

Universidad de Córdoba  
Facultad de Ciencias de la Educación  
Departamento de Psicología



UNIVERSIDAD DE CÓRDOBA

La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

The selection of evidence-based psychological treatments.  
An analysis to integrate the scientific data with the assistance reality

Tesis Doctoral presentada por:

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Programa de Doctorado de Ciencias Sociales y Jurídicas

Córdoba, 2019

TITULO: *La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial*

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**TÍTULO DE LA TESIS:** La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial.

**DOCTORANDO:** Mario Gálvez Lara

#### **INFORME RAZONADO DEL DIRECTOR DE LA TESIS**

La tesis "*La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial*", presentada por D. Mario Gálvez Lara, es un trabajo original que desde mi punto de vista cuenta con todos los requisitos científico-académicos para ser autorizada para la presentación y defensa como tesis doctoral por compendio de artículos y mención internacional. De dicha investigación han derivado varios trabajos científicos entre los que destaco:

- Moriana, J. A., Gálvez-Lara, M. y Corpas, J. (2017). Psychological treatments for mental disorders in adults: A review of the evidence of leading international organizations. *Clinical Psychology Review*, 54, 29-43. doi: 10.1016/j.cpr.2017.03.008. JCR IF: 9.577. Q1 (2/127) Psychology, Clinical.
- Gálvez-Lara, M., Corpas, J., Moreno, E., Venceslá, J. F., Sánchez-Raya, A. y Moriana, J. A. (2018). Psychological treatments for mental disorders in children and adolescents: a review of the evidence of leading international organizations. *Clinical Child & Family Psychology Review*, 21, 366-387. doi: 10.1007/s10567-018-0257-6. JCR IF: 3.600. Q1 (16/127) Psychology, Clinical.
- Gálvez-Lara, M., Corpas, J., Venceslá, J. F. y Moriana, J. A. (2019). Evidence-based brief psychological treatment for emotional disorders in primary and specialized care: study protocol of a randomized controlled trial. *Frontiers in Psychology*, 9, 2674. doi: 10.3389/fpsyg.2018.02674. JCR IF: 2.089. Q2 (39/135) Psychology, Multidisciplinary.

Actualmente hay un cuarto artículo en revisión y se han presentado algunos trabajos en formato póster, comunicaciones en congresos y varios capítulos de libro.

El doctorando ha sido muy constante en su trabajo y su nivel de motivación le ha llevado a realizar una estancia en Estados Unidos para la obtención del doctorado internacional. Dentro de la tesis ha sabido integrar conocimientos de metodologías de investigación primaria científica-experimental (RCTs/ECA), utilización de encuestas, y otras de revisión y metanálisis enfocadas al desarrollo de una línea de investigación de interés científico y profesional de primera magnitud.

Por todas estas razones, pienso que la presente tesis doctoral supone un importante avance científico por lo que recomendamos su aceptación y autorización para realizar el acto de defensa pública para la obtención del título de doctor por la Universidad de Córdoba.

Por todo ello, se autoriza la presentación de la tesis doctoral.

Córdoba, 13 de febrero de 2019

Firma del director

Fdo.: Juan Antonio Moriana Elvira



Esta tesis doctoral ha sido presentada por compendio de publicaciones, optando al doctorado con mención internacional. Su realización ha sido posible gracias a la financiación del proyecto “PsiBrief” (PSI2014-56368-R) por parte del Ministerio de Economía y Competitividad del Gobierno de España en la convocatoria de 2014 de proyectos de I+D “Retos de investigación” y a la beca de movilidad internacional “Doctorado hacia la excelencia” de la Universidad de Córdoba del curso 2015/2016.



# Agradecimientos

*Quisiera dar las gracias a todas las personas que, de un modo u otro, han contribuido a la realización de este trabajo.*

*A Juan Antonio Moriana, mi director, me siento muy afortunado de haberte conocido. Gracias por haberme dado la oportunidad de trabajar contigo y crecer académicamente. Confiaste en mí sin apenas conocerme y desde nuestra primera reunión me hiciste sentir que era capaz de realizar una tesis doctoral y desarrollar una carrera investigadora. Esa reunión cambió mi vida. Si hoy estoy donde estoy es, sin duda, gracias a ti.*

*Al Dr. Steven Proctor, gracias por acogerme durante tres meses en el Institutional Scientific Research Center de la Albizu University de Miami (EEUU). También me gustaría dar las gracias a todos los profesores y compañeros que me hicieron sentir un miembro más de la universidad, haciendo de esta estancia una experiencia inolvidable.*

*A mis padres, desde siempre me inculcasteis la importancia de la dedicación y el esfuerzo, requisitos indispensables para realizar este trabajo. Gracias por haberme dado la libertad de tomar mis propias decisiones desde que era muy joven. Esas decisiones me han permitido ser muy feliz con lo que hago y me han llevado a ser la persona que hoy soy. Pero sobre todo, gracias por haberme animado a continuar en aquel momento en el que quise tirar la toalla. Siempre os estaré agradecido por ello.*

*A Irene, mi hermana, aunque nunca te lo he dicho, eres un apoyo fundamental en mi vida. Gracias por estar ahí siempre que te necesito.*

*A Eva, mi pareja y compañera de vida, has sido una parte muy importante de este trabajo. Gracias por tu compañía, por tu comprensión, por tu paciencia y por tu apoyo incondicional durante todos estos años. Este camino ha sido más fácil gracias a ti.*





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## Extended abstract

Nowadays there is a wide variety of psychological interventions to treat mental disorders, meaning that professionals have to weigh up which one is more effective to reach the therapeutic objectives. In this sense, during the last decades, explicit criteria have been established to determine whether a treatment is effective or not.

The scientific evaluation of psychological treatments began to be systematized in the mid-twentieth century, reaching its peak during the 1980s and 1990s with the appearance of numerous randomized controlled trials (RCTs) and meta-analyses. The proliferation of quality studies led to the emergence of a series of organizations aimed to review and disseminate those treatments supported by research and made existing institutions such as the American Psychological Association (APA) also pursue that goal.

Between 1995 and 1998, a task force of the Division 12 (Society of Clinical Psychology) of the APA published several reports that identified treatments with empirical support and proposed the criteria that could be used to determine if a treatment is effective. These reports were published for Psychology students to be trained in therapies with demonstrated efficacy, and to inform practicing clinical psychologists, health insurers, and the public in general, about the existence of these treatments.

Possibly, the most relevant contributions of the lists of effective treatments were establishing the explicit criteria that allow assessing the quality of the evidence of the interventions and the creation of institutions acting as mediators between research and clinical practice, serving as a reference and as a source of consultation for clinicians and academics. However, the systems used to determine the evidence for each intervention vary between institutions. In fact, they usually follow different assessment criteria, which suggests that the recommendations may differ from one organization to another. In

addition, despite the endeavors made by different organizations to transfer the information provided by the research to the different actors involved, numerous studies have suggested that the knowledge held by psychologists concerning evidence-based treatments (EBTs) may be limited, suggesting that there is a need for more training, dissemination and implementation of these treatments.

Some of the proposals made to improve the dissemination of these treatments among applied psychologists suggest the adaptation of the interventions to real situations of application and promoting the training of these professionals in the psychological treatment from a transdiagnostic perspective. An example of this matter may consist in developing intervention protocols composed of less than 10 sessions. This treatment modality is not sufficiently represented in the recommendations of the main organizations, but it is often applied in public and private settings in an unstructured or improvised manner. Regarding the use of a transdiagnostic treatment, its implementation would benefit clinical practice, since it may allow developing treatment modules that could be used in patients with different diagnoses or problems, which may allow avoiding that psychologists have to be trained in numerous and complex specific treatments for each disorder.

Under this situation several objectives have been proposed. To accomplish them, this doctoral thesis, composed of four independent but intertwined studies, was conducted. The first study gathered the recommended EBTs for mental disorders in adults by different organizations in order to determine the level of existing agreement. To that end, the recommendations proposed by Division 12 of the APA, the National Institute for Health and Care Excellence (NICE), the Cochrane Collaboration and the Australian Psychological Society (APS) were reviewed following the PRISMA methodology for systematic reviews. A total of 135 treatments for 23 mental disorders were compiled and the degree of similarity among the recommendations proposed by each organization was analyzed. Results showed that the agreement among institutions was low for most of the disorders, observing discrepancies in the evidence presented by each one of them. These discrepancies might be due to a combination of reasons: possible biases in the procedures or in the evaluation committees, different studies reviewed by each organization to recommend a certain treatment, the use of different criteria to graduate the level of evidence, and the reviews of existing evidence were conducted in different time periods.

The second study shares the aims of the previous study but focused on children and adolescents. For this, following the PRISMA methodology, the same organizations reviewed in Study 1 were analyzed, with the exception that the recommendations proposed by Division 53 (Society of Clinical Child and Adolescent Psychology) of the APA were used instead of the proposed by Division 12. A total of 137 treatments for 17 mental disorders were compiled and the degree of agreement among the recommendations proposed by each organization was examined. Results were similar to those obtained in study 1. A low agreement for most of the disorders was observed, and the same discrepancies discussed above were found.

The third study aimed to determine the impact that EBTs have on the clinical practice of psychologists trained in Spain. In order to achieve this objective, a retrospective single-group ex post facto study was designed. Results confirmed that the use of EBTs by psychologists is limited, highlighting cognitive-behavioral therapies above other treatments. After analyzing some possible personal variables that could explain the use of EBTs, results indicated that the type of professional accreditation and the years of clinical experience could be related to the use of EBTs.

Finally, the fourth study was directed to designing a protocol of an RCT in which the efficacy of a brief therapy adaptation of the "Unified Protocol for the transdiagnostic treatment of emotional disorders" will be examined. For this, an RCT was developed with five groups (brief therapy based on the Unified Protocol; conventional psychological treatment; conventional psychological treatment plus pharmacological therapy; minimum intervention based on basic psychoeducational information, counseling and bibliotherapy; and usual pharmacological treatment), which would be carried out in public health centers. In this way, brief therapy will be compared with other treatment modalities frequently used in the public health system. The protocol follows the recommendations for intervention trials proposed in the SPIRIT statement -Standard Protocol Item: Recommendations for Interventional Trials-, and the rules for the communication of the trials proposed in the CONSORT statement -Consolidated Standards of Reporting Trials-. The findings of this RCT will be described in future publications, since due to the time limit for the development of this doctoral thesis, only the design of the trial and the start of its implementation were proposed as a plausible goal.

