de 29 de Octubre al que se inscribe la presente tesis doctoral) en la Universitat Jaume I, para las modalidades de Doctorado con mención Internacional y Doctorado por compendio de publicaciones, los artículos científicos que dan cuerpo a esta tesis han sido redactados en lengua inglesa siendo el idioma habitual de comunicación científica. Han sido incluidos en castellano el resumen, la introducción, los objetivos, hipótesis, y la discusión general de la tesis, siguiendo dicha normativa.

Table 1. Doctoral dissertation as a compendium of publications

Chapter	Article
1	Quero, S., Campos, D., Riera del Amo, A., Bretón-López, J., Tortella-Feliu, M., Baños, R., & Botella, C. (2015). NO-FEAR Airlines: A Computer-aided Self-help Treatment for Flying Phobia. *Annual Review of CyberTherapy and Telemedicine*, *13*, 197-201. ISSN: 1554-8716.
2	Campos, D., Bretón-López, J., Botella, C., Mira, A., Castilla, D., Baños, R.M., Tortella-Feliu, M. & Quero, S. (2016). An Internet-based treatment for flying phobia (NO-FEAR Airlines): study protocol for a randomized controlled trial. *BMC Psychiatry, 16*:296. doi: 10.1186/s12888-016-0996-1.
3	Campos, D., Bretón-López, J., Botella, C., Mira, A., Castilla, D., Baños, R., Tortella-Feliu, M., & Quero, S. Efficacy of an Internet-based Exposure treatment for Flying Phobia (*NO-FEAR Airlines*) with and without therapist guidance: A randomized controlled trial. Submitted.
4	Campos, D., Mira, A., Bretón-López, J., Castilla, D., Botella, C., Baños, R., & Quero, S. The acceptability of an Internet-based Exposure Treatment for Flying Phobia with and without therapist guidance: Patients' Expectations, Satisfaction, Treatment Preferences and Usability. Submitted.

Resumen

Las Tecnologías de la Información y la Comunicación (TICs) se presentan como herramientas útiles a la hora de combatir algunas limitaciones con las que cuentan los tratamientos basados en la evidencia: problemas de aceptación y acceso al tratamiento. El uso de tratamientos computarizados ofrece una serie de ventajas entre las que destacamos la mejora de la aceptación por parte de los pacientes al proporcionar tratamientos más atractivos y menos aversivos. Además, Internet facilita el acceso a los tratamientos basados en la evidencia, llegando a más personas que los necesitan, con una menor implicación del clínico. En el caso concreto de la fobia a volar (FV), la investigación ha demostrado la utilidad de los tratamientos asistidos por ordenador como una alternativa a los tratamientos de exposición in vivo, asociados a mayores costes y niveles de aversión. Sin embargo, hasta la fecha, no se ha publicado ningún estudio controlado que investigue la eficacia y aceptación de un tratamiento computarizado auto-aplicado a través de Internet para la FV. El objetivo general de esta tesis doctoral es investigar la eficacia y aceptación de *SIN MIEDO Airlines*, un tratamiento de exposición asistido por ordenador auto-aplicado a través de Internet para el tratamiento de la FV, en un estudio controlado aleatorizado (ECA). La presente tesis doctoral está formada por un compendio de publicaciones que abarca principalmente cuatro capítulos específicos. Cada capítulo está formado por un artículo científico con el objetivo de recoger los siguientes puntos, respectivamente: 1) Presentando *SIN MIEDO Airlines*; 2) Protocolo del estudio; 3) Eficacia de *SIN MIEDO Airlines*; 4) Aceptación de *SIN MIEDO Airlines*. Los resultados de la tesis doctoral avalan la eficacia de *SIN MIEDO Airlines* (con y sin apoyo terapéutico) frente a un grupo control de lista de espera. El tratamiento *online* obtuvo una buena aceptación de los pacientes por lo que se refiere a expectativas, satisfacción, opinión y usabilidad con el programa, independientemente de si se proporcionaba o no apoyo del terapeuta. No obstante, los participantes en general prefirieron la condición con apoyo. En conclusión, *SIN MIEDO Airlines* ha demostrado ser una herramienta eficaz para el tratamiento de la FV, ayudando a mejorar la técnica de exposición en términos de aceptación y acceso al tratamiento.

Abstract

Information and Communication Technologies (ICTs) are shown as useful tools to overcome the barriers in the implementation of evidence-based treatments: acceptance issues and barriers to access the treatment. Computerized treatments offer remarkable advantages such as better acceptance by patients since they provide engaging and less aversive treatments. Moreover, Internet enhances access to the treatment, reaching more people in need and saving clinicians' time. Specifically for Flying phobia (FP), some studies point out the usefulness of computer-assisted exposure programs as an alternative to in vivo exposure that is related to higher costs and aversiveness levels. Nevertheless, as far as we know, no randomized controlled trial has been published to investigate the efficacy and acceptability of an Internet-based treatment for FP. The main purpose of this doctoral dissertation is to assess the effectiveness and patients' acceptance of *NO-FEAR Airlines* – an internet-based treatment for FP – in an RCT. The present dissertation as compendium of publications is mainly composed of four chapters that comprise a scientific article as follows: 1) Introducing *NO-FEAR Airlines*; 2) Study protocol: A randomized controlled trial; 3) The effectiveness of *NO-FEAR Airlines*; 4) The acceptability of *NO-FEAR Airlines*. Results showed the efficacy of *NO-FEAR Airlines* (with and without therapist guidance) compared to a waiting list control group. The online program was well-accepted by the participants in terms of expectations, satisfaction, opinion, and usability regardless of whether therapist guidance was provided. However, participants overall preferred the therapist-guided condition. In conclusion, *NO-FEAR Airlines* has proven to be an effective tool for FP treatment and can help to enhance the exposure technique, improving patients' acceptance and access to the treatment.

Introducción general

En la actualidad existen tratamientos psicológicos basados en la evidencia para una gran variedad de trastornos mentales (APA, 2005; NICE, 2009). Dichos tratamientos se recogen en manuales y guías sobre buenas prácticas clínicas, estableciéndose como tratamientos de elección (p.ej., Nathan, y Gorman, 2015). No obstante, a pesar de estos avances, los tratamientos basados en la evidencia no siempre llegan a las personas que los necesitan y/o presentan limitaciones en su aceptación (Harvey, y Gumport, 2015; Kazdin 2014; Kazdin, y Rabbitt, 2013). Autores como Kazdin (2015) plantean la necesidad de establecer nuevos modelos de intervención que impliquen nuevas maneras de proporcionar tratamiento en el ámbito de la salud mental.

En este contexto las Tecnologías de la Información y la Comunicación (TICs) surgen como herramientas útiles a la hora de combatir dichas limitaciones. En concreto, los tratamientos computarizados se han establecido como una forma eficaz de proporcionar terapia cognitivo-conductual (TCC) (Adelman, Panza, Bartley, Bontempo, y Bloch, 2014). La TCC computarizada (TCCc) puede definirse como psicoterapia de enfoque cognitivo-conductual que emplea programas de ordenador para administrar una parte significativa del contenido terapéutico, o bien utiliza programas de ordenador para apoyar el trabajo del terapeuta (Wright, Beck, y Thase, 2008; Wright, 2004). En este sentido, la TCCc incluiría el uso de distintas tecnologías como son los programas multimedia asistidos por ordenador, la realidad virtual o los dispositivos móviles (Spurgeon, y Wright, 2010). Muchos autores han defendido la utilidad de estas estrategias de intervención, culminando en el reconocimiento del movimiento *Improving Access to Psychological Therapies Programme* (IAPT) (Clark, 2009; Layard et al., 2007), logrando además, su inclusión como alternativa para la aplicación de los tratamientos psicológicos basados en la evidencia en las recomendaciones de las Guías Clínicas elaboradas por *The National Institute of Clinical Excellence* (*NICE Guidelines,* www.nice.org.uk/guidance).

En el caso particular de las fobias específicas (FE), la TCCc se propone como una forma de mejorar la técnica de exposición *in vivo*. La exposición *in vivo*, es el tratamiento de elección para el abordaje de las FE. Sin embargo, también ha

sido relacionada con una serie de barreras en su implementación, entorpeciendo y limitando su aplicación. Estas limitaciones tienen que ver con la aceptación y acceso al tratamiento, mencionadas anteriormente. La investigación señala que afrontar las situaciones temidas *in vivo*, genera un alto nivel de aversión en los pacientes, hecho que se traduce en un alto porcentaje de pacientes que abandonan el tratamiento o rechazan empezarlo cuando se les informa del procedimiento a seguir (García-Palacios, Botella, Hoffman, y Fabregat, 2007; García-Palacios, Hoffman, Kwong, Tsai, y Botella, 2001). Esta característica puede ser una de las explicaciones por la que los clínicos se muestren reacios a utilizar dicha técnica, considerándola una "cura cruel y éticamente inapropiada" (p.ej., Deacon, y Farrell, 2013; Olatunji, Deacon, y Abramowitz, 2009). Respecto al acceso al tratamiento, hay una serie de limitaciones derivadas de las características de las FE que, sumadas a las propias barreras de acceso de la TCC, hacen que sea especialmente relevante dedicar esfuerzos orientados a este fin. Estas limitaciones son principalmente: 1) la mayoría de las personas que padecen una fobia nunca buscan tratamiento (solo el 7,8% lo hace), generalmente porque se sienten avergonzadas o no saben que existen formas eficaces de tratarlas; 2) de éstas, pocas reciben un tratamiento adecuado (alrededor del 8%); 3) existe una marcada dificultad o restricción de acceso al estímulo temido; 4) dificultad para controlar variables importantes en la exposición (p.ej., duración de las sesiones, moduladores, jerarquía de exposición, etc.); 5) violación del anonimato al hacer la sesión fuera de consulta; 6) costes adicionales derivados de la exposición *in vivo* (p.ej., viajes en tren, aviones, autobús, etc.) (Boyd, 1990; Mackenzie, Reynolds, Cairney, Streiner, y Sareen, 2011; Rothbaum, Hodges, Smith, Lee, y Price, 2000; Stinson et al., 2007).

Diversos autores han planteado que el uso de las TICs puede ser especialmente importante en el caso del tratamiento de la Fobia a Volar (FV), como una alternativa a las limitaciones previamente comentadas. Los estudios señalan que la FV puede beneficiarse ampliamente de las TICs como son la terapia de exposición con Realidad Virtual (TERV) y los programas de exposición asistidos por ordenador. En este sentido, la TERV ha demostrado ser eficaz y bien valorada por los pacientes en el tratamiento de la FV (p.ej., Botella, Osma, García-Palacios, Quero, y Baños, 2004; Cárdenas et al., 2016, Mühlberger, 2003; Rothbaum et al., 2006). Por otra parte, los programas de exposición asistidos por ordenador se presentan como una opción más sencilla y

económica que la TERV obteniendo resultados similares en el tratamiento de la FV (Tortella-Feliu, Bornas, y Llabrés, 2008; Tortella-Feliu et al., 2011). Este hecho implica un menor coste tanto en su desarrollo como en su aplicación. Además, los autores plantean que dichos programas computarizados pueden ser auto-aplicados por el propio paciente en consulta reduciéndose en gran medida la implicación del terapeuta a lo largo de las sesiones de exposición y, en consecuencia, en el proceso terapéutico (Tortella-Feliu et al., 2011).

En este punto cabe remarcar el potencial que presenta el uso de Internet. Dada la eficacia de los programas de exposición auto-administrados a través del ordenador, Internet supone un novedoso modo de hacer llegar estos tratamientos eficaces a las personas que necesitan ayuda, sin necesidad de desplazarse. Por lo tanto, las ventajas que presenta la TCCc pueden verse potenciadas por el uso añadido de Internet, mejorando el acceso al tratamiento. Hasta la fecha Internet ha demostrado ser una forma eficaz y eficiente de proporcionar tratamiento para una gran variedad de trastornos psicológicos (Andersson, 2016; Peñate, y Fumero, 2016). Los autores plantean que los tratamientos auto-aplicados a través de Internet constituyen una serie de ventajas a distintos niveles como son: mayor accesibilidad, versatilidad, seguridad, aceptación, anonimato, coste-efectividad y conveniencia (Andersson y Titov, 2014; Andrews, Newby, y Williams, 2015; Peñate, 2012).

A pesar de las ventajas que presenta Internet para administrar programas de tratamiento psicológico, poco se ha estudiado en el campo de las FE. La literatura revisada muestra únicamente dos estudios controlados aleatorizados (ECA) dirigidos al tratamiento de FE: uno en fobia a las arañas (Andersson et al., 2009) y otro en fobia a las serpientes (Anderson et al., 2013). Aunque existen otros estudios de intervenciones online que incluyen fobias entre los trastornos abordados (p.ej., Kok, van Straten, Beekman, y Cuijpers, 2014; Schneider, Mataix-Cols, Marks, y Bachofen, 2005; Schröder, Jelinek, y Moritz, 2017), solamente los llevados a cabo por Andersson et al. (2009, 2013) se centran exclusivamente en tratar la FE a través de un tratamiento de exposición vía Internet. Por otro lado, la mayoría de los estudios revisados que incluyen la exposición entre sus componentes de tratamiento utilizan Internet como una forma de hacer llegar la intervención a los pacientes, proporcionando guías (pdf descargables o vídeos instructivos) para que ellos mismos se expongan a las situaciones temidas. Esto mismo sucede en las investigaciones de Anderson et al. (2009, 2013). Sin embargo, en este caso o con esta forma de proceder el

potencial que ofrecen las TICs para administrar la exposición se ve reducida. Botella et al. (2010) en uno de los primeros trabajos que utilizó Internet para el tratamiento de la ansiedad social (en concreto, miedo a hablar en público), señalaron la importancia de incluir ambientes de exposición compuestos por estímulos relevantes (en este caso audiencias reales grabadas en vídeo) junto con procedimientos de auto-ayuda como parte del tratamiento auto-aplicado a través de Internet. De esta forma, incluyendo programas multimedia de exposición que simulen la situación temida y que sean auto-administrados a través de Internet, se optimiza el potencial que ofrecen las TICs, resultando en una mejora de la técnica de exposición. Los autores plantean que este enfoque puede suponer una forma menos aversiva de afrontar los miedos en comparación con la exposición *in vivo*, por lo que puede mejorar la aceptación y accesibilidad, pudiendo llegar a un mayor número de personas (Botella et al., 2009).

Otro tema de relevancia en los tratamientos auto-aplicados a través de Internet, hace referencia al papel o la necesidad de proporcionar apoyo durante la intervención. En la actualidad existen estudios que remarcan la utilidad del apoyo para mejorar la adherencia y los resultados del tratamiento (Andersson y Cuijpers, 2009; Richards, y Richardson, 2012). No obstante, otros estudios respaldan la utilidad de las intervenciones totalmente auto-aplicadas a través de Internet con resultados similares a las intervenciones *online* con apoyo del terapeuta (p.ej., Karyotaki et al., 2017; Titov et al., 2009). Además, tal y como se plantea en una reciente revisión sistemática, los tamaños del efecto obtenidos en los tratamientos *online* guiados por el terapeuta podrían ser menores de lo informado previamente (Baumeister, Reichler, Munzinger, y Lin, 2014). Como se ha señalado en algunos estudios, las intervenciones completamente auto-aplicadas vía Internet podrían funcionar a través de apoyo y refuerzo automatizado sin la necesidad de contar con apoyo humano, suponiendo un menor coste al reducir la implicación del clínico (Kelders, Kok, Ossebaard, y Van Gemert-Pijnen, 2012; Lancee, van den Bout, Sorbi, y van Straten, 2013; Mira et al., 2017). En esta línea, algunos autores plantean que un breve contacto humano antes de empezar el programa (p.ej., llamada telefónica inicial) podría ser suficiente para influir en los efectos del tratamiento, reduciendo la necesidad de contacto humano a través del mismo (Boettcher, Berger, y Renneberg, 2012). Además, otro aspecto a considerar aquí es la gravedad de los trastornos a los que se dirige la intervención. En este sentido, se plantea que problemas más

sencillos como las FE podrían requerir una menor guía o contacto del terapeuta, mientras que en problemas más graves el apoyo del clínico podría ser de mayor relevancia (Botella et al., 2010; Menchola, Arkowitz, y Burke, 2007). En suma, y teniendo en cuenta lo anterior, vemos que los resultados disponibles en la literatura sobre la implicación del apoyo del terapeuta durante las intervenciones auto-aplicadas a través de Internet no son concluyentes. Por lo que se requiere más investigación que arroje luz sobre esta cuestión, teniendo en cuenta, a su vez, el problema al que se dirigen.

En relación a los planteamientos y hallazgos anteriormente mencionados, consideramos que la FV es una buena candidata para beneficiarse del tratamiento computarizado a través de Internet. No obstante, hasta la fecha no se ha publicado ningún ECA que muestre la eficacia y aceptación de un tratamiento psicológico auto-administrado a través de Internet para la FV.

Tomando como punto de partida los trabajos y hallazgos de Tortella-Feliu et al. (2008, 2011), el grupo de investigación Labpsitec (Universitat Jaume I) en colaboración con Labhuman (Universidad Politécnica de Valencia) y LabCSD (Universitat de les Illes Balears) ha desarrollado un programa computarizado totalmente auto-aplicado a través de Internet que incluye escenarios de exposición a imágenes y sonidos reales relacionados con distintas situaciones de FV: *SIN MIEDO Airlines* (*NO-FEAR Airlines*).

Objetivos

Objetivo general

El objetivo de la presente tesis doctoral es analizar en un estudio controlado aleatorizado la eficacia y eficiencia de un programa de tratamiento computarizado para la fobia a volar (FV) aplicado a través de Internet en dos modalidades (totalmente auto-aplicado y auto-aplicado con apoyo del terapeuta) frente a un grupo control de lista de espera.

Objetivos específicos

a) Analizar la eficacia del tratamiento auto-aplicado a través de Internet (con y sin apoyo del terapeuta) en distintas variables clínicas y medidas conductuales relacionadas con la FV, en comparación con el grupo control de lista de espera.
b) Estudiar la eficacia diferencial del tratamiento aplicado a través de Internet para la FV en sus dos modalidades de administración: totalmente auto-aplicado vs. auto-aplicado con apoyo por parte del terapeuta.
c) Analizar si los cambios tras el tratamiento online (con y sin apoyo del terapeuta) se mantienen en el seguimiento.
d) Analizar la aceptación del tratamiento auto-aplicado a través de Internet (con y sin apoyo del terapeuta) para la FV en términos de expectativas, satisfacción, preferencias, opinión y usabilidad.
e) Estudiar la aceptación diferencial del tratamiento aplicado a través de Internet para la FV en sus dos modalidades de administración: totalmente auto-aplicado vs. auto-aplicado con apoyo por parte del terapeuta.

Hipótesis

Teniendo en cuenta los objetivos anteriormente planteados, las hipótesis sometidas a prueba fueron las siguientes:

H1. El tratamiento auto-aplicado a través de Internet (con y sin apoyo del terapeuta) será eficaz para el tratamiento de la FV en comparación con el grupo control de lista de espera.

H2. No se observarán diferencias estadísticamente significativas en variables de eficacia entre los dos modos de administrar el tratamiento (con y sin apoyo del terapeuta).

H3. Los cambios alcanzados tras el tratamiento online (con y sin apoyo del terapeuta) se mantendrán en el seguimiento.

H4. El tratamiento auto-aplicado a través de Internet (con y sin apoyo del terapeuta) será bien valorado por los pacientes en términos de aceptación.

H5. No se observarán diferencias estadísticamente significativas en variables de aceptación entre los dos modos de administrar el tratamiento (con y sin apoyo del terapeuta).

Chapter 1: Introducing *NO-FEAR Airlines*

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NO-FEAR Airlines: A Computer-aided Self-help Treatment for Flying Phobia

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Abstract

In vivo exposure is the treatment of choice for specific phobias. However, this treatment is linked to a number of limitations in its implementation. Therefore, it is important to develop strategies for improving treatment adherence, acceptance, and dissemination of evidence-based treatments. Information and Communication Technologies, specifically, computerized programs boast advantages in treating flying phobia. *NO-FEAR Airlines* is a Computer-aided Self-help Treatment for this problem, which can be self-applied via Internet. *NO-FEAR Airlines* treatment protocol comprises three therapeutic components: psychoeducation, exposure and overlearning. Exposure is carried out through 6 scenarios that are composed by images and real sounds related to a flight in process. The aim of the present work is to describe *NO-FEAR Airlines* program.

Keywords. Specific phobia, Flying Phobia, Computer-aided treatments, Self-help, Computer-Assisted Exposure, Internet based therapy.

1. Introduction

One of the most prevalent phobias in our society is Flying Phobia (FP), showing a prevalence rate around 2.5% in the adult population [1]. This problem can, therefore, have a profound impact on professional, social and family life, and can substantially affect marital or relationship satisfaction [2]. *In vivo exposure* is the treatment of choice for specific phobias [3]. Despite that, this treatment is linked to a number of limitations in its implementation such as low acceptance on the part of therapists and patients, high dropout rates, limited access to treatment and difficulties in its application in the clinical context [4, 5]. Particularly relevant is the problem of dissemination (evidence based treatments do not reach all people that need them). It is important to develop new strategies to apply exposure. Information and Communication Technologies (ICTs) can improve treatment adherence and acceptance, and also help to reach a higher number of patients than traditional face to face therapy [6]. Specifically, computerized programs boast remarkable advantages in treating FP: a reduction in direct therapeutic contact time, the possibility of standardizing treatment to the maximum, the low cost- which allows a greater extension- and, perhaps most importantly, the access to patients who would not be very willing to go through live exposure (a real flight) with a steep exposure gradient [7]. Furthermore, Internet is a useful tool for disseminate and providing effective psychological treatments [8]. The Computer Assisted Fear of Flight Treatment (CAFFT) program developed by LabCSD research group has proven to be effective for FP in several studies [9, 10]. Authors concluded that the application of exposure through interactive computer programs is especially recommended for FP [11]. However, as far as we know, no controlled study for FP has been published so far to test the efficacy of a computerized program completely self-applied via Internet. A new version of CAFFT has been developed by LabPsiTec (Laboratory of psychology and technology, Universitat Jaume I) in collaboration with LabHuman (Polytechnic University of Valencia) and LabCDS (Universitat de les Illes Balears), which can be totally self-applied through the Internet: *NO-FEAR Airlines*. The aim of the present work is to describe *NO-FEAR Airlines* program.

2. Method

NO-FEAR Airlines is a computerized-aided program for FP that can be self-administered via Internet. This program allows people with FP to be exposed to images and sounds related to their phobic fears on a standard personal computer. Figure 1.1 shows the Home page of the program. Here information related to FP, the treatment, *NO-FEAR Airlines* program, as well as information about the research groups that have developed it is provided.

Figure 1.1. ***NO-FEAR Airlines: Home page***

NO-FEAR Airlines includes an assessment protocol and an exposure-based cognitive-behavioral treatment (CBT) protocol.

The *assessment protocol* includes a short screening with 19 questions about FP, related problems (i.e., claustrophobia, panic disorder, agoraphobia and acrophobia) and exclusion criteria. After that, the program carries out a pre-treatment evaluation including primary and secondary outcomes measures, as well as expectations and disposition toward the system. During treatment, *NO-FEAR Airlines* records: initial fear level regarding to each exposure scenario, the highest level of anxiety experienced during the exposure to the scenarios, number of cycles performed in each exposure scenario and the sense of presence and reality judgment after the exposure to “the flight” scenario. At the end of the treatment, the system applies the same assessment instruments (post-treatment evaluation) and at 3 and 12-month follow-ups.

The *treatment protocol* comprises 3 therapeutic components: psychoeducation, exposure and overlearning. These three key aspects are based on techniques that have proven efficacy and meet the recommendations of the guidelines on

good clinical practice state by international associations of psychology such as the American Psychological Association (www.apa.org) and the National Institute for Health and Clinical Excellence (www.nice.org.uk).

a) Psychoeducation component provides information about what the program will consist of as well as specific information related to FP. Specifically, the program teaches about how many people are affected by the problem; what kinds of people are affected; the physiological, cognitive and behavioral (or avoidance) components of FP; how it begins, how it is maintained and how to cope with the problem. This section contains text, vignettes and illustrations in order to make the therapeutic content more attractive for the patients (Figure 1. 2).

Figure 1. 2. *Screenshot* of *Psychoeducation* section

b) *Exposure* is conducted through 6 scenarios that are composed by images and real sounds related to the flight process: (1) flight preparation, (2) a series of activities immediately prior to flying on the day of the flight, (3) boarding and taking off, (4) the central part of the flight (see Figure 1. 3), (5) the descent of the aircraft, approach to the runway and landing, (6) sequence with images and auditory stimuli related to plane crashes. Exposure scenarios are presented following an exposure hierarchy automatically constructed in the pre-treatment evaluation. During exposure scenarios, the system asks (every 3 minutes) the maximum anxiety level experienced on a scale ranging from 0 “no anxiety” to 10 “high anxiety”. Exposure to each stage ends when the participant indicates an anxiety level lower than 3, in order to achieve the habituation process.

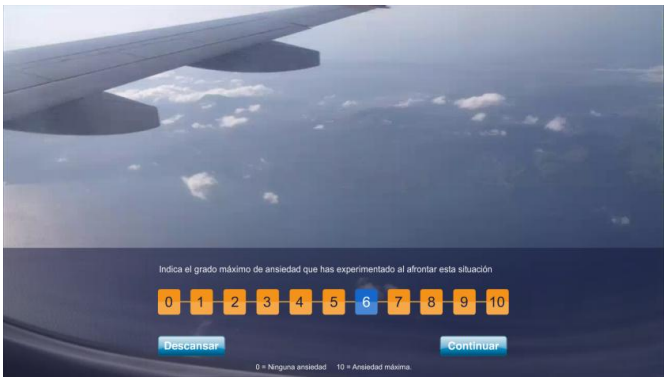

Figure 1. 3. *Screenshot* of *flight* exposure scenario

c) Overlearning component is offered as an additional exposure in all scenarios. Patient can choose to practice *overlearning* at will, according to their needs. This component aims to review some of the exposed situations and strengthen the achievements. Patient may be exposed to the above scenarios but with a higher degree of difficulty during which storm conditions and turbulence are simulated.

The duration of treatment depends on the rate of each patient. All they will be advised to do around two exposure sessions per week, taking a few days off between sessions. Therefore, it is estimated that in three or four weeks the treatment can be completed, with a maximum period of six weeks. However, each participant will be free to keep rate he/she needs. Furthermore, after the program, all patients will be encouraged to take a real flight. *NO-FEAR Airlines* provides guidelines to meet this test flight through downloadable material.

3. Results

A RCT to determine the efficacy of this program, compared to a waiting list control group, is being currently in progress. The role of support (with minimal contact versus with no contact) in the treatment via Internet for FP will also be examined.

4. Conclusions

NO-FEAR Airlines tries to provide an effective and useful tool to help people who may need it. This Internet based program has been designed to facilitate the acceptance and the access to treatment for FP. Furthermore, the comparison between the self-applied treatment groups will provide relevant data to the debate about the role of the therapist in the psychological treatments administered via Internet, specifically regarding FP treatment.

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Chapter 2: Study protocol

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An Internet-based treatment for Flying Phobia (*NO-FEAR Airlines*): Study protocol for a Randomized Controlled Trial

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Abstract

Background: Flying phobia (FP) is a common and disabling mental disorder. Although *in vivo exposure* is the treatment of choice, it is linked to a number of limitations in its implementation. Particularly important, is the limited access to the feared stimulus (i.e., plane). Moreover, the economic cost of *in vivo exposure* should be specially considered as well as the difficulty of applying the exposure technique in an appropriate way; controlling important variables such as the duration of the exposure or the number of sessions. ICTs could help to reduce these limitations. Computer-assisted treatments have remarkable advantages in treating FP. Furthermore, they can be delivered through the Internet, increasing their advantages and reaching more people in need. The Internet has been established as an effective way to treat a wide range of mental disorders. However, as far as we know, no controlled studies exist on FP treatment via the Internet. This study aims to evaluate the efficacy of an Internet-based treatment for FP (*NO-FEAR Airlines*) versus a waiting list control group. Secondary objectives will be to explore two ways of delivering *NO-FEAR Airlines*, with or without therapist guidance, and study the patients' acceptance of the program. This paper presents the study protocol.

Methods/design: The study is a randomized controlled trial. A minimum of 57 participants will be randomly assigned to three conditions: a) *NO-FEAR Airlines* totally self-applied, b) *NO-FEAR Airlines* with therapist guidance, or c) a waiting list control group (6 weeks). Primary outcomes measures will be the *Fear of*

Flying Questionnaire-II and the *Fear of Flying Scale*. Secondary outcomes will be included to assess other relevant clinical measures, such as the *Fear and Avoidance Scales*, *Clinician Severity Scale,* and *Patient's Improvement scale*. Analyses of post-treatment flights will be conducted. Treatment acceptance and preference measures will also be included. Intention-to-treat and per protocol analyses will be conducted.

Discussion: An Internet-based treatment for FP could have considerable advantages in managing *in vivo exposure* limitations, specifically in terms of access to treatment, acceptance, adherence, and the cost-effectiveness of the intervention. This is the first randomized controlled trial to study this issue.

Trial registration: Clinicaltrials.gov: NCT02298478. Trial registration date 3 November 2014.

Study status: Ongoing: Recruitment

Keywords: Internet-based exposure, Virtual Reality, Randomized controlled trial, Flying phobia, Self-help

Background

Flying Phobia (FP) is a common and disabling disorder classified as a situational specific phobia [1]. The symptoms of FP can encompass several diagnostic categories (such as panic disorder, agoraphobia, claustrophobia, or acrophobia), making diagnosis and treatment complex [2, 3]. Recent studies have established a lifetime prevalence of approximately 2.5% of the adult population [4], although previous epidemiological studies reported prevalence estimates ranging from 10% to 40% [5, 6]. Moreover, research has pointed out that around 25% of the adult population suffers from anxiety when taking a flight, about 10% avoid flying due to the intensity of their fear, and approximately 20% depend on alcohol or anxiolytics to fly [7].

Consequences of FP are far-reaching, resulting in substantial social costs from the patient's perspective, which for some authors are incalculable [8], as well as the costs for aeronautical companies [9, 10]. Interference caused by this problem is diverse and varies depending on personal demands or needs, as well as patients' geographical location. According to Busscher et al. [2], 7% of the population experience serious interference in daily life and social functioning due to FP. Personal consequences of suffering from FP may consist of limited professional opportunities or leisure options and changing or disrupted relationships, and it often causes shame and emotional distress when the person faces the thought of flying [4, 11, 12].