In conclusion, there are significant differences among the psychological treatments recommended by the organizations included in this work due to the use of different procedures to evaluate and grade the quality of the evidence. In addition, despite the effort made by these institutions to disseminate the results of scientific research among applied professionals, it has been demonstrated that the divulgation of these findings has not been sufficiently successful among Spanish psychologists. Finally, with the aim of testing an intervention that fits the realities of healthcare public services, the protocol for a brief intervention under a transdiagnostic approach has been designed to be carried out in public health centers. In the case that the results of the study were favorable, including this type of therapies would decongest the healthcare system.

## Introducción

La presente tesis doctoral nace dentro del marco del Proyecto “PsiBrief” (PSI2014-56368-R), financiado por el Ministerio de Economía y Competitividad del Gobierno de España en la convocatoria de 2014 de proyectos de I+D “Retos de investigación”. El objetivo principal de dicho proyecto era realizar un ensayo controlado aleatorizado (ECA) que evaluara la eficacia de una terapia psicológica que pudiera ser llevada a cabo en los servicios públicos de atención primaria, con la posible inclusión de la figura del psicólogo clínico dentro de este ámbito asistencial, y compararla con la de otras intervenciones habituales para el abordaje de los trastornos emocionales en atención primaria y especializada.

Con el propósito de configurar las intervenciones que podrían ser incluidas en dicho ECA, como etapa inicial, se realizaron una serie de búsquedas bibliográficas sobre tratamientos eficaces para los trastornos de ansiedad y depresión. En estas búsquedas, además de ECAs, revisiones sistemáticas y metaanálisis, también se consultaron los listados y guías de tratamiento de la *American Psychological Association* (APA) y del *National Institute for Health and Care Excellence* (NICE). En este momento, al analizar las recomendaciones de estas instituciones, se observó la presencia de algunas discrepancias en los tratamientos incluidos para diversos trastornos mentales, no solo para ansiedad y depresión.

Este resultado estimuló el objetivo de realizar un análisis pormenorizado de los tratamientos recomendados por diferentes organizaciones para los trastornos mentales, lo cual ayudaría a determinar los posibles tratamientos de elección. Tras una comprobación superficial de las diferentes recomendaciones y debido a la magnitud de los resultados preliminares, se tomó la decisión de configurar dichos análisis como los dos primeros

estudios de esta tesis doctoral. Concretamente, en el estudio 1 se realizaría el análisis de los tratamientos psicológicos recomendados para los diferentes trastornos mentales en población adulta, mientras que en el estudio 2 se analizarían los tratamientos recomendados en población infantil y adolescente.

De forma simultánea, tras observar la falta de acuerdo existente entre las instituciones revisadas, se cuestionó cómo esta podría afectar a la formación que los psicólogos recibían acerca de los tratamientos más adecuados para un determinado trastorno, tanto en el ámbito universitario como a lo largo de su capacitación laboral (especialista en psicología clínica, másteres profesionalizadores, cursos de formación, etc.). Por lo tanto, para intentar responder a esta cuestión, se planteó como objetivo realizar un estudio que determinara el impacto que los tratamientos basados en la evidencia ejercen sobre la práctica clínica de los psicólogos formados en España (estudio 3).

Por último, tras el análisis preliminar de los tratamientos recomendados por las diferentes organizaciones, se observó que las terapias breves (menos de diez sesiones) apenas tenían representación. Sin embargo, si la mayoría de los pacientes interrumpen la terapia dentro de las diez primeras sesiones (Rondón, Otálora y Salamanca, 2009), unido a que las mejoras más importantes en la sintomatología de los pacientes ocurren dentro de ese rango de consultas (Lyons y Low, 2009), cobra sentido someter a validación científica terapias cuya duración sea menor a diez sesiones. Además, debido a su duración y bajo coste, las terapias breves se adecuarían a la realidad asistencial de los servicios públicos de salud, pudiendo ser fácilmente incluidas en los niveles de Atención Primaria. Por este motivo, se optó por incluir una modalidad de terapia breve en el diseño del ECA. Para ello, se decidió adaptar a este tipo de intervención el “Protocolo Unificado para el tratamiento transdiagnóstico de los trastornos emocionales” (PU), desarrollado por el equipo de David H. Barlow. Esta decisión estuvo motivada por dos razones. En primer lugar, el abordaje psicológico desde una perspectiva transdiagnóstica, enfocada en un conjunto de principios terapéuticos comunes, facilitaría la diseminación y el entrenamiento del tratamiento (Barlow, Allen y Choate, 2004). En segundo lugar, la eficacia del PU para el tratamiento de los trastornos emocionales ha sido ampliamente demostrada, siendo uno de los protocolos transdiagnósticos con mayor evidencia empírica (Ito et al., 2016; Reinholt y Krogh, 2014).

Debido a todas las gestiones asociadas a la configuración y desarrollo del ECA, que han supuesto un retraso en la puesta en marcha del mismo (comités de investigación y ética, plataformas de registro y evaluación de ensayos clínicos, entrenamiento de los profesionales que llevarían a cabo las diferentes intervenciones, tiempo de ejecución de los tratamientos, evaluación a los seis meses de seguimiento, etc.), y al límite de tiempo para realizar esta tesis doctoral, se decidió incluir como cuarto estudio el diseño del protocolo de dicho ECA. Los resultados que se deriven de este ensayo serán presentados en publicaciones futuras.

Finalmente, la consideración de estas cuatro propuestas, centradas en la elección de tratamientos psicológicos basados en la evidencia, ha permitido realizar un análisis desde diferentes perspectivas para integrar los datos científicos obtenidos hasta el momento con la realidad asistencial y con la formación que actualmente reciben los psicólogos en ejercicio.

Una vez definido el contexto en el que se desarrolla esta tesis doctoral, a continuación se comenta brevemente su estructura, dividida principalmente en dos partes. En la primera parte se revisan los fundamentos teóricos y los antecedentes existentes en la literatura que han sustentado este trabajo. El primer capítulo nos sitúa en el contexto de los tratamientos psicológicos basados en la evidencia. En el segundo capítulo se hace un recorrido por algunas de las diferentes propuestas existentes para evaluar la evidencia científica de los tratamientos. El capítulo tercero analiza las variables y condicionantes relacionados con el distanciamiento existente entre la investigación científica y la psicología aplicada. Por último, el cuarto capítulo versa sobre la mejora de la adecuación de los tratamientos psicológicos a las situaciones reales de aplicación. En la segunda parte se exponen los diferentes estudios que componen esta tesis doctoral, incluyendo los objetivos e hipótesis planteadas, la metodología llevada a cabo y los resultados obtenidos. Por último, se incluye una sección de discusión general y conclusiones donde se comentan los principales hallazgos obtenidos en los diferentes estudios y las conclusiones derivadas de los mismos.





# PRIMERA PARTE

## Marco teórico



# Capítulo 1

## Tratamientos psicológicos basados en la evidencia

### 1.1. Introducción

Los diversos enfoques y paradigmas de la psicología han dado lugar a la aparición de una enorme variedad de tratamientos psicológicos, llegándose a inventariar más de 250 terapias psicológicas diferentes (Herink, 1980) y más de 400 técnicas y variantes asociadas (Kazdin, 1986). Ante esta diversidad de opciones, plantearse qué terapias son más eficaces para alcanzar los objetivos terapéuticos debería ser una cuestión clave para cualquier profesional de la psicología. Para responder a esta pregunta sería conveniente hacer uso de la evidencia científica, que es definida como aquellos “hallazgos empíricos derivados de análisis y métodos sistemáticos de investigación, que incluyen estudios descriptivos y de intervención, análisis de datos cualitativos y cuantitativos, estudios de evaluación, metaanálisis y estudios de costo-efectividad” (Tseng, 2009, p 13).

En este sentido, la psicología basada en la evidencia es un modelo teórico que busca demostrar empíricamente sus proposiciones a través del control experimental, haciendo legítimos aquellos tratamientos o teorías que presenten pruebas que los respalden (Moriana y Martínez, 2011). Este modelo teórico utiliza algunos de los principios de la medicina basada en la evidencia, que ha sido definida como “el uso concienzudo, explícito y juicioso de la mejor evidencia actualizada en la toma de decisiones para atender a los pacientes” (Sackett, Rosenberg, Gray, Haynes y Richardson, 1996, pp. 71-72).

En la actualidad, los ensayos controlados aleatorizados (ECAs) son considerados la forma más fiable de demostrar que una intervención es efectiva (Akobeng, 2005). En este tipo de estudios, los pacientes son asignados de forma aleatoria a varias condiciones de intervención o control, siendo esta última un tratamiento habitual, un placebo o ninguna intervención. Aunque la existencia de uno o dos ECAs con un diseño metodológico de calidad suele ser un requisito para alcanzar los primeros niveles en los diferentes sistemas de clasificación de la evidencia, es recomendable que los resultados de los ensayos individuales sean respaldados por revisiones sistemáticas y metaanálisis.

A continuación se definen las características de ambos tipos de estudio, ya que al igual que los ECAs, son términos que estarán muy presentes a lo largo de esta tesis doctoral. Así, una revisión sistemática sería una síntesis descriptiva de los resultados de diversos estudios individuales mediante una serie de métodos sistematizados, entre los que estarían la búsqueda exhaustiva de todos los artículos potencialmente relevantes y el uso de criterios explícitos y reproducibles en la selección de artículos para su revisión (Cook, Mulrow y Haynes, 1997). En cambio, un metaanálisis sería una revisión sistemática en la que, además, se obtiene un índice cuantitativo de la magnitud del efecto de cada estudio y se utilizan pruebas estadísticas para integrar dichos efectos (Sánchez-Meca, 2010). Debido a que las revisiones sistemáticas y los metaanálisis tienen como objetivo acumular sistemáticamente las evidencias obtenidas en los estudios individuales sobre una problemática común, la lectura de este tipo de informes aporta a los profesionales una visión global de la evidencia científica de esa problemática (Sánchez-Meca y Botella, 2010).

## **1.2. Evolución histórica de la evaluación científica de los tratamientos psicológicos**

Como se ha comentado en el apartado anterior, la psicología basada en la evidencia se apoya en los principios de la medicina, teniendo como referencia la metodología usada en los ensayos clínicos con fármacos. Las primeras referencias de la medicina basada en la evidencia las encontramos en 1747, cuando James Lind, ayudante de cirujano de la armada británica, realizó un simple ensayo clínico para intentar curar el escorbuto. Desde los tiempos de Cristóbal Colón, los médicos de la marina venían observando que, durante los largos viajes en barco, los marineros enfermaban presentando inflamación de las encías, caída de los dientes y hemorragias que le llegaban a causar la muerte. Lind sospechaba que esta enfermedad podría estar relacionada con la dieta de los marineros, por lo que escogió a doce marineros de su tripulación que

presentaban los síntomas del escorbuto y los asignó aleatoriamente a diferentes dietas. Al cabo de unas semanas comprobó que el grupo de marineros que había estado consumiendo una ración diaria de naranjas y limones se recuperó por completo. Posteriormente, Lind administró esta dieta al resto de enfermos, generalizándose los resultados. Sin embargo, a pesar de ser uno de los primeros ensayos clínicos basados en la evidencia y de la importancia que supuso en cuanto al número de vidas salvadas, el ejército no asumió este descubrimiento hasta cuarenta años después, ya que sus médicos desconfiaron de los resultados de Lind, que no era más que una ayudante de cirujano (Matthews, 2007). A partir de estos hallazgos, la medicina fue adoptando progresivamente criterios científicos basados en la evidencia para todas sus intervenciones quirúrgicas y farmacológicas (Moriana y Martínez, 2011).

En el ámbito de la psicología, el estudio de la eficacia de los tratamientos psicológicos, asumiendo que “solo la ciencia puede distinguir las buenas intervenciones de las malas” (Westen, Novotny y Thompson-Brenner, 2004a, p. 632), ha supuesto uno de los avances más importantes. Los primeros antecedentes de la psicología basada en la evidencia aparecen en la última década del siglo XIX, cuando Lightner Witmer, uno de los precursores de la psicología clínica, comenzó a entrenar a psicólogos en las mejores opciones terapéuticas hasta el momento para que pudieran aplicarlas a sus pacientes (McReynolds, 1997).

Hasta finales de los años veinte la evaluación de la eficacia de los tratamientos se había centrado en el estudio de casos individuales. Durante las siguientes décadas se empezó a debatir sobre qué terapias eran más efectivas en términos de porcentajes de éxito. Sin embargo, fue tras la II Guerra Mundial cuando se comenzó a intentar llevar a cabo una evaluación científica de los tratamientos, con el objetivo de conocer qué terapias resultaban eficaces para tratar a las personas con trastornos psicológicos producidos por el conflicto bélico (Labrador, Echeburúa y Becoña, 2000).

No obstante, hasta la publicación de un polémico trabajo por parte de Hans Eysenck en 1952, no se empezó a sistematizar la evaluación científica de los tratamientos psicológicos (Martínez-Nuñez, Primero y Moriana, 2011). Eysenck (1952), tras revisar una serie de estudios publicados hasta ese momento, concluyó que el 60 % de los pacientes tratados con psicoterapia mejoraba, mientras que el 70 % de los pacientes que no recibían ningún tipo de tratamiento lo hacía de forma espontánea. Estos resultados parecían indicar que la psicoterapia no ejercía ningún beneficio sobre los pacientes. Sin

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embargo, a partir de finales de los años setenta aparecen importantes metaanálisis que contradicen los resultados del trabajo de Eysenck, destacando los beneficios de las terapias psicológicas respecto a la no intervención (Andrews y Harvey, 1981; Landman y Dawes, 1982; Lipsey y Wilson, 1993; Shapiro y Shapiro, 1982; Smith y Glass, 1977).

Se pueden distinguir tres etapas en la evaluación científica de los tratamientos psicológicos (Goldfried y Wolfe, 1996). En la primera de ellas (entre 1950 y 1960), las investigaciones se centraron en determinar si la terapia psicológica era eficaz mediante estudios de caso único y estudios poco controlados carentes de fiabilidad que comparaban sujetos tratados con psicoterapia y sujetos no tratados. En la segunda etapa (entre 1960 y 1980), el objetivo de la investigación era demostrar qué tratamientos psicológicos eran más efectivos para un determinado problema, comparando el grupo que recibía la intervención con un grupo control (lista de espera, placebo o tratamiento convencional). Las investigaciones de esta etapa tenían carencias metodológicas relacionadas, sobre todo, con las muestras de población que empleaban. En la tercera etapa (a partir de los años 80), la calidad de los estudios mejoró considerablemente y se generalizó el uso de ECAs, metaanálisis y revisiones sistemáticas. Con el objetivo de obtener resultados más fiables y generalizables, se empezaron a utilizar tratamientos manualizados llevados a cabo por terapeutas entrenados, se comenzó a evaluar la adherencia al tratamiento y se mejoró la selección de los sujetos.

Con el aumento de los ECAs y los metaanálisis en esta última etapa, surgieron organizaciones que tenían como objetivo revisar y difundir los tratamientos apoyados empíricamente. Este es el caso de la *Cochrane Collaboration*, en 1993, y el *National Institute for Health and Care Excellence* (NICE) de Reino Unido, en 1999. Así mismo, la *American Psychological Association* (APA) y otras instituciones públicas y privadas también comenzaron a perseguir este objetivo (Moriana y Martínez, 2011).

### **1.3. Surgimiento de los tratamientos psicológicos basados en la evidencia**

En 1993, la División 12 (*Society of Clinical Psychology*) de la APA lideró una comisión para evaluar la eficacia de los tratamientos psicológicos para los diferentes trastornos mentales, dando lugar a la creación de la *Task Force on Promotion and Dissemination of Psychological Procedures*, coordinada por Dianne Chambles. Esta comisión publicó un informe que identificaba los tratamientos apoyados por la investigación y proponía los criterios que podrían usarse para establecer que un determinado tratamiento pudiera ser considerado “tratamiento empíricamente validado”

(APA Task Force, 1995). Los autores del informe distinguieron dos categorías con diferente grado de apoyo empírico, “tratamientos bien establecidos” y “tratamientos probablemente eficaces”, y sugirieron que el resto de los tratamientos deberían ser considerados “tratamientos experimentales”. Entre 1996 y 1998 se publicaron nuevos informes con el objetivo de actualizar los listados de tratamientos y los criterios de validación empírica (Chambless et al., 1996; 1998), apareciendo en el último de ellos 16 “tratamientos bien establecidos” y 55 “tratamientos probablemente eficaces” (Chambless et al., 1998). En la Tabla 1.1. se muestran los criterios presentados en este último informe.

**Tabla 1.1. Criterios para los “tratamientos empíricamente validados”**

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**Tratamientos bien establecidos**

- I. Al menos dos buenos diseños experimentales entre grupos que demuestren su eficacia en una o más de las siguientes formas:
  - A. Sus resultados son superiores a un grupo que utilice fármacos placebo, a un grupo placebo psicológico o a otro tratamiento.
  - B. Equivalente a un tratamiento ya establecido en experimentos con un tamaño de la muestra adecuado
- II. Una serie importante de diseños experimentales de caso único ( $n \geq 9$ ) que demuestren su eficacia. Estos experimentos deben haber:
  - A. usado diseños experimentales adecuados
  - B. comparado la intervención con otro tratamiento como en el criterio IA

*Criterios adicionales para I y II*

- III. Los experimentos deben ser llevados a cabo con manuales de tratamiento
- IV. Las características de las muestras de participantes deben estar claramente especificadas
- V. Los efectos deben haber sido demostrados por al menos dos investigadores o equipos de investigación independientes

**Tratamientos probablemente eficaces**

- I. Dos experimentos que muestren que el tratamiento es superior (de forma estadísticamente significativa) a un grupo control de lista de espera, o
- II. Uno o más experimentos que cumplan los criterios de los tratamientos bien establecidos IA o IB, III y IV, pero no V, o
- III. Una pequeña serie de diseños experimentales de caso único ( $n \geq 3$ ) que cumplan con los criterios de los tratamientos bien establecidos II, III y IV

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Adaptado de “Update on empirically validated therapies, II”, por D. Chambless et al., 1998, *The Clinical Psychologist*, 51, 3–16.

Aunque la publicación de los listados de tratamientos apoyados por la investigación tenía como objetivo fomentar una formación en este tipo de terapias para los estudiantes de psicología, informar a los psicólogos clínicos en ejercicio sobre los tratamientos psicológicos que estaban apoyados por la investigación, así como informar al público en general y a las aseguradoras sanitarias de la existencia de estos tratamientos (APA Task Force, 1995), su aparición generó bastante polémica (Chambless y Ollendick,



2001). En este sentido, Estupiñá (2012) señala que los listados fueron criticados por tres razones principales: 1) el término “tratamiento empíricamente validado” puede sugerir que el resto de tratamientos son inválidos o ineficaces, quedando deslegitimados ante el público y ante las compañías aseguradoras; 2) el enfoque aplicado en la elaboración de los listados favorece las terapias conductuales o cognitivo-conductuales sobre otros paradigmas clínicos menos centrados en procedimientos de estandarización como la manualización del tratamiento; y 3) los listados de tratamientos están planteados desde la hipótesis de que el elemento activo del tratamiento psicológico es la técnica, lo que va en contra de las corrientes psicológicas que plantean que el agente activo de la terapia es la relación terapéutica.

En 1998, el término “tratamiento empíricamente validado” fue reemplazado por “tratamiento con apoyo empírico” (TAE) para hacer frente a la crítica planteada por Garfield (1996), que consideraba imposible poder validar por completo un tratamiento. Así Chambless y Hollon (1998) definieron los TAEs como “aquellos tratamientos psicológicos claramente especificados que demuestran ser eficaces en la investigación controlada con una población determinada” (p. 7). Diez años más tarde, Kazdin (2008) planteó el término “tratamiento basado en la evidencia” (TBE) como sinónimo de TAE, definiéndolo como “intervenciones o técnicas (p. ej. terapia cognitiva para la depresión, terapia de exposición para la ansiedad) que han producido un cambio terapéutico en ensayos controlados” (p. 147). El uso de este último término es apoyado por Silverman y Hinswaw (2008), quienes consideran que la palabra “evidencia” es fácilmente entendible para aquellos que no estén familiarizados con el tema y es consistente con el término “práctica basada en la evidencia” (este concepto será definido y abordado en el siguiente apartado de este capítulo).

Aunque en la definición que Chambless y Hollon (1998) propusieron para los TAEs aparece el término “eficaces”, estos autores señalaron que los tratamientos debían ser evaluados en términos de eficacia, efectividad y eficiencia. Estos conceptos fueron diferenciados por Turner, Beidel, Spaulding y Brown (1995), planteando que la eficacia de un tratamiento hacía referencia a la mejora de los sujetos en investigaciones controladas, la efectividad era entendida como el logro de resultados beneficiosos en la práctica clínica habitual, y el concepto de eficiencia aludía a la obtención del mayor beneficio con el menor coste posible.