There are evidence-based psychological interventions for FP [13, 14], and the most effective treatment approach for this problem is *in vivo exposure* [4]. Studies report that more than 90% of participants whose treatment included *in vivo exposure* continued to fly at one- to four-year follow-up [14]. However, this technique is linked to a number of limitations in its implementation, related to access and acceptance by patients and therapists [15]. With regard to treatment accessibility, most people suffering from phobias never seek help [16], only 7.8% search for a treatment [17], and only 8% of patients receive a specific treatment for their problem [18]. There could be several reasons for this, such as long waiting lists, lack of evidence-based treatment offered by healthcare systems, and insufficient therapist training to apply the exposure technique [19-21]. As for patients' acceptance of *in vivo* exposure, around 25% reject the treatment when they are informed about the procedure, or they drop-out during treatment [15, 22]. In addition, some authors have considered exposure to be a cruel cure,

inhumane, and ethically inappropriate [15, 23]. Furthermore, *in vivo* exposure involves lack of confidentiality or high associated costs when it has to be conducted outside the therapist's office [13]. And, finally, but particularly important in FP, is the limited access to the feared stimulus (i.e., airport or plane) [24]. Moreover, for this specific phobia the economic cost of in vivo exposure should be specially considered as well as the difficulty of applying the exposure technique in an appropriate way; that is, controlling important variables such as the duration of the exposure or the number of sessions.

According to Kazdin [21], there is a need for new models to deliver mental health and reduce the burdens of mental illness. In the case of FP treatment, it is necessary to improve exposure therapy in terms of adherence and acceptance, and help to reach a higher number of patients than with traditional face to face therapy. Information and Communication Technologies (ICTs) can be useful in this endeavor. Specifically, Computer-assisted treatments such as virtual reality exposure therapy (VRET) and computer-assisted exposure have noteworthy advantages in treating FP. Some of these advantages are: providing an intermediate step between the therapist's office and the real world; the possibility of standardizing treatment as much as possible with a steep exposure gradient; its low cost and accessibility for patients who would not be very willing to subject themselves to live exposure (a real flight); a reduction in direct therapeutic contact time; confidentiality compared to *in vivo* exposure conducted in a public place; and better acceptance by patients and therapists because it evokes lower anxiety levels [13, 25-27].

VRET has been shown to be effective for FP treatment in several meta-analyses and systematic reviews [28-31]. Regarding computer-assisted exposure programs for FP, the literature shows only one system that has efficacy data. Bornas et al. (2001) developed a computer-assisted exposure program (*Computer Assisted Fear of Flight Treatment, CAFFT)* that has been shown to be effective in several studies [27, 32]. In this regard, Tortella-Feliu et al. [32] pointed out that the *CAFFT program* (with therapist presence and self-administered in the lab) and a VR system [26] equally reduced FP outcomes at post-treatment and 1-year follow-up. These data suggest that less sophisticated and cheaper devices might be sufficient to produce satisfactory outcomes.

On the other hand, this type of computer-assisted treatment can be delivered through the Internet, which would improve the advantages of this way of applying exposure, reaching more people in need. The Internet has been shown to be an

effective tool for treating a broad range of psychological disorders and psychiatric conditions, particularly depression and anxiety disorders [33-35], and it can address common treatment barriers such as limited access to mental health treatments [35]. Specifically, authors have pointed out five main advantages: efficacy, effectiveness, safety, geographical reach, acceptability, and convenience [36]. However, according to Andersson [33], in spite of the fact that specific phobias are common, only two studies with self-help Internet-based programs have been published, one on spider phobia [37] and one on snake phobia [38].

However, despite the proven efficacy of these programs, there are still some questions that remain unclear, such as the impact of clinician guidance. To date, evidence shows that guidance is a beneficial feature that leads to better adherence and better outcomes in programs administered through the Internet [34, 39-41]. Nevertheless, other authors have shown that unguided self-help interventions are useful alternatives with similar outcomes that might work using automated reinforcement [40, 42, 43]. Moreover, the results so far indicate a small but significant effect size of these self-help interventions compared to a control condition [43-47]. Therefore, more research is needed to examine and determine critical key aspects of clinician guidance that promote positive effects [36].

In sum, the Internet is a useful and effective tool for providing psychological treatments, and there is a large body of research about this topic. However, no published study has explored these issues in the research on FP. As far as we know, no controlled FP study has been published to test the efficacy of an Internet-based treatment.

The purpose of the randomized control trial (RCT) described in this study protocol is to investigate the effectiveness of an Internet-based exposure treatment for FP (*NO-FEAR Airlines*) versus a waiting list control group. Secondary objectives are: a) to explore two ways of delivering *NO-FEAR Airlines*, with or without therapist guidance, and b) to study the patients' acceptance through expectations, preferences, and satisfaction with the online program. This paper presents the study design.

Methods/Design

Study Design

A three-armed simple-blind RCT will be conducted. Participants will be randomized into three groups: 1) Internet-based exposure treatment for FP without therapist guidance (*NO-FEAR Airlines* totally self-applied); 2) Internet-based exposure treatment for FP with therapist guidance (brief weekly call) (*NO-FEAR Airlines* with therapist guidance); and 3) a waiting list control group. Participants in the control group will be randomly assigned to one of the two treatment conditions after spending time on the waiting list (6 weeks) for ethical reasons. The study was registered under clinicaltrials.gov (NCT02298478) and will be conducted following the CONSORT statement (Consolidated Standards Of Reporting Trials, http://www.consort-statement.org), the CONSORT-EHEALTH guidelines [48] and the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) [49, 50]. SPIRIT checklist (http://www.spirit-statement.org/spirit-statement/) were followed for the reporting of the present study protocol. Figure 2.1. shows the flowchart for the study

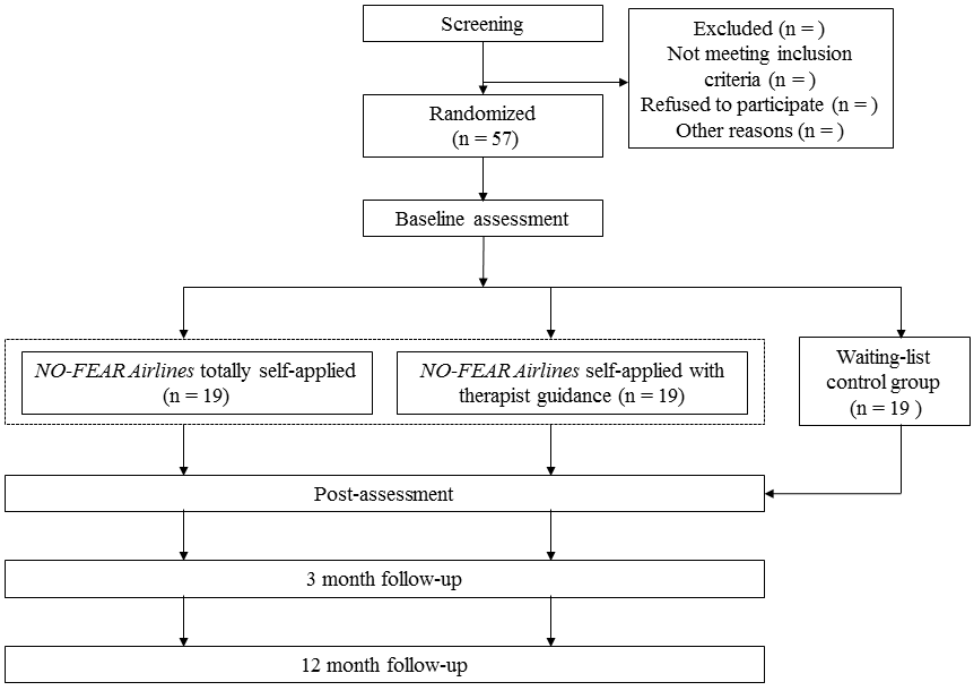

Figure 2.1. Study Flowchart

Sample size and power calculations

Power calculations and Internet dropout rates (30%) [51, 52] were taken into consideration to estimate the necessary sample size to detect a large effect size (d = 1) with a power of 0.80 and an alpha of 0.05, based on a similar study [32] and recent systematic reviews [36]. The RCT will recruit a minimum of 57 participants, who will be randomly allocated to one of 3 experimental conditions.

Ethics

This trial received approval from the Ethics Committee of Universitat Jaume I (Castellón, Spain) (20 December 2014) and will be conducted in compliance with the study protocol, the Declaration of Helsinki, and good clinical practice. Data security/confidentially will be guaranteed; all relevant EU and Spanish legislation on privacy will be observed and respected. Access to the Internet platform is through a unique username-password combination, and all transferred data will be secured following the AES (Advanced Encryption Standard) polynomial m(x) = x8 + x4 + x3 + x + 1. The consent form will be explained and required from all participants. Important protocol modifications will be communicated to relevant parties (i.e., trial participants, trial registries, journals, ethical committee and researchers).

Eligibility criteria

The study sample will consist of adults from 18 years old who meet the Diagnostic and Statistical manual for Mental Health Disorders-Version 5 (DSM-5) (APA, 2013) criteria for specific, situational phobia (FP). They are required to have adequate knowledge to understand and read Spanish, access to the Internet, and the ability to use a computer. Exclusion criteria for the study are as follows: a) receiving psychological treatment for FP; b) diagnosis of a severe mental disorder: abuse or dependence on alcohol or other substances, psychotic disorder, dementia or bipolar disorder; c) presence of depressive symptomatology, suicidal ideation or plan; d) Presence of heart disease; e) Pregnant women (from the fourth month). Receiving 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.

Participants with comorbid and related disorders (i.e., panic disorder, agoraphobia, claustrophobia or acrophobia) will be included when FP is the primary diagnosis. Participants who do not meet the inclusion criteria will be encouraged to seek treatment alternatives better suited to their specific needs.

Recruitment, randomization and blinding

The study will be advertised online via professional websites (i.e., LinkedIn), non-professional social-networks (i.e., Facebook and twitter), and advertisements in newspapers. Furthermore, posters will be placed in local universities (Universitat Jaume I and Universitat de València) and travel agencies. People who are interested will be directed to the research website (www.fobiavolar.es), where they will find further information about the study and what participation entails, as well as an informed consent form. Individuals can request participation through the website and by signing the informed consent form. After website registration, the clinical team will contact participants by telephone to screen for the inclusion and exclusion criteria and explain the research terms (i.e., study design, treatment length, or treatment rationale). Participants who meet the criteria will be administered a diagnostic telephone interview at the time of the screening, or another time will be arranged. Then, participants will be randomly assigned to one of the three experimental groups. The allocation schedule will be generated through a computer randomization program (Epidat 4.0) by an independent researcher who will be unaware of the characteristics of the study. The allocation schedule will be communicated to the study researchers via phone call. Patients will agree to participate before the random allocation and without knowing to which treatment they will be assigned. However, for practical reasons, participants and researchers will not be blind to the treatment conditions. Participants will be free at any time to withdraw from the treatment or the study without giving any explanation.

Intervention

NO-FEAR Airlines is a computer-aided exposure treatment program for FP that can be self-administered via the Internet [43]. This program allows people who are afraid of flying to be exposed to images and sounds related to their phobic fears on a standard personal computer from home. *NO-FEAR Airlines* was developed by LabPsiTec (Laboratory of psychology and technology, Universitat Jaume I, and University of Valencia) in collaboration with LabCDS (University of

Balearic Islands). It is a new version based on a previous program *Computer Assisted Fear of Flight Treatment* (CAFFT), created by the LabCSD research group [54, 55], and designed to be completely self-applied over the Internet.

NO-FEAR Airlines includes both an *assessment protocol* and a *treatment protocol*. The *assessment protocol* provides a short screening with 19 questions about FP, related problems (i.e., claustrophobia, panic disorder, agoraphobia, and acrophobia), and exclusion criteria. After that, the program carries out a pre-treatment evaluation that includes primary and secondary outcome measures. The *treatment protocol* consists of 3 therapeutic components: psychoeducation, exposure, and overlearning. These three key aspects are based on techniques that have been shown to be effective and conform to recommendations from guidelines on good clinical practice published by international psychology associations such as the American Psychological Association (APA) (www.apa.org) and the National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk).

The *Psychoeducation* component provides information about what the program will contain, as well as specific information related to FP. Specifically, the program teaches: how many people are affected by the problem; what kinds of people are affected; the physiological, cognitive, and behavioral (or avoidance) components of FP; how it begins and is maintained; and how to cope with the problem. This section contains text, vignettes, and illustrations, in order to make the therapeutic content more attractive to the patient.

Exposure is conducted through 6 scenarios composed of images and real sounds related to the flight process: (1) flight preparation, (2) airport, (3) boarding and taking off, (4) the central part of the flight, (5) the airplane's descent, approach to the runway, and landing, (6) sequences with images and auditory stimuli related to plane crashes. During the exposure scenarios, the system asks (every 3 minutes) the participant about his/her maximum anxiety level experienced on a scale ranging from 0 "no anxiety" to 10 "high anxiety". Exposure to each stage ends when the participant indicates an anxiety level lower than 3, in order to achieve the habituation process. Each exposure scenario contains a maximum of 20 cycles (1 cycle consists of images and sounds for 3 minutes). If the participant exceeds the maximum, the scenario will be presented again at the end. It is possible to take a break from the exposure and between scenarios; however, the program will not advance to the next scenario until the user overcomes the current stage (anxiety level under 3).

Overlearning component. Additional exposure (to each scenario) in order to achieve overlearning is offered to the patients. They may choose the scenarios they want to confront according to their needs. This component aims to review some of the exposed situations and guarantee/reinforce the achievements. The patient may be exposed to the aforementioned scenarios, but with a higher degree of difficulty because this time, storm conditions and turbulence will be simulated.

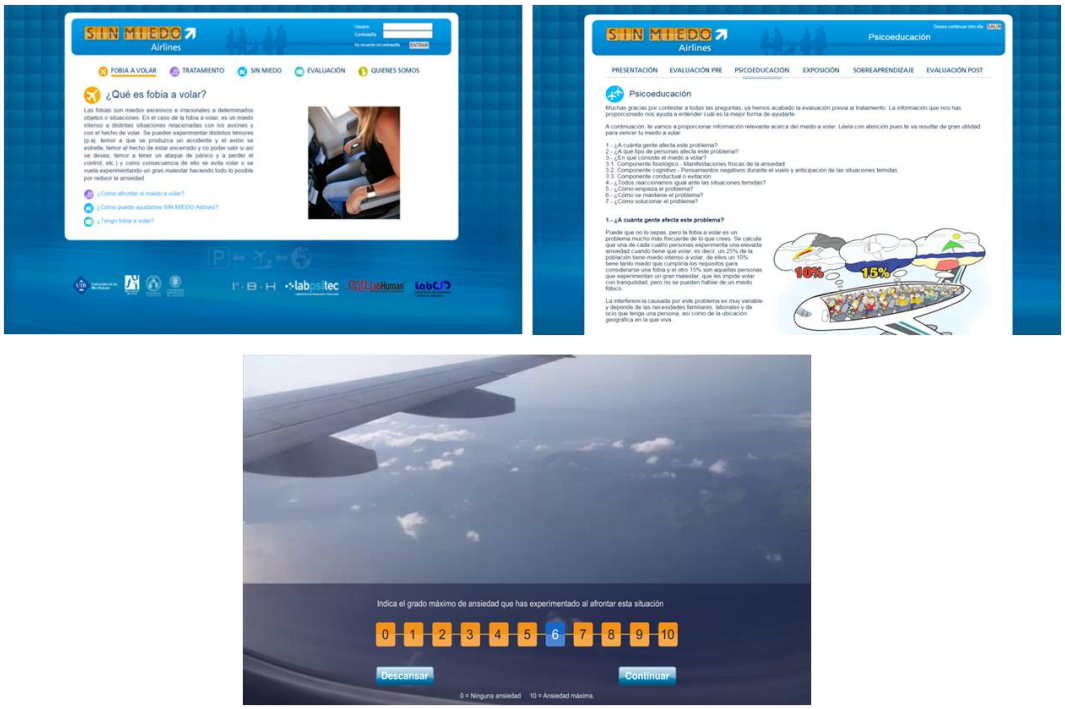

Figure 2.2. *NO-FEAR Airlines* "screenshots": Home, Psychoeducation and *flight* exposure scenario

The length of the treatment depends on the pace of each patient. Patients will be advised to carry out about two exposures scenarios per week, taking a few days off between sessions. It is estimated that the treatment can be completed in three or four weeks, with a maximum period of six weeks. However, each participant will be free to advance at his/her own pace. Furthermore, after the program, all the patients will be encouraged to take a real flight. *NO-FEAR Airlines* provides guidelines to cope with this test flight through downloadable material. At the end of the treatment, the system provides post-treatment and 3- and 12-month follow-up assessments.

The program described will be implemented in two formats: 1) *NO-FEAR Airlines* completely self-applied. Participants who meet the inclusion criteria and after having signed the informed consent form, will access the program and self-administer the treatment following the guidelines described above. In this treatment condition, participants will only receive automatic support provided by the program. Technical assistance (i.e., web accessibility problems or forgotten password) will be provided if necessary. 2) *NO-FEAR Airlines* with therapist guidance. In this case, participants will also self-administer the treatment via the Internet, and they will receive minimal therapist support. Guidance content will be standardized, although it can be tailored to individual patients' needs. Therapist guidance will consist of a brief weekly phone call (maximum 5 minutes) aimed to assess and guide the participant's progress by providing feedback and reinforcement. In addition, the therapist will check for any problems and remind the participant about the recommended treatment pace. Patients can receive up to 6 telephone calls over a 4 to 6 week period, and so they have a maximum of 30 minutes of therapeutic support. Trained and experienced psychologists will provide the telephone support. Support calls in any case will have additional clinical content.

Instruments

Participants will be assessed at baseline, post-treatment, and 3- and 12-month follow-ups. Assessments will be conducted via call phone, a commercial online survey system (www.surveymonkey.com), and the *NO-FEAR Airlines* program. Both participants and therapists will receive email reminders of each assessment time. The study variables and assessment times are summarized in Table 2.1.

Diagnostic interview

The Anxiety Disorders Interview Schedule for DSM-IV-TR (ADIS-IV) [56]. The section on specific phobias will be used. Moreover, DSM-5 criteria will be considered. In cases of comorbidity, other sections of the ADIS-IV (i.e., panic disorder or agoraphobia) will be used. ADIS-IV is an excellent interview for assessing anxiety disorders and has adequate psychometric properties [57].

Table 2.1 Study measures, time of assessment, and source of measurement

Measures	Aim	Time of assessment	Source of measurement
ADIS-IV	Diagnosis	BL, post-T and FU	Phone Call
Sociodemographic data	Gender, age, education, occupation, marital status	BL	
FFQ-II	Severity of the FP	BL, post-T and FU	*NO-FEAR Airlines*
FFS	Severity of the FP	BL, post-T and FU	Phone Call
Fear and Avoidance Scales	Fear avoidance, and the degree of belief in catastrophic thought related to the main target behavior	BL, post-T and FU	Phone Call
Clinician Severity Scale	Severity of the patient's phobia	BL, post-T and FU	Phone Call
Patient's Improvement Scale	Patient's improvement assessment	BL, post-T and FU	Phone Call
Treatment Preferences Questionnaire	Participant's treatment preferences	BL, post-T and FU	Phone Call
ESQ	Expectations and satisfaction with the treatment	BL, post-T and FU	Phone Call
Measures related to flying phobia	Duration of the problem, flights taken, Safety behaviors, presence of negative experience flying	BL, post-T and FU	*NO-FEAR Airlines*
Anxiety during exposure	Maximum level of anxiety experienced during the exposure scenarios	During exposure scenarios	*NO-FEAR Airlines*
Cycles of exposure scenarios	Number of cycles in each exposure scenario	After exposure scenarios	*NO-FEAR Airlines*

BL, Baseline; Post-T, post-treatment; FU, 3- and 12-month follow-ups; ADIS-IV, The Anxiety Disorders Interview Schedule for DSM-IV-TR; FP, Flying phobia; FFQ-II, Fear of Flying Questionnaire-II; FFS, Fear of Flying Scale; ESQ, Expectations and satisfaction Questionnaire.

Primary outcomes

The Fear of Flying Questionnaire-II (*FFQ-II*) [58] is a 30-item self-report instrument that describes situations related to flying: anxiety during flight, anxiety experienced getting on the plane, and anxiety experienced during the observation of neutral or unpleasant flying-related situations. For each item, respondents rated their degree of discomfort associated with the situation on a scale from 1 to 9 (1 = not at all, 9 = very much). Scores ranged from 30 to 270. As reported by Bornas et al. [58], internal consistency was α = .97, and retest reliability (15-day retest period) was r = .92.

The Fear of Flying scale (*FFS*) [59] is a 21-item self-report measure to assess fear associated with various air travel situations. Fear elicited by each situation was rated on a 5-point scale (0 = *not at all*, 4 = *very much*), with scores ranging from 0 to 84. For the original FFS [59], Cronbach's alpha was .94, and retest reliability (at three months) was .86.

Secondary outcomes

Socio-demographic variables

The following socio-demographic variables will be collected: gender, age, marital status, educational level, and work status.

Other relevant clinical measures

Fear and Avoidance Scales (adapted from Marks & Mathews [60]) are used to assess participants' fear and avoidance on a scale ranging from 0 ("No fear at all," "I never avoid") to 10 ("Severe fear," "I always avoid") related to the main target behavior: "flying". The degree of belief in the catastrophic thought related to the target behavior will also be assessed on a 0 ("I do not believe the thought at all") to 10 (the thought is totally true) scale.

The Clinician Severity Scale (adapted from Di Nardo, Brown & Barlow [61]). The clinician rates the severity of the patient's phobia on a scale from 0 to 8, where 0 = symptom free and 8 = extremely severe.

The Patient's Improvement Scale (Adapted from the Clinical Global Impression scale, CGI; Guy [62]). One item on the CGI scale was adapted in order to assess the level of improvement achieved by the patient (compared to the baseline

status) on a 7-point scale (1 “much worse” to 7 “much better”). This scale is answered by the patient.

Other measures recorded by the system

Measures related to FP. NO-FEAR Airlines provides a short assessment of fear and avoidance of flying and checks the following issues: the duration of the problem, how many times the patient has taken a flight, whether safety behaviors were used (e.g., alcohol intake, distraction), and whether the participant has had any negative experiences with flying.

Maximum level of anxiety experienced during the exposure scenarios. During exposure to the scenarios, the system asks the user about the maximum anxiety experienced every 3 minutes, on a scale from 0 “No anxiety” to 10 “maximum anxiety”. The exposure session ends when the anxiety level is less than 3.

Number of cycles in each exposure scenario. The NO-FEAR Airlines system also records the numbers of cycles participants perform in each exposure scenario. One cycle consists of an exposure duration of 3 minutes.

Treatment acceptance measures

Treatment Expectations and satisfaction scales (adapted from Borkovec & Nau) [63]. This questionnaire measures participants’ expectations before treatment and their satisfaction with it. It includes six items rated from 0 (‘not at all’) to 10 (‘very much’); questions address how logical the treatment seems, to what extent the patient expected to be satisfied with it, whether the patient would recommend the treatment to others, whether it would be useful in treating other problems, the treatment’s usefulness for the patient’s problem, and to what extent it could be aversive. Participants will answer the Expectations scale after the therapist explains the rationale for the treatment they would receive (with or without therapist support) and before beginning the treatment. The satisfaction scale will be completed once treatment is finished. This adaptation has been used in previous studies [64, 65].

Treatment Preferences Questionnaire. This instrument was specifically developed for this research. It is composed of 5 questions designed to measure participants’ preferences about both treatment conditions included in this study (with and without therapist support): (1) Preference (“*If you could have chosen between the two treatments, which one would you have chosen?*”; (2) Subjective

effectiveness ("*Which of these two treatments do you think would have been the most effective in helping you to overcome your problem?*"; 3) Logic (*Which of these two treatments do you think would have been the most logical to help you overcome your problem*); (4) Subjective aversion ("*Which of these two treatments do you think would have been the most aversive?*") and (5) Recommendation ("*Which of these two treatments would you recommend to a friend with the same problem you have?*"). Questions have two response options in accordance with the two treatment conditions. This scale will be completed before participants know the treatment condition assigned and after treatment.

Qualitative interview. This interview was also specifically developed for this research. It contains 11 items designed to assess participants' opinions about the *NO-FEAR Airlines* program and the support received. The interview includes questions rated on a 1 to 5 scale (1= *very little*; 5= *very much*) and Dichotomous Questions ("*Yes*" or "*No*"). Additionally, options to extend the participants' qualitative responses are available.

Statistical analysis

Intention-to-treat (ITT) and per protocol analyses (PPA) will be conducted following the CONSORT recommendations and SPIRIT guidelines for reporting the results [48-50]. Differences in demographic and baseline clinical characteristics will be computed using Chi-square tests for categorical variables and analysis of variance (ANOVA) for continuous data. ANOVA will be conducted to explore the effects of the treatments on all primary and secondary outcomes. Analyses of post-treatment flights will be carried out using Chi-square tests to evaluate group differences, including the number of flights taken and number of safety behaviours performed. Moreover, effect sizes and confidence intervals of the mean will be conducted, following the author's recommendations and recent literature [66, 67]. Assuming that missing data will be missing at random, it will be handled using multiple imputations (MI) [68]. All analyses will be conducted using IBM SPSS statistics for Windows, version 22.

In any case, the state of the art of analytic methodology for RCT will be reviewed before analyzing the data, in order to apply the most appropriate statistical analysis procedure.

Discussion

This study protocol describes a RCT designed to evaluate the effectiveness of an Internet-based exposure treatment for FP (*NO-FEAR Airlines*), compared to a waiting list group. In addition, two ways of delivering *NO-FEAR Airlines* (with or without therapist guidance) will be explored and tested. Finally, the patients' acceptance of this program will be studied.

The use of an Internet-based treatment for FP could have remarkable advantages for overcoming the limitations of *exposure in vivo*, specifically in terms of access to treatment, acceptance, adherence, and cost-effectiveness of the intervention. These self-applied interventions improve the possibility of reaching people in need, improving the access to evidence-based treatments [33, 36], and opening up the possibility of fully standardizing the treatment [26, 32]. Furthermore, they may have better acceptance among patients and therapists because they produce lower anxiety levels with a steep exposure gradient through simulated environments [22, 36], thus promoting better adherence and avoiding dropouts. Finally, from a cost-effectiveness perspective, the reduction in direct therapeutic contact time is important, as Internet-based self-applied treatments save therapist time compared to traditional, face-to-face treatments [69]. These advantages help to address Kazdin and Blase's [19] and Emmelkamp et al. [70] proposal that psychotherapy research needs to develop interventions that can be applied to more patients in a simpler and more cost-effective way.

Another aim of the present study is to examine the efficacy of a completely self-applied intervention for FP (without therapist guidance, only the initial call phone contact with the therapist) and find out whether this intervention makes it possible to reduce the therapist time even more. In this case, Internet-based interventions would be easier to implement in primary care and, therefore, reach more people in need. As explained above, to date, studies about the relative benefits of guided vs. unguided support in Internet delivered interventions have reached different conclusions. The literature shows that guidance is a beneficial feature resulting in better adherence and better outcomes [34, 39-41]. However, some studies have shown the efficacy of self-guided treatments (without any contact or support from a therapist, consultant or researcher) [43-47, 71]. Furthermore, unguided interventions have been shown to be much easier to implement and less costly than guided web-based interventions [72], and so it is important to continue to

study their effectiveness. Thus, more research is needed to examine this issue [36].

It is important to highlight that the relative benefits of guided vs. unguided support in Internet delivered interventions for FP remain unexplored. Our data could provide information about this new and necessary topic; showing the possibility and potential of completely self-applied interventions in reducing the cost of treatment for people with FP.

The strengths of this study are: First, this is the first RCT to test an Internet-based exposure treatment for FP. Second, the treatment components (psychoeducation, exposure, and overlearning) are based on effective techniques and conform to the recommendations of the guidelines on good clinical practice (i.e., APA and NICE) [1, 73]. Third, *NO-FEAR Airlines* is a new version based on the *CAFFT* program, which has proven its efficacy in different studies for FP treatment [27]. This study will provide additional data for the study of FP treatment using computer-assisted exposure, in line with other authors [32].

Finally, there are several limitations that should be mentioned. First, the measurements (i.e., diagnostic interview and questionnaires) will be conducted online and via phone calls. Although some studies have shown the utility of online assessment and its concordance with traditional assessment [74-76], some evidence suggests that psychometric properties may change when assessment is conducted via the web [77]. Second, dropout rates are expected to be high (around 30%), according to the literature [51, 52]. For this reason, dropout rates have been taken into account in the sample size calculation. Third, due to the heterogeneity of FP, the presence of comorbid disorders such as panic, agoraphobia, claustrophobia, and acrophobia may influence the study outcome measures. Although participants with comorbid disorders will not be excluded if FP is the primary diagnosis, this fact will be taken into account in the data analysis.

In summary, the results will contribute to the growing research on Internet-delivered treatments and the treatment of FP. *NO-FEAR Airlines* is intended to be an effective and useful tool to help people who may need it. This program has been designed to enhance the adherence, acceptance, and access to exposure-based treatments for FP. Finally, results from this study could help to improve the *exposure* technique application.

Abbreviations

ANOVA: Analysis of variance; APA: American Psychological Association; AES: Advanced Encryption Standard; CAFFT: Computer Assisted Fear of Flying Treatment; CGI: Clinical Global Impression scale; CONSORT: Consolidated Standards Of Reporting Trials; DSM-5: Diagnostic and Statistical manual for Mental Health Disorders-Version 5; FFS: Fear of Flying scale; FFQ-II: Fear of Flying Questionnaire-II; FP: Flying phobia; ICTs: Information and Communication Technologies; ITT: Intention-to-treat; LabCDS: Laboratorio de Conducta y Sistemas Dinámicos; LabPsiTec: Laboratory of psychology and technology; MI: Multiple Imputations; NICE: National Institute for Health and Clinical Excellence; PPA: Per protocol analyses; RCT: Randomized Control Trial; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; VRET: virtual reality exposure therapy.

Declarations

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Availability of data and material

It is not possible to share the data because the study is in progress. We are now at the stage of data recruitment. Only principal investigators will have access to the final trial dataset and it will be considered to publish. Trial results will be communicated to participants, healthcare professionals, the public, and other relevant groups (i.e., via professional websites, non-professional social-networks, and announcements in newspapers). The research team will make the findings publically available at national and international conferences, and in peer-reviewed journal publications.