Son muchos los autores que han cuestionado el hecho de que los resultados de los ECAs realizados en contextos de investigación puedan ser extrapolados a situaciones clínicas, ya que las terapias utilizadas en estudios de eficacia suelen estar más entrenadas y estructuradas que las utilizadas en contextos clínicos habituales (Goldfried y Wolfe, 1996, Gonzales y Chambers, 2002; Norcross, 1999; Seligman, 1996). Sin embargo, la evidencia acerca de la eficacia diferencial de los tratamientos administrados en investigación frente a los administrados en contextos clínicos es contradictoria (Tolin, McKay, Forman, Klonsky y Thombs, 2015). Además, Silverman y Hinswhaw (2008) sugieren que la eficacia y la efectividad podrían llegar a converger, ya que muchos estudios de eficacia gozan de una elevada validez externa (característica de los estudios de efectividad) y algunos estudios de efectividad presentan una validez interna considerable gracias al control experimental (característica de los estudios de eficacia).

En esta línea, a pesar de las distinciones que se han realizado a lo largo de los últimos años entre los términos “eficacia” y “efectividad”, su uso indiferenciado y su tratamiento como sinónimos es muy habitual. Un ejemplo de esta situación lo tenemos en dos de los manuales que mayor impacto han tenido para la psicología clínica basada en la evidencia en nuestro país: *Guía para la elección de tratamientos psicológicos efectivos* (Labrador, Echeburúa, y Becoña, 2000) y *Guía de tratamientos psicológicos eficaces* (Pérez, Fernández, Fernández, y Amigo, 2003). Además, las diferentes organizaciones que serán revisadas durante este trabajo utilizan ambos términos de forma habitual. Así, por ejemplo, las divisiones 12 y 53 de la APA utilizan el término “eficaz” en sus criterios para evaluar la calidad de la evidencia, mientras que para recomendar los diferentes tratamientos usan el término “efectivo”. Por este motivo, a no ser que se indique lo contrario, los términos eficacia y efectividad serán usados como sinónimos a lo largo de esta tesis doctoral.

#### **1.4. Más allá de los tratamientos con apoyo empírico: las prácticas basadas en la evidencia**

En disonancia con el planteamiento de que el éxito terapéutico se debe a la terapia utilizada, algunas investigaciones indican que las diferencias entre terapias no son significativas, planteando que las diferentes terapias son igualmente eficaces (Castonguay y Beutler, 2006; Gibbons et al., 1993; Livesley, 2007; Norcross, 2011). Estos autores sugieren que la mayoría de las psicoterapias estructuradas son bastante equivalentes en términos de efectividad y que ciertos factores, como las características del paciente, las

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características del terapeuta y la relación terapéutica, contribuyen al cambio más que la psicoterapia practicada. Aunque la *Task Force on Promotion and Dissemination of Psychological Procedure* no negó la importancia de la relación terapéutica, esta tuvo una importancia secundaria para los procedimientos específicos que fueron estudiados (Goldfried, 2013). Con el objetivo de establecer la importancia de la relación terapeuta-paciente en los procesos de cambio terapéutico, la División 29 (*Psychotherapy*) de la APA estableció un grupo de trabajo para identificar, operacionalizar y diseminar la información sobre relaciones terapéuticas con apoyo empírico, determinando que elementos como la alianza terapéutica, la empatía del terapeuta o el estilo de afrontamiento del paciente serían responsables del cambio terapéutico (Norcross y Hill, 2004).

De todos los elementos que componen la relación terapéutica, la alianza ha sido el que se ha estudiado con mayor frecuencia (Castonguay, Constantino, Boswell y Kraus, 2011). Este concepto hace referencia no solo a la conexión entre terapeuta y paciente, sino también al acuerdo sobre los objetivos de la terapia y los métodos que se utilizarán para alcanzarlos (Bordin, 1979). Numerosos estudios indican que una alianza terapéutica positiva está asociada con una mejora en los síntomas de los pacientes (Castonguay, Goldfried, Wiser, Raue y Hayes, 1996; Crits-Christoph, Gibbons y Mukherjee, 2013; Horvath, Del Re, Flückiger y Symonds, 2011; Muran y Barber, 2010). Por tanto, algunos autores postulan que existe una sinergia entre la relación terapéutica y la terapia utilizada en el proceso de cambio terapéutico, ya que una buena relación terapéutica aumenta la probabilidad de que el paciente se involucre en la terapia, y la implementación exitosa de la terapia puede mejorar la relación terapéutica (Goldfried y Davila, 2005).

Con el objetivo de hacer frente a la polémica generada desde la aparición de los listados de TBEs, la APA propuso la definición de “práctica psicológica basada en la evidencia” (PPBE) como “la integración de la mejor investigación disponible con la pericia clínica en el contexto de las características, la cultura y las preferencias del paciente” (APA, 2006, p. 273). Esta definición es similar a la de “práctica basada en la evidencia” (PBE) propuesta por Sackett, Straus, Richardson, Rosenberg y Haynes (2000) como “la integración de la mejor evidencia científica con la pericia clínica y los valores del paciente” (p.147). Al igual que para los tratamientos psicológicos, Kazdin (2008) planteó su propia definición de PBE basándose en las dos anteriores: “práctica clínica que se basa en la evidencia sobre las intervenciones, la pericia clínica y las necesidades,

valores y preferencias del paciente y su integración en la toma de decisiones sobre la atención individual” (p. 147).

Por lo tanto, el concepto de PBE podría entenderse como un proceso de toma de decisiones formado por tres pilares, a menudo referido como el “*three-legged stool*” de las PBEs (Spring, 2007): 1) la evidencia científica disponible; 2) la pericia clínica, que es el resultado de la combinación de la formación académica acumulada, la capacitación y la experiencia clínica, e incluye los procesos de evaluación, diagnóstico, formulación de casos y planificación del tratamiento (Satterfield et al., 2009); y 3) las preferencias del paciente, que incluyen factores tales como las características del cliente, los valores, el contexto, la identidad sociocultural, el estado funcional, la disposición al cambio, el historial de desarrollo y el grado de apoyo social (APA, 2006).

### **1.5. Conclusión**

La evaluación de la evidencia científica de los tratamientos psicológicos ha evolucionado enormemente desde que, a mediados del siglo XX, Eysenck pusiera de manifiesto que la terapia psicológica no producía beneficio alguno sobre los pacientes. A partir de entonces comenzaron a surgir numerosos ECAs, revisiones sistemáticas y metaanálisis con el objeto de establecer si una determinada terapia era eficaz o no.

En la década de los 90 surgieron los primeros informes en los que se especificaban los tratamientos que tenían evidencia empírica y los requisitos que debían cumplir para ser considerados como tales (TBEs). Este planteamiento focalizaba el éxito de la terapia en el tratamiento utilizado, motivo por el cual fue objeto de numerosas críticas.

Para hacer frente a la polémica generada, años más tarde surge el concepto “PBE”, que tiene en cuenta no solo los resultados de la investigación, sino también la pericia clínica y las características del paciente. Así, mientras que desde la perspectiva de los TBEs se plantea si un determinado tratamiento funciona para un trastorno concreto bajo circunstancias específicas, la PBE se pregunta qué pruebas de investigación ayudarán al psicólogo a obtener el mejor resultado con un determinado paciente.

Por lo tanto, la evaluación de la evidencia de los tratamientos psicológicos se encuentra en un proceso continuo de evolución, cuya metodología y sistematicidad ha mejorado notablemente a lo largo de los años. Sin embargo, como se manifiesta a lo largo de esta tesis doctoral, los procedimientos de evaluación de la evidencia aún presentan deficiencias que se deberían solucionar.



## Capítulo 2

# Diferentes propuestas para evaluar los tratamientos basados en la evidencia

### 2.1. Introducción

Posiblemente, las mayores contribuciones de los listados de TBEs tengan que ver con el establecimiento de criterios explícitos para juzgar la calidad de la evidencia de las diversas intervenciones y con la creación de instituciones que actúan como mediadoras entre la investigación y la práctica clínica, sirviendo como referencia y fuente de consulta para clínicos y académicos. Estas instituciones ofrecen sus recomendaciones de tratamiento en forma de guías, que son definidas por Moriana y Martínez (2011) como “pronunciamientos, declaraciones o informes que sugieren y/o recomiendan unas líneas de intervención determinadas, así como un comportamiento especificado del profesional ante diversas situaciones” (p. 85). La APA distingue entre dos tipos de guías, guías de tratamiento y guías de práctica clínica. Esta institución plantea que las guías de tratamiento ofrecen recomendaciones específicas acerca de los tratamientos que podrán ser ofrecidos a los pacientes (APA, 2002a), mientras que las guías de práctica clínica son sugerencias a los profesionales sobre su conducta y los temas a considerar en áreas particulares de la práctica psicológica (APA, 2002b). Así, en este capítulo se abordarán las propuestas para evaluar la calidad de la evidencia que las diferentes organizaciones analizadas en esta tesis doctoral utilizan para la elaboración de sus guías de tratamiento.

Kazdin (2018) expone que, para la mayoría de las recomendaciones y declaraciones sobre TBEs, un tratamiento es considerado basado en la evidencia si cumple la mayor parte de los siguientes criterios: 1) comparaciones del tratamiento con una condición de control, 2) asignación aleatoria de los participantes al tratamiento y a la condición de control, 3) especificación cuidadosa de la población, 4) uso de manuales de tratamiento que especifiquen con detalle el procedimiento terapéutico, 5) múltiples medidas de cambio terapéutico, 6) diferencias estadísticamente significativas al final del periodo de intervención entre el tratamiento y la condición de control, y 7) replicación de los resultados por un investigador o equipo de investigación independiente que pueda reproducir los hallazgos obtenidos en el estudio original. Sin embargo, la evaluación de la evidencia sigue a menudo diferentes criterios y grados de valoración, lo que induce a pensar que la fiabilidad entre listados y guías de tratamiento en cuanto a su construcción y análisis es significativamente distinta (Primero y Moriana, 2011).

Aunque son numerosas las organizaciones que han generado listados y guías de tratamiento en las últimas décadas, la elección de las cinco instituciones que se han revisado a lo largo de esta tesis doctoral ha estado motivada por varias razones. En primer lugar, las divisiones 12 (*Society of Clinical Psychology*) y 53 (*Society of Clinical Child and Adolescent Psychology*) de la APA son organismos pioneros en la evaluación y promoción de TBEs. En segundo lugar, el NICE y la *Cochrane Collaboration* son organizaciones de prestigio reconocido a nivel internacional en la elaboración de recomendaciones sobre todo tipo de terapias basadas en la evidencia en una amplia gama de trastornos y problemas de salud. Por último, la *Australian Psychological Society* (APS) aporta, de forma muy clara y rigurosa, información sobre la eficacia de una amplia variedad de tratamientos psicológicos para los diversos trastornos mentales.

## **2.2. División 12 (*Society of Clinical Psychology*) de la *American Psychological Association* (APA)**

La APA es la principal organización científica y profesional que representa a la psicología en los Estados Unidos. Las 54 divisiones que la componen representan diferentes subdisciplinas de la psicología (p. ej. psicología clínica, psicología social ...) o diferentes tópicos como envejecimiento o minorías étnicas. La División 12 (*Society of Clinical Psychology*) incluye a los miembros de la APA que están activos en la práctica, investigación o enseñanza en el ámbito de la psicología clínica. Dicha división desarrolló en 2008 una versión *online* del listado de TBEs (<https://www.div12.org/psychological->

[treatments/](#)) con el objetivo de mejorar su difusión y ser fácilmente revisada en respuesta a los nuevos hallazgos de investigación.

A día de hoy, la División 12 de la APA sigue actualizando el listado de TBEs de forma *online* en base a los criterios de Chambless et al. (1998), clasificando los tratamientos en cinco niveles de evidencia o apoyo experimental: “tratamientos con apoyo experimental fuerte”, “tratamientos con apoyo experimental modesto”, “tratamientos con apoyo experimental controvertido”, “tratamientos sin apoyo experimental” y “tratamientos potencialmente peligrosos” (ver tabla 2.1). Además del nivel de evidencia y los ECAs, metaanálisis y revisiones sistemáticas en los que se apoya, la web de la División 12 ofrece para la mayoría de los tratamientos un breve resumen de sus principales características y una serie de recursos para la intervención (manuales, materiales de entrenamiento, instrumentos de evaluación, libros de autoayuda, aplicaciones para *smartphones* y vídeos demostrativos).

**Tabla 2.1. Criterios utilizados actualmente por la División 12 de APA para clasificar la evidencia de los tratamientos**

<b>Tratamientos con apoyo experimental fuerte</b>	Cumplen los criterios para ser considerados “tratamientos bien establecidos” (Chambless et al., 1998)
<b>Tratamientos con apoyo experimental modesto</b>	Cumplen los criterios para ser considerados “tratamientos probablemente eficaces” (Chambless et al., 1998)
<b>Tratamientos con apoyo experimental controvertido</b>	Cumplen una de las siguientes condiciones: <ul style="list-style-type: none"> <li>– Los estudios de un tratamiento dado arrojan resultados contradictorios</li> <li>– El tratamiento es eficaz pero el argumento de dicha eficacia está en desacuerdo con la evidencia científica</li> </ul>
<b>Tratamientos sin apoyo experimental</b>	No cumplen los criterios para ser considerados “tratamientos probablemente eficaces” (Chambless et al., 1998)
<b>Tratamientos potencialmente peligrosos</b>	Pueden ejercer efectos negativos en los pacientes

Adaptado de <https://www.div12.org/psychological-treatments/>



Normalmente, el requisito para que un tratamiento sea considerado basado en la evidencia es la existencia de dos estudios bien diseñados llevados a cabo por dos equipos de investigadores diferentes. Sin embargo, en la actualidad, las conclusiones sobre los efectos del tratamiento suelen tomarse en base a revisiones sistemáticas cuantitativas (metaanálisis) que incluyen múltiples ECAs, ya que la robustez de las conclusiones de los metaanálisis es mayor que la de unos pocos ECAs (Kazdin, 2018). En esta línea, en el año 2015, la División 12 de la APA inició un proceso de revisión de los listados de TBEs usando las recomendaciones propuestas por Tolin et al. (2015), consistentes en utilizar las revisiones sistemáticas y metaanálisis ya existentes. Hasta la fecha de la redacción de esta tesis doctoral, tan solo ha sido revisado el estatus de la terapia de exposición y prevención de respuesta para el trastorno obsesivo-compulsivo.

Tolin et al. (2015) proponen un método que comienza con la evaluación de todas las revisiones sistemáticas y metaanálisis de alta calidad existentes en la literatura. Para que una revisión sistemática sea incluida en el proceso de revisión de los listados, debe considerarse que esta tiene suficiente calidad según la lista de control AMSTAR - *Ameasurement Tool to Assess Systematic Reviews*- (Shea, Bouter et al., 2007; Shea, Grimshaw et al., 2007). El proceso debe continuar con la evaluación de la relevancia clínica y el riesgo de sesgo. Por un lado, para asegurar la relevancia clínica de la revisión sistemática (validez externa), esta debe definir la población de interés, la intervención, los comparadores, los resultados que se evalúan, la temporalidad y el contexto. Por otro lado, para evaluar el riesgo de sesgo de las revisiones sistemáticas, estos autores recomiendan utilizar la herramienta desarrollada por la *Cochrane Collaboration* (Higgins et al., 2011), que incluye la evaluación de las siguientes fuentes potenciales de sesgo: generación de la secuencia de aleatorización, ocultamiento de la secuencia de aleatorización, enmascaramiento de investigadores, personal implicado en el estudio o participantes en el estudio, enmascaramiento de la evaluación o medida de los resultados, datos de los resultados incompletos y descripción selectiva de los resultados.

Una vez confirmada la calidad de la revisión sistemática, Tolin et al. (2015) plantean evaluar la calidad de la evidencia de los resultados de dicha revisión utilizando el sistema GRADE -*Grades of Recommendation, Assessment, Development, and Evaluation*- (Atkins et al., 2004; Balshem et al., 2011). Este sistema clasifica la calidad de la evidencia en cuatro niveles (alta, moderada, baja y muy baja), considerando la evidencia para cada resultado presente en la revisión sistemática de forma separada. La

tabla 2.2 muestra el significado de los cuatro niveles de evidencia y compara su definición más actual con la definición anterior. En el sistema GRADE, los ECAs tendrían de inicio una evidencia de alta calidad, mientras que los estudios observacionales tendrían una evidencia de baja calidad. Sin embargo, dicha evidencia podría degradarse o aumentarse en base a diversos factores. Por un lado, las limitaciones del estudio, la inconsistencia de los resultados, la evidencia indirecta, la imprecisión de los resultados y el sesgo de publicación harían disminuir la calidad de la evidencia. Por otro lado, factores tales como una gran magnitud del efecto, la evidencia de un gradiente de respuesta, o el hecho de que todas las variables de confusión plausibles hayan reducido el efecto podrían aumentar la calidad de la evidencia (Atkins et al., 2004; Balshem et al., 2011).

**Tabla 2.2. Significado de los cuatro niveles de evidencia propuestos por GRADE**

Calidad	Definición actual (Balshem et al., 2011)	Definición anterior (Atkins et al., 2004)
<b>Alta</b> ⊕⊕⊕⊕	Estamos muy seguros de que el verdadero efecto se encuentra cerca de la estimación del efecto	Es muy poco probable que nuevas investigaciones cambien nuestra confianza en la estimación del efecto
<b>Moderada</b> ⊕⊕⊕○	Tenemos una confianza moderada en la estimación del efecto: el verdadero efecto es probable que esté cerca de la estimación del efecto, pero hay una posibilidad de que sea sustancialmente diferente	Es probable que nuevas investigaciones tengan un impacto importante en nuestra confianza en la estimación del efecto y puedan cambiar la estimación
<b>Baja</b> ⊕⊕○○	Nuestra confianza en la estimación del efecto es limitada: el verdadero efecto puede ser sustancialmente diferente de la estimación del efecto	Es probable que nuevas investigaciones tengan un impacto importante en nuestra confianza en la estimación del efecto y es probable que cambie la estimación
<b>Muy baja</b> ⊕○○○	Tenemos muy poca confianza en la estimación del efecto: es probable que el verdadero efecto sea sustancialmente diferente de la estimación del efecto	Cualquier estimación del efecto es muy incierta

Adaptado de “GRADE guidelines: 3. Rating the quality of evidence”, por H. Balshem et al., 2011, *Journal of Clinical Epidemiology*, 64(4), 401-406.

En base a la calidad de la evidencia de las revisiones sistemáticas y metaanálisis disponibles, evaluada mediante el sistema GRADE, Tolin et al. (2015) proponen actualizar los listados de TBEs según un sistema jerárquico de recomendación de cuatro niveles: “recomendación muy fuerte”, “recomendación fuerte”, “recomendación débil” y “evidencia insuficiente” (ver tabla 2.3).

**Tabla 2.3. Criterios propuestos por Tolin et al. (2015) para actualizar los listados de TBEs**

<b>Recomendación muy fuerte</b>	Todas la siguientes: <ul style="list-style-type: none"><li>– Existe evidencia de alta calidad de que el tratamiento produce un efecto clínicamente significativo en los síntomas del trastorno que se está tratando</li><li>– Existe evidencia de alta calidad de que el tratamiento produce un efecto clínicamente significativo en los resultados funcionales</li><li>– Existe evidencia de alta calidad de que el tratamiento produce un efecto clínicamente significativo sobre los síntomas y/o los resultados funcionales al menos 3 meses después de la interrupción del tratamiento</li><li>– Al menos un estudio bien realizado ha demostrado efectividad en entornos no relacionados con la investigación (p. ej. entornos que ofrecen atención clínica rutinaria, como centros comunitarios de salud mental, centros de tratamiento para pacientes internados o ambulatorios, o centros de práctica privada)</li></ul>
<b>Recomendación fuerte</b>	Al menos una de las siguientes: <ul style="list-style-type: none"><li>– Existe evidencia de moderada a alta calidad de que el tratamiento produce un efecto clínicamente significativo sobre los síntomas del trastorno que se está tratando</li><li>– Existe evidencia de moderada a alta calidad de que el tratamiento produce un efecto clínicamente significativo en los resultados funcionales</li></ul>
<b>Recomendación débil</b>	Cualquiera de las siguientes: <ul style="list-style-type: none"><li>– Solo existen pruebas de baja o muy baja calidad de que el tratamiento produce un efecto clínicamente significativo en los síntomas del trastorno que se está tratando</li><li>– Solo existen pruebas de baja o muy baja calidad de que el tratamiento produce un efecto clínicamente significativo sobre los síntomas del trastorno que se está tratando, así como sobre los resultados funcionales</li><li>– Existe evidencia de moderada a alta calidad de que el efecto del tratamiento, aunque estadísticamente significativo, puede no ser de una magnitud clínicamente significativa</li></ul>
<b>Evidencia insuficiente</b>	Cualquiera de las siguientes: <ul style="list-style-type: none"><li>– No hay una revisión sistemática disponible</li><li>– Los resultados de los estudios de tratamiento no satisfacen los criterios mínimos para una recomendación débil</li></ul>

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Adaptado de “Empirically supported treatment: Recommendations for a new model”, por D. F. Tolin, D. Mckay, E. M. Forman, E. D. Klonsky y B. D. Thombs, 2015, *Clinical Psychology: Science and Practice*, 22(4), 317–338.