Authors' contributions

DC[a] drafted the manuscript with important contributions from SQ, JB-L and CB. DC[a], in collaboration with SQ and JB-L designed the study and participated in each of its phases. AM collaborated in the manuscript development and participated in each study phase. CB, DC[b], RB and MT-F carried out the Internet based adaptation of the treatment protocol with important contributions of SQ and JB-L. All authors participated in the review and revision of the manuscript and have approved the final manuscript to be published.

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Competing interests

The authors declare that they have no competing interests.

Consent for publication

"Not applicable" in this section.

Ethics approval and consent to participate

We confirm that any aspect of the work covered in this manuscript that has involved human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript. The study was approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain) (20 December 2014). All participants interested in participating will sign an informed consent form.

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Chapter 3: Effectiveness of *NO-FEAR Airlines*

This chapter has been has been submitted as:

Campos, D., Bretón-López, J., Botella, C., Mira, A., Castilla, D., Baños, R., Tortella-Feliu, M., & Quero, S. Efficacy of an Internet-based Exposure treatment for Flying Phobia (*NO-FEAR Airlines*) with and without therapist guidance: A randomized controlled trial.

Efficacy of an Internet-based Exposure treatment for Flying Phobia (*NO-FEAR Airlines*) with and without therapist guidance: A randomized controlled trial

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Abstract

Background: Internet-based treatments appear to be a promising way to enhance the in vivo exposure approach, specifically in terms of acceptability and access to treatment. However, the literature on specific phobias is scarce, and, as far as we know, there are no studies on Flying Phobia (FP). This study aims to investigate the effectiveness of an Internet-based exposure treatment for FP (*NO-FEAR Airlines)* that includes exposure scenarios composed of images and sounds, versus a waiting-list control group. A secondary aim is to explore two ways of delivering *NO-FEAR Airlines*, with and without therapist guidance.

Methods: A randomized controlled trial (RCT) was conducted in which 69 participants were allocated to: 1) *NO-FEAR Airlines* totally self-applied, 2) *NO-FEAR Airlines* with therapist guidance, 3) a waiting-list control group. Primary outcome measures were the *Fear of Flying Questionnaire-II* and the *Fear of Flying Scale*. Secondary outcomes included the *Fear and Avoidance Scales*, *Clinician Severity Scale,* and *Patient's Improvement scale*. *Behavioral outcomes* (post-treatment flights and safety behaviors) were also included. Mixed-models analyses with no ad hoc imputations were conducted for primary and secondary outcome measures.

Results: *NO-FEAR Airlines* (with and without therapist guidance) was significantly effective, compared to the waiting list control group, on all primary and secondary outcomes (all *p*s < .05). Significant improvements were also found in both treatment groups for diagnostic status and reliable change indexes.

Regarding behavioral outcomes, significant differences were found at post-treatment for safety behaviors, compared to the waiting list. Treatment gains were maintained at 3-month follow-up. No significant differences were found between the two ways of delivering the intervention.

Conclusion: FP can be treated effectively via the Internet. *NO-FEAR Airlines* helps to enhance the exposure technique and provide access to evidence-based psychological treatment to more people in need. These data are congruent with previous studies highlighting the usefulness of computer-assisted exposure programs for FP, and they contribute to the literature on Internet-based interventions. To the best of our knowledge, this is the first RCT to investigate the effectiveness of an Internet-based treatment for FP and explore two ways of delivering the intervention (with and without therapist guidance).

Trial registration: Clinicaltrials.gov: NCT02298478. Trial registration date 3 November 2014.

Keywords: Internet-based exposure; Therapist guidance; Randomized controlled trial; Flying phobia; Self-help.

Background

Flying phobia (FP) is a disabling disorder classified as a specific situational phobia [1], although authors also highlight its heterogeneous nature because FP symptoms can be influenced by many other fears [2–4]. Up to 7% of the population experience acute interference in daily and social life functioning due to FP [5]. Furthermore, around a quarter of the population (25%) suffer from anxiety when taking a flight, approximately 20% depend on alcohol or anxiolytics to fly, and about 10% avoid flying due to the intensity of their fear [6].

Research to date has pointed out that the most effective treatment approach for specific phobias (including FP) is in vivo exposure, recommending it as the treatment of choice [4,7]. Specifically for FP, evidence indicates that more than 90% of participants whose treatment included in vivo exposure continued to fly at one- to four-year follow-up [8]. Despite this evidence, the in vivo exposure technique is linked to several limitations in its implementation, such as low acceptance among therapists and patients and difficulties in accessing the treatment. Regarding acceptance, some authors have considered in vivo exposure to be a cruel cure and ethically inappropriate [9,10]. Around 25% of patients reject starting the treatment when they are informed about the procedure, or they drop-out during treatment because they consider it too aversive [11]. In terms of accessibility, only 7.8% of people suffering from phobias seek help [12], and very few of them (8%) receive a specific treatment for their problem [13]. In addition, in vivo exposure involves lack of confidentiality and high associated costs when conducted outside the therapist's office [14]. Two issues that are particularly important in FP treatment are the economic cost of in vivo exposure and the additional difficulty of applying the exposure technique in an appropriate way (controlling important variables such as the duration of the exposure or the number of sessions) – due to the limited access to the feared stimulus (i.e., airport or airplane) [15].

Therefore, there is a demand for better types of exposure therapy. Specifically for FP, there is a need to improve the adherence, acceptance, and accessibility of the exposure therapy. Information and Communication Technologies (ICTs) can be useful for overcoming these issues, for example, through computerized treatments such as virtual reality exposure therapy (VRET) and computer-assisted exposure programs. The efficacy of VRET has been shown in several

meta-analyses and systematic reviews for the treatment of anxiety disorders [16–19], including FP [6,14,20,21]. However, some authors suggest that less sophisticated and cheaper devices might be sufficient to produce satisfactory outcomes in FP [22]. Thus, Tortella-Feliu et al. [23] showed that a computer-assisted exposure program was as effective as VRET in FP treatment. Moreover, no significant differences were found between two ways of delivering this computer-assisted exposure treatment (with therapist assistance throughout the exposure vs. self-administered in the lab). According to these authors, the data also suggest that therapist involvement might be minimized in FP treatment using computer-assisted exposure programs.

An additional approach to using ICTs is to deliver psychological treatments over the Internet. In the past decade, the Internet has been established as a useful and effective tool to treat several psychological disorders [24–26]. Particularly for anxiety disorders, Internet-based treatments are highly effective and show comparable clinical outcomes to face-to-face treatment and large effect sizes compared to control groups (waiting list or placebo treatment) [27–29]. Moreover, authors especially recommend the use of self-applied interventions via the Internet for anxiety disorders because of their numerous advantages, including greater accessibility, versatility, safety, anonymity, acceptability, convenience, and cost-effectiveness [30–33].

Despite these findings and recommendations, research on Internet-based treatments for specific phobias is still scare. To date, the literature reviewed shows two randomized controlled trials (RCT), one on spider phobia [34] and one on snake phobia [35]. Similarly, Botella et al. [36] showed preliminary data from a series of cases about a self-applied telepsychology program using an intranet to treat small animal phobia (spiders, cockroaches, and mice). Moreover, other studies have pointed out the efficacy of Internet-based treatments for several disorders, including specific phobia. One example is the study by Kok, van Straten, Beekman and Cuijpers [37] who examined the efficacy of an Internet-based exposure intervention with weekly support for outpatients waiting for face-to-face psychotherapy for several phobias. In addition, several studies have tested the FearFighter™ program [38] for the treatment of panic and phobia disorders [39–41], which is used in the mental health services in England [42]. Finally, from a transdiagnostic perspective, Schöder, Jelinek and Moritz [43] conducted a randomized controlled trial of an Internet intervention for individuals with panic and phobias.

Regarding studies designed for specific phobia treatments, Andersson et al. [34,35] found large within-group effect sizes for self-administered Internet treatments guided by the therapist from a distance, although in both studies the one-session exposure treatment (OST) was more effective than the self-administered Internet interventions. Nevertheless, as the authors noted, it is important to take into account that the Internet treatments used in both studies consisted of self-administered exposure, rather than a treatment delivered through a computer [35]. These treatments were mainly provided in the form of downloadable pdf files and a video sent to participants illustrating the exposure principles. Internet-based treatments usually include guidelines for exposure to the feared situations (i.e., downloadable pdf files), but without providing significant exposure stimuli (i.e., self-administered exposure scenarios through the computer). As some authors suggest, this may be especially relevant in treating specific phobias and other anxiety disorders [44,45]. In line with the recommendations made by Botella et al. [44], we suggest that the combination of new technologies (i.e., multimedia exposure scenarios) and self-help procedures could be a useful clinical tool for the treatment of other psychological disorders, such as FP.

An important research issue in psychological treatments delivered via the Internet is the impact of guidance. Meta-analyses and systematic reviews have shown the beneficial feature of providing guidance throughout the intervention because it leads to better adherence and outcomes [46–49]. Although the literature suggests that the qualifications of those providing guidance (technicians vs. clinicians) might be of minor importance [47], some evidence highlights the superiority of guided interventions over unguided interventions [49]. Nevertheless, authors have recently shown that the magnitude of these differences is smaller than what was suggested in previous meta-analyses [47]. In addition, studies have pointed out that self-guided interventions are useful alternatives with similar outcomes that might work using automated reinforcement and no human support [50–53]. Despite these findings, there is no research on this issue in specific phobias, revealing the need for further research on this topic, particularly in FP.

In sum, there is a growing body of evidence about the effectiveness of Internet-based treatments to treat psychological disorders. However, the literature on specific phobias is scarce in this regard, and few studies have focused on the usefulness of the Internet in delivering systematic exposure through the

computer. To the best of our knowledge, no published RCT has tested the efficacy of an Internet-based exposure treatment for FP. Therefore, the aim of this study is to investigate the effectiveness of an Internet-based exposure treatment for FP (*NO-FEAR Airlines)* that includes exposure scenarios composed of images and real sounds, versus a waiting list control group, in a randomized controlled trial (RCT). A secondary aim is to explore two ways of delivering *NO-FEAR Airlines*, with and without therapist guidance.

Methods

Study design

This study was a randomized controlled trial (RCT), in which participants were randomly allocated to three groups: 1) Internet-based exposure treatment for FP without therapist guidance (*NO-FEAR Airlines* totally self-applied, NFA); 2) Internet-based exposure treatment for FP with therapist guidance (*NO-FEAR Airlines* with therapist guidance, NFA + TG); and 3) a waiting list (WL) control group. For ethical reasons, participants in the WL group were randomly assigned to one of the two treatment conditions after spending time on the waiting list (6 weeks), thus leaving no control group for the follow-up measurements. The trial was registered at ClinicalTrials.gov (NCT02298478) on November 3, 2014. This trial received approval from the Ethics Committee of Universitat Jaume I (Castellón, Spain) (20 December 2014) and was conducted in compliance with the study protocol, following the CONSORT statement (Consolidated Standards Of Reporting Trials, http://www.consort-statement.org), the CONSORT-EHEALTH guidelines [54], the APA guidelines for the practice of telepsychology [55], the Declaration of Helsinki, and good clinical practice. Details of the study protocol have been reported elsewhere [56]. Two changes from the original protocol were made: 1) Missing data were handled using Intent-to-treat (ITT) mixed-model analyses without any ad hoc imputations rather than using analysis of variance (ANOVA) with multiple imputations (MI), based on the authors' recommendation and due to the large amount of missing data at follow-up [57,58]; 2) the 12-month follow-up could not be completed because of project time limits and funding. Therefore, only data from the 3-month follow-up are reported. Figure 3.1 shows the flow diagram.

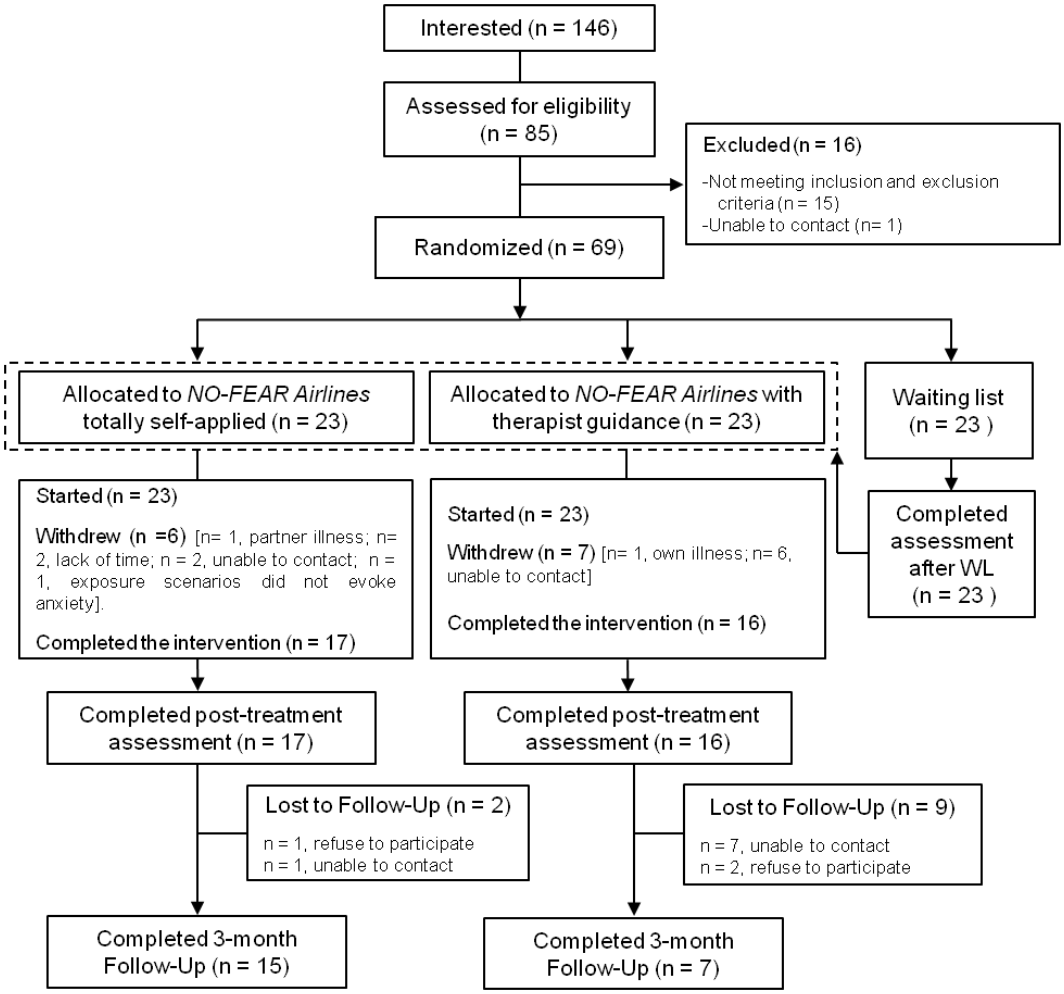

Figure 3.1. Flow diagram

Sample size

Power calculations and Internet attrition rates (30%) [59,60] indicated that a sample size of 57 participants (19 in each group), as a minimum, would be sufficient to detect a large effect size (d = 1) with a power of .80 and an alpha of .05, based on a similar study [23] and recent systematic reviews [33].

Participants, recruitment and randomization

The study was advertised online via professional websites (i.e., LinkedIn), non-professional social-networks (i.e., Facebook and twitter), and announcements placed in local universities and in the local media (newspapers and radios). People who were interested in participating in the study registered on the website [61] and signed the informed consent form. The clinical team contacted participants by telephone or through the *skype* platform in the case of international calls, in order to screen accessibility criteria and explain the terms of

the research. The inclusion criteria were: a) being at least 18 years old; b) meeting DSM-5 criteria for specific, situational phobia (FP) [1]; c) having adequate knowledge to understand and read Spanish; d) having access to the Internet; e) and ability to use a computer. The exclusion criteria were: a) receiving psychological treatment for FP; b) diagnosis of a severe mental disorder (abuse or dependence on alcohol or other substances, psychotic disorder, dementia, or bipolar disorder); c) presence of depressive symptomatology, suicidal ideation or plan; d) presence of heart disease; e) and pregnant women (from the fourth month). Participants with comorbid and related disorders (i.e., panic disorder, agoraphobia, claustrophobia, or acrophobia) were included when FP was the primary diagnosis. Receiving pharmacological treatment was not an exclusion criterion, but any increase and/or change in the medication during the study period implied the participant's exclusion from subsequent analyses. A decrease in pharmacological treatment was accepted.

Participants who meet the criteria were administered a baseline telephone assessment that included the diagnostic interview. After that, they were randomly assigned to one of the three experimental groups (n = 69). A computer-generated randomization list was created using the Epidat 4.0 program [62], by an independent researcher who was unaware of the characteristics of the study and had no clinical involvement in the trial or access to the study data. The allocation scheme was communicated to clinicians via a phone call. In the same way, researchers contacted participants to explain the condition to which they had been allocated, and access to the program was provided if required. Thus, researchers and participants were blind to the experimental condition during the assessment at baseline, and patients agreed to participate before knowing the random allocation. However, they could not be blind to the treatment conditions for practical reasons. Participants were free at any time to withdraw from the study without giving any explanation. Access and participation in the study did not involve payment in any case.

Intervention

NO-FEAR Airlines is a computer-aided exposure treatment for FP that can be completely self-applied via the Internet [56,63]. This Internet-based intervention allows people who are afraid of flying to be exposed to images and real sounds related to their phobic fears on a standard personal computer. The graphical user interface was designed according to visual flying metaphors (i.e., Airline motifs)

and with linear navigation, in order to optimize the treatment structure and make the treatment easier and more attractive to the users (Figure 3.2). Based on this design, the user can only continue on to the next section or take a break and continue later from the same place.

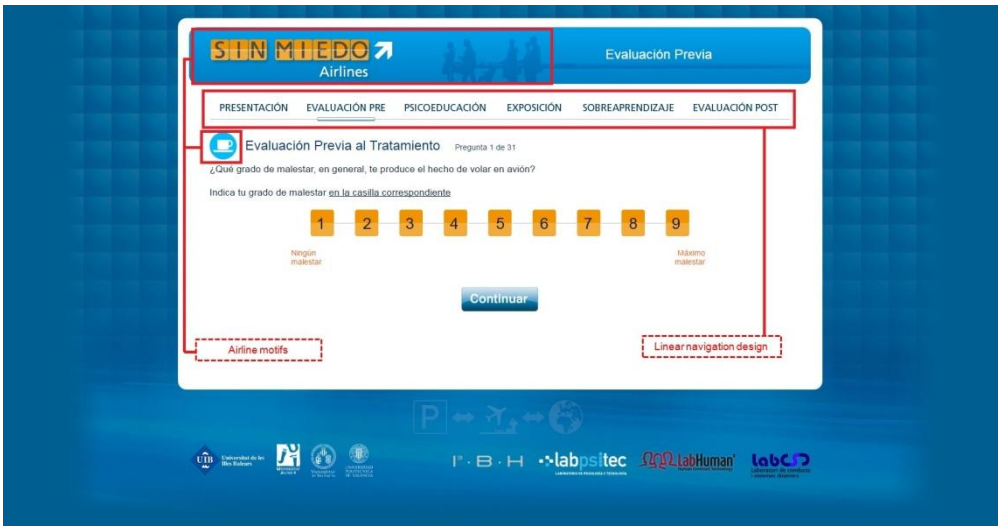

Figure 3.2. *NO-FEAR Airlines* "screenshot": Linear navigation design and Airline motif examples

The program includes both an *assessment protocol* and a *treatment protocol* which includes three therapeutic components (psychoeducation, exposure, and overlearning), following the guidelines for good clinical practice [1,42]. First, *psychoeducation* includes specific information related to FP (i.e., how many people are affected, or how the problem begins and is maintained), using text, vignettes, and illustrations. Then, the *exposure* component is provided by the system, depending on the patient's anxiety level recorded in the assessment (based on the FFQ-II questionnaire scores [64]). *Exposure* is performed through six scenarios composed of significant stimuli such as images and real sounds related to flying situations: (1) flight preparation, (2) airport, (3) boarding and taking off, (4) the central part of the flight, (5) the airplane's descent, approach to the runway, and landing, (6) sequences with images and auditory stimuli related to plane crashes. The system advances to the next scenario when the user overcomes the current stage (anxiety level below 3 on a scale ranging from 0 "no anxiety" to 10 "high anxiety"). Thus, the program reacts in real time to each patient's needs on the exposure task. After completing all the exposure scenarios, *overlearning* is offered as additional exposure, and participants may choose the scenarios that they want to confront based on their needs – from the

same scenarios as in the exposure stage (except the air crash news scenario) – with a higher degree of difficulty, simulating storm conditions and turbulence.

All participants were advised to participate in about two exposure scenarios per week, taking a few days off between sessions. It was estimated that the treatment could be completed in three or four weeks, with a maximum period of six weeks. However, each participant was free to advance at his/her own pace. Furthermore, after the program, all the patients were encouraged to take a real flight. Although it was recommended that the flight be taken within two weeks after finishing the treatment, participants could schedule it based on their possibilities. The cost of the flight was paid for by each participant. *NO-FEAR Airlines* provides guidelines to cope with this test flight through downloadable material (pdf files). At the end of the treatment, the system provides post-treatment and follow-up assessments.

The program described was implemented in two formats: 1) NO-FEAR Airlines totally self-applied. Participants received the completely self-applied treatment and only automatic support was provided throughout the program (i.e., automatic reinforcement after each exposure scenario). Technical assistance (i.e., web accessibility problems or forgotten password) was provided, if necessary. 2) NO-FEAR Airlines with therapist guidance. In this case, participants also self-administered the treatment via the Internet and received minimal telephone support from the therapist. Therapist guidance consisted of a brief weekly phone call (maximum 5 min), to assess and guide the participant's progress by providing feedback and reinforcement until s/he had finished the treatment. Thus, patients could receive up to 6 telephone calls, and so they had a maximum of 30 minutes of therapeutic support. In addition, the therapist checked for any problems and reminded the participant about the recommended treatment pace. Guidance content was standardized; although it could be tailored depending on patients' needs (see Figure 3.3 for details). However, support calls could not include any additional clinical content. Telephone guidance was provided by trained and experienced psychologists.

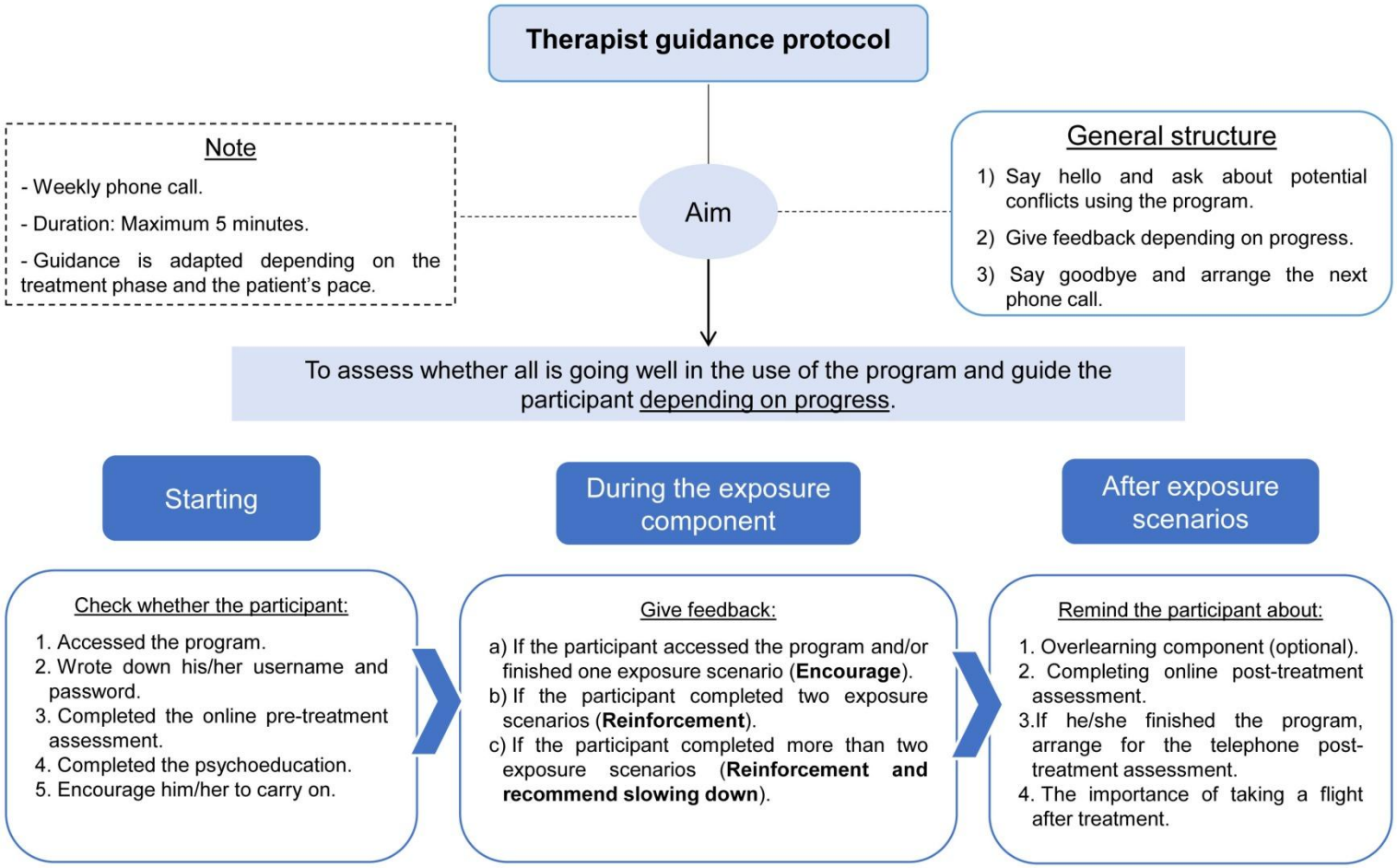

Figure 3.3. Therapist guidance protocol

Outcomes

Assessments were conducted via phone call, a commercial online survey system (www.surveymonkey.com), and the *NO-FEAR Airlines* program. Participants were assessed at baseline, post-treatment, and 3-month follow-up. A detailed description of the measures and sources of assessment can be found in the study protocol [56]. Measures included in this study were as follows:

Diagnostic interview. The Anxiety Disorders Interview Schedule for DSM-IV-TR (ADIS-IV) [65]. *Primary outcomes*. The Fear of Flying Questionnaire-II (FFQ-II) [64]; The Fear of Flying scale (*FFS*) [66]. *Secondary outcomes*. Fear and Avoidance Scales (adapted from Marks & Mathews [67]); The Clinician Severity Scale (adapted from Di Nardo, Brown & Barlow [68]); The Patient's Improvement Scale (Adapted from the Clinical Global Impression Scale [69]). *Measures related to FP.* The duration of the problem; how many times the patient has taken a flight; whether safety behaviors were used (e.g., alcohol intake, distraction); and whether the participant has had any negative experiences with flying.

Statistical methods

Group differences in participants' socio-demographic and clinical data at baseline were examined using one-way analyses of variance (ANOVAs) for continuous data and chi-square tests (χ^2) for categorical variables. Intent-to-treat (ITT) mixed model analyses without any ad hoc imputations were conducted to handle missing data due to participant drop-out [70]. This approach uses all available data, it does not involve any substitution of missing values with supposed or estimated values, and it does not assume that the last measurement is stable (the last observation carried forward assumption) [71,72]. Mixed model analyses are appropriate for RCTs with multiple time points and pre-to post-only designs [57]. The assumption that data were missing completely at random (MCAR) was evaluated using Little's MCAR test. A linear mixed-model for each outcome measure was implemented using the MIXED procedure with one random intercept per subject. An identity covariance structure was specified to model the covariance structure of the random intercept. For each outcome, *time* was treated as within-group factor and *group* as a between-group factor. Significant effects were followed up with pairwise comparisons. Separate mixed model analyses were conducted to compare changes from baseline in each intervention to 3-month follow-up. Effect sizes (Cohen's *d*) were calculated for within- and between-group comparisons [73–76]. The reliable change index (RCI) [77] for

primary outcome measures (FFQ-II and FSS) was calculated based on the completer sample (participants who provided data at post- and follow-up assessments, respectively). Chi-square tests were performed to evaluate group differences in RCI rates, behavioral outcomes (post-treatment flights and safety behaviors), and participant diagnostic status for completers. All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 23.

Results

Participant flow and attrition

The recruitment started on September 2015 and ended on August 2016. Initially, as the flow diagram shows (Figure 3.1), 146 people were interested in the study, and 85 of them were assessed for eligibility criteria. At this stage, 16 participants were excluded from the study. Finally, 69 participants were included in the study, and they were randomly allocated to each experimental condition (*NO-FEAR Airlines* totally self-applied, n = 23; *NO-FEAR Airlines* with therapist guidance, n = 23; and WL, n = 23). Of those who started the program (n = 46), 13 participants (28.26%) withdrew from the treatment conditions. No significant differences were found between the two treatment groups in attrition rates at post-treatment. At 3-month follow-up, a total of 22 participants (47.83%) completed the assessment, with significant differences between groups (χ^2 (1) = 5.576; p = .018). The last participant completed the 3-month follow-up on December 2016. In the WL control group, data from 23 participants were obtained after they had spent 6 weeks on the waiting list (100% retention). Data were missing completely at random (MCAR) (p > .05).

Baseline data and participant characteristics

Table 3.1 shows participants' sociodemographic and clinical data for each group. No statistically significant differences were found on any sociodemographic or participant's data, or on primary and secondary outcomes at baseline. Overall, participants came from Spain (91.3 %, n = 63), Colombia (2.9 %, n = 2), Chile (1.4 %, n = 1), Cuba (1.4 %, n = 1), USA (1.4 %, n = 1), and Italy (1.4 %, n = 1). They were not receiving stable medication, except four participants who were receiving anxiolytics to treat anxiety symptoms, with no significant differences between groups. There were no increases and/or changes in the medication intake during the study.