### **2.3. División 53 (*Society of Clinical Child and Adolescent Psychology*) de la *American Psychological Association* (APA)**

La División 53 (*Society of Clinical Child and Adolescent Psychology*) de la APA incluye a los miembros que están activos en el ámbito de la psicología clínica infantil y adolescente. Esta institución se plantea como objetivo promover la investigación científica, la formación y práctica clínica en estos rangos de edad como medio para mejorar la salud mental de niños, adolescentes y sus familias.

A lo largo de las dos últimas décadas, la División 53 ha publicado sus listados de TBEs en la revista *Journal of Clinical Child and Adolescent Psychology*, actualizándolos también de forma online (<http://effectivechildtherapy.org/>). A través de tres volúmenes especiales sobre TBEs (Lonigan, Elbert y Johnson, 1998; Silverman y Hinshaw, 2008; Southam-Gerow y Prinstein, 2014), la División 53 ha ido actualizando sus listados y los criterios utilizados. En el volumen de 1998 (Lonigan et al., 1998) utilizaron los mismos criterios propuestos por Chambless et al. (1998). En el volumen editado en 2008, Silverman y Hinshaw (2008) graduaron la evidencia en cuatro niveles: “tratamientos bien establecidos”, “tratamientos probablemente eficaces”, “tratamientos posiblemente eficaces” y “tratamientos experimentales”. El nuevo nivel (“tratamientos posiblemente eficaces”) daba lugar a una elección más matizada entre “tratamiento experimental” y “tratamiento probablemente eficaz”, e incluía aquellos tratamientos que estaban apoyados por un “buen” estudio que mostrara que el tratamiento era eficaz en ausencia de pruebas contradictorias. En la última actualización (Southam-Gerow y Prinstein, 2014) añadieron un quinto e inferior nivel de evidencia (“tratamientos de eficacia cuestionable”) para incluir aquellos tratamientos probados que no han obtenido un efecto beneficioso en comparación con cualquier condición de control (ver tabla 2.4).

Actualmente, la División 53 plantea que los tratamientos experimentales podrían ser considerados para aquellos síntomas o trastornos de niños y/o adolescentes en los que haya opciones terapéuticas limitadas. En cambio, los tratamientos de eficacia cuestionable no serían una buena opción terapéutica.

La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

**Tabla 2.4. Criterios utilizados actualmente por la División 53 de APA para clasificar la evidencia de los tratamientos**

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**Nivel 1: Tratamientos bien establecidos**

1.1 Eficacia demostrada por el tratamiento en una de las siguientes formas:

1.1.a. Resultados estadísticamente superiores a un grupo que utilice fármacos placebo, a un grupo placebo psicológico o a otro tratamiento activo

O

1.1.b. Equivalente (o no significativamente diferente) a un tratamiento ya establecido en experimentos

Y

1.1.c. Al menos dos escenarios independientes de investigación llevados a cabo por dos equipos de investigación independientes que demuestran la eficacia

Y

1.2 Todos los criterios metodológicos siguientes:

M.1. Estudios con un diseño controlado aleatorizado

M.2. Se usaron manuales de tratamiento o equivalentes lógicos para el tratamiento

M.3. Criterios de inclusión de la población claramente definidos

M.4. Se usaron medidas de evaluación de resultados fiables y válidas para medir los problemas específicos (como mínimo)

M.5. Se usaron análisis de datos apropiados y el tamaño de la muestra fue suficiente para detectar los efectos esperados

**Nivel 2: Tratamientos probablemente eficaces**

2.1. Al menos dos buenos experimentos que muestren que el tratamiento es superior (de forma estadísticamente significativa) a un grupo control de lista de espera

O

2.2. Uno (o más) experimentos que cumplan los criterios de los tratamientos bien establecidos excepto el criterio 1.1.c.

Y

2.3. Todos los criterios metodológicos: M1, M2, M3, M4 y M5

**Nivel 3: Tratamientos posiblemente eficaces**

3.1. Al menos un buen ensayo controlado aleatorizado que muestre que el tratamiento es superior a un grupo control de lista de espera

Y

3.2. Todos los criterios metodológicos: M1, M2, M3, M4 y M5

O

3.3. Dos o más estudios clínicos que muestren la eficacia del tratamiento, con dos o más cumpliendo los criterios metodológicos M2, M3, M4 y M5, pero ninguno de ellos es un ensayo clínico aleatorizado

**Nivel 4: Tratamientos experimentales**

4.1. Aún no se ha probado en un ensayo controlado aleatorizado

O

4.2 Probado en uno o más estudios clínicos sin cumplir los criterios del nivel 3

**Nivel 5: Tratamientos de eficacia cuestionable**

5.1. Inferior a otro tratamiento activo y/o grupo control de lista de espera en experimentos bien diseñados, es decir, la única evidencia disponible sugiere que el tratamiento no produce un efecto beneficioso

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Adaptado de “Evidence base updates: The evolution of the evaluation of psychological treatments for children and adolescents”, por M. A. Southam-Gerow y M. J. Prinstein, 2014, *Journal of Clinical Child & Adolescent Psychology*, 43(1), 1–6.

#### **2.4. *National Institute for Health and Care Excellence (NICE)***

Esta organización es responsable de proporcionar información basada en evidencias sobre salud y atención social a los *National Health Services* (NHS) de Reino Unido. Sus competencias abarcan desde el suministro de información y asesoramiento acerca del tratamiento de trastornos y enfermedades que cubren todas las especialidades de la salud, hasta el lanzamiento de campañas y programas de prevención. NICE publica guías clínicas, guías de diagnóstico, guías de evaluación de tecnología, guías de procedimientos de intervención y guías de salud pública, entre otras, que hacen recomendaciones basadas en la evidencia en una amplia gama de temas de salud, salud pública y atención social (Moriani y Martínez, 2011).

Cada guía es encargada a un comité de expertos diferente cuyos miembros pertenecen a la práctica clínica, a la salud pública y a la asistencia social. Además, todos los comités incluyen al menos dos miembros legos, que pueden ser pacientes, cuidadores, usuarios de servicios o el público en general (NICE, 2017). Los comités llevan a cabo revisiones sistemáticas y metaanálisis para evaluar y comparar los beneficios y la relación coste-efectividad de las diferentes formas de tratamiento incluidas en cada guía. En su página web (<https://www.nice.org.uk/>) se pueden consultar las diferentes guías publicadas por este organismo, que en el momento de la redacción de esta tesis doctoral ascendían a más de 1400.

En un primer momento, NICE se basó en la propuesta de Mann (1996) y en la de Eccles y Mason (2001) para clasificar la evidencia de los tratamientos en sus guías clínicas. Este sistema organiza la evidencia en varios niveles a los que le corresponden diferentes grados de recomendación (ver tabla 2.5). En los últimos años, NICE ha ido incorporando el sistema GRADE (Atkins et al., 2004) en las actualizaciones de sus guías clínicas.

La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

**Tabla 2.5. Niveles de evidencia y grados de recomendación propuestos por NICE basados en las propuestas de Mann (1996) y Eccles y Mason (2001)**

Nivel de evidencia	Grado de recomendación
<b>I</b> Evidencia obtenida de un único ECA o un metaanálisis de ECAs	<b>A</b> Al menos un ECA como parte de un cuerpo de literatura de buena calidad general y consistencia (evidencia de nivel I) que aborda la recomendación específica sin extrapolación
<b>IIa</b> Evidencia obtenida de al menos un estudio controlado bien diseñado sin aleatorización	<b>B</b> Estudios clínicos bien realizados sin aleatorización sobre el tema de la recomendación (evidencia de nivel II y III), o extrapolación de resultados obtenidos mediante ECAs
<b>IIb</b> Evidencia obtenida de al menos un estudio cuasiexperimental bien diseñado	
<b>III</b> Evidencia obtenida de estudios descriptivos no experimentales bien diseñados (estudios comparativos, estudios correlacionales y estudios de casos)	
<b>IV</b> Evidencia obtenida de informes y opiniones de comités de expertos y/o experiencias clínicas de autoridades reconocidas	<b>C</b> Informes y opiniones de comités de expertos y/o experiencias clínicas de autoridades reconocidas (nivel de evidencia IV) o extrapolación de resultados obtenidos mediante estudios con un nivel de evidencia I o II. Esta clasificación indica que no existen estudios clínicos directamente aplicables de buena calidad
	<b>GPP</b> Recomendaciones basadas en la experiencia clínica del grupo de desarrollo de la guía

Adaptado de *Post-traumatic stress disorder*, por National Institute for Health and Care Excellence, 2005, London: The British Psychological Society and The Royal College of Psychiatrists.

## 2.5. Cochrane Collaboration

Esta organización fue fundada en 1993 por la Universidad de Oxford con el objetivo de analizar y divulgar aquellos estudios que cumplieran unos requisitos metodológicos adecuados. En su página web (<https://www.cochrane.org/>) informa que está formada por una red de investigadores, profesionales, pacientes y cuidadores de más de 130 países que trabajan de forma cooperativa para proporcionar datos basados en la evidencia, a fin de facilitar la toma de decisiones sobre qué tratamiento elegir para un

trastorno o problema de salud en particular. Los colaboradores de Cochrane están afiliados a la organización a través de grupos de revisión relacionados con temas de salud. Estos grupos están establecidos en todo el mundo y la mayor parte de su trabajo se realiza *online*. Cada grupo es una "mini-organización" en sí mismo, con sus propios fondos, sitio web y carga de trabajo. En función de sus intereses, experiencia o ubicación geográfica, los colaboradores se unen a un grupo o, en algunos casos, a varios grupos (Higgins y Green, 2011).

Los grupos Cochrane realizan revisiones sistemáticas y metaanálisis sobre todo tipo de enfermedades. Las revisiones proporcionan un resumen de los resultados de los estudios disponibles, principalmente ECAs, que presentan información sobre la efectividad de las intervenciones en un tema de salud específico. Estas revisiones, almacenadas en la *Cochrane Library* (se accede desde la página web de la organización), se han incrementado enormemente en los últimos años. Un informe publicado por Green y McDonald (2005) señalaba que la *Cochrane Library* recogía más de 2000 revisiones publicadas, cerca de 1500 protocolos y más de 415000 ECAs compilados. En la actualidad, la *Cochrane Library* incluye más de 7700 revisiones, cerca de 2500 protocolos y compila más de un millón de ECAs.

Respecto a la evidencia de los tratamientos, Cochrane informa sobre las pruebas a favor y en contra para facilitar la toma de decisiones en el cuidado de la salud. A partir del año 2010, Cochrane comenzó a utilizar el modelo GRADE (Atkins et al., 2004) como criterio para determinar la calidad de la evidencia.

## **2.6. Australian Psychological Society (APS)**

La APS es la principal organización profesional para psicólogos en Australia, cuyas funciones se llevan a cabo a través de más de 200 grupos de miembros activos dentro de la sociedad. La práctica basada en la evidencia se ha convertido en un tema central en la prestación de servicios de salud en Australia y, como tal, los programas de salud patrocinados por su gobierno requieren el uso de intervenciones basadas en la evidencia como un medio para discernir la asignación de fondos (APS, 2010).

En el año 2010, esta organización publicó una revisión exhaustiva de la evidencia disponible hasta el mes de enero de ese mismo año. En ella se examinó la eficacia de una amplia gama de intervenciones psicológicas en trastornos mentales que afectan a adultos, adolescentes y niños (APS, 2010), con el objetivo de apoyar la prestación de servicios psicológicos bajo las iniciativas gubernamentales de salud mental. Para establecer el nivel



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de evidencia de los tratamientos incluidos en la revisión, la APS utilizó los criterios desarrollados por el *National Health and Medical Research Council* (NHMRC) de Australia (NHMRC, 1999): Nivel I, revisión sistemática de todos los ECAs relevantes; Nivel II, al menos un ECA diseñado adecuadamente; Nivel III-1, ensayos controlados no aleatorizados bien diseñados (asignación alternativa o algún otro método); Nivel III-2, estudios comparativos con controles concurrentes y asignación no aleatoria (estudios de cohortes) o series temporales interrumpidas con un grupo control; Nivel III-3, estudios comparativos con control histórico, dos o más estudios de un solo brazo o series temporales interrumpidas sin un grupo de control paralelo; y Nivel IV, serie de casos, ya sea después de la prueba o antes de la prueba y después de la prueba.

## 2.7. Otras instituciones que divulgan tratamientos psicológicos basados en la evidencia

Como se comentó al inicio de este capítulo, las organizaciones descritas en los apartados anteriores no han sido las únicas que ha tenido como objetivo revisar y divulgar los TBEs. Así, numerosas instituciones públicas y privadas han ido generando listados y guías de tratamiento a lo largo de las últimas décadas. A continuación, en la tabla 2.6 se muestran algunos ejemplos.

**Tabla 2.6. Otras instituciones que divulgan TBEs**

Institución	País	Enlace web
Scottish Intercollegiate Guidelines Network	Escocia	<a href="https://www.sign.ac.uk">https://www.sign.ac.uk</a>
Sistema Nacional de Salud	España	<a href="http://portal.guiasalud.es/web/guest/guias-practica-clinica">http://portal.guiasalud.es/web/guest/guias-practica-clinica</a>
Haute Autorité de Santé	Francia	<a href="https://www.has-sante.fr/portail/">https://www.has-sante.fr/portail/</a>
Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften	Alemania	<a href="http://www.awmf.org/en/clinical-practice-guidelines">http://www.awmf.org/en/clinical-practice-guidelines</a>
Canadian Psychological Association	Canadá	<a href="https://cpa.ca/practice/resourcesofinterest/">https://cpa.ca/practice/resourcesofinterest/</a>
Substance Abuse and Mental Health Services Administration (SAMHSA)	EEUU	<a href="https://www.samhsa.gov/treatment/mental-disorders">https://www.samhsa.gov/treatment/mental-disorders</a>
Instituto Mexicano del Seguro Social	México	<a href="http://www.imss.gob.mx/guias_practic clinica?field_categoria_gs_value=30">http://www.imss.gob.mx/guias_practic clinica?field_categoria_gs_value=30</a>

## **2.8. Conclusión**

Desde que se desarrollaron los primeros criterios para determinar qué tratamientos psicológicos podrían ser considerados basados en la evidencia, han surgido numerosas organizaciones que han incluido entre sus objetivos difundir y recomendar este tipo de tratamientos. Muchas de estas instituciones han creado sus propios criterios y procedimientos de evaluación, dando lugar a la coexistencia, a día de hoy, de numerosos sistemas para graduar la calidad de la evidencia de las diferentes intervenciones psicológicas.

No es propio de una disciplina científica como la psicología el hecho de que cada organización tenga sus propios criterios y sistemas para determinar qué tratamientos se deben recomendar y cuáles no. Además, cabría esperar que las recomendaciones acerca de los tratamientos de elección para los distintos trastornos pudieran diferir de una institución a otra, cuestión esta que se corrobora a lo largo de la tesis.

De este modo, la comunidad científica debería promover un consenso internacional para establecer criterios y procedimientos de evaluación comunes que determinen qué terapias psicológicas tienen un efecto beneficioso para los pacientes y cuáles carecen de pruebas suficientes que avalen su eficacia.



## Capítulo 3

# La existencia de discrepancias entre los resultados de la investigación y la práctica clínica

### 3.1. Introducción

En las últimas décadas, la evaluación de la eficacia de los tratamientos psicológicos se ha convertido en una cuestión determinante. Echeburúa, Corral y Salaberría (2010) plantean que esto es debido, entre otras razones, a que el avance científico de la psicología clínica requiere acotar las terapias que son efectivas y sus componentes activos, y al hecho de que las terapias psicológicas están incorporadas en los centros públicos de salud. Estos autores sugieren también que la psicología basada en la evidencia ha permitido que los organismos públicos y las compañías aseguradoras dispongan de criterios establecidos para ofertar únicamente aquellos tratamientos que han demostrado tener un apoyo empírico, que los profesores universitarios cuenten con una guía para formar a los estudiantes de psicología en terapias que hayan demostrado su eficacia y que los pacientes puedan saber qué tipo de ayuda buscar para hacer frente a sus problemas psicológicos. Cuestiones estas planteadas como objetivo de la *Task Force on Promotion and Dissemination of Psychological Procedures* a la hora de publicar los listados de tratamientos apoyados por la investigación (APA Task Force, 1995).

Sin embargo, a pesar de las ventajas aportadas por la psicología basada en la evidencia, numerosos estudios sugieren que los hallazgos obtenidos por parte de la investigación tienen poco impacto sobre la práctica clínica, no llegando a consolidarse en

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los ámbitos aplicados (Barlow, Bullis, Comer y Ametaj, 2013; Beutler, 2000; Herbert, 2003; Kazdin, 2011), y una escasa presencia en los contenidos formativos de los programas de psicología clínica (Echeburúa, Corral y Salaberría, 2005). Además, según Kazdin (2018, p. 82), “la mayoría de los tratamientos en uso no están respaldados por la evidencia y muchos tratamientos apoyados no son de uso generalizado”.

Algunos estudios han mostrado que los psicólogos, en muchas ocasiones, no están utilizando TBEs para el abordaje de los problemas psicológicos de sus pacientes (Dobson y Beshai, 2013; Insel, 2010; Shafran et al., 2009). Por ejemplo, como señala Lilienfeld (2010), pocas personas con depresión y trastorno de pánico son intervenidas con TBEs, mientras que, en Reino Unido, el tratamiento más usado para el trastorno de estrés postraumático es el counselling, a pesar de la existencia de guías de tratamiento que recomiendan las intervenciones psicológicas centradas en el trauma como tratamiento de elección (Dozois, 2013). En otras ocasiones, aunque los psicólogos utilicen TBEs, no siempre usan todos los elementos clave de la terapia (Stobie, Taylor, Quigley, Ewing y Salkovskis, 2007). Así, los resultados de una encuesta indicaron que, aunque el 88 % de los psicólogos encuestados usaban técnicas cognitivo-conductuales para tratar la ansiedad, la mayoría de ellos no usaban la exposición con prevención de respuesta en el tratamiento del trastorno obsesivo-compulsivo ni la exposición interoceptiva en el trastorno de pánico (Freiheit, Vye, Swan y Cady, 2004).

Esta situación ha dado lugar a que ampliamente se hable de la existencia de una brecha entre la investigación científica y la psicología aplicada (Babione, 2010; Boisvert y Faust, 2006; Castonguay, Barkham, Lutz y McAleavy, 2013; Kazdin, 2008, 2011, 2018; Lilienfeld, 2010; Ruscio y Holohan, 2006; Shafran et al., 2009; Westen et al., 2004a; Wilson, Armoutliev, Yakunina y Werth, 2009). Esta divergencia entre la investigación y la práctica clínica, además de ser una limitación profesional para el investigador y el clínico, puede tener un impacto negativo en el bienestar del paciente (Constantino, Coyne y Gomez Penedo, 2017), ya que, si los resultados de la investigación no son aplicados a la práctica diaria, los pacientes no se podrán beneficiar del conocimiento acumulado (Tasca et al., 2015).

### **3.2. Posibles razones que explican la existencia de discrepancias entre la investigación y la práctica aplicada**

Existen varios argumentos que podrían explicar las razones por las cuales los psicólogos aplicados no usan o valoran la literatura científica. Algunos autores sugieren que el hecho de que los ECAs sean apropiados para la investigación en medicina no implica que necesariamente sean la forma más adecuada de investigar los resultados de la psicoterapia (Westen y Morrison, 2001). Así, numerosos terapeutas alegan que los ECAs no deberían ser el “estándar de oro” de la investigación en psicología clínica, sugiriendo que estos no aportan mayor evidencia que los estudios cualitativos (Gyani, Shafran, Rose y Lee, 2015; Wachtel, 2009). Además, argumentan que las muestras de pacientes utilizadas en los ECAs suelen ser de baja gravedad y complejidad sintomática, y no representan a los pacientes que se pueden encontrar en la práctica clínica (Gyani et al., 2015, Nelson, Steele y Mize, 2006). Esto no es del todo cierto, ya que, en ocasiones, los pacientes suelen ser excluidos de los ECAs por no cumplir criterios de severidad y de duración de los síntomas (Stirman, DeRubeis, Crits-Christoph y Brody, 2003; Stirman, DeRubeis, Crits-Christoph y Rothman, 2005).

En relación con el argumento anterior, los psicólogos clínicos sienten, a menudo, que los hallazgos de la investigación no reflejan la realidad de la práctica clínica (Tasca et al., 2015), por lo que, debido a la diferencia existente entre intervenir bajo condiciones controladas e intervenir en situaciones cotidianas, dichos hallazgos no pueden ser extrapolables a contextos de tratamiento habituales (Ruscio y Holohan, 2006; McLeod et al., 2017; Santucci, Thomassin, Petrovic y Weisz, 2015). Sin embargo, los resultados al respecto son contradictorios, ya que otros autores han concluido que la mayoría de los estudios de efectividad obtienen resultados comparables a los obtenidos en situaciones de investigación controlada (Hunsley y Lee, 2007).

Algunos terapeutas proponen que existe una incompatibilidad entre centrarse en la alianza terapéutica y basar la práctica clínica en los resultados de la investigación, considerando que la alianza terapéutica es más importante que la técnica usada (Stewart, Stirman y Chambless, 2012). Además, afirman que no usan tratamientos manualizados debido a que los consideran muy rígidos, lo que iría en detrimento de la alianza terapéutica (Gyani et al., 2015).

Otra razón que puede estar manteniendo la brecha entre la investigación y la práctica clínica es la creencia de que aprender a realizar paso a paso un tratamiento específico es más importante que el aprendizaje sobre TBEs (Stewart et al., 2012). Esta creencia puede ser debida al hecho de considerar que todas las terapias psicológicas son igualmente efectivas, planteamiento ampliamente conocido como “el veredicto del pájaro Dodo” (Rosenzweig, 1936). Aunque existen numerosas evidencias en contra de este planteamiento (Cautilli, 2006; Ehlers, Bisson, Clark y Yule, 2010; Lilienfeld, 2007; Norcross, 1995), un reciente metaanálisis de 84 estudios sobre intervenciones psicológicas en depresión sugiere la posibilidad de que el efecto beneficioso de la terapia psicológica se deba a factores comunes a todas las terapias (Palpacuer et al., 2017).

A pesar del ingente esfuerzo realizado por las diferentes organizaciones para trasladar la información aportada por la investigación a los diferentes actores involucrados (p. ej. a través de la publicación de listados y guías de tratamiento de forma *online*), la mayoría de los avances en el terreno de los tratamientos psicológicos se divulgan a través de revistas científicas, pudiendo ocasionar que esa información no llegue a los sectores profesionales aplicados (Echeburúa et al., 2010). En este sentido, en una encuesta realizada a psicólogos clínicos, el 47 % informó que leía artículos científicos al menos una vez al mes, el 21 % menos de una vez al mes, mientras que el 32 % nunca leía revistas científicas (Beutler, Williams, Wakefield y Entwistle, 1995). Por lo tanto, pocos profesionales de la psicología clínica leen revistas científicas, prefiriendo leer materiales que se centren en cómo practicar una determinada técnica (Stewart y Chambless, 2007).

Una encuesta en la misma línea que la anterior, realizada a miembros de la *Society for Psychotherapy Research* (SPR), dio como resultado que las publicaciones científicas eran la fuente de información menos útil para su práctica clínica, por detrás de la experiencia clínica acumulada y la consulta o supervisión con otros profesionales (Safran, Abreu, Ogilvie y DeMaria, 2011). Estos resultados se han repetido a lo largo de múltiples encuestas (Addis, 2002; Beutler et al., 1995; Gyani, Sharan, Myles y Rose, 2014; Morrow-Bradley y Elliott, 1986; Stewart y Chambless, 2007; Stewart et al., 2012; Stewart, Chambless y Stirman, 2018), por lo que podemos afirmar que la mayoría de los psicólogos clínicos se basan en su experiencia clínica o en la de sus compañeros para tomar sus decisiones de tratamiento. Sin embargo, algunos estudios han demostrado que la experiencia clínica puede estar sesgada (Dawes, Faust y Meehl, 1989) y el hecho de

basar la toma de decisiones exclusivamente en la experiencia puede provocar que los terapeutas no usen los elementos clave del tratamiento (Stobie et al., 2007; Waller, 2009).

En relación con la influencia que la investigación científica puede ejercer sobre la elección de una determinada orientación terapéutica, un estudio realizado con 736 psicólogos de Reino Unido encontró que la evidencia científica era poco relevante a la hora elegir dicha orientación, mientras que elementos como la intuición, el entrenamiento clínico y la experiencia personal con la terapia eran más determinantes para llevar a cabo esa elección (Gyani et al., 2014). Además, algunos estudios han encontrado que los profesionales de la psicología con orientación psicodinámica valoraban la investigación científica en menor medida que otros profesionales con una orientación teórica diferente (Morrow-Bradley y Elliot, 1986; Safran et al., 2011), mientras que los terapeutas cognitivo-conductuales tenían un punto de vista más positivo hacia la evidencia científica que los terapeutas de otras orientaciones (Gyani et al., 2014; Stewart y Chambless, 2007).

Además de la orientación terapéutica, Malhotra (2015) señala que factores personales tales como la edad del profesional, el nivel educativo, los años de experiencia clínica y el contexto laboral pueden estar influenciando la integración de la evidencia científica dentro de la práctica clínica. En relación con la edad, los profesionales más jóvenes tienden a usar con mayor frecuencia TBEs que aquellos con más edad (Aarons y Sawizky, 2006). La revisión realizada por Beidas y Kendall (2010) mostró que los psicólogos con un mayor nivel educativo y con más años de experiencia clínica tenían una actitud más favorable para implementar terapias manualizadas basadas en la evidencia. Respecto al ámbito laboral, Gyani et al. (2014) encontraron que los terapeutas que trabajaban en el *National Health Service* (NHS) de Reino Unido usan TBEs en mayor medida que los terapeutas que trabajaban en el ámbito privado.

### **3.3. Propuestas para reducir las discrepancias entre la investigación y la práctica clínica**

Dozois (2013) propone una serie de sugerencias para investigadores y clínicos con el objetivo de reducir las divergencias entre la investigación y la práctica clínica. A los investigadores les plantea cuatro sugerencias: a) mejorar las estrategias de difusión de los resultados de la investigación; b) aumentar la comunicación con los clínicos; c) incrementar la investigación en mecanismos de cambio para entender por qué un determinado tratamiento funciona; y d) capacitar a los estudiantes no solo en cómo administrar los TBEs, sino también en cómo pensar críticamente para tomar decisiones



clínicas en el contexto de las necesidades del paciente. En cuanto a las recomendaciones para los clínicos, estas tienen como objetivo hacer más sistemáticas sus intervenciones, ya que les plantea que evalúen de forma rutinaria con instrumentos fiables y válidos el progreso de los pacientes, y que registren sus experiencias clínicas de modo que las puedan transferir a la siguiente generación de profesionales de la psicología.

Respecto a la difusión de los resultados de la investigación, se ha demostrado que si la información se presenta en un formato legible y fácil de usar es más probable que sea utilizada por los profesionales aplicados (Michie y Lester, 2005). Además, una de las mayores influencias para que un terapeuta considere utilizar un TBEs es la credibilidad del agente de cambio y sus características personales (Schmidt y Taylor, 2002).

En relación con la mejora de la comunicación entre investigadores y clínicos, los investigadores suelen quejarse de que los clínicos no leen literatura científica y basan sus intervenciones en una experiencia clínica mal articulada, mientras que los clínicos lamentan que las investigaciones suelen llevarse a cabo por personas con poca o ninguna experiencia clínica (Goldfried, 2018). Además, investigadores y clínicos pueden tener diferentes prioridades para la investigación y el tratamiento, por lo que el hecho de que las cuestiones relevantes a la investigación en psicoterapia sean planteadas exclusivamente por los investigadores hace menos probable que los clínicos adopten los resultados de la investigación para tomar sus decisiones en la práctica clínica (Tasca et al., 2015). Así, al hablar de incremento de la comunicación entre investigador y clínico, Dozois (2013) plantea que esta comunicación debe ser bidireccional, ya que los investigadores necesitan escuchar por parte de los clínicos lo que funciona en la práctica diaria. Este aumento bidireccional de la comunicación hará que los clínicos sean más propensos a usar los hallazgos de la investigación y ocasionará una mayor colaboración entre ambos sectores (Goldfried, 2010).

En cuanto al hecho de incrementar la investigación en mecanismos de cambio, es cierto que la mayoría de las guías de tratamiento incluyen TBEs que son, en realidad, paquetes de tratamiento formados por varias técnicas o intervenciones (Tolin et al., 2015). Estos paquetes de tratamiento se suelen evaluar sin identificar sus mecanismos causales, por lo que no podemos conocer qué aspectos del tratamiento están detrás del cambio terapéutico (Gonzales y Chambers, 2002). Esto puede ocasionar que, dentro de un paquete de tratamiento, estemos utilizando técnicas que en realidad son inefectivas. Por lo tanto, desde hace más de una década se está proponiendo que la próxima generación de estudios

de investigación se centren en evaluar técnicas o estrategias de intervención más simples, con el objetivo de determinar qué es útil, inocuo o dañino en cada tratamiento y, por tanto, poder realizar cambios que mejoren su eficacia (Westen, Novotny y Thompson-Brenner, 2004b).

Respecto a la necesidad de capacitar a los estudiantes y profesionales en la administración de TBEs y en el proceso de toma de decisiones clínicas, Gallo y Barlow (2012) subrayan que aportarles información sobre TBEs y mejorar su acceso a materiales que los capaciten para utilizar estos tratamientos serían elementos clave para superar los obstáculos en la realización de prácticas terapéuticas que estén basadas en la evidencia.

Por último, en relación con las recomendaciones que Dozois (2013) propone para los profesionales aplicados, administrar instrumentos de evaluación válidos y fiables les ayudará a determinar si una intervención es efectiva y a tomar decisiones de tratamiento menos sesgadas por sus propias impresiones (Dozois y Dobson, 2010; Fitzpatrick, 2012). Además, si los clínicos registran y codifican la información obtenida en su intervenciones, se podría “incorporar dicha información dentro de la investigación diseñada para probar hipótesis y agregar más apoyo a lo que parece ser cierto a partir de los datos recopilados en la práctica” (Kazdin, 2008, p. 155).

### **3.4. Conclusión**

Son muchos los autores que han sugerido que los hallazgos obtenidos por parte de la investigación tienen poco impacto sobre la práctica clínica, ya que estos no se consolidan en los ámbitos aplicados y tienen poca presencia en los contenidos formativos de los programas de psicología clínica.

Entre las posibles razones que podrían explicar esta situación estaría el hecho de que algunos psicólogos piensen que los resultados de la investigación no reflejan la realidad de la práctica clínica, sientan que es incompatible centrarse en la alianza terapéutica y basar la práctica clínica en los resultados de la investigación, o crean que es más importante saber realizar paso a paso un tratamiento que aprender sobre TBEs. Igualmente, dado que la mayoría de los resultados de la investigación son publicados en revistas científicas, es posible que dicha información no llegue a los sectores profesionales aplicados. Además, factores personales como la orientación terapéutica, la edad del profesional, el nivel educativo, los años de experiencia clínica y el contexto laboral pueden estar influenciando la integración de la evidencia científica dentro de los ámbitos aplicados.

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Con el objetivo de reducir estas discrepancias, se han planteado una serie de medidas. Entre ellas, se