Table 3.1. Demographic and participant data

	NFA (n = 23)	*NFA + TG* (n = 23)	WL (n = 23)	Statistics
Age	36.30 (8.14) [range = 21-50]	38.87 (13.56) [range = 20-65]	34.13 (9.00) [range = 21-53]	F(2,69)= 1.173 *p* = .316
Sex				
Male	8 (34.8%)	6 (26.1%)	5 (21.7%)	$\chi^2(2) = 1.02$
Female	15 (65.2%)	17 (73.9%)	18 (78.3%)	*p* = .601
Marital status				
Married	12 (52.2%)	11 (47.8%)	10 (43.5%)	χ^2 (4) =.74
Single	10 (43.5%)	11 (47.8%)	11 (47.8%)	*p* = .946
Divorced/Separated	1 (4.3%)	1 (4.3%)	2 (8.7%)	
Educational status				
Primary studies	-	-	1 (4.3%)	$\chi^2(4) = 5.49$
Secondary school	2 (8.7%)	7 (30.4%)	5 (21.7%)	*p* = .240
University education	21 (91.3%)	16 (69.6%)	17 (73.9%)	
Employment status				
Student	4 (17.4%)	4 (17.4%)	1 (4.3%)	$\chi^2(8) = 12.41$
Unemployed	4 (17.4%)	4 (17.4%)	1 (4.3%)	*p* = .134
Employed	15 (65.2%)	12 (52.2%)	2 (8.7%)	
Retired	-	3 (13%)	19 (82.6%)	
Medication				
Yes	1 (4.3%)	2 (8.7%)	1 (4.3%)	$\chi^2(2) = .53$
No	22 (95.7%)	21 (91.3%)	22 (95.7%)	*p* = .767
Experience Flying*?*				
Yes	21 (91.3%)	20 (87%)	22 (95.6%)	$\chi^2(2) = 1.20$
No	2 (8.7%)	3 (13%)	1 (4.4%)	*p* = .547
Duration of Phobia				
< 6 months	1 (4.3%)	1 (4.4%)	1 (4.4%)	$\chi^2(8)=2.145$
6 –12 months	0 (0%)	1 (4.4%)	1 (4.4%)	*p* = .976
1 – 5 years	3 (13%)	3 (13%)	3 (13%)	
6 – 10 years	7 (30.4%)	7 (30.4%)	7 (30.4%)	
> 11 years	12 (52.2%)	11 (47.8%)	11 (47.8%)	

Note. Means and standard deviations (SD) are represented for age (years). NFA. NO-FEAR Airlines totally self-applied without therapist guidance. NFA + TG. NO-FEAR Airlines with Therapist guidance. WL. Waiting list.

Effectiveness: change in primary and secondary outcomes at pre-post

Primary outcomes

The main effects of Time and Group were qualified by a significant interaction for *FFQ-II* (F(2, 57.48) = 21.151; $p < .001$) and *FFS* (F (2, 57.58) = 29.301; $p < .001$). For both primary outcomes, within-group comparisons indicated significant pre-to-post reductions in the two treatment groups with large effect sizes, and non-significant changes in the WL control group (see Table 3.2 for details). Between-group comparisons revealed that participants who received the treatment (with and without therapist guidance) scored lower at post-treatment, compared to the

WL group, with large effect sizes (see Table 3.3). There were no statistically significant differences between the two treatment groups at post-treatment. The power achieved by the comparison between the two Internet groups was .25 on the FFQ-II with an effect size of d = .23 (alpha of .05).

Secondary outcomes

Regarding secondary outcome measures, the main effects of Time and Group were qualified by a significant interaction for the Clinician Severity Scale ($F(2, 62.13) = 34.867$; $p < .001$) and the Fear and Avoidance Scales related to the main target behavior (taking a flight) [Fear ($F(2, 64.54) = 17.906$; $p < .001$), Avoidance ($F(2, 57.52) = 21.242$; $p < .001$), and the degree of Belief in the main catastrophic thought ($F(2, 60.14) = 24.771$; $p < .001$)]. Results of within-group comparisons showed significant reductions on these measures in the two treatment groups, corresponding to large effect sizes (see Table 3.2). There were no significant changes in the WL group. At post-treatment, between-group comparisons revealed that the two treatment groups scored significantly lower on all the secondary outcome measures, compared to WL, and non-significant differences were found between the two ways of delivering the Internet-based treatment (with and without therapist guidance) (Table 3.3).

For the Patient's Improvement Scale assessed at post-treatment, results showed a significant main effect of Group ($F(2, 52)=20.807$; $p < .001$), indicating that the improvement achieved and reported by patients was statistically higher in the Internet-based treatment groups (with and without therapist guidance) compared to WL with large effect sizes (Table 3.3). The differences between the two treatment groups were not statistically significant.

Maintenance of treatment gains at 3-month follow-up

Separate linear mixed model analyses yielded a significant main effect of Time on all the primary and secondary outcomes (all ps < .001), except for the Patient's improvement Scale. Overall, within-group comparisons revealed significant changes from baseline to 3-month follow-up in the two treatment groups, indicating maintenance of the treatment gains. In addition, taken together, within-group effect sizes were higher for the pre-treatment to 3-month follow-up change than for the pre- to post-treatment change (see Table 3.2). Between-group comparisons did not reveal significant differences between the two Internet-based treatment groups (with and without therapist guidance) at 3-month follow-up (Table 3.3).

Table 3.2. Means, standard deviations and within-group effect sizes for primary and secondary outcomes at pre-, post-treatment, and 3-month follow-up

	NO-FEAR Airlines totally self-applied					*NO-FEAR Airlines* with therapist guidance					Waiting list		
	Pre (n = 23)	Post (n = 17)	FW (n = 15)	Pre vs. Post	Pre vs. FW	Pre (n = 23)	Post (n = 15)	FW (n = 7)	Pre vs. Post	Pre vs. FW	Pre (n = 23)	Post (n = 23)	Pre vs. Post
				d (95%CI)	d (95%CI)				d (95%CI)	d (95%CI)			d (95%CI)
FFQ-II	202.57 (33.54)	149.29 (46.35)	132.85 (46.35)	d = 1.53 (.94, 2.13)	d = 2.01 (1.29, 2.71)	215.19 (29.69)	138.53 (55.53)	124.57 (67.85)	d = 2.49 (1.55, 3.43)	d = 2.95 (1.87, 4.02)	205.35 (49.64)	204.52 (48.54)	d = .02 (-.18, .30)
FFS	65.91 (6.93)	48.24 (9.80)	44.53 (11.49)	d = 2.46 (1.63, 3.29)	d = 2.98 (1.94, 4.02)	66.96 (6.94)	47.75 (17.00)	44.00 (14.93)	d = 2.67 (1.75, 3.59)	d = 2.88 (.79, 5.00)	63.96 (12.28)	65.18 (11.85)	d = -.10 (-.33, .13)
TB													
Fear	9.26 (.86)	5.29 (1.36)	5.73 (2.02)	d = 4.46 (3.00, 5.91)	d = 3.91 (2.38, 5.43)	9.26 (.864)	5.13 (2.33)	4.29 (2.93)	d = 4.64 (3.12, 6.16)	d = 5.03 (1.30, 8.75)	9.22 (1.20)	8.17 (2.41)	d = .84 (.50, 1.19)
Avoidance	8.00 (2.43)	4.18 (2.33)	3.33 (2.82)	d = 1.52 (.92, 2.16)	d = 1.82 (.98, 2.65)	8.57 (1.62)	4.25 (3.55)	2.29 (2.98)	d = 2.57 (1.61, 3.54)	d = 3.37 (.57, 6.17)	8.04 (2.84)	8.14 (2.83)	d = -.03 (-.17, .10)
Belief	8.74 (1.01)	5.35 (2.15)	5.13 (3.25)	d = 3.24 (2.14, 4.35)	d = 3.38 (1.93, 4.83)	8.78 (1.51)	4.88 (2.66)	3.57 (2.88)	d = 2.49 (1.53, 3.45)	d = 3.00 (.51, 5.49)	8.83 (1.61)	8.77 (1.63)	d = .04 (-.17,.24)
Severity	7.30 (.56)	4.18 (1.51)	3.53 (1.77)	d = 5.38 (3.64, 7.11)	d = 6.37 (3.76, 8.97)	7.40 (.72)	4.19 (2.37)	2.86 (1.77)	d = 4.30 (2.85, 5.76)	d = 5.49 (1.43, 9.54)	7.26 (1.10)	7.27 (1.20)	d = -.01 (-.21, .20)
Improvement	–	5.41 (.80)	5.67 (.90)	–	–	–	5.44 (1.09)	6.14 (.90)	–	–	–	3.91 (.68)	–

Note. Means and standard deviations (SD) are represented for each primary and secondary outcome measure. Pre. Pre-treatment. Post. Post-treatment. FW. 3-month follow-up. FFQ-II. Fear of Flying questionnaire. FFS. Fear of Flying Scale. TB. Target Behavior. Belief. Degree of belief on the main irrational thought related to the target behavior. Severity. The Clinician Severity Scale. Improvement. The Patient's Improvement Scale.
* p < .05. ** p < .01. *** p < .001.

Table 3.3. Between-group comparisons and effect sizes on primary and secondary outcome measures at post-treatment and 3-month follow-up

		Post-treatment		3-month follow-up	
		Mean dif.	*d* (95%CI)	Mean dif.	*d* (95%CI)
FFQ-II					
	NFA vs. WL	-57.78***	*d* = -1.13 (-1.81, -.46)	–	
	NFA + TG vs. WL	-66.45***	*d* = -1.27 (-1.98, -.56)	–	
	NFA vs. NFA + TG	8.67	*d* = .23 (-.46, .93)	-.25	*d* = .15 (-.77, 1.07)
FFS					
	NFA vs. WL	-17.23***	*d* = -1.51 (-.2.13, -.71)	–	
	NFA + TG vs. WL	-17.68***	*d* = -1.21 (-1.92, -.49)	–	
	NFA vs. NFA + TG	.46	*d* = .03 (-.66, .73)	-.53	*d* = .04 (-.86, .94)
TB					
Fear	NFA vs. WL	-.2.86***	*d* = -1.40 (-2.10,-.69)	–	
	NFA + TG vs. WL	-3.06***	*d* = -1.25 (-1.96, -.54)	–	
	NFA vs. NFA + TG	.21	*d* = .08 (-.06, .78)	1.08	*d* = .34 (-.01, .68)
Avoidance					
	NFA vs. WL	-3.83***	*d* = -1.48 (-2.19, -.76)	–	
	NFA + TG vs. WL	-3.83***	*d* = -1.21 (-1.91, -.51)	–	
	NFA vs. NFA + TG	.004	*d* = -.02 (-.71, .66)	.66	*d* = .35 (-.55, 1.25)
Belief					
	NFA vs. WL	-3.42***	*d* = -1.79 (-2.54, -1.04)	–	
	NFA + TG vs. WL	-3.95***	*d* = -1.80 (-2.56, -1.04)	–	
	NFA vs. NFA + TG	.53	*d* = .19 (-.49, .87)	1.08	*d* = .48 (-.43, 1.40)
Severity					
	NFA vs. WL	-3.07***	*d* = -2.25 (-3.10, -1.45)	–	
	NFA + TG vs. WL	-3.11***	*d* = -1.69 (-2.44, -.94)	–	
	NFA vs. NFA + TG	.04	*d* = -.01 (-.69, .68)	.42	*d* = .36 (-.54, 1.39)
Improvement					
	NFA vs. WL	1.50***	*d* = 2.00 (1.23, 2.46)	–	
	NFA + TG vs. WL	1.53***	*d* = 1.71 (.96, 2.46)	–	
	NFA vs. NFA + TG	-.26	*d* = -.03 (-.71, .65)	-1.64	*d* = -.51 (-1.42, .40)

Note. NFA. NO-FEAR Airlines totally self-applied without therapist guidance. NFA + TG. NO-FEAR Airlines with Therapist guidance. Mean dif. Mean differences. WL. Waiting list. *d*. Cohen's *d*. CI. Confidence interval. FFQ-II. Fear of Flying questionnaire. FFS. Fear of Flying Scale. TB. Target Behavior. Belief. Degree of belief on the main irrational thought related to the target behavior. Severity. The Clinician Severity Scale. Improvement. The Patient's Improvement Scale. * p < .05. ** p < .01. *** p < .001.

Clinically meaningful improvement: Reliable change

Figure 3.4 presents the proportion of completers in each condition who were recovered, improved, unimproved, or deteriorated at post-treatment and 3-month follow-up. At post-treatment, statistically significant differences were found between the three conditions in these percentages on the *FFQ-II* ($\chi^2(2) = 9.82$; $p < .01$) and the *FSS* ($\chi^2(4) = 31.972$; $p < .001$). Overall, participants who had received the Internet-based interventions (with and without therapist guidance) showed higher recovered percentage compared to WL. Regarding reliable change at 3-month follow-up, *NO-FEAR Airlines* with therapist guidance revealed higher percentages of recovered participants on the *FFS* compared to the totally self-applied intervention, although no statistically significant differences were found on *FSS* ($\chi^2(1) = 1.027$; $p = .311$) or *FFQ-II* ($\chi^2(1) = .02$; $p = .888$).

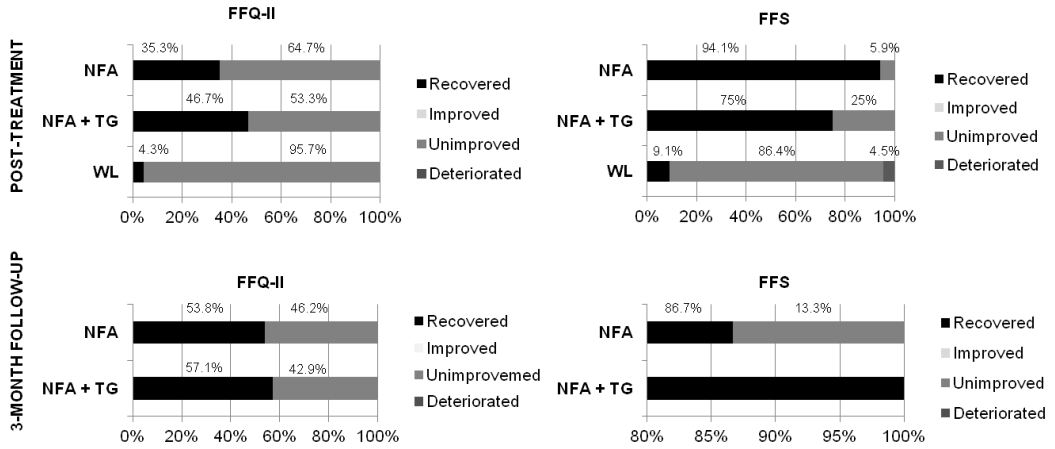

Figure 3.4. Reliable change

Percentage of the completer sample in each condition corresponding to recovered, improved, unimproved, or deteriorated. FFQ-II. Fear of Flying Questionnaire. FFS. Fear of Flying Scale. NFA. NO-FEAR Airlines. NFA + TG. NO-FEAR Airlines with therapist guidance. WL. Waiting list.

Diagnostic status and behavioral outcomes

Results for diagnostic status and behavioral outcome measures (post-treatment flights and safety behaviors) are shown in Table 3.4. Analyses revealed statistically significant differences between groups at post-treatment for FP diagnostic status, safety behaviors, and number of safety behaviors. Specifically, both treatment groups (with and without therapist guidance) scored lower than the WL group: they had a lower percentage of FP diagnosis, the number of participants who reported using safety behaviors was lower, and they used fewer safety behaviors. No statistically significant differences were found at 3-month follow-up on diagnostic status or the behavioral outcome measures.

Table 3.4. Diagnostic status and behavioral outcome measures at post-treatment and 3-month follow-up

		NFA		NFA + TG		WL	
		Post (n = 17)	FW (n = 15)	Post (n = 15)	FW (n = 7)	Post (n = 23)	Statistics
FP Diagnosis	*Yes*	11	6	9	3	23	Post: $\chi^2(2) = 10.709$; $p < .10$
	No	6	9	6	4	0	FW: $\chi^2(1) = .175$; $p = .676$
Post-treatment flights	*Yes*	5	12	3	3	3	Post: $\chi^2(2) = 1.514$; $p = .469$
	No	12	3	12	4	20	FW: $\chi^2(1) = 1.257$; $p = .262$
Number of flights taken							
	0	12	3	12	3	20	Post: $\chi^2(6) = 3.059$; $p = .801$
	2	4	9	3	2	0	FW: $\chi^2(4) = 3.101$; $p = .541$
	4	1	2	0	2	2	
	6	0	1	0	0	1	
Safety behaviors	*Yes*	2	7	1	2	18	Post: $\chi^2(2) = 25.408$; $p < .01$
	No	15	8	14	5	5	FW: $\chi^2(1) = 1.174$; $p = .279$
Number of safety behaviors							
	0	15	7	14	5	1	Post: $\chi^2(14) = 41.357$; $p < .001$
	1-3	2	6	1	1	16	FW: $\chi^2(4) = 4.982$; $p < .289$
	4-6	0	0	0	1	5	
	7-9	0	0	0	0	1	

Note**.** NFA. *NO-FEAR Airlines* totally self-applied**.** NFA + TG**.** *NO-FEAR Airlines* with therapist guidance. FP. Flying Phobia. Post. Post-treatment. FW. 3-month follow-up.

Discussion

The aim of this study was to investigate the effectiveness of an Internet-based exposure treatment for FP (*NO-FEAR Airlines*) compared to a WL control group in an RCT. Overall, the data revealed that the self-applied online intervention (with and without therapist guidance) was effective in treating FP, compared to the WL, with large between-group effect sizes at post-treatment. Results showed a statistically significant change from pre to post treatment on all primary and secondary outcome measures, corresponding to large within-group effect sizes in both Internet-based treatment groups. Regarding the diagnostic status and reliable change indexes, significant improvements were found in the two treatment groups compared to the WL. In addition, these treatment gains were maintained at 3-month follow-up, and overall higher effect sizes were found compared to the pre-to-post change. These findings are in line with previous studies showing the efficacy of computer-assisted exposure programs for FP treatment [22,23].

An important research issue addressed in this study involves the use of the Internet to deliver self-administered exposure to the feared stimuli. *NO-FEAR Airlines* includes self-administered exposure scenarios composed of images and real sounds to provide systematic exposure through the computer. Therefore, results from the present study show that the combination of new technologies and self-help procedures is a useful clinical tool for FP treatment, as authors have also found for fear of public speaking [44]. It is also worth highlighting that, in addition to being effective, *NO-FEAR Airlines* seems to be well accepted by participants because none of the participants refused to start the treatment when they were informed about the procedure. This fact is especially relevant because it might suggest that Internet-based exposure treatment is a useful alternative to in vivo exposure, providing a less frightening way for participants to confront their fears [45]. As stated above, to date, most of the Internet-based treatments that include the exposure technique provide guidelines to face the feared stimuli through downloadable pdf files rather than through multimedia exposure scenarios. Given these findings, along with the recent advances and growing technological developments, further research is needed to improve Internet-based treatments that include exposure among their treatment components.

A secondary aim of this study was to explore the impact of therapist guidance. Our results overall indicate that providing a weekly phone call from a therapist did not significantly affect treatment outcomes at post-treatment or 3-month follow-up. These findings are congruent with studies suggesting that therapist involvement might be minimized for FP treatment using computer-assisted exposure programs [23], and they contradict other findings showing the superiority of guided interventions over unguided interventions [49]. In this regard, it is important to note some issues that could explain our results. First, *NO-FEAR Airlines* was designed with linear navigation to make the treatment easier and ensure that participants only continue on to the next section (or exposure scenario) when they are ready. Moreover, after participants had overcome each exposure scenario, automated reminders and reinforcements were provided through text displayed on the screen. As various authors suggested, if the self-applied program is well structured and designed, and automated support is provided throughout the intervention, the role of human guidance might be less important [50–52,78–80]. Second, all the participants received an initial phone call from a therapist who explained the research and conducted the screening procedures and telephone interviews. Research has highlighted that providing brief initial human contact before starting the treatment might be sufficient to produce an effect on the treatment outcomes, reducing the need for or impact of guidance throughout the treatment [81]. Third, therapist guidance might have different implications depending on the disorder addressed. Thus, it is also necessary to consider studies indicating that, whereas self-help interventions without therapist contact can be useful to treat simple psychological disorders (i.e, specific phobias), they may be insufficient for more severe mental disorders [44,82]. Although there is recent evidence showing the utility of self-guided Internet Interventions for severe disorders (i.e., depression) [51], this issue remains unclear. Moreover, and despite our findings, research focusing on specific phobia treatment is scarce. There are only two RCT on Internet-based treatments but both involve direct self-exposure guided by the therapist from a distance, without addressing this topic [34,35]. More research is needed to continue to explore the impact of guidance depending on the disorder treated.

In summary, our results point out the efficacy of *NO-FEAR Airlines* with and without therapist guidance. However, there are some limitations that should be mentioned. First, assessments were conducted online and via phone calls. Although several studies have shown the usefulness of Internet and telephone

administered assessments [83–85], some authors suggest that psychometric properties may change [86]. Second, missing data at 3-month follow-up were higher than expected, and no 12-month follow-up was available. Even though *NO-FEAR Airlines* sent automated reminders to participants and researchers to complete the assessment, we were unable to contact many of them, and they did not complete the 3-month follow-up. These facts limit our conclusions about long-term treatment gains. Further efforts are required in the future to provide 12-month follow-up data. Third, the interpretation of the behavioral outcome measures was compromised, due to the lower number of participants taking a flight after the treatment and the missing data rates, mentioned above. Given the importance of taking a flight after the treatment, outlined in several studies [8,14,87], further efforts are needed in this regard. We suggest that the use of persuasive technologies [79] to provide guidance and reinforcement after the treatment, as well as the use of short intervention packages (via web or mobile) to review or practice before taking a flight, could be useful in this endeavor. Finally, the study design and sample size calculations were mainly conducted as a superiority trial rather than as an equivalence trial [88–90]. Therefore, we can state that both ways of delivering the treatment (with and without therapist guidance) were effective for the treatment of FP, compared to the WL, but we cannot conclude that both conditions were equally efficacious. Future studies should be carried out to formally assess these issues. According to our data, future studies would include a minimum of 144 participants to achieve a power of .80.

As far as we know, this is the first RCT to investigate the effectiveness of an Internet-based intervention for FP and explore two ways of delivering the treatment (with and without therapist guidance). Overall, our findings indicate that FP can be effectively treated via the Internet. This study contributes to the literature on Internet-based interventions and adds additional data to the research on the use of computer-assisted exposure programs for FP treatment.

Conclusions

The Internet-based treatment (*NO-FEAR Airlines*) was effective for treating FP, compared to a WL, regardless of whether therapist guidance was provided or not. *NO-FEAR Airlines* includes significant self-administered exposure scenarios composed of images and real sounds to enhance the exposure technique for FP treatment. This program helps to improve access to evidence-based psychological treatment and reach more people who may need it.

List of abbreviations

ANOVA: Analysis of variance; APA: American Psychological Association; CI: Confidence Interval; CGI: Clinical Global Impression scale; CONSORT: Consolidated Standards of Reporting Trials; DSM-5: Diagnostic and Statistical manual for Mental Health Disorders-Version 5; FFS: Fear of Flying scale; FFQ-II: Fear of Flying Questionnaire-II; FP: Flying phobia; FW: Follow-up. ICTs: Information and Communication Technologies; ITT: Intention-to-treat; MI: Multiple Imputations; NICE: National Institute for Health and Clinical Excellence; NFA: NO-FEAR Airlines; TB: Target Behavior. TG: Therapist guidance RCT: Randomized Control Trial; VRET: virtual reality exposure therapy. WL. Waiting list.

Declarations

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Availability of data and material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request

Authors' contributions

DC[a] drafted the manuscript, with important contributions from SQ, JB-L. DC[a], in collaboration with SQ, and JB-L, designed the study and participated in each of its phases. AM collaborated in the manuscript development and participated in each study phase. CB, DC[b], RB and MT-F carried out the Internet-based adaptation of the treatment protocol, with important contributions of SQ and JB-L. All authors participated in the review and revision of the manuscript and approved the final manuscript to be published.

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Competing interests

The authors declare that they have no competing interests.

Consent for publication

“Not applicable” in this section.

Ethics approval and consent to participate

We confirm that any aspect of the work covered in this manuscript that involved human patients has been conducted with the ethical approval of all relevant bodies, and that such approvals are acknowledged within the manuscript. The study was approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain) (20 December 2014). All participants interested in participating signed an informed consent form.

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Chapter 4: Acceptability of *NO-FEAR Airlines*

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The acceptability of an Internet-based Exposure Treatment for Flying Phobia with and without therapist guidance: Patients' Expectations, Satisfaction, Treatment Preferences and Usability

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Abstract

Internet-based treatments have been tested for several psychological disorders. However, few studies have directly assessed the acceptability of these self-applied interventions in terms of expectations, satisfaction, treatment preferences, and usability. Moreover, no studies provide this type of data for an Internet-based treatment for Flying Phobia (FP) with and without therapist guidance. The aim of this study was to analyze the acceptability of an Internet-based treatment for FP (*NO-FEAR Airlines*) that includes exposure scenarios composed of images and real sounds. A secondary aim was to compare patients' acceptance of two ways of delivering this treatment (with or without therapist guidance). The sample included 46 participants from a randomized control trial who had received the self-applied intervention with (n = 23) or without therapist guidance (n = 23). All participants completed an assessment protocol conducted online and by telephone at pre- and post-treatment. Results showed good expectations, satisfaction, opinion, and usability, regardless of the presence of therapist guidance, including low aversiveness levels before and after the intervention. However, participants generally preferred the therapist-supported condition. In conclusion, *NO-FEAR Airlines* is a well-accepted Internet-based treatment that can help to enhance the application of the exposure technique, improving patients' acceptance and access to FP treatment.

Keywords: Internet-based exposure; Expectations; Satisfaction; Treatment preferences; Usability; Flying phobia.

Highlights

- Acceptability of an Internet-based exposure treatment for Flying phobia was studied.
- Results showed good expectations and satisfaction, regardless of whether therapist guidance was provided.
- Participants preferred the Internet-based treatment with therapist guidance.
- Aversiveness levels were low in both conditions (with and without support).
- *NO-FEAR Airlines* achieved excellent ratings on the Usability scale.

1. Introduction

Internet- and computer-based treatments have been tested and can be considered evidence based treatments for several psychological disorders (Anderson, 2016; Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Hedman, Ljótsson, & Lindefors, 2012; Sijbrandij, Kunovski & Cuijpers, 2016). Specifically, for anxiety disorders (including panic, specific phobias, social anxiety disorder, and generalized anxiety disorder), Internet-based treatments have shown large effect sizes compared to control groups (waiting list or placebo treatment) and equal or greater effects when compared to face-to-face treatment (i.e., Mewton, Smith, Rossouw, & Andrews, 2014; Olthuis, Watt, Bailey, Hayden, & Stewart, 2016; Peñate & Fumero, 2016; Reger, & Gahm, 2009).

Authors have pointed out that the use of the Internet to deliver psychological treatment can help to address common mental health treatment barriers, specifically in terms of access and geographical reach, versatility, safety, acceptability and convenience (Andersson & Titov, 2014; Andrews, Newby & Williams, 2015; Peñate, 2012). Focusing on the specific phobias, Internet-based treatments can help to overcome the limitations of *in vivo* exposure, such as low acceptance by patients and therapists and the difficulties in accessing treatment outlined in several studies (Deacon & Farrell, 2013; Garcia-Palacios, Botella, Hoffman, & Fabregat, 2007; Olatunji, Deacon, & Abramowitz, 2009).

Although the implementation of Internet-based interventions is promising, some challenges remain (Kaltenthaler et al., 2006; Whitfield, & Williams, 2004). One important issue in research related on self-applied programs is acceptability. Although clinical effectiveness is important, the acceptability of Internet-based treatments is an additional criterion that is likely to affect their implementation (Wallin et al., 2016). Acceptability refers to the degree to which patients (or other users) are satisfied or at ease with a service and willing to use it (Peñate & Fumero, 2016; Rush & Scott, 2004). A treatment is acceptable when it is perceived as fair and reasonable, appropriate, and non-intrusive in addressing a problem (Kazdin, 1980; Wallin et al., 2016). Following the recommendations of the United Kingdom technology appraisal of computerized treatments, evaluation of treatment acceptability must also be a priority (Kaltenthaler et al., 2006). In fact, taking an intervention's acceptability into account can improve adherence (Santana & Fontenelle, 2011) and outcomes (Swift, & Callahan, 2009). Some

variables related to treatment acceptability are expectations, satisfaction, treatment preferences, and usability (Botella, et al., 2009, 2016a,b). The literature suggests that *expectations* may be crucial to the psychotherapy process and its outcomes (Greenberg, Constantino, & Bruce, 2006), and positive expectations have been associated with better outcomes (De Graaf, Huibers, Riper, Gerhards, & Arntz, 2009; Goossens, Vlaeyen, Hidding, Kole-Snijders, & Evers, 2005). Moreover, *satisfaction* is another important variable because it provides information about the feasibility of the intervention, helping to optimize its effectiveness (De Graaf et al., 2009; Marks, Cavanagh & Gega, 2007). Treatment *preferences*, the systems or interventions that are preferred by patients, are considered a way to enhance clinical utility, increasing treatment adherence and outcomes (Bachofen et al., 1999; Bretón-López et al., 2015, García-Palacios, Hoffman, Kwong, Tsai, & Botella, 2001; Tarrier, Liversidge, & Gregg, 2006).

In spite of the importance of treatment acceptability, few studies have focused on its assessment in Internet-based interventions (i.e., Botella et al., 2009, 2016b; Montero-Marín et al., 2015; Wootton,Titov, Dear, Spence, & Kemp, 2011) and most of them provide only indirect data (i.e., Carrad et al., 2011; Gun, Titov, & Andrews, 2011). The most commonly used rating to measure acceptability is program adherence (De Graaf et al., 2009; Kay-Lambkin, Baker, Kelly, & Lewin, 2011). Although this information about the completion rate is quite important, it is necessary to evaluate acceptability more directly, as Kaltenthaler et al. (2006) concluded in their systematic review. Regarding *usability* testing, it has been described as a method for evaluating user performance and acceptance of a product during its development process (Kushniruk, 2002). Results from usability studies can help us to enhance the technology developed. However, few studies have assessed usability or ease of use issues in Internet- and Computer-based Interventions (Anderson, Zimand, Schmertz, & Ferrer, 2007; Botella et al., 2016; Castilla et al., 2016; Currie, McGrath, & Day, 2010; Stjernswärd & Östman, 2011). As Currie et al. (2010) claimed, research testing user perceptions of usability in computerized mental health self-help programs is still in its infancy, in spite of their advances and advantages.

Studies on Internet-based treatments for specific phobias are scarce. The literature reviewed reveal two small trials, one on spider phobia (Andersson et al., 2009) and one on snake phobia (Andersson et al., 2013), but the authors did not assess the treatments' acceptance. In a series of cases, Botella et al. (2008) provided preliminary data on the acceptability of a self-applied telepsychology

program using an intranet to treat small animal phobia (spiders, cockroaches, and mice). In addition, Kok, van Straten, Beekman and Cuijpers (2014) pointed out that an Internet-based exposure intervention with weekly support was well accepted in outpatients waiting for face-to-face psychotherapy for several phobias (including specific phobia), although a high dropout rate was observed (only 13.3% finished the intervention). Recently, Schöder, Jelinek and Moritz (2017) conducted a randomized controlled trial of a transdiagnostic Internet intervention for individuals with panic and phobias, and they evaluated satisfaction with the program. Participants reported a moderate level of satisfaction. Furthermore, the authors pointed out that attitudes toward psychological online interventions moderated the effects of the program, as there was a substantial increase in benefits in patients with more positive attitudes.

Regarding Flying Phobia (FP), some computer-assisted treatments have shown patient acceptance, but Internet was not used to deliver them (i.e., Bretón-López et al., 2015; Tortella-Feliu et al., 2011). Tortella-Feliu et al. (2011) carried out a randomized trial comparing three computer-aided exposure treatments for FP: virtual reality exposure treatment assisted by a therapist, computer-aided exposure with a therapist present throughout the exposure sessions, and self-administered computer-aided exposure. The three interventions were well accepted without compromising their efficacy. Based on data from Tortella-Feliu et al. (2011), Bretón-López et al. (2015) pointed out that participants' preferences for the three interventions differed in terms of subjective effectiveness, recommendation to others, and aversiveness. According to the authors, "facing the flight situation in a more realistic way makes the participants judge the treatment as more aversive" (Bretón-López et al., 2015). In this regard, decreasing treatments' aversiveness is a key feature and an ethical commitment in efforts to improve the application of the exposure technique (Deacon & Farrell, 2013; Garcia-Palacios et al., 2007; Olatunji et al., 2009). Thus, research on patients' acceptance of computer-assisted exposure using significant stimuli is especially relevant. Particularly in the case of FP, the application of exposure through interactive computer programs and Internet-based delivery is specifically recommended because it can produce lower aversion levels and reach more people in need.

Another relevant research issue that might be related to Internet-based treatments' acceptability is the degree of support or guidance provided during the intervention process (Gilbody et al., 2016; Johansson & Andersson, 2012).

Recently, a growing body of research has been conducted to determine the role of human support in these interventions, and the literature shows the importance of providing this support (i.e., Richards, & Richardson, 2012). Meta-analyses have shown that Internet- and computer-based treatments that offer some level of professional support or guidance produce larger effect sizes and lower dropout rates than self-help programs without any support (Andersson, & Cuijpers, 2009; Richards, & Richardson, 2012). Patients generally reported greater satisfaction with therapist-supported Internet-based interventions; however, as explained above, patients' satisfaction was not formally assessed (Olthuis et al., 2016). Other recent studies have found no significant differences in adherence between conditions with and without human support (Kelders, Bohlmeijer, Pots, van Gemert-Pijnen, 2015; Mira et al., 2017). Thus, it is interesting to continue to investigate whether there are differences in acceptability depending on the support provided.

As far as we know, no studies have directly assessed these variables to determine the user acceptability of an Internet-based program for FP that includes exposure scenarios composed of images and real sounds. The aim of the present study is to examine the acceptability of *NO-FEAR Airlines* in terms of expectations, satisfaction, treatment preferences, and usability. A secondary aim is to explore the patients' acceptance of two ways of delivering the program, with and without therapist guidance.

2. Material and methods

2.1. Research design

This study employed a randomized control design where all the participants were randomly allocated to three groups (Campos et al., 2016): 1) Internet-based exposure treatment for FP without therapist guidance (*NO-FEAR Airlines* totally self-applied); 2) Internet-based exposure treatment for FP with therapist guidance (brief weekly call) (*NO-FEAR Airlines* with therapist guidance); and 3) a waiting list control. In the present study, data from participants allocated to the two treatment conditions were analyzed. The RCT was registered under clinicaltrials.gov (NCT02298478), approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain) (20 December 2014) and conducted in compliance with the study protocol, the Declaration of Helsinki, the CONSORT

statements (http://www.consort-statement.org) and CONSORT-EHEALTH guidelines (Eysenbach, 2011), and good clinical practice.

2.2. Participants

The final sample included in this study was composed of 46 participants (*NO-FEAR Airlines* totally self-applied, *n* = 23; *NO-FEAR Airlines* with therapist guidance, *n* = 23). Of the total sample, 32 participants were women and 14 men. The mean age was 37.59 years (SD = 11.13) ranging from 20 to 65 years. Most of the participants had a university degree (80.4%) or secondary studies (19.6%). With regard to marital status, 50% were married, 45.7% single, and 4.3% separated or divorced. Most of the sample were employed (58.7 %), 17.4% were students, 17.4% were unemployed, and 6.5% were retired. Participants came from Spain (89%), Colombia (4.3%), the USA (2.2%), Cuba (2.2%) and Italy (2.2%). Regarding pharmacological treatment, 93.5% of the participants were not taking any regular medication, and 6.5% of the sample were receiving anxiolytics to treat anxiety symptoms.

2.3. Recruitment and procedure

Recruitment was carried out *online* using professional websites (i.e., LinkedIn) and non-professional social-networks (i.e., Facebook and twitter), as well as advertisements in newspapers and posters placed in local universities. People who were interested requested participation through the research website (www.fobiavolar.es) and by signing the informed consent form. All participants were contacted by telephone to screen them for the inclusion and exclusion criteria and explain the research terms. Participants who met the criteria received a diagnostic telephone interview, and they were randomly assigned to one of the three experimental groups using a computer randomization program (Epidat 4.0) run by an independent researcher who was unaware of the characteristics of the study. Before starting the treatment, participants allocated to the two treatment conditions (totally self-applied or self-applied with therapist guidance) received a brief explanation of the rationale for the treatment (including each experimental condition) and how to use the program. After that, participants reported their preferences without knowing to which treatment they had been assigned. Next, researchers told patients the condition to which they had been randomly allocated, and they assessed their expectations about the treatment. At post-treatment, participants reported their satisfaction, their preferences, and the

usability of the program. A detailed description of the recruitment process and procedure is provided in the study protocol (Campos et al., 2016).

2.4. Inclusion and exclusion criteria

The inclusion criteria were: adults who were 18 years old or more and met the Diagnostic and Statistical manual for Mental Health Disorders-Version 5 (DSM-5) (APA, 2013) criteria for specific, situational phobia (FP); sufficient knowledge to understand and read Spanish; the ability to use a computer; and access to the Internet. Exclusion criteria were: receiving psychological treatment for FP; diagnosis of a severe mental disorder (abuse or dependence on alcohol or other substances, psychotic disorder, dementia, or bipolar disorder); presence of depressive symptomatology, suicidal ideation or plan; presence of heart disease; pregnancy (from the fourth month). Participants with comorbid and related disorders (i.e., panic disorder, agoraphobia, claustrophobia, or acrophobia) were included when FP was the primary diagnosis. Receiving pharmacological treatment was not an exclusion criterion during the study period, but any increase and/or change in the medication implied the participant's exclusion from the study. A decrease in pharmacological treatment was accepted.

2.5. Measures

2.5.1 Anxiety Disorders Interview Schedule for DSM-IV-TR (ADIS-IV)

ADIS-IV is a semi-structured interview used to determine the diagnostic status and quantify different features related to the phobia (on a scale from 0 to 8). The section on specific phobias was used in this study. This interview has been validated in Spanish and shows adequate psychometric properties (Antony, Orsillo, & Roemer, 2001; Brown, Barlow, & Di Nardo, 1994; Di Nardo, Brown, & Barlow, 1994).

2.5.2 Treatment preferences questionnaire

The *Treatment preferences questionnaire* was specifically developed for this research (Campos et al., 2016). This instrument is composed of 5 questions designed to measure participants' preferences for the two treatment conditions included in the study (with and without therapist support): (1) *Preference* ("If you could have chosen between the two treatments, which one would you have chosen?"; (2) *Subjective effectiveness* ("Which of these two treatments do you

think would have been the most effective in helping you to overcome your problem?"; 3) *Logic* (Which of these two treatments do you think would have been the most logical to help you overcome your problem); (4) *Subjective aversion* ("Which of these two treatments do you think would have been the most aversive?") and (5) *Recommendation* ("Which of these two treatments would you recommend to a friend with the same problem you have?"). Questions have two response options based on the two treatment conditions.

2.5.3 Treatment Expectations and satisfaction scales

These questionnaires were adapted from Borkovec and Nau (1972) to measure participants' expectations before treatment and their later satisfaction with it. Each scale includes six items rated from 0 ('not at all') to 10 ('very much'). The questions addressed how logical the treatment seemed, to what extent the patient expected to be satisfied with it, whether the patient would recommend the treatment to others, whether it would be useful in treating other problems, the treatment's usefulness for the patient's problem, and to what extent it could be aversive. This adaptation has been used in several studies (Botella et al., 2016a,b; Botella et al, 2009; Quero et al., 2013; Tortella-Feliu et al., 2011).

2.5.4 Qualitative interview

A *Qualitative interview* was also specifically developed to assess participants' opinions about the *NO-FEAR Airlines* program and the support received. This interview included 10 questions rated on a scale from 1 to 5 (1= *very little*; 5= *very much*) and Dichotomous Questions ("Yes" or "No"). Additionally, options to extend the participants' qualitative responses were available.

2.5.5 Usability and Acceptability Questionnaire

This instrument was adapted from the System Usability Scale (SUS) (Bangor, Kortum, & Miller, 2008; Brooke, 1996) in order to assess the usability of a service or product and the acceptance of technology by the people who use it. The SUS has been shown to be a valuable and robust tool for assessing the quality of a wide range of user interfaces, as it is easy to use and understand (Bangor, Kortum, & Miller, 2009; Botella et al., 2016b). This scale includes 10 statements rated on a 5-point scale measuring agreement with the statement (0=*strongly disagree*; 4=*strongly agree*). The final score is obtained by adding the scores on each item and multiplying the result by 2.5. Scores range from 0 to 100, where

higher scores indicate better usability, according to Bangor et al., (2008, 2009) (see Figure 4.1). We replaced the word "system" with "*NO-FEAR Airlines*", and we adapted some items to assess: learnability, capacity to use, orientation, effectiveness, ecological model, ease of instructions, visibility, intention to use, utility, and ease of use. The Usability and Acceptability Questionnaire is currently being validated by our research group, and a short-form consisting of 7 items was used in a previous study, showing a Cronbach's Alpha of .94 (Castilla et al., 2016).

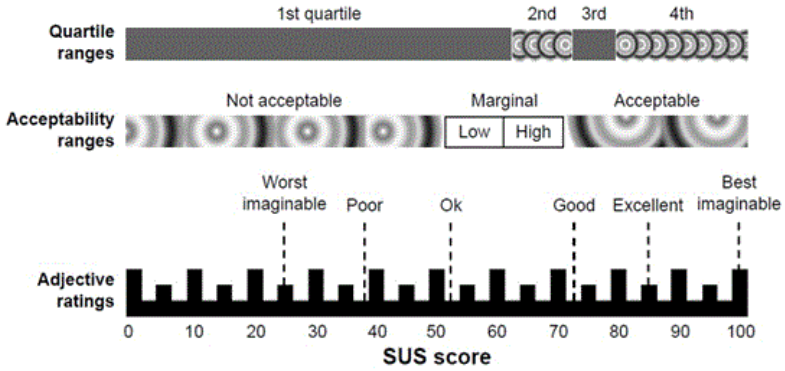

Figure 4.1. A comparison of mean SUS scores by quartile, adjective ratings, and the acceptability of the overall SUS score (Bangor et al., 2008, 2009)

2.6. Treatment program

NO-FEAR Airlines is an Internet-based exposure treatment for FP. This program was designed to be completely self-applied over the Internet, and it allows people who are afraid of flying to be exposed to images and sounds related to their phobic fears on a standard personal computer. From a clinical point of view, *NO-FEAR Airlines* is based on a previous program, Computer Assisted Fear of Flight Treatment (CAFFT) (Tortella-Feliu, Bornas, Llabrés, 2008; Tortella-Feliu et al., 2011). *NO-FEAR Airlines* was designed with linear navigation (Figure 4.2), i.e. the patient can only continue on to the next section. This design helps to optimize the treatment structure (assessment, psychoeducation, exposure, and overlearning). The graphical user interface includes visual flying metaphors in order to improve immersion and the sense of presence in the exposure scenarios

Figure 4.2.Navigation structure of the system

The program includes both an *assessment protocol* and a *treatment protocol.* The *treatment protocol* has three therapeutic components: psychoeducation, exposure, and overlearning. *Psychoeducation* consists of information about what the program will contain, as well as specific information related to FP using text, vignettes, and illustrations, in order to make the therapeutic content more attractive to the patient. The *Exposure* component is provided through six scenarios composed of significant stimuli such as images and real sounds related to the flight process: (1) flight preparation, (2) airport, (3) boarding and taking off, (4) the central part of the flight, (5) the airplane's descent, approach to the runway, and landing, (6) sequences with images and auditory stimuli related to plane crashes. Exposure presents the different scenarios depending on the patient's anxiety level collected in the assessment (based on the FFQ-II questionnaire scores; Bornas, Tortella-Feliu, García de la Banda, Fullana, & Llabrés, 1999). Therefore, the system reacts in real time to the exposure needs of each patient, organizing the scenes from low to high anxiety. *Overlearning* is offered as additional exposure (to each scenario). Patients can choose the scenarios they want to face based on their needs, with a higher degree of difficulty when storm conditions and turbulence are simulated. The length of the treatment depends on each patient's pace. Patients were advised to carry out approximately two exposure scenarios per week, taking a few days off between sessions, although each participant was free to advance at his/her own pace within a maximum period of six weeks. A detailed description of *NO-FEAR Airlines* can be found in Quero et al. (2015) and Campos et al. (2016).

The program described above was delivered in two formats: 1) *NO-FEAR Airlines* completely self-applied. Participants self-administered the Internet-based

treatment, and only automatic support was provided by the program. Technical assistance (i.e., web accessibility problems or forgotten password) was provided if necessary. 2) *NO-FEAR Airlines* with therapist guidance. In this case, participants self-applied the treatment over the Internet and received minimal therapist support consisting of a brief weekly phone call (maximum 5 min) to assess and guide the participant's progress by providing feedback and reinforcement until s/he had finished the treatment. In addition, the therapist checked for any problems and reminded the participant about the recommended treatment pace. Guidance content was standardized, although it could be tailored to patients' needs. However, support calls had additional clinical content. Telephone support was provided by trained and experienced psychologists.

2.7. Statistics and data analysis

Socio-demographic and participant data were examined by applying chi-square tests for categorical variables and Student's *t*-tests for continuous data. Group differences were studied using chi-squares tests for participants' preference patterns and multivariate analysis of variance (MANOVA) for expectations, satisfaction, usability, and the quantitative statements from the opinion' interview. The SUS adjective rating scale (Bangor et al. 2008, 2009) was used to provide a qualitative comparison of usability scores. All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 23.

3. Results

3.1. Socio-demographic and participant data

Socio-demographic and participants' data are presented in Table 4.1. No statistical differences were found between conditions (with and without therapist guidance) on demographical data and medication intake patterns.

Table 4.1. Socio-demographic and participant data

	NO-FEAR Airlines totally self-applied (N = 23)	*NO-FEAR Airlines* self-applied with therapist guidance (N = 23)
Age	36.30 (8.14)	38.87 (13.56)
Sex		
Male	8 (30.8%)	6 (26.1%)
Female	15 (65.2%)	17 (73.9%)
Marital status		
Married	12 (52.2%)	11 (47.8%)
Single	10 (43.5%)	11 (47.8%)
Divorced	1 (4.3%)	1 (4.3%)
Educational level		
Secondary school	2 (8.7%)	7 (30.4%)
Universitary education	21 (91.3%)	16 (69.6%)
Occupation		
Student	4 (17.4%)	4 (17.4%)
Unemployed	4 (17.4%)	4 (17.4%)
Employed	15 (65.2%)	12 (52.2%)
Retired	-	3 (13.0%)
Medication		
Yes	1 (4.3)	2 (8.7%)
No	22 (95.7%)	21 (91.3%)

Note: Means and standard deviations (SD) are represented for age.

3.2. Attrition and adherence

Forty-six participants started the program and completed the pre-treatment assessment. From the total sample, 13 participants (28.26%) withdrew from the program: 6 in the NO-FEAR Airlines completely self-applied condition (13.04%) and 7 in the NO-FEAR Airlines self-applied with therapist support condition (15.22%). No significant differences in attrition rates were found between the treatment conditions. Dropout reasons were reported as follows: own illness (N = 1), partner illness (N = 1), exposure scenarios did not evoke anxiety (N = 1), lack of time (N = 1), unable to contact them (N = 9). At post-treatment, assessment

data on treatment acceptance were obtained from 33 participants (NO-FEAR Airlines totally self-applied, n = 17; NO-FEAR Airlines with therapist guidance, n = 16).

3.3. Preferences

Chi-square (χ^2) results revealed significant differences between treatment conditions on all preference measures, except *aversiveness* at baseline and post-treatment. Before treatment, most participants (71.7%) preferred the condition with therapist guidance ($\chi^2 = 8.70$; $p < .01$), 87% considered it more effective than the completely self-applied condition ($\chi^2 = 25.13$; $p < .001$), 82.6% of participants reported the therapist-supported condition as more logical ($\chi^2 = 19.57$; $p < .001$), and 82.6% of participants would recommend it to a friend who had the same problem ($\chi^2 = 19.57$; $p < .001$). In addition, the totally self-applied condition was considered more aversive by 60.9% of participants, although statistically significant differences were not found.

After treatment, 72.7% of participants continued to prefer the self-applied treatment with therapist guidance ($\chi^2 = 6.82$; $p < .01$), 84.8% considered it more effective ($\chi^2 = 16.03$; $p < .001$), 90.9% assessed this condition as more logical ($\chi^2 = 22.09$; $p < .001$), and 87.9% would recommend it to a friend who had the same problem ($\chi^2 = 18.95$; $p < .001$). Regarding aversiveness, 54.5% of participants chose the totally self-applied as the most aversive condition ($\chi^2 = .273$; $p = .602$), but no significant differences were reported between groups.

3.4. Expectations and satisfaction

As Table 4.2 shows, results from analyzing participants' expectations and satisfaction with the Internet-based program revealed high scores on all expectations and satisfaction measures, except aversiveness, which obtained low scores. MANOVA analysis did not reveal significant differences between the two ways of delivering the treatment on any of the expectations and satisfaction measures.

Table 4.2. Expectations and satisfaction scores

	Expectations	*Satisfaction*
	Mean (SD)	*Mean (SD)*
1. *Logical*		
NFA	8.17 (1.23)	8.12 (1.54)
NFA + TG	8.48 (1.41)	7.75 (1.91)
Total Sample	8.33 (1.32)	7.94 (1.71)
2. *Satisfaction* with the Internet-based program		
NFA	8.40 (1.75)	7.35 (1.97)
NFA + TG	8.87 (1.46)	7.06(1.98)
Total Sample	8.63 (1.61)	7.21 (1.95)
3. *Recommend* to others		
NFA	8.74 (1.36)	8.18 (1.98)
NFA + TG	8.74 (1.42)	8.31 (2.08)
Total Sample	8.74 (1.37)	8.24 (2.00)
4. *Usefulness* for treating other psychological problems		
NFA	7.00 (1.98)	6.82 (2.13)
NFA + TG	7.70 (2.14)	6.56 (2.30)
Total Sample	7.34 (2.07)	6.69 (2.19)
5. Usefulness for treating their problem		
NFA	7.74 (1.71)	7.24 (2.05)
NFA + TG	8.26 (2.00)	6.75 (3.04)
Total Sample	8.00 (1.86)	7.00 (2.55)
6. *Aversiveness*		
NFA	2.61 (3.26)	2.35 (2.67)
NFA + TG	2.35 (2.98)	1.75 (2.11)
Total Sample	2.48 (3.10)	2.06 (2.39)

Note: SD. Standard Deviation. NFA. NO-FEAR *Airlines* totally self-applied. NFA + TG. NO-FEAR *Airlines* with Therapist guidance.

3.5. Opinion interview

Results from the opinion interview revealed that the exposure scenarios were assessed as useful (Mean = 3.48; standard deviation (SD) = .91). All program components were valued as helpful, and no statistical differences were found between treatment conditions. Regarding exposure scenarios, the sounds of each scenario were considered more useful than the fixed images (Table 4.3). Qualitative opinions of some participants pointed out that they would prefer navigable images such as 360º view images or short videos with movement images. In addition, 72.7% of participants would like to have access to the program after completing the treatment for the first time, in order to use it in the future and go over it between flights.

Finally, participants who received the weekly therapist guidance pointed out that they liked it (Mean = 4.56; SD = .81) and considered it useful (Mean = 4.25; SD = 1.06), expressing a positive opinion ranging from a lot and extremely. Participants allocated to the completely self-applied condition said they would like to receive the therapist support and rated it as helpful between moderately and extremely. [(Mean = 3.35; SD = 1.45), (Mean = 3.11; SD = 1.36), respectively].

Table 4.3. Opinion interview

Statement	*NO-FEAR Airlines* totally self-applied	*NO-FEAR Airlines* self-applied with therapist guidance	*Total Sample*
1. Exposure scenarios usefulness	3.53 (.72)	3.44 (1.09)	3.48 (.91)
2. Fixed pictures' usefulness	2.82 (1.07)	3.25 (1.13)	3.03 (1.10)
3. Sounds' usefulness	4.53 (.62)	4.18 (.98)	4.36 (.82)
4. Psychoeducation component's usefulness	3.76 (1.15)	3.56 (1.15)	3.67 (1.14)
5. Overlearning usefulness	3.47 (1.28)	3.88 (1.09)	3.67 (1.19)
6. If you had access, would you use the program in the future?			
Yes	76.5%	68.8%	72.9%
No	23.5%	31.3%	27.3%

Note: Means and standard deviations (SD) are represented.

3.6. Usability and acceptability

Usability and acceptability scores are shown in Table 4.4. According to Bangor et al. (2009), results reveal that *NO-FEAR Airlines* showed high acceptability levels among participants, and it was classified as excellent on the Usability adjective rating scale (see Figure 1). The MANOVA analysis did not reveal statistical differences between groups ($F(10,22) = .986$; $p = .483$).

Table 4.4. Usability and Acceptability Questionnaire: Means and standard deviations

	NO-FEAR Airlines totally self-applied	*NO-FEAR Airlines* self-applied with therapist guidance	*Total Sample*
1. People could learn to use *NO-FEAR Airlines* quickly	3.71 (.47)	3.63 (.81)	3.67 (.65)
2. I felt confident using *NO-FEAR Airlines*	3.82 (.39)	3.75 (.44)	3.79 (.42)
3. Generally, I knew what I had to do at all times	3.59 (.62)	3.87 (.34)	3.73 (.52)
4. Once I had learned how to use *NO-FEAR Airlines,* I could do the tasks quickly	3.71 (.99)	3.25 (1.48)	3.49 (1.25)
5. *NO-FEAR Airlines* could be used anywhere and in any context	2.88 (1.17)	2.56 (1.50)	2.72 (1.33)
6. *NO-FEAR Airlines'* instructions are easy to follow	3.53 (1.01)	3.81 (.40)	3.67 (.77)
7. Font size and row button size are sufficient for me	3.71 (.99)	3.81 (.40)	3.76 (.75)
8. I would like to use this system frequently	3.10 (1.03)	2.88 (1.15)	2.97 (1.09)
9. Overall, I think *NO-FEAR Airlines* is quite useful to me	2.88 (.93)	3.00 (1.26)	2.94 (1.09)
10. Overall, I think *NO-FEAR Airlines* is easy to use	3.88 (.33)	3.81 (.40)	3.85 (.36)
Overall score	86.91 (10.73)	85.94 (11.21)	86.44 (10.81)

Note: Means and standard deviations (SD) are represented.

4. Discussion

The present study aimed to analyze the acceptability of an Internet-based treatment for Flying Phobia (FP) (*NO-FEAR Airlines*) that includes exposure scenarios composed of images and real sounds. A secondary aim was to compare patients' acceptance of two ways of delivering this self-applied treatment (with or without therapist guidance). On the one hand, results for *adherence* showed that most of the participants completed the online intervention (71.24%). Thus, the dropout rate was in line with other studies that used the Internet to deliver psychological treatment (around 30%) (i.e., Melville, Casey, & Kavanagh, 2010; Spek et al., 2007; Van Ballegooijen et al., 2014). Nevertheless, this result contrasts with Kok et al. (2014), who found a high attrition rate in treatments for phobic outpatients. On the other hand, no differences in adherence were found in the present study when considering therapist guidance. Data on the impact of support on adherence to Internet-based Interventions is

inconsistent and varies across studies (Andersson & Cuijpers, 2009; Hilvert-Bruce, Rossouw, Wong, Sunderland, & Andrews, 2012; Kelders et al., 2015 Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012; Mira et al., 2017; Musiat & Tarrier, 2014; Richards & Richardsson, 2012).

Regarding treatment *preferences* assessed at pre- and post-intervention, results indicated that participants generally preferred the self-applied condition with therapist guidance. They considered this treatment condition to be more effective and more logical, and they would recommend it more than the totally self-applied condition, although no differences were found when aversiveness was considered. These results suggest that therapist guidance was not relevant in deciding which condition they would prefer in terms of aversiveness, but it clearly affected the patients' preferences overall. These findings are congruent with studies that recommend the need to offer support, guidance, and reinforcement to the participant during exposure in self-applied treatments, and this support has been related to patients' preferences (Bretón-López et al., 2015). It is interesting that in this study, the therapist's guidance did not include clinical content, which is linked to the important issue of who is providing the support and what kind of guidance is required. Although few studies have been carried out on acceptability variables, the literature suggests that the qualifications of the people providing the guidance (technicians vs clinicians) might not be very important (i.e., Baumeister, Reichler, Munzinger, & Lin, 2014). Generally, authors suggest that, depending on the degree of structure of the Internet intervention model adopted, guidance can be mainly practical and supportive, based on reinforcement rather than explicitly therapeutic content (Andersson & Titot, 2014). Thus, guidance could be provided through automated reinforcement and persuasive technologies (Kelders et al., 2012, 2015). This idea agrees with authors who indicate that unguided Internet-based interventions can work similarly with automated guidance and no human support (i.e., Karyotaki et al., 2017; Mira, et al., 2017; Lancee, van den Bout, Sorbi, & van Straten, 2013; Titov et al., 2009). Therefore, we suggest that including automated guidance and making patients aware of it could help to reduce these differences in preferences for Internet interventions delivered with or without therapist guidance.

By contrast, participants in both groups reported high *expectations* and *satisfaction* scores, including low aversiveness levels towards the Internet-based exposure before and after the treatment. These results coincide with previous studies showing that computer-assisted treatments are well accepted, in terms of

expectations and satisfaction to treat FP (i.e., Tortella-Feliu et al., 2008, 2011). They are also consistent with studies conducted with Internet-based interventions for specific phobias and other anxiety disorders, where participants also reported positive expectations and high satisfaction (i.e., Andrews et al., 2010; Botella et al., 2008, 2009, 2016b; MacGregor, Hayward, Peck, & Wilkes, 2009). It is true that patient satisfaction has generally been found to be higher in therapist-supported Internet-based interventions (Olthuis et al., 2016), However, coinciding with our results, other studies have found that providing therapist support does not affect satisfaction (i.e., Mira et at., 2017; Titov et al., 2010). In addition, the data on aversiveness are especially relevant. As pointed out above, participants in both intervention groups reported lower aversiveness levels toward the Internet-based exposure intervention in the evaluation of both expectations and satisfaction. Moreover, no differences were found in treatment preferences related to aversiveness, and the number of participants who preferred the supported intervention declined after treatment. This is important because reducing aversion is a major challenge in exposure treatment for phobias (Deacon & Farrell, 2013; Garcia-Palacios et al., 2007; Olatunji, et al., 2009). These results suggest that *NO-FEAR Airlines,* with and without therapist guidance, could help to improve the exposure technique's acceptance due to its reduced exposure aversiveness. According to Botella et al (2009), Internet-delivered treatments may be particularly valuable to patients who are reluctant to start an *in vivo* exposure intervention because they provide a less frightening way to confront their fears.

Regarding the results obtained from the *opinion interview*, all the program components (i.e., psychoeducation, exposure, and overlearning) were accepted and found to be useful by the participants, agreeing with studies using computer-assisted treatment for FP (Tortella-Feliu et al., 2008). Focusing particularly on exposure scenarios features, sounds were rated as more useful than fixed pictures. These data are consistent with previous findings highlighting the critical role of sound in evoking anxiety in patients with FP (i.e., Bornas, Fullana, Tortella-Feliu, Llabrés, & García de la Banda, 2001; Tortella-Feliu et al., 2011). In addition, some participants suggested including navigable images like 360º pictures or short videos with movement images in order to improve the scenarios and evoke a greater sense of presence. This issue addresses an interesting question related to improving exposure by creating more realistic exposure scenarios. However, according to Tortella-Feliu et al. (2011), literature has shown

that treatment effects are not enhanced by enriching computer-generated exposure environments or creating more sophisticated immersive conditions (Bornas, Tortella-Feliu, & Llabrés, 2006; Bornas, Tortella-Feliu, Fullana, & Llabres, 2001; Mühlberger, Wiedemann, & Pauli, 2003; Tortella-Feliu, et al., 2011). Moreover, some authors have suggested that, particularly referring to the flight situation, facing the feared situation in a more realistic way may evoke higher aversiveness levels (Bretón-López et al., 2015), which could hinder the treatment's acceptability. However, more research is needed on this topic.

Finally, *usability* results would place *NO-FEAR Airlines* between the third and fourth quartile, achieving the *excellent* rating on the Usability adjective rating scale in both intervention conditions and showing that receiving therapist guidance did not affect the system's usability. Based on the technology acceptance model (TAM), authors have suggested that one of the factors that can be related to the intention to use a product in the future is ease of use (Carvalho, Guimarães, Ferreira, & Freitas, 2012; Davis, 1989; Davis, Bagozzi, & Warshaw, 1992; Huang, & Liao, 2014). Therefore, efforts to research and ensure the usability of Internet-based treatments might lead more people to accept Internet to treat their psychological problems, continue to use it in the future, and recommend it to friends and family. Thus, an important challenge in psychological treatments is improved, that is, their dissemination (Kazdin & Rabbit, 2013).

In summary, our results showed that *NO-FEAR airlines* was well accepted among participants, with no differences when considering therapist guidance, in terms of attrition rates, expectations, satisfaction, opinions and usability. However, participants preferred the self-applied condition with therapist guidance. Therefore, our results partially agree with studies that highlighted the role of therapist guidance to enhance treatments' acceptability (Olthuis et al., 2016). According to our findings, we suggest these inconsistencies could point out that the role of therapist guidance has different implications depending on the disorder involved. Thus, in specific phobias - specifically in FP - therapist guidance might not seem to be relevant in improving treatment acceptability, particularly regarding attrition rates, expectations, satisfaction, opinion and usability. A further explanation could be related to the fact that all the participants were contacted by a therapist at pre- and post-treatment to explain the research criteria and design and conduct the subsequent assessments. Studies have found that providing initial human contact enhances the treatment (i.e., Boettcher,

Berger, & Renneberg, 2012). Nevertheless, based on our data, therapist guidance affects treatment preferences. More research is needed to formally assess the acceptability of Internet-based treatments depending on the support provided.

In conclusion, together our results highlight good acceptability by the patients of *NO-FEAR airlines* for the treatment of FP, with and without therapist guidance. However, the present study presents some limitations that should be mentioned. First, assessments were conducted online and via phone calls. Some authors suggest that psychometric properties may change when assessment is conducted via the web (i.e., Buchanan, Johnson, & Goldberg, 2005), although several studies have shown the usefulness of Internet and telephone administered assessments and their concordance with traditional face-to-face assessment (Campos et al., 2015; Carlbring et al. 2007, Hedman et al., 2010, 2013). Second, another limitation to consider is that participants requested access to the study voluntarily online. Thus, people who wanted to participate might be especially interested in receiving a treatment delivered via the Internet and more likely to accept the program by expressing a favorable opinion. Future research might examine these issues in other contexts (i.e., primary care). Finally, usability assessment was based on one questionnaire rather than on qualitative feedback that might indicate overall program impressions. This could interfere with the interpretation of the usability testing and its subsequent use for program improvement or refinement (Currie et al., 2010). In the future, qualitative analyses should be included to report detailed and complementary data on program usability and participants' opinions.

In sum, to the best of our knowledge, this is the first study to analyze patients' acceptance of an Internet-based program that includes exposure scenarios composed of images and real sounds for the treatment of FP, comparing two delivery methods - with and without therapist guidance. *NO-FEAR Airlines* is presented as a well-accepted FP treatment self-applied via the Internet. This program helps to enhance the application of the exposure technique, improving patients' acceptance and access to FP treatment. Further research is needed to investigate and develop increasingly sophisticated Internet-based programs that include different technologies (i.e., persuasive technologies and more sophisticated and relevant exposure scenarios) in order to improve acceptance and access to evidence-based psychological interventions.

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Conflict of Interest

The authors declare no conflict of interest.

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Discusión general de los resultados

El **objetivo general** de la presente tesis doctoral se dirigió a analizar la eficacia y eficiencia de un programa de tratamiento computarizado para la fobia a volar (FV) aplicado a través de Internet (*SIN MIEDO Airlines*) en dos modalidades (totalmente auto-aplicado y auto-aplicado con apoyo del terapeuta) frente a un grupo control de lista de espera en un ECA).

De acuerdo con las hipótesis planteadas, los resultados del estudio ponen de manifiesto la **eficacia** de *SIN MIEDO Airlines* (con y sin apoyo del terapeuta) para el tratamiento de la FV en comparación con el grupo control de lista de espera. Además, los cambios alcanzados tras la intervención se mantuvieron en aquellos participantes que completaron el seguimiento a los 3 meses. Estos hallazgos son congruentes con los resultados encontrados por Tortella-Feliu et al. (2008, 2011) que muestran la eficacia y aceptación de los programas de exposición asistidos por ordenador para el tratamiento de la FV. Además, los datos van en la línea de los estudios que remarcan la utilidad de Internet para administrar tratamientos psicológicos (Andersson, 2016; Peñate, y Fumero, 2016). No obstante, es importante señalar que hasta donde nosotros sabemos este es el primer estudio controlado aleatorizado en investigar la eficacia de un tratamiento online para la FV.

En este estudio, Internet ha demostrado ser una herramienta eficaz para administrar un tratamiento computarizado basado en la exposición, como es *SIN MIEDO Airlines*, que incluye imágenes y sonidos reales relacionados con situaciones de FV. Además, los participantes valoraron el programa *online* de forma positiva mostrando una buena **aceptación** del mismo. Éstos informaron bajos niveles de aversión frente a la intervención, tanto antes como después del tratamiento, y ningún participante rechazó empezar el tratamiento basado en la técnica de exposición. En este sentido, nuestros resultados suponen un avance importante en el campo concreto de la FV y añaden evidencias al respecto en el ámbito del tratamiento de las FE. La exposición *in vivo*, como se ha comentado previamente, está asociada con una baja aceptación y una serie de limitaciones relacionadas con el acceso al tratamiento. De esta forma, los tratamientos computarizados aplicados a través de Internet son una herramienta clínica útil

para proporcionar ambientes de exposición significativos, sin comprometer su eficacia, mejorando su aceptación al generar menores niveles de aversión. De acuerdo con Botella et al. (2009), los tratamientos computarizados administrados a través de Internet podrían ser especialmente recomendables para los pacientes que son reacios a empezar un tratamiento de exposición *in vivo* ya que proporcionan una forma menos aversiva de afrontar los miedos. Sin embargo, tal y como hemos señalado anteriormente, los tratamientos online que incluyen el componente de exposición en su intervención no suelen proporcionar escenarios de exposición multimedia que puedan ser realizados a través del ordenador. Esto limita y empobrece el potencial de dichas intervenciones. Por este motivo, a partir de los resultados obtenidos en esta tesis doctoral y siguiendo a Botella et al., (2010), se recomienda la combinación de programas multimedia asistidos por ordenador que incluyan escenarios de exposición y procedimientos de auto-ayuda (p.ej., Internet) con el fin de mejorar los tratamientos existentes. En resumen, el uso de este tipo de intervenciones conlleva una serie de ventajas a diferentes niveles, como recogimos en Campos et al. (2016): mejora el acceso al tratamiento, llegando a más personas que lo necesitan; abre la posibilidad de estandarizar el tratamiento al máximo; permite controlar importantes variables de la exposición como son la duración y el número de sesiones; y puede mejorar la aceptación de los pacientes y terapeutas al producir menores niveles de ansiedad a través de una jerarquía de exposición a distintos ambientes multimedia.

Por otra parte, cabe señalar que a lo largo de la presente tesis doctoral se aportan datos sobre el papel del **apoyo del terapeuta** en un tratamiento computarizado auto-aplicado a través de Internet para la FV. En términos de *eficacia*, de acuerdo con la hipótesis planteada, no se observaron diferencias estadísticamente significativas en las distintas variables clínicas en función de si se proporcionaba o no apoyo por parte del terapeuta. Estos resultados sugieren que ambas modalidades de intervención (totalmente auto-aplicada y auto-aplicada con apoyo del terapeuta) fueron eficaces en el tratamiento de la FV, estando de acuerdo con los estudios que defienden que las intervenciones sin apoyo del terapeuta pueden funcionar con apoyo automatizado y sin necesidad de contacto humano (p.ej., Karyotaki et al., 2017; Mira et al., 2017). Así, nuestros resultados van en la línea de aquellos autores que plantean que problemas más sencillos como las FE podrían requerir una menor guía o contacto del terapeuta en comparación con problemas mentales más graves (Botella et al., 2010;

Menchola, Arkowitz, y Burke, 2007). Además, los hallazgos de esta tesis doctoral son congruentes con los resultados obtenidos por Tortella-Feliu et al. (2011), señalando que la implicación del terapeuta puede ser reducida en el tratamiento de la FV por medio de los programas de exposición asistidos por ordenador.

Respecto a las variables de *aceptación*, ambas formas de administrar la intervención *online* (con y sin apoyo del terapeuta) fueron bien valoradas por los pacientes y no se observaron diferencias estadísticamente significativas en términos de expectativas, satisfacción, opinión y usabilidad. No obstante, en general los participantes preferían de forma significativa la intervención con apoyo del terapeuta, tanto antes como después de recibir el tratamiento. Estos resultados podrían sugerir la necesidad de atender a las preferencias de los usuarios, tal y como se señala en los estudios que plantean que éstas son consideradas como una forma de mejorar las intervenciones, pudiendo aumentar la adherencia y los resultados de eficacia de las mismas (p.ej., Bretón-López et al., 2015; Tarrier, Liversidge, y Gregg, 2006; Soucy, y Hadjistavropoulos, 2017). En nuestro caso, aunque ambas formas de administrar la intervención fueron bien valoradas y no se encontraron diferencias en términos de eficacia, el estudio de las preferencias hacia el tratamiento podría tener repercusiones a distintos niveles, los cuales no han sido analizados en el presente estudio. Por ejemplo, podría repercutir en la motivación y el compromiso de los pacientes de cara a completar el tratamiento, siendo más propenso el abandono o incluso interferir en los resultados del tratamiento como consecuencia de una menor implicación con el mismo al no ser la opción preferida. En un contexto de atención primaria o práctica clínica privada, fuera del ámbito de la investigación, atender a las necesidades individuales evaluando las preferencias de los participantes y proporcionado tratamientos acorde a éstas podría ser de especial relevancia, repercutiendo en una mejora de la aceptación de los tratamientos psicológicos basados en la evidencia. Otro aspecto importante, que emerge a partir de estas reflexiones, hace referencia a la necesidad de educar a los pacientes sobre los tratamientos auto-aplicados a través de Internet (Soucy, Owens, Hadjistavropoulos, Dirkse, y Dear, 2016). En concreto, a partir de los resultados obtenidos en la presente tesis doctoral y dado que no se encuentran diferencias en otras variables de aceptación en función del apoyo, podría ser de utilidad educar a los pacientes sobre el funcionamiento de las intervenciones auto-aplicadas y de cómo éstas pueden funcionar de forma eficaz con apoyo automatizado. Tal y como sugerimos en el capítulo 4, la inclusión de guía o

apoyo automatizado, haciendo conscientes a los pacientes de ello, podría ayudar a reducir estas diferencias en preferencias a favor del tratamiento auto-aplicado a través Internet con apoyo del terapeuta.

En resumen, los resultados obtenidos en este trabajo apoyan la utilidad de las intervenciones totalmente auto-aplicadas a través de Internet. Este modo de proporcionar tratamiento psicológico implica una manera eficaz y eficiente de intervenir en la FV, mejorando la técnica de exposición. Concretamente, mejorando la aceptación del tratamiento, el acceso al mismo y minimizando la implicación del clínico. Dadas las limitaciones de los tratamientos basados en la evidencia y los problemas en su diseminación se requieren esfuerzos en diseñar intervenciones que tengan en cuenta estos aspectos.

La presente tesis doctoral cuenta con una serie de **fortalezas** que respaldan la validez de los resultados obtenidos y que se detallan a continuación:

- Se empleó un diseño de ECA con un grupo control de lista de espera.
- El estudio se registró en la web de ensayos clínicos clinicaltrials.gov (NCT02298478) (3 de noviembre de 2014).
- El estudio fue aprobado por el comité de ética de la Universitat Jaume I de Castellón (20 de diciembre 2014).
- El protocolo del estudio se publicó en una revistada internacional con factor de impacto (*BMC psychiatry*).
- El estudio controlado aleatorizado se llevó a cabo en compilación con el protocolo del estudio (Campos et al., 2016), la declaración CONSORT (Consolidated Standards Of Reporting Trials, http://www.consort-statement.org), las guías CONSORT E-HEALTH (Eysenbach, G. (2011), los estándares para la práctica de telepsicología (APA, 2013) y la Declaración de Helsinki.
- Se realizó el cálculo del tamaño muestral de acuerdo al objetivo principal y basado en tamaños del efecto obtenidos en la literatura (p.ej., Andrews et al., 2015; Tortella-Feliu et al., 2011), arrojando el mínimo de participantes a reclutar. También se tuvo en cuenta la tasa de abandonos obtenida en las intervenciones *online* (alrededor del 30%) (Speck, 2007; Van Ballegooijen, 2014), aumentando el número de participantes en cada grupo para combatir los posibles abandonos.

- Los análisis estadísticos utilizados para comprobar los efectos del tratamiento en las medidas principales y secundarias se llevaron a cabo de acuerdo con los principios de intención de tratar (Intent-to-treat, ITT) sin ninguna imputación ad hoc y siguiendo el uso de modelos mixtos (Salim, Mackinnon, Christensen, y Griffiths, 2008). Este enfoque está especialmente recomendado para ensayos clínicos con medidas repetidas (Gueorguieva, y Krystal, 2004; Hesser, 2015). Una de sus fortalezas es que la imputación o estimación de valores perdidos no es requerida, ya que se tienen en cuenta todos los datos disponibles en cada momento de evaluación, controlando el efecto de los valores faltantes.
- Se calcularon los tamaños del efecto intra y entre grupos, proporcionando los Intervalos de Confianza correspondientes (95%IC). De acuerdo con las recomendación de los autores, las conclusiones de este estudio no se basaron exclusivamente en la interpretación de los nivel de significación (valores *p*) (Cumming, 2014; Cumming, y Calin-Jageman, 2016).
- Se incluyó el cálculo de Índices de Cambio Fiable (ICF) como estimadores del cambio clínicamente significativo.
- Se evaluó la aceptabilidad del tratamiento por parte de los pacientes incluyendo distintas variables de aceptación (expectativas, satisfacción, preferencias de tratamiento, opinión y usabilidad). Como se ha mencionado previamente, pocos estudios tienen en cuenta estos aspectos.

Adicionalmente a estas fortalezas metodológicas, ***SIN MIEDO Airlines*** cuenta con una serie de características a tener en consideración:

- Está basado en un programa de exposición asistido por ordenador que ha demostrado su eficacia en distintos estudios (Tortella-Feliu et al., 2008, 2011).
- La interfaz gráfica está basada en la estética de las Aerolíneas para favorecer el sentido de inmersión y motivación de los participantes.
- Desde un punto de vista técnico, ha sido diseñado con navegación lineal para optimizar la estructura del tratamiento, resultando en una intervención sencilla y fácil de manejar.

- Incluye un protocolo de evaluación online que se completa al inicio, al finalizar y a los seguimientos.
- Envía recordatorios automatizados de las evaluaciones (post-tratamiento y seguimientos) tanto a pacientes como a terapeutas.
- Está formado por componentes terapéuticos eficaces (psicoeducación, exposición y sobreaprendizaje) siguiendo las recomendaciones de las guías sobre buenas prácticas clínicas (APA y NICE).
- Incluye escenarios de exposición a imágenes y sonidos reales permitiendo controlar variables importantes para la exposición (p.ej., jerarquía de exposición).

El presente estudio cuenta con una serie de **limitaciones** generales que deben tenerse en cuenta a la hora de interpretar los resultados presentados. Las limitaciones específicas referidas a los estudios de eficacia y aceptación han sido mencionadas en los capítulos correspondientes.

- Los participantes contactaron de forma voluntaria para participar en el estudio, por lo que éstos podrían estar especialmente interesados en recibir un tratamiento auto-aplicado a través de Internet.
- Las evaluaciones se llevaron a cabo *online* y a través de llamadas telefónicas. A pesar de que los estudios muestran la utilidad de estas herramientas para administrar evaluaciones psicológicas (p.ej., Campos et al., 2015; Hedman et al., 2010, 2013), algunos autores señalan que las propiedades psicométricas de los instrumentos podrían verse comprometidas (p.ej., Buchanan, Johnson, y Goldberg, 2005).
- La tasa de abandonos fue alta, tal y como se esperaba, de acuerdo con los estudios de intervenciones vía Internet (alrededor de 30%) (Speck, 2007; Van Ballegooijen, 2014). No obstante, esto se tuvo en cuenta a la hora de analizar los datos, buscando y aplicando la metodología estadística más adecuada.
- Por limitaciones de tiempo y finalización de la beca que financió la presente tesis doctoral, el seguimiento de los 12 meses no se pudo incluir en la presente memoria. Este hecho compromete la investigación del mantenimiento de los beneficios de *SIN MIEDO Airlines* a largo plazo. No obstante, dichos datos se están recogiendo en la actualidad, por lo que

en un futuro se llevarán a cabo esfuerzos para informar de estos resultados.

- Como consecuencia de la heterogeneidad de la FV, la presencia y comorbilidad con otros trastornos psicológicos relacionados tales como pánico, agorafobia, claustrofobia y acrofobia, podría influir en los resultados de este estudio. Aunque se llevaron a cabo evaluaciones clínicas y uno de los criterios de exclusión recogía este aspecto, se incluyeron participantes con síntomas o trastornos comorbidos siempre que el problema principal fuera la FV. En un futuro se requieren estudios que tengan en cuenta estas características y exploren la posible eficacia diferencial de *SIN MIEDO Airlines* según las características psicopatológicas de los pacientes.
- No se tuvo en cuenta el grado de inmersión o sentido de presencia y juicio de realidad de los participantes en cada escenario de exposición, así como su posible influencia en los resultados.

Teniendo en cuenta los hallazgos y limitaciones señaladas a lo largo de la presente tesis doctoral se plantean una serie de cuestiones interesantes a abordar en un futuro, consolidando o abriendo **futuras líneas de investigación**.

En primer lugar, uno de los aspectos a considerar en un futuro es el grado de inmersión y sentido de presencia en los escenarios de exposición multimedia. Se plantea como una cuestión interesante si la creación e inclusión de ambientes con un mayor grado de realismo mejora los resultados de la terapia. En este sentido, hay algunas evidencias que muestran como la inclusión de ambientes de exposición más sofisticados no mejora los efectos del tratamiento (p.ej., Mühlberger, Wiedemann, y Pauli, 2003), y podrían, además, generar niveles más altos de aversión en los pacientes (Bretón-López et al., 2015). No obstante, algunos participantes podrían preferir escenarios con un mayor grado de inmersión, como se señala en la presente tesis doctoral. Basándonos en nuestros resultados, a pesar de que los escenarios de exposición fueron eficaces y bien valorados por los usuarios, la inclusión de ambientes que favorezcan la inmersión y el sentido de presencia como son las imágenes navegables (o de 360º) o vídeos cortos con imágenes en movimiento, podría mejorar el programa presentado, aprovechando los recientes avances tecnológicos. La literatura a este respecto no es concluyente, por lo que se requieren más estudios en este sentido. En la actualidad, nuestro grupo de

investigación ha puesto en marcha un ECA para investigar la eficacia diferencial de *SIN MIEDO Airlines* utilizando dos procedimientos para llevar a cabo la exposición: escenarios compuestos por imágenes fijas vs. imágenes navegables.

Los datos obtenidos en la presente tesis doctoral muestran que tanto realizar la intervención completamente auto-aplicada como con apoyo del terapeuta es eficaz en el tratamiento de la FV. No obstante, en un futuro se requieren estudios que directamente aborden este objetivo como hipótesis principal. En este sentido, se recomienda llevar a cabo un estudio con un mayor tamaño muestral y, por tanto, poder estadístico, siguiendo un diseño de equivalencia (Flight, y Julious, 2015; Greene, Morland, Durkalski, y Frueh, 2008) que compruebe la hipótesis de si los dos métodos de administrar *SIN MIEDO Airlines* (con y sin apoyo del terapeuta) son igual de eficaces, persiguiendo confirmar los hallazgos obtenidos en el presente estudio.

Por otra parte, se requieren estudios que se centren en la investigación y puesta en marcha de estrategias específicas para combatir el alto porcentaje de abandonos obtenidos en las intervenciones *online* (alrededor del 30%). La inclusión de tecnologías persuasivas y apoyo automatizado se presentan como herramientas útiles para este fin (Kelders, 2012). Además, el estudio de las características de los abandonos puede ser de utilidad en este sentido, ayudando a optimizar y ajustar las intervenciones *online* identificando predictores de abandono y grupos de riesgo. Aunque existen algunos estudios al respecto en el campo de las intervenciones online (p.ej., Karyotaki et al., 2015), la investigación en FE (incluyendo la FV) es escasa.

Otro aspecto a considerar en un futuro hace referencia a la relación entre variables clínicas y variables de aceptación. A pesar de que en esta tesis doctoral se han abordado ambos temas por separado, el estudio conjunto de estas variables podría proveer información adicional sobre la eficacia y eficiencia de *SIN MIEDO Airlines.* En la actualidad, dichos análisis se están llevando a cabo y serán presentados en el 22nd CyberPsychology, CyberTherapy and Social Networking Conference (CYPSY22) que tendrá lugar el 26-28 de Junio (2017), incluyéndose su publicación en la Annual Review of Cybertherapy and Telemedicine (ARCTT – http://www.arctt.info).

Un tema de especial relevancia es la transferencia de los resultados desde un contexto de investigación a un contexto de práctica clínica, tanto en el ámbito de la sanidad pública como privada. La investigación en psicología clínica promueve

el uso de nuevos métodos y herramientas de intervención con el fin de que la sociedad y, en concreto los pacientes que lo necesiten, puedan beneficiarse de éstos. Por este motivo, es crucial que se dediquen esfuerzos en poner a disposición del público estos programas que han mostrado su eficacia en ensayos clínicos controlados. En este sentido, podemos encontrar en la literatura autores que investigan sobre la aplicabilidad y generalización de los hallazgos encontrados en el campo de la TCCc (p.ej., Wilks, Zieve, y Lessing, 2016). La puesta en marcha de acciones dirigidas a la trasferencia e implementación de la TCCc, puede arrojar luz sobre la viabilidad de los tratamientos online en otros contextos fuera del marco de investigación.

Por último, y relacionado con el párrafo anterior, es importante hacer énfasis en la diseminación de los tratamientos auto-aplicados a través de Internet. Las intervenciones psicológicas a través de Internet son una forma eficaz de proporcionar tratamientos basados en la evidencia y, por tanto, una forma de mejorar el acceso al tratamiento. Por este motivo, es necesario que la sociedad las conozca, entienda cómo funcionan y sepan cómo acceder a ellas. Por ello educar a los potenciales usuarios como son pacientes y clínicos sobre esto es fundamental. De acuerdo con Soucy y Hadjistavropoulos (2017), se requieren métodos que mejoren la percepción de las personas acerca de las intervenciones *online*. Una estrategia que podría ser de utilidad para perseguir este fin es el uso de vídeos divulgativos que presenten de forma clara y sencilla los principales hallazgos y ventajas de los tratamientos *online.* Este planteamiento, junto con el recurso de las redes sociales, puede favorecer la diseminación de las intervenciones a través de Internet, mejorando el acceso a los tratamientos basados en la evidencia.

Conclusiones

1. *SIN MIEDO Airlines* (con y sin apoyo del terapeuta) fue eficaz para el tratamiento de la FV en comparación con el grupo control de lista de espera.
2. No se encontraron diferencias estadísticamente significativas entre los dos modos de administrar *SIN MIEDO Airlines* (con y sin apoyo del terapeuta) en las distintas variables de eficacia.
3. Los cambios alcanzados tras el tratamiento online (con y sin apoyo del terapeuta) se mantuvieron en el seguimiento de los 3 meses.
4. *SIN MIEDO Airlines* fue bien valorado por los pacientes en términos de aceptación (expectativas, satisfacción, opinión y usabilidad).
5. No se observaron diferencias estadísticamente significativas entre los dos modos de administrar *SIN MIEDO Airlines* (con y sin apoyo del terapeuta) en las variables de aceptación, a excepción de las preferencias del tratamiento. En general, los participantes prefirieron la condición con apoyo del terapeuta.

Conclusions

1. *NO-FEAR Airlines* (with and without therapist guidance) was significantly effective for FP treatment compared to the waiting list control group.
2. No significant differences were found between the two ways of delivering *NO-FEAR Airlines* (with and without therapist guidance) in the different efficacy outcome measures.
3. Changes made after the online treatment (with and without therapist guidance) were maintained at 3-month follow-up.
4. *NO-FEAR Airlines* was well assessed by the patients in terms of expectations, satisfaction, opinion and usability.
5. No significant differences were found between both conditions (with and without therapist guidance) in acceptance measures, except for preferences. Overall, participants preferred the supported intervention.

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Anexos

ANEXO 1

labpsitec www.labpsitec.es

SIN MIEDO Airlines

CONSENTIMIENTO INFORMADO: "SIN MIEDO Airlines"

Tu participación en este estudio implica el acceso al programa **SIN MIEDO Airlines**. El objetivo principal del tratamiento es ayudarte para que seas capaz de afrontar las situaciones temidas relacionadas con el hecho de volar y, en el caso de que ahora seas capaz de volar, que dejes de utilizar estrategias para protegerte (como recurrir al alcohol o a los fármacos ansiolíticos).

Este programa contiene una serie de situaciones relacionadas con los aviones, y con el hecho de volar, a las que puedes exponerte de forma progresiva, estructurada y sistemática. Este programa lo podrás realizar desde tu casa, totalmente autoaplicado a través de Internet. Por lo que será necesario tener acceso a un ordenador y a Internet. Una vez hayas acabado el tratamiento deberías realizar un vuelo para comprobar los cambios alcanzados. Es un paso esencial para que superes tu miedo. Y conviene que lo hagas lo antes posible, alrededor de unos 15 días después de haber acabado con el tratamiento. En este momento, puede que te resulte difícil pensar en la idea de volar, pero una vez realizado el tratamiento te va a resultar mucho más fácil.

En el estudio habrá tres grupos. Un grupo tendrá acceso al programa **SIN MIEDO Airlines** de forma totalmente auto-aplicada, otro grupo también tendrá acceso al programa auto-aplicado y recibirá apoyo semanal por parte de un terapeuta (llamada telefónica), y otro grupo formará parte de una lista de espera. Al grupo lista espera, se le ofrecerá la posibilidad de realizar el tratamiento tras el periodo de tiempo que dura el tratamiento de los otros dos grupos (seis semanas).

La asignación a cada uno de los grupos será aleatoria. Te informaremos por teléfono a qué grupo perteneces. En caso de poder participar, el tratamiento sería gratuito.

La auto-administración del programa tendrá una duración recomendada de entre 3-4 semanas y un duración máxima de 6 semanas.

Para valorar si el programa puede ser de ayuda en tu caso, solicitamos tu colaboración para contestar una evaluación inicial. El tiempo requerido para cumplimentar todos los instrumentos es de aproximadamente 30-40 minutos.

Al finalizar el tratamiento, solicitaremos de nuevo tu colaboración para valorar en qué medida te ha sido útil el programa, así como a los 3 y 12 meses con el objetivo de realizar un seguimiento.

Acepto de manera libre mi participación en el estudio:

"SIN MIEDO Airlines"

Entiendo la naturaleza y el propósito de los procedimientos que entrañan el presente estudio que se me han comunicado previamente.

Entiendo que la investigación está diseñada para promover el conocimiento científico y que la Universitat Jaume I de Castellón usará los datos que yo le proporcione sólo y exclusivamente para esta investigación.

Entiendo que los datos que 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.

Nombre y apellidos en MAYÚSCULAS: _____

DNI: _____

Fecha y Lugar: _____

Firma del participante:

ANEXO 2

UNIVERSITAT JAUME·I

20 December 2014

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 "Efficacy of a Computer-aided Self-help Treatment for Flying Phobia: A Randomized Controlled Trial", 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

ANEXO 3

SIN MIEDO Airlines

GUIÓN SCREENING TELEFÓNICO

Este guión 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 les hagamos llegar la información de la misma manera.

1.- Saludar.
2.- Asegurarse de que hablamos con la persona correcta. En caso de no estar disponible informar que la llamaremos más tarde.

"Mi nombre es …….. Te llamo de parte del equipo de investigación Labpsitec, de la Universitat Jaume I de Castellón. Te pusiste en contacto con nosotros por el estudio de miedo a volar "SIN MIEDO Airlines". Queremos agradecerte tu interés en colaborar en nuestro estudio y pedirte disculpas si te hemos hecho esperar".

"*Esta llamada telefónica tiene el objetivo de explicarte en qué consistirá el estudio y si estás interesado/a, valorar si puedes participar en el mismo*".

"Tu participación en este estudio implicaría: ***1)*** *el acceso al programa de tratamiento SIN MIEDO Airlines, para ayudarte a que seas capaz de afrontar las situaciones temidas relacionadas con el hecho de volar y, en el caso de que ahora seas capaz de volar, que dejes de utilizar estrategias para protegerte (como recurrir al alcohol o a los fármacos ansiolíticos). Este programa lo podrás realizar desde tu casa, totalmente auto-aplicado a través de Internet. En el* ***estudio*** *habrá tres grupos. Un grupo tendrá acceso al programa* ***SIN MIEDO Airlines*** *de forma totalmente auto-aplicada, otro grupo también tendrá acceso al programa auto-aplicado y recibirá apoyo semanal por parte de un terapeuta (llamada telefónica), y otro grupo formará parte de una lista de espera. Al grupo lista espera, se le ofrecerá la posibilidad de realizar el tratamiento tras el periodo de tiempo que dura el tratamiento de los otros dos grupos (aproximadamente seis semanas). La asignación a cada uno de los grupos será aleatoria. Te informaremos por*

labpsitec

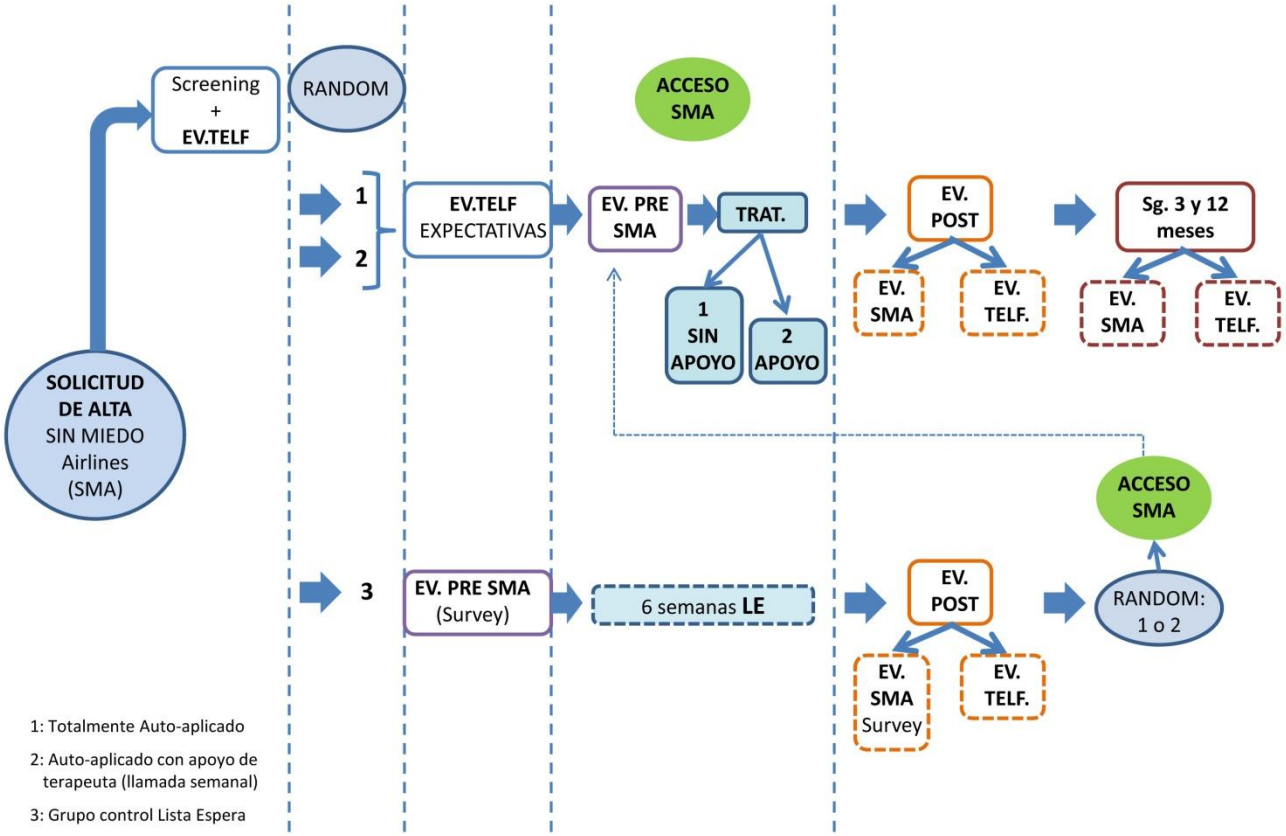
teléfono a qué grupo perteneces. En caso de poder participar, el tratamiento sería gratuito.

2) *Para valorar si el programa puede ser de utilidad en tu caso, así como conocer en qué medida te ha beneficiado al finalizar es importante que te comprometas a realizar una evaluación inicial, una evaluación al finalizar el programa, así como dos seguimientos a los 3 y 12 meses. Estas evaluaciones se realizarán a través de Internet y por teléfono, por lo que en ningún momento se requerirá tu desplazamiento.* ***3)*** *Por último, también es importante que una vez hayas acabado el tratamiento realices un vuelo para comprobar los cambios alcanzados. Es un paso esencial para que superes tu miedo. Y conviene que lo hagas lo antes posible, alrededor de unos 15 días después de haber acabado con el tratamiento". En este momento, puede que te resulte difícil pensar en la idea de volar, pero una vez realizado el tratamiento te va a resultar mucho más fácil* (Enviar consentimiento informado).

SI LA PERSONA SIGUE INTERESADA, SE LE PASAN LAS PREGUNTAS DEL SCREENING TELEFÓNICO (A continuación te voy a hacer una serie de preguntas…). SE CONFIRMA SI PUEDE ENTRAR EN EL ESTUDIO. SE LE PIDEN DATOS COMPLETOS DE NOMBRE-APELLIDOS-TELEFÓNO e E-MAIL (comprobar que esté correcto en el sistema). SE LE DA UNA CITA TELEFÓNICA PARA LA EVALUACION PRE (o se hace en el momento si dispone de entre 30 y 40 minutos).

Se realiza la EVALUACIÓN PRE (seguir protocolo evaluación) y se informa que tras valorar la entrevista inicial con el equipo clínico se le llamará de nuevo para comunicarle si puede participar en el estudio. De ser así, se le comunicará la condición asignada y los pasos a seguir.

ANEXO 4


Screening
+
EV.TELF
RANDOM
ACCESO SMA
SOLICITUD DE ALTA SIN MIEDO Airlines (SMA)
1
2
EV.TELF EXPECTATIVAS
EV. PRE SMA
TRAT.
1 SIN APOYO
2 APOYO
EV. POST
EV. SMA
EV. TELF.
Sg. 3 y 12 meses
EV. SMA
EV. TELF.
3
EV. PRE SMA (Survey)
6 semanas LE
EV. POST
EV. SMA Survey
EV. TELF.
ACCESO SMA
RANDOM: 1 o 2
1: Totalmente Auto-aplicado
2: Auto-aplicado con apoyo de terapeuta (llamada semanal)
3: Grupo control Lista Espera

ANEXO 5

SIN MIEDO Airlines

¿Tienes **miedo** o **fobia a volar**?

Desde la Universidad te ofrecemos

Tratamiento GRATUITO a través de **Internet**

Si tienes entre 18 y 65 años y deseas participar, entra en nuestra web y evalúa si es adecuado para ti en: www.fobiavolar.uji.es/public/evaluacion

O contacta con nosotros

llamando al **964387644**, o enviando un correo a **volar@uji.es**

labpsitec
LABORATORIO DE PSICOLOGÍA Y TECNOLOGÍA

www.labpsitec.uji.es

UNIVERSITAT JAUME·I

VNIVERSITAT DE VALÈNCIA

ANEXO 6

QUIENES SOMOS

Labpsitec, LabHuman y LabCSD

- Son **laboratorios de investigación** pertenecientes a tres **universidades** españolas.
- Llevamos varios años investigando las posibilidades que las **Tecnologías de la Información y la Comunicación** (TICs) (p.ej., realidad virtual, realidad aumentada, Internet, etc.) ofrecen en el ámbito de la psicología clínica.
- La idea original y la primera implementación de un programa de exposición basado en imágenes relacionadas con la fobia a volar, fue desarrollada por el grupo **Labcsd** a través del programa CAFFT que ha demostrado su eficacia en distintos estudios.
- El presente programa auto-aplicado online, **SIN MIEDO Airlines**, es el resultado final de todas estas investigaciones que se iniciaron hace más de 10 años.

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Universitat de les Illes Balears
www.labcsd.cat

PARA MÁS INFORMACIÓN

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labpsitec

LabHuman
Human Centered Technology

UNIVERSITAT JAUME·I

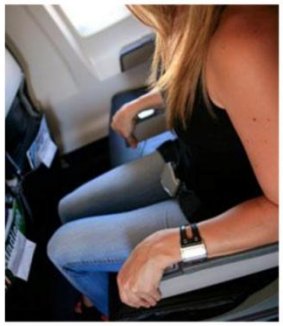
VNIVERSITAT DE VALÈNCIA

labCSD
Laboratori de Conducta i Sistemes Dinàmics

UIB Universitat de les Illes Balears

SIN MIEDO Airlines

UN PROGRAMA DE TRATAMIENTO AUTO-APLICADO A TRAVÉS DE INTERNET PARA LA FOBIA A VOLAR



Entra en:

www.fobiavolar.es

o llama al:

964 38 7644

FOBIA A VOLAR

- Las **fobias** son miedos excesivos e irracionales a determinados objetos o situaciones.
- La **fobia a volar** es un miedo intenso a distintas situaciones relacionadas con los aviones y con el hecho de volar.
- Se pueden experimentar distintos temores (p.ej. temor a que se produzca un accidente, a tener un ataque de pánico, a perder el control, etc.) y como consecuencia de ello **se evita volar** o se vuela experimentando un **gran malestar**.

- Un aspecto importante que hace que la fobia a volar se mantenga es la **evitación**. Esto es, no enfrentarse a las situaciones temidas.
- Aunque **evitar** estas situaciones suponga un **alivio a corto plazo** del malestar, a la larga suele dar lugar a problemas importantes (por ejemplo, no poder viajar en avión, o experimentar un malestar intenso durante el vuelo) que tienen consecuencias negativas como: tener limitaciones en el trabajo, perder unas vacaciones, dejar de conocer muchos lugares, etc.).

TRATAMIENTO

- El **objetivo principal** del tratamiento es ayudarte para que seas capaz de afrontar las situaciones relacionadas con volar y, en el caso de que ahora seas capaz de volar, que dejes de utilizar estrategias para protegerte (como recurrir al alcohol o a los fármacos ansiolíticos).
- Esto se consigue mediante una técnica llamada **exposición**, que consiste en afrontar, paso a paso, y de forma controlada las situaciones que temes.
- Es una técnica que ha demostrado eficacia en numerosos estudios y se recomienda en las guías sobre buenas prácticas clínicas de las asociaciones internacionales de psicología (American Psychological Association y National Institute for Health and Clinical Excellence).

EVALUACIÓN

Si estás interesado/a en recibir tratamiento gratuito accede a :

www.fobiavolar.es

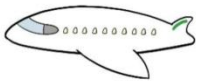
1) Regístrate en el sistema e indica tu número de teléfono para que podamos llamarte y realizar la selección para el tratamiento.

2) Para un correcto funcionamiento de este programa, se recomienda utilizar el **navegador Chrome.**

3) Es necesario que tengas instalada la última versión de FlashPlayer.

O también puedes ponerte en contacto con nosotros en el **964 38 7644**

SIN MIEDO



- **SIN MIEDO Airlines** es un programa auto-aplicado a través de Internet para el tratamiento de la fobia o el miedo a volar.
- Te lo puedes aplicar tú mismo, paso a paso y a tu ritmo, desde tu casa o cualquier lugar que tenga acceso a Internet.
- **Duración:** Este tratamiento tiene una duración aproximada de entre **3 y 4 semanas**, aunque puede variar dependiendo del ritmo al que tú lo realices.
- Este programa está formado por una serie de **imágenes y sonidos** relacionadas con los aviones, y con el hecho de volar, a las que puedes exponerte de forma progresiva, estructurada y sistemática.

Componentes principales

- **SIN MIEDO Airlines** sigue una perspectiva cognitiva-conductual basada en la técnica de la exposición.
- Está formado por los siguientes componentes de tratamiento psicológico:

  → **Psicoeducación** acerca de la fobia a volar.

  → **Exposición** a 6 escenarios compuestos por imágenes y sonidos reales.

  → **Sobreaprendizaje.** Mismos escenarios de exposición con mayor grado de dificultad (p.ej., turbulencias) con el objetivo de repasar y afianzar los logros.

ANEXO 7

WHO ARE WE?

Labpsitec, LabHuman, and LabCSD

•We are three research labs from three different Spanish universities.

•We have spent several years researching the possibilities that Information and Communication Technologies (ICTs) offer in the clinical psychology field (i.e., virtual reality, augmented reality, the Internet…).

•NO-FEAR airlines is based on CAFFT program developed by **Labcsd. CAFFT** is a computer-aided exposure treatment for flying phobia that has proved to be effective in several studies.

•This self-applied program via the Internet, **NO-FEAR Airlines**, is the final result of all theses studies initiated over 10 years ago.

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CONTACT US FOR MORE INFORMATION:

volar@uji.es

labpsitec www.labpsitec.es

LabHuman Human Centered Technology

Universitat Jaume I

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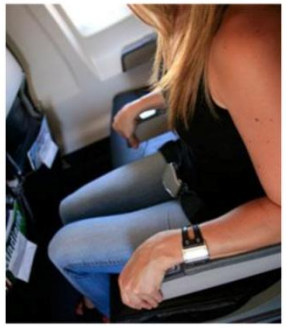
labCSD Laboratori de Conducta i Sistemes Dinàmics

UIB Universitat de les Illes Balears

SIN MIEDO Airlines

NO-FEAR Airlines

A SELF-HELP TREATMENT FOR FLYING PHOBIA APPLIED THROUGH THE INTERNET



Visit our website*:

www.fobiavolar.es

*Just available in Spanish

FLYING PHOBIA

- **Phobias** are irrational fears of an object or situation.
- **Flying Phobia** is an intense fear towards specific situations related to airplanes and flying.
- Different types of fear can be experienced (i.e., having an accident, suffering a panic attack, losing control…).
- People avoid flying situations as a result of a fear to fly.

- **Avoidance** is a key feature for the maintenance of phobias.
- Avoidance leads to a reduction of **short-term** suffering. However, as for the **long-term**, problems remain, resulting in some negative consequences (i.e., work impairment, missing holidays, not being able to visit family,…).

TREATMENT

- **Main goal**: To help you being able to cope with situations related to flying and to stop using strategies to protect you (i.e., Intake of alcohol or anxiolityc drugs).
- This is achieved trough an exposure technique which involves the exposure of the patient to the feared object or context, step by step and without any danger, in order to overcome their anxiety.
- Exposure technique have been proved efficient in several studies and it is recommended in clinical guidelines (American Psychological Association and National Institute for Health and Clinical Excellence).

ASSESSMENT

If you are interested in receiving free treatment access, visit the website:

www.fobiavolar.es

Or you can contact us at

+34 964 38 7644

NO-FEAR Airlines

- ***NO-FEAR Airlines*** is a self-applied program via the Internet for the flying phobia treatment.
- You can follow it on your own, step by step and at your own pace, from home or anywhere with an Internet access.
- **Duration:** This treatment takes about 3 to 4 weeks, but it depends on the frequency you access it.
- This program allows people who are afraid to fly to be exposed to **images and sounds** related to their phobic fears on a standard personal computer from home: structured, progressively and systematically.

KEY COMPONENTS

- ***NO-FEAR Airlines*** follows a cognitive-behavioral perspective based on exposure technique.
- The treatment protocol comprises 3 therapeutic components:

→**Psychoeducation** related to flying phobia.

→**Exposure** to 6 scenarios composed by sounds and real images .

→**Overlearning.** The same exposure scenarios with greater difficulty (i.e.., turbulences effect).

ANEXO 8

ID_____

PROTOCOLO DE EVALUACIÓN PRE TRATAMIENTO (FUERA DEL SISTEMA)

☐ Totalmente auto-aplicado
☐ Auto-aplicado con apoyo mínimo
☐ Grupo control lista de espera

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Fecha:___/___/201_

SCREENING TELEFÓNICO

Nota para el entrevistador: Contactar con el participante, explicarle brevemente el estudio y realizar el screening. Después del screening, citar para la evaluación telefónica o realizarla en el momento (entre 30 y 45 minutos aprox.)

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SCREENING TELEFÓNICO

Código del Participante: _____ Fecha y hora *screening*: _____

Nombre completo: _____

1	¿Qué edad tienes? (De 18-65 años)_____		
2	¿Entiendes y lees bien el español?	Tiene que responder sí	NO SÍ
3	¿Tienes acceso a Internet en casa y dirección de e-mail? e-mail:_____	Tiene que responder sí	NO SÍ
4	¿Manejas el ordenador a nivel de usuario? (p.ej., búsquedas en Internet, acceso a páginas web, etc.)	Tiene que responder sí	NO SÍ
5	¿Actualmente estás recibiendo un tratamiento psicológico?	Tiene que responder no	NO SÍ
6	¿Has recibido algún tratamiento psicológico durante el último año? Si su respuesta es sí, explorar: _____	Tiene que responder no	NO SÍ
7	¿Has tomado alcohol u otras drogas en las **últimas 4 semanas**? Por ejemplo: cannabis, éxtasis, anfetaminas, cocaína, heroína, etc. Si su respuesta es sí, cuál y con qué frecuencia: _____	Tiene que responder no. Si contesta sí, explorar si sólo se trata de consumo ocasional (P.ej., fines de semana)	NO SÍ
8	*Si es mujer*: ¿Estás embarazada en este momento?	Tiene que responder no	NO SÍ
9	¿Cómo has conocido el estudio? _____ _____		

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VARIABLES SOCIODEMOGRÁFICAS

SEXO:

- ☐ Mujer
- ☐ Hombre

FECHA DE NACIMIENTO (dd/mm/aaaa): ___ /___ / _____ **EDAD** ____

LUGAR DE RESIDENCIA: _____

ESTADO CIVIL:

- ☐ Casado/a o emparejado/a
- ☐ Soltero/a
- ☐ Separado/a Divorciado/a
- ☐ Viudo/a

CONVIVENCIA:

- ☐ Domicilio propio solo/a
- ☐ Domicilio propio con la pareja
- ☐ Domicilio propio con pareja y/o hijos
- ☐ Domicilio de familiares
- ☐ Domicilio de vecinos o amigos
- ☐ Residencia
- ☐ Otros (especificar):

NIVEL DE ESTUDIOS:

- ☐ No sabe leer ni escribir
- ☐ No cursado estudios pero sabe leer y escribir
- ☐ Graduado escolar (Estudios primarios)
- ☐ Estudios secundarios (BUP, bachillerato superior, COU, PREU, FP II)
- ☐ Estudios universitarios
- ☐ Otros (especificar):

SITUACIÓN LABORAL:

- □ Estudiante
- □ Ama de casa
- □ Desempleado/a Con subsidio o Sin subsidio
- □ Empleado/a
- □ Empleado/a pero está de baja laboral (ILT). Fecha inicio (dd/mm/aaaa): __/__/____
- □ Jubilado/a
- □ Incapacitado/a invalidez permanente
- □ Otros (especificar):

COMENTARIOS:

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CONTROL MEDICACIÓN

1) En el momento de la evaluación inicial, ¿tomaba algún tipo de medicación para controlar su ansiedad? ❑ SI ❑ NO

Si la repuesta es SI, anotar nombre y dosis de la medicación.

Nombre	Dosis

¿Cuánto tiempo lleva tomando esta medicación?

2) ¿Ha comenzado a tomar medicación durante el tratamiento?

Si la respuesta es SI, anotar nombre y dosis de la medicación.

Nombre	Dosis

¿Cuánto tiempo después de iniciar el tratamiento comenzó a tomar medicación?

3) Desde que inicio el tratamiento la dosis de medicación (señalar una opción):

___permanece igual

___ha aumentado en _____

___ha disminuido en _____

___ha sido discontinuada “altogether”

___ha sido añadida otra medicación. Nombre y dosis _____

Fecha:___/___/201_

EVALUACIÓN TELEFÓNICA

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ENTREVISTA ESTRUCTURADA PARA LOS TRASTORNOS DE ANSIEDAD PARA EL DSM-IV (ADIS-IV-L) FOBIA ESPECÍFICA

I. ENTREVISTA INICIAL

Para cada situación, evalúe separadamente el nivel de miedo y el grado de evitación utilizando la siguiente escala:

0	1	2	3	4	5	6	7	8
Ningún miedo Nunca evita		Miedo ligero Raramente evita		Miedo moderado A veces evita		Miedo severo A menudo evita		Miedo muy severo Siempre evita

Para cada situación, pregunte por episodios actuales y pasados:

1. **Actualmente, teme o tiene la necesidad de evitar cosas tales como: Alguna vez ha temido o ha sentido la necesidad de evitar cosas tales como:**

Si el paciente confirma un miedo específico actual, cuando se le pregunta acerca de miedos pasados hacia el mismo objeto/ situación estas preguntas deben ser para determinar la presencia de episodios discretos de malestar anteriores (p. ej. "Desde que el miedo empezó, ¿ha habido períodos de tiempo en los que no se sentía molesto por él?") Usar el espacio para los comentarios para anotar otra información clínicamente relevante (p. ej. La frecuencia con la que se presentan las situaciones temidas).

		ACTUAL		COMENTARIOS	PASADO	
		MIEDO	EVITACIÓN		MIEDO	EVITACIÓN
	Aviones					
	Alturas					
	Ascensores/espacios cerrados					
	Otros					

II. EPISODIOS ACTUALES

Complete para cada miedo específico que potencialmente puede tener gravedad clínica: Si hay evidencia de un episodio discreto pasado, introduzca esta sección de la entrevista con: **Ahora quiero hacerle una serie de preguntas acerca de sus miedos específicos actuales.**

A. Miedo específico #1: AVIONES

1. ¿Qué le preocupa que suceda en esta situación?

   _____

   _____

2. ¿Experimenta usted ansiedad prácticamente todas las veces que se encuentra con _____? SÍ_____ NO_____

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3. ¿Aparece la ansiedad tan pronto como usted se encuentra con la situación o cuando va a encontrarse con la situación, o a veces la ansiedad aparece más tarde o de forma inesperada?

ANTICIPADA INMEDIATA DEMORADA

4. a. ¿Está usted ansioso en esa situación porque tiene miedo de tener un ataque de pánico inesperado? SÍ NO

EN CASO AFIRMATIVO,

4. b. En otras ocasiones en las que usted se ha expuesto a _____, ¿ha experimentado un aumento rápido e inesperado del miedo/ ansiedad? SÍ NO

EN CASO AFIRMATIVO, ¿dónde ocurrió esto?_____

En caso de que conteste AFIRMATIVAMENTE 4a. o 4b., considere si el miedo podría explicarse por la presencia de un trastorno de pánico.

5. De qué modo interfiere este miedo en su vida (p. ej. Rutinas cotidianas, trabajo, actividades sociales)?; ¿Cuánto malestar le produce este miedo?

Interferencia: _____ Malestar: _____

0	1	2	3	4	5	6	7	8
Nada		Ligero		Moderado		Severo		Muy severo

6. a. ¿Cuándo empezó la ansiedad por _____ a ser un problema que le causaba un gran malestar o una gran interferencia en su vida? *(Nota: si el paciente es vago en la fecha de comienzo, intentar averiguar más información específica p. ej. Asociando el comienzo con sucesos vitales objetivos)*

_____

Fecha de inicio_____Mes_____Año

6. b. ¿Puede recordar usted alguna cosa que pueda haberle producido este miedo?

_____

_____

B. Miedo específico #2: ……..

1. ¿Qué le preocupa que suceda en esta situación?

_____

_____

____

2. ¿Experimenta usted ansiedad prácticamente todas las veces que se encuentra con _____? SÍ_____ NO_____

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3. ¿Aparece la ansiedad tan pronto como usted se encuentra con la situación o cuando va a encontrarse con la situación, o a veces la ansiedad aparece más tarde o de forma inesperada?

ANTICIPADA INMEDIATA DEMORADA

4. a. ¿Está usted ansioso en esa situación porque tiene miedo de tener un ataque de pánico inesperado? SÍ NO

EN CASO AFIRMATIVO,

4. b. En otras ocasiones en las que usted se ha expuesto a _____, ¿ha experimentado un aumento rápido e inesperado del miedo/ ansiedad?
SÍ NO

EN CASO AFIRMATIVO, ¿dónde ocurrió esto?_____

En caso de que conteste AFIRMATIVAMENTE 4a. o 4b., considere si el miedo podría explicarse por la presencia de un trastorno de pánico.

5. De qué modo interfiere este miedo en su vida (p. ej. Rutinas cotidianas, trabajo, actividades sociales)?; ¿Cuánto malestar le produce este miedo?

Interferencia: _____ Malestar: _____

0	1	2	3	4	5	6	7	8
Nada		Ligero		Moderado		Severo		Muy severo

6. a. ¿Cuándo empezó la ansiedad por _____ a ser un problema que le causaba un gran malestar o una gran interferencia en su vida? *(Nota: si el paciente es vago en la fecha de comienzo, intentar averiguar más información específica p. ej. Asociando el comienzo con sucesos vitales objetivos)*

_____

Fecha de inicio_____Mes_____Año

6. b. ¿Puede recordar usted alguna cosa que pueda haberle producido este miedo?

_____

_____

II. EPISODIOS PASADOS

Complete para cada miedo específico que potencialmente pudo tener gravedad clínica: **Ahora quiero hacerle una serie de preguntas acerca de sus miedos específicos <u>pasados.</u>**

A. Miedo específico #1: _____

1. ¿Qué le preocupaba que sucediera en esa situación?
   _____
   _____

2. ¿Experimentaba usted ansiedad prácticamente todas las veces que se encontraba con _____? SÍ_____ NO_____

3. ¿Aparecía la ansiedad tan pronto como usted se encontraba con esa situación o cuando iba a encontrarse con la situación, o agunas veces la ansiedad aparece más tarde o de forma inesperada?
   INMEDIATA_____ DEMORADA_____

4. a. ¿Estaba usted ansioso en esa situación porque tenía miedo de tener un ataque de pánico inesperado? SÍ_____ NO_____

EN CASO AFIRMATIVO

4. b. En otras ocasiones en las que usted se ha expuesto a _____, ¿ha experimentado un aumento rápido e inesperado del miedo/ ansiedad?
   SÍ_____ NO_____

EN CASO AFIRMATIVO, ¿dónde ocurrió esto?_____

En caso de que conteste AFIRMATIVAMENTE 4ª. o 4b., considere si el miedo podría explicarse por la presencia de un trastorno de pánico.

5. ¿De qué modo interfirió este miedo en su vida (p. ej. Rutinas cotidianas, trabajo, actividades sociales)?; ¿Cuánto malestar le produjo este miedo?

Interferencia: _____ Malestar: _____

0	1	2	3	4	5	6	7	8
Nada		Ligero		Moderado		Severo		Muy severo

6. a. ¿Cuándo empezó la ansiedad por _____ a ser un problema que le causaba un gran malestar o una gran interferencia en su vida? *(Nota: si el paciente es vago en la fecha de comienzo, intentar averiguar más información específica p. ej. Asociando el comienzo con sucesos vitales objetivos)*

_____
Fecha de inicio_____Mes_____Año

6. b. ¿Puede recordar usted alguna cosa que pueda haberle producido este miedo?
   _____
   _____

7. a. ¿Cuándo dejó de ser la ansiedad por _____ un problema y usted ya se encontraba cómodo con _____, o ya no le causaba un gran malestar o ya no interfería en su vida?

   _____

   _____

Fecha de remisión: _____Mes _____Año_____

7. b. ¿Puede recordar alguna razón (o razones) por las que ya no estaba ansioso a causa de esta situación?

   _____

   _____

IV. INVESTIGACIÓN

Las preguntas deben referirse a los episodios actuales de malestar.

A. SÍNTOMAS DE ATAQUE DE PÁNICO

1. Miedo específico #1: _____

   Nota: señalar también para miedo especifico #2:_____

Experimenta usted _____cuando se encuentra con_____?

0	1	2	3	4	5	6	7	8	9	10
Nada		Ligero		Moderado			Severo		Muy severo	

1. Palpitaciones, sacudidas del corazón o elevación de la frecuencia cardiaca	__	8. Escalofríos, sofocaciones o rubor	__
2. Sudoración	__	9. Vértigo, sensaciones de inestabilidad, mareo o desmayo	__
3. Temblores o sacudidas	__	10. Sensación de irrealidad o de estar separado de uno mismo (despersonalización)	__
4. Sensaciones de ahogo o falta de aliento	__	11. Sensación de entumecimiento u hormigueo	__
5. Sensación de atragantamiento	__	12. Miedo a morir	__
6. Dolor o malestar torácico	__	13. Miedo a volverse loco	__
7. Náuseas o molestias abdominales	__	14. Miedo a perder el control	__

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ENTREVISTA ESTRUCTURADA FOBIA A VOLAR (VERSIÓN BREVE)

1. ¿Con qué frecuencia tiene que volar?_____

De los siguientes sucesos, indique, en una escala de 0 a 10 (donde 0= nada en absoluto y 10= totalmente) en qué medida cree que cada una de estas cosas podría sucederle en una situación de vuelo:

El avión podría chocar con otro avión	0	1	2	3	4	5	6	7	8	9	10
Podría haber problemas con los motores (incendiarse, desprenderse, atascarse,…)	0	1	2	3	4	5	6	7	8	9	10
El avión podría estallar	0	1	2	3	4	5	6	7	8	9	10
El avión podría caerse desde el cielo	0	1	2	3	4	5	6	7	8	9	10
Podría entrar en una tormenta	0	1	2	3	4	5	6	7	8	9	10
Un ala podría caerse o averiarse	0	1	2	3	4	5	6	7	8	9	10
El tren de aterrizaje podría no funcionar	0	1	2	3	4	5	6	7	8	9	10

2. ¿Cuándo aparece la ansiedad: **antes** incluso de que se encuentre con la situación, **tan pronto** como se encuentra con la situación, o **más tarde**, de forma inesperada?

ANTICIPATORIA_____INMEDIATA_____DEMORADA_____

3.1 Si indica que padece **ansiedad anticipatoria**: ¿Cuánto tiempo antes de que se tenga que enfrentar con el hecho de volar aparece la ansiedad?

Días antes_____
Horas antes_____
En el aeropuerto_____
Sólo pensarlo_____

3.2 Si indica que aparece ansiedad demorada, ¿Cuánto tiempo después de enfrentarse al hecho de volar aparece la ansiedad?_____

3. ¿Cuándo desaparece la ansiedad o el malestar? (Especificar si en algún momento del vuelo)
_____
_____
_____

4. ¿Cuándo voló por primera vez? _____¿Cómo fue ese vuelo?_____
_____

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5. ¿Hay alguna circunstancia que haga su miedo más o menos intenso?

- Viajar solo	más	menos	indiferente
- Viajar acompañado	más	menos	indiferente
- Viajar con buen tiempo	más	menos	indiferente
- Viajar con mal tiempo	más	menos	indiferente
- Viajes cortos	más	menos	indiferente
- Viajes largos	más	menos	indiferente
- Viajes por vacaciones	más	menos	indiferente
- Viajes por trabajo	más	menos	indiferente

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ESCALA DE EVITACIÓN

(Adaptada de Marks y Mathews, 1979)

Ahora te pediremos que señales cuánto miedo experimentas e indiques con qué frecuencia evitas la conducta-objetivo ***VOLAR*** según la siguiente escala.

ESCALA DE MIEDO Y EVITACIÓN

	0	1	2	3	4	5	6	7	8	9	10
Miedo	Nada		Poco			Algo		Bastante			Mucho
Evitación	Nunca		Pocas veces			Algunas veces		Muchas veces			Siempre

Conducta	MIEDO	EVITACIÓN
1. Volar		

PENSAMIENTOS NEGATIVOS ASOCIADOS A LA CONDUCTA OBJETIVO

Señala a continuación el pensamiento que hace que te resulte difícil realizar la conducta objetivo, así como el grado de creencia que tienes acerca de la veracidad de cada uno de los pensamientos negativos.

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

Pensamientos	Grado de creencia
1.	
2.	

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ESCALA DE MIEDO A VOLAR

(Fear of Flying Scale, FSS; Haug et al., 1987)

A continuación te presentamos una serie de situaciones o acciones que están relacionadas con el hecho de volar. Señala en qué medida cada una de esas situaciones te provoca ansiedad, siguiendo la siguiente escala:

1	2	3	4
Ninguna ansiedad	Alguna ansiedad	Bastante ansiedad	Mucha ansiedad

	Ninguna ansiedad	Alguna ansiedad	Bastante ansiedad	Mucha ansiedad
1. Ver un avión en vuelo	1	2	3	4
2. Ver un avión en televisión o en una película	1	2	3	4
3. Oír hablar a otros sobre viajar en avión	1	2	3	4
4. Llevar a otros al aeropuerto	1	2	3	4
5. Planificar un viaje en avión	1	2	3	4
6. Tomar la decisión de viajar en avión (con el billete comprado)	1	2	3	4
7. Ir hacia el aeropuerto (cuando va a viajar en avión)	1	2	3	4
8. Esperar el momento de la salida	1	2	3	4
9. Entrar en el avión	1	2	3	4
10. Estar sentado dentro del avión mientras éste permanece todavía en tierra	1	2	3	4
11. Se cierran las puertas del avión	1	2	3	4
12. El avión toma la salida por la pista de despegue	1	2	3	4
13. Oír la aceleración del motor	1	2	3	4
14. El avión acelera y despega	1	2	3	4
15. El avión aumenta de altitud	1	2	3	4
16. Mirar por la ventana durante el vuelo	1	2	3	4
17. El avión se mueve por las nubes o el viento	1	2	3	4
18. El avión vibra fuertemente en una turbulencia	1	2	3	4
19. El avión empieza a descender	1	2	3	4
20. El avión aterriza	1	2	3	4
21. El avión pone el freno y reduce velocidad	1	2	3	4

Nota para el entrevistador: una vez finalizada la primera parte de la entrevista telefónica se valorará la inclusión en el proyecto y se contactará de nuevo con el participante para comunicarle si puede participar en el estudio. En este punto también se le explican las distintas condiciones del estudio y se le envía un consentimiento informado con toda la información para que firme y nos envíe.

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ESCALA DE VALORACIÓN DEL CLÍNICO
(Adaptación de la clinician´s ratings del ADIS-IV, Di Nardo, Brown y Barlow, 1994)

Nombre..... Código/DNI..... Edad..... Género: ❑Mujer ❑Hombre
Condición: ..... Diagnóstico..... Fecha.....
Número de sesión: .....

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

AUSENTE	LEVE	MODERADA	GRAVE	MUY GRAVE
0----------1----------2----------3----------4----------5----------6----------7----------8				
Ninguna	Ligeramente perturbadora/ no realmente incapacitante	Definitivamente perturbadora/ incapacitante	Marcadamente perturbadora/ incapacitante	Muy gravemente perturbadora/ incapacitante

Nota importante: La valoración de esta escala se realizará tras la evaluación diagnóstica.

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 Inc.

CUESTIONARIOS

2ª LLAMADA TELEFÓNICA

Nota para el entrevistador: Una vez finalizada la primera parte de la entrevista telefónica se valorará la inclusión en el proyecto y se contactará de nuevo con el participante para comunicarle si puede participar en el estudio.

- Si se aleatoriza a SIN MIEDO Airlines: Se explican las dos condiciones de tratamiento y se evalúa preferencias. Después, se le dice la condición a la que se le ha asignado de forma aleatoria y se le pregunta expectativas de tratamiento.

- Si es Lista de Espera: Le daremos el enlace al survey monkey y en 6 semanas volveremos a contactar con él.

A continuación, te vamos a realizar una serie de preguntas sobre el proyecto en el que vas a participar. Te explicaremos las distintas condiciones de tratamiento y te preguntaremos por tus preferencias, antes de saber a qué condición has sigo asignado/a de forma aleatoria. Después te diremos qué condición experimental te ha tocado y te preguntaremos por tus expectativas antes del tratamiento que estás a punto de empezar.

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BREVE EXPLICACIÓN DEL TRATAMIENTO.

El programa de tratamiento que te ofrecemos (SIN MIEDO Airlines) permite a las personas con miedo a volar exponerse a imágenes y sonidos relacionados con su miedo en un ordenador estándar, desde su casa, a través de Internet. Es decir, te lo puedes aplicar tu mismo, paso a paso y a tu ritmo.

La técnica de exposición a las situaciones temidas es el tratamiento psicológico más eficaz para la fobia a volar. Es una técnica que ha demostrado eficacia en numerosos estudios y por ello se recomienda en las guías sobre buenas prácticas clínicas de las asociaciones internacionales de psicología (*American Psychological Association* y *National Institute for Health and Clinical Excellence*). El principio de la exposición supone que al enfrentarse a la situación temida se experimentará ansiedad, pero progresivamente la persona se irá habituando a la situación y esa ansiedad irá disminuyendo. Lo importante es permanecer en la situación hasta que la ansiedad disminuya.

Este programa contiene una serie de situaciones relacionadas con los aviones, y con el hecho de volar, a las que puedes exponerte de forma progresiva, estructurada y sistemática. Al finalizar la exposición podrás elegir si quieres repetir alguno de los escenarios de exposición aumentando un poco la dificultad (condiciones de lluvia y turbulencias). Además, al inicio, encontrarás información sobre el miedo a volar que te puede resultar de utilidad para afrontar tu miedo. Lo recomendado es que realices dos escenarios de exposición a la semana, dejando algún día de descanso entre medio, por lo que en 3-4 semanas podrías finalizar el tratamiento. No obstante, puedes seguir el ritmo que tú prefieras, hasta alcanzar un máximo de 6 semanas (un escenario a la semana). Una vez hayas terminado el tratamiento deberías realizar un vuelo para comprobar los cambios alcanzados. Es un paso esencial para que superes tu miedo. Y conviene que lo hagas lo antes posible, alrededor de unos 15 días después de haber acabado con el tratamiento. A lo largo del tratamiento, encontrarás pautas esenciales para que puedas planificar este vuelo, a medida que te vayas sintiendo más preparado/a.

En el estudio que vas a participar, como ya sabes, hay dos condiciones de tratamiento y un grupo control lista de espera a las que serás asignado de forma aleatoria por un programa informático. Las dos condiciones de tratamiento son las siguientes:

1) Tratamiento totalmente auto-aplicado a través del programa “SIN MIEDO Airlines”. Recibirás acceso al programa para que lo completes a través de Internet al ritmo que tú desees. En esta condición no habrá contacto por parte del equipo clínico, más que el apoyo del propio programa, hasta que finalices el tratamiento. En este momento nos volveremos a poner en contacto contigo.
2) Tratamiento auto-aplicado a través del programa “SIN MIEDO Airlines” con apoyo mínimo por parte de terapeuta. Recibirás acceso al programa para que lo completes a través de Internet al ritmo que tú desees. Además, recibirás una llamada telefónica semanal de un terapeuta para valorar tus avances y progresos con el programa de tratamiento.

Los participantes que sean asignados al grupo de “Lista de Espera” podrán acceder al tratamiento de forma voluntaria pasadas 6 semanas. ***Se les envía por correo el enlace del survey.*

labpsitec

SIN MIEDO Airlines

ESCALA DE PREFERENCIAS

Por favor, después de haber leído la breve descripción sobre el tratamiento y las dos condiciones de tratamiento de este estudio, contesta a las siguientes preguntas: (Nota: sin saber cuál es su condición todavía).

1. Si pudieras elegir entre las DOS condiciones de tratamiento, ¿Cuál elegirías?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado con contacto mínimo por parte del terapeuta.

2. ¿Cuál de estas dos condiciones de tratamiento, consideras que puede ser más eficaz o útil para ayudarte a superar tu problema?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado a través de Internet con contacto mínimo por parte del terapeuta.

3. ¿Cuál de estas dos condiciones de tratamiento, consideras que es más lógica para ayudarte a superar tu problema?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado a través de Internet con contacto mínimo por parte del terapeuta.

4. ¿Cuál de estas dos condiciones de tratamiento, consideras que puede ser más aversiva (desagradable, molesta)?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado a través de Internet con contacto mínimo por parte del terapeuta.

5. ¿Cuál de estas dos condiciones de tratamiento, recomendarías a un amigo que tuviera el mismo problema?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado a través de Internet con contacto mínimo por parte del terapeuta.

labpsitec

SIN MIEDO Airlines

Escala de expectativas sobre el tratamiento

(Adaptado de Borkovec y Nau, 1972)

Nota para el entrevistador: Antes de que el participante responda esta escala **se le dice la condición de tratamiento asignada.**

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

☐ Totalmente auto-aplicado

☐ Auto-aplicado con apoyo mínimo

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

0 1 2 3 4 5 6 7 8 9 10

Nada Muchísimo

2.- ¿En qué medida te satisface el tratamiento que va a recibir?

0 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?

0 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?

0 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?

0 1 2 3 4 5 6 7 8 9 10

Nada Muchísimo

6.- ¿En qué medida este tratamiento te resulta aversivo (desagradable o molesto)?

0 1 2 3 4 5 6 7 8 9 10

Nada Muchísimo

labpsitec

Muchas gracias por contestar a todas nuestras preguntas. Has terminado la primera parte de la evaluación del estudio. Ahora ya puedes acceder al programa de tratamiento. En unos días recibirás el usuario y la contraseña en tu correo electrónico. Recuerda cambiar tu contraseña y recordarla para poder acceder al programa.

De nuevo, gracias por tu colaboración y esperamos que puedas sacarle el máximo partido a este programa de tratamiento auto-aplicado a través de Internet para el miedo a volar.

ANEXO 9

ID_____

PROTOCOLO DE EVALUACIÓN POST TRATAMIENTO (FUERA DEL SISTEMA)

☐ Totalmente auto-aplicado
☐ Auto-aplicado con apoyo mínimo
☐ Lista de Espera

Fecha:___/___/201_

EVALUACIÓN TELEFÓNICA

SIN MIEDO Airlines

ENTREVISTA ESTRUCTURADA PARA LOS TRASTORNOS DE ANSIEDAD PARA EL DSM-IV (ADIS-IV-L) FOBIA ESPECÍFICA

Nota para los terapeutas: Evaluar también los trastornos comórbidos evaluados en el PRE.

I. ENTREVISTA INICIAL

Para cada situación, evalúe separadamente el nivel de miedo y el grado de evitación utilizando la siguiente escala:

0	1	2	3	4	5	6	7	8
Ningún miedo Nunca evita		Miedo ligero Raramente evita		Miedo moderado A veces evita		Miedo severo A menudo evita		Miedo muy severo Siempre evita

Para cada situación, pregunte por episodios actuales y pasados:

1. **Actualmente, teme o tiene la necesidad de evitar cosas tales como: Alguna vez ha temido o ha sentido la necesidad de evitar cosas tales como:**

Si el paciente confirma un miedo específico actual, cuando se le pregunta acerca de miedos pasados hacia el mismo objeto/ situación estas preguntas deben ser para determinar la presencia de episodios discretos de malestar anteriores (p. ej. "Desde que el miedo empezó, ¿ha habido períodos de tiempo en los que no se sentía molesto por él?") Usar el espacio para los comentarios para anotar otra información clínicamente relevante (p. ej. La frecuencia con la que se presentan las situaciones temidas).

		ACTUAL		COMENTARIOS	PASADO	
		MIEDO	EVITACIÓN		MIEDO	EVITACIÓN
	Aviones					
	Alturas					
	Ascensores/espacios cerrados					
	Otros					

II. EPISODIOS ACTUALES

Complete para cada miedo específico que potencialmente puede tener gravedad clínica: Si hay evidencia de un episodio discreto pasado, introduzca esta sección de la entrevista con: **Ahora quiero hacerle una serie de preguntas acerca de sus miedos específicos actuales.**

A. Miedo específico #1: AVIONES

1. ¿Qué le preocupa que suceda en esta situación?

_____

_____

2. ¿Experimenta usted ansiedad prácticamente todas las veces que se encuentra con _____? SÍ_____ NO_____

3. ¿Aparece la ansiedad tan pronto como usted se encuentra con la situación o cuando va a encontrarse con la situación, o a veces la ansiedad aparece más tarde o de forma inesperada?

ANTICIPADA INMEDIATA DEMORADA

4. a. ¿Está usted ansioso en esa situación porque tiene miedo de tener un ataque de pánico inesperado? SÍ NO

EN CASO AFIRMATIVO,

4. b. En otras ocasiones en las que usted se ha expuesto a _____, ¿ha experimentado un aumento rápido e inesperado del miedo/ ansiedad? SÍ NO

EN CASO AFIRMATIVO, ¿dónde ocurrió esto?_____

En caso de que conteste AFIRMATIVAMENTE 4a. o 4b., considere si el miedo podría explicarse por la presencia de un trastorno de pánico.

5. De qué modo interfiere este miedo en su vida (p. ej. Rutinas cotidianas, trabajo, actividades sociales)?; ¿Cuánto malestar le produce este miedo?

Interferencia: _____ Malestar: _____

0	1	2	3	4	5	6	7	8
Nada		Ligero		Moderado		Severo		Muy severo

6. a. ¿Cuándo empezó la ansiedad por _____ a ser un problema que le causaba un gran malestar o una gran interferencia en su vida? *(Nota: si el paciente es vago en la fecha de comienzo, intentar averiguar más información específica p. ej. Asociando el comienzo con sucesos vitales objetivos)*

_____

Fecha de inicio_____Mes_____Año

6. b. ¿Puede recordar usted alguna cosa que pueda haberle producido este miedo?

_____

_____

B. Miedo específico #2: ……..

1. ¿Qué le preocupa que suceda en esta situación?
_____
_____
____

2. ¿Experimenta usted ansiedad prácticamente todas las veces que se encuentra con _____? SÍ_____ NO_____

3. ¿Aparece la ansiedad tan pronto como usted se encuentra con la situación o cuando va a encontrarse con la situación, o a veces la ansiedad aparece más tarde o de forma inesperada?

ANTICIPADA INMEDIATA DEMORADA

4. a. ¿Está usted ansioso en esa situación porque tiene miedo de tener un ataque de pánico inesperado? SÍ NO

EN CASO AFIRMATIVO,

4. b. En otras ocasiones en las que usted se ha expuesto a _____, ¿ha experimentado un aumento rápido e inesperado del miedo/ ansiedad? SÍ NO

EN CASO AFIRMATIVO, ¿dónde ocurrió esto?_____

En caso de que conteste AFIRMATIVAMENTE 4a. o 4b., considere si el miedo podría explicarse por la presencia de un trastorno de pánico.

5. De qué modo interfiere este miedo en su vida (p. ej. Rutinas cotidianas, trabajo, actividades sociales)?; ¿Cuánto malestar le produce este miedo?

Interferencia: _____ Malestar: _____

0	1	2	3	4	5	6	7	8
Nada		Ligero		Moderado		Severo		Muy severo

6. a. ¿Cuándo empezó la ansiedad por _____ a ser un problema que le causaba un gran malestar o una gran interferencia en su vida? *(Nota: si el paciente es vago en la fecha de comienzo, intentar averiguar más información específica p. ej. Asociando el comienzo con sucesos vitales objetivos)*

_____
Fecha de inicio_____Mes_____Año

6. b. ¿Puede recordar usted alguna cosa que pueda haberle producido este miedo?
_____
_____

IV. INVESTIGACIÓN

Las preguntas deben referirse a los episodios actuales de malestar.

A. SÍNTOMAS DE ATAQUE DE PÁNICO
1. Miedo específico #1: _____

Nota: señalar también para miedo especifico #2:_____

Experimenta usted _____cuando se encuentra con_____?

0	1	2	3	4	5	6	7	8	9	10
Nada		Ligero		Moderado			Severo		Muy severo	

1. Palpitaciones, sacudidas del corazón o elevación de la frecuencia cardiaca	__	8. Escalofríos, sofocaciones o rubor	__
2. Sudoración	__	9. Vértigo, sensaciones de inestabilidad, mareo o desmayo	__
3. Temblores o sacudidas	__	10. Sensación de irrealidad o de estar separado de uno mismo (despersonalización)	__
4. Sensaciones de ahogo o falta de aliento	__	11. Sensación de entumecimiento u hormigueo	__
5. Sensación de atragantamiento	__	12. Miedo a morir	__
6. Dolor o malestar torácico	__	13. Miedo a volverse loco	__
7. Náuseas o molestias abdominales	__	14. Miedo a perder el control	__

SIN MIEDO Airlines

CONTROL MEDICACIÓN

1) En el momento de la evaluación inicial, ¿tomaba algún tipo de medicación para controlar su ansiedad? ❑ SI ❑ NO

Si la repuesta es SI, anotar nombre y dosis de la medicación.

Nombre	Dosis

¿Cuánto tiempo lleva tomando esta medicación?

2) ¿Ha comenzado a tomar medicación durante el tratamiento?

Si la respuesta es SI, anotar nombre y dosis de la medicación.

Nombre	Dosis

¿Cuánto tiempo después de iniciar el tratamiento comenzó a tomar medicación?

3) Desde que inicio el tratamiento la dosis de medicación (señalar una opción):

___permanece igual

___ha aumentado en _____

___ha disminuido en _____

___ha sido discontinuada “altogether”

___ha sido añadida otra medicación. Nombre y dosis _____

ENTREVISTA ESTRUCTURADA FOBIA A VOLAR (VERSIÓN BREVE)

1. ¿Con qué frecuencia tiene que volar?_____

NOTA PARA EL ENTREVISTADOR: Preguntar si ha volado después de finalizar el tratamiento. SI/NO. ¿Cuántas veces?____

¿Qué nivel de ansiedad experimentaste (0 a 10)?

Antes del vuelo_____ Durante el vuelo _____ Después del vuelo_____

De los siguientes sucesos, indique, en una escala de 0 a 10 (donde 0= nada en absoluto y 10= totalmente) en qué medida cree que cada una de estas cosas podría sucederle en una situación de vuelo:

El avión podría chocar con otro avión	0	1	2	3	4	5	6	7	8	9	10
Podría haber problemas con los motores (incendiarse, desprenderse, atascarse,…)	0	1	2	3	4	5	6	7	8	9	10
El avión podría estallar	0	1	2	3	4	5	6	7	8	9	10
El avión podría caerse desde el cielo	0	1	2	3	4	5	6	7	8	9	10
Podría entrar en una tormenta	0	1	2	3	4	5	6	7	8	9	10
Un ala podría caerse o averiarse	0	1	2	3	4	5	6	7	8	9	10
El tren de aterrizaje podría no funcionar	0	1	2	3	4	5	6	7	8	9	10

2. ¿Cuándo aparece la ansiedad: **antes** incluso de que se encuentre con la situación, **tan pronto** como se encuentra con la situación, o **más tarde**, de forma inesperada? **ESTO LO HA CONTESTADO CON ANTERIORIDAD RECORDAR SU RESPUESTA E INDAGAR SOBRE LA ANTICIPACIÓN**

ANTICIPATORIA_____INMEDIATA_____DEMORADA_____

3.1 Si indica que padece **ansiedad anticipatoria**: ¿Cuánto tiempo antes de que se tenga que enfrentar con el hecho de volar aparece la ansiedad?

Días antes_____
Horas antes_____
En el aeropuerto_____
Sólo pensarlo_____

3.2 Si indica que aparece ansiedad demorada, ¿Cuánto tiempo después de enfrentarse al hecho de volar aparece la ansiedad?_____

3. ¿Cuándo desaparece la ansiedad o el malestar? (Especificar si en algún momento del vuelo o cuando finaliza el vuelo)_____
_____
_____

4. ¿Hay alguna circunstancia que haga su miedo más o menos intenso?

- Viajar solo:	más	menos	indiferente
- Viajar acompañado	más	menos	indiferente
- Viajar con buen tiempo	más	menos	indiferente
- Viajar con mal tiempo	más	menos	indiferente
- Viajes cortos	más	menos	indiferente
- Viajes largos	más	menos	indiferente
- Viajes por vacaciones	más	menos	indiferente
- Viajes por trabajo	más	menos	indiferente

ESCALA DE EVITACIÓN

(Adaptada de Marks y Mathews, 1979)

Ahora te pediremos que señales cuánto miedo experimentas e indiques con qué frecuencia evitas la conducta-objetivo ***VOLAR*** según la siguiente escala.

ESCALA DE MIEDO Y EVITACIÓN

	0	1	2	3	4	5	6	7	8	9	10
Miedo	Nada		Poco			Algo		Bastante			Mucho
Evitación	Nunca		Pocas veces			Algunas veces		Muchas veces			Siempre

Conducta	MIEDO	EVITACIÓN
1. Volar		

PENSAMIENTOS NEGATIVOS ASOCIADOS A LA CONDUCTA OBJETIVO

Señala a continuación el pensamiento que hace que te resulte difícil realizar la conducta objetivo, así como el grado de creencia que tienes acerca de la veracidad de cada uno de los pensamientos negativos.

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

Pensamientos	Grado de creencia
1.	
2.	

Nota: Valorar los mismos pensamientos que en el PRE y especificar el principal.

SIN MIEDO Airlines

ENTREVISTA CUALITATIVA "SIN MIEDO Airlines"

1. ¿En qué medida consideras que los escenarios de exposición del programa "SIN MIEDO Airlines" han sido una herramienta útil para afrontar tu miedo a volar?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

¿Por qué?

2. ¿En qué medida consideras que el uso de imágenes fijas en los diferentes escenarios del programa es una herramienta útil para ayudarte a realizar la exposición?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

¿Por qué?

3. ¿En qué medida consideras que el uso de sonidos reales en los diferentes escenarios del programa es una herramienta útil para ayudarte a realizar la exposición?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

¿Por qué?

4. ¿En qué medida consideras que la información proporcionada por el programa "SIN MIEDO Arlines" sobre la fobia a volar (p.ej., a cuántas personas afecta o en qué consiste el miedo a volar) te ha resultado útil para afrontar tu miedo a volar?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

5. ¿En qué medida consideras que el componente de sobre-aprendizaje (opcional) resulta útil para afrontar el miedo a volar?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

6. ¿Crees que es útil tener a tu disposición el programa "SIN MIEDO Airlines" durante más tiempo una vez finalizado el tratamiento. ¿Por qué?

1. Sí

2. No

7. SÓLO PARA LA CONDICIÓN CON APOYO: ¿En qué medida te ha gustado recibir una breve llamada telefónica de apoyo semanal por parte del terapeuta?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

¿Por qué?

8. SÓLO PARA LA CONDICIÓN CON APOYO → ¿En qué medida has considerado útil esa llamada telefónica de apoyo semanal por parte del terapeuta? ¿Por qué?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

¿Por qué?

9. SÓLO PARA LA CONDICIÓN SIN APOYO → ¿En qué medida te habría gustado recibir una breve llamada telefónica de apoyo semanal (máximo 5 minutos) por parte de un terapeuta?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

¿Por qué?

10. SÓLO PARA LA CONDICIÓN SIN APOYO → ¿En qué medida consideras que te habría ayudado recibir esa breve llamada telefónica de apoyo semanal?

1	2	3	4	5
Muy poco	Poco	Algo	Mucho	Muchísimo

¿Por qué?

11. Opinión general sobre el programa de intervención.

ESCALA DE VALORACIÓN DEL CLÍNICO

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

Nombre..... Código/DNI..... Edad..... Género: ❑ Mujer ❑ Hombre Condición: ..... Diagnóstico..... Fecha..... Número de sesión: .....

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

AUSENTE	LEVE	MODERADA	GRAVE	MUY GRAVE
0----------1----------2----------3----------4----------5----------6----------7----------8				
Ninguna	Ligeramente perturbadora/ no realmente incapacitante	Definitivamente perturbadora/ incapacitante	Marcadamente perturbadora/ incapacitante	Muy gravemente perturbadora/ incapacitante

Nota importante: La valoración de esta escala se realizará tras la evaluación diagnóstica.

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 Inc.

ESCALA DE MIEDO A VOLAR

(Fear of Flying Scale, FSS; Haug et al., 1987)

A continuación te presentamos una serie de situaciones o acciones que están relacionadas con el hecho de volar. Señala en qué medida cada una de esas situaciones te provoca ansiedad, siguiendo la siguiente escala:

1	2	3	4
Ninguna ansiedad	Alguna ansiedad	Bastante ansiedad	Mucha ansiedad

	Ninguna ansiedad	Alguna ansiedad	Bastante ansiedad	Mucha ansiedad
1. Ver un avión en vuelo	1	2	3	4
2. Ver un avión en televisión o en una película	1	2	3	4
3. Oír hablar a otros sobre viajar en avión	1	2	3	4
4. Llevar a otros al aeropuerto	1	2	3	4
5. Planificar un viaje en avión	1	2	3	4
6. Tomar la decisión de viajar en avión (con el billete comprado)	1	2	3	4
7. Ir hacia el aeropuerto (cuando va a viajar en avión)	1	2	3	4
8. Esperar el momento de la salida	1	2	3	4
9. Entrar en el avión	1	2	3	4
10. Estar sentado dentro del avión mientras éste permanece todavía en tierra	1	2	3	4
11. Se cierran las puertas del avión	1	2	3	4
12. El avión toma la salida por la pista de despegue	1	2	3	4
13. Oír la aceleración del motor	1	2	3	4
14. El avión acelera y despega	1	2	3	4
15. El avión aumenta de altitud	1	2	3	4
16. Mirar por la ventana durante el vuelo	1	2	3	4
17. El avión se mueve por las nubes o el viento	1	2	3	4
18. El avión vibra fuertemente en una turbulencia	1	2	3	4
19. El avión empieza a descender	1	2	3	4
20. El avión aterriza	1	2	3	4
21. El avión pone el freno y reduce velocidad	1	2	3	4

SIN MIEDO Airlines

Valoración de Mejoría

(Adaptado de Guy, 1976)

Respecto al inicio del tratamiento, me he encontrado:

1	2	3	4	5	6	7
Mucho peor	**Bastante peor**	**Un poco peor**	**Sin cambios**	**Un poco mejor**	**Bastante mejor**	**Mucho mejor**

SIN MIEDO Airlines

Escala de Opinion sobre el tratamiento

(Adaptado de Borkovec y Nau, 1972)

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?

0	1	2	3	4	5	6	7	8	9	10
Nada										Muchísimo

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

0	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?

0	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?

0	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?

0	1	2	3	4	5	6	7	8	9	10
Nada										Muchísimo

6.- ¿En qué medida este tratamiento te ha resultado aversivo (desagradable, molesto)?

0	1	2	3	4	5	6	7	8	9	10
Nada										Muchísimo

ESCALA DE PREFERENCIAS

Por favor, después de haber finalizado el programa de tratamiento "SIN MIEDO Airlines" para el miedo a volar, contesta a las siguientes preguntas.

1. Si hubieras podido elegir entre las DOS condiciones de tratamiento, ¿Cuál hubieras elegido?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado con contacto mínimo por parte del terapeuta.

2. ¿Cuál de estas dos condiciones de tratamiento, consideras que es más eficaz o útil para el tratamiento del miedo a volar?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado a través de Internet con contacto mínimo por parte del terapeuta.

3. ¿Cuál de estas dos condiciones de tratamiento, consideras que es más lógica para el tratamiento del miedo a volar?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado a través de Internet con contacto mínimo por parte del terapeuta.

4. ¿Cuál de estas dos condiciones de tratamiento, consideras que es más aversiva (desagradable, molesta)?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado a través de Internet con contacto mínimo por parte del terapeuta.

5. ¿Cuál de estas dos condiciones de tratamiento, recomendarías a un amigo que tuviera el mismo problema?

a) "SIN MIEDO Airlines" totalmente auto-aplicado a través de Internet (sin contacto del terapeuta durante el tratamiento).

b) "SIN MIEDO Airlines" auto-aplicado a través de Internet con contacto mínimo por parte del terapeuta.

CUESTIONARIO DE USABILIDAD Y ACEPTABILIDAD (CUA)

(Labpsitec, 2010)

Para cada una de las siguientes afirmaciones, marque la opción que mejor describa su opinión.

1-Pienso que la mayoría de las personas podrían aprender muy rápidamente a utilizar "SIN MIEDO Airlines".

Totalmente en desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

2-Me he sentido seguro de mí mismo (capaz) utilizando "SIN MIEDO Airlines".

Totalmente en desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

3-En general, he sabido qué tenía que hacer en cada momento. Por ejemplo, cuando he querido pulsar un botón concreto he sabido cómo hacerlo y lo he conseguido.

Siempre	Casi siempre	Frecuentemente	A veces	Nunca
☐	☐	☐	☐	☐

4-Una vez que he aprendido a usar "SIN MIEDO Airlines" he podido realizar las tareas rápidamente.

Totalmente desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

5- "SIN MIEDO Airlines" puede utilizarse en cualquier lugar y en cualquier contexto.

Totalmente en desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

6-Las instrucciones de "SIN MIEDO Airlines" son fáciles.

Totalmente en desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

7-El tamaño de letra y de los botones es suficiente para mí.

Totalmente en desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

8- Me gustaría utilizar este sistema frecuentemente.

Totalmente en desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

9-En general, creo que "SIN MIEDO Airlines" es muy útil para mí.

Totalmente en desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

10-En general, creo que "SIN MIEDO Airlines" es fácil de usar.

Totalmente en desacuerdo	Algo en desacuerdo	Ni de acuerdo ni en desacuerdo	Bastante de acuerdo	Totalmente de acuerdo
☐	☐	☐	☐	☐

Muchas gracias por contestar a todas nuestras preguntas***. Has terminado la evaluación después de completar "SIN MIEDO Airlines". Recuerda la importancia de poner en práctica lo aprendido.

A los 3 y 12 meses de haber finalizado el tratamiento nos volveremos a poner en contacto contigo para realizar los seguimientos acordados y valorar cómo estás en relación a tu miedo a volar. Recibirás un correo electrónico recordatorio unos días antes de que nos pongamos en contacto contigo. En ese momento, tendrás que volver a acceder a la página web de *SIN MIEDO Airlines* para contestar unas preguntas y, posteriormente, nos pondremos en contacto contigo a través de una llamada telefónica.

De nuevo, muchas gracias por tu colaboración.

***** Si es la condición lista de espera (LE) se agradece su participación y se explica que en estos momentos puede recibir tratamiento, si sigue interesado. Se asignará alguna de las dos condiciones de tratamiento (al azar) y se le facilitará el acceso al programa.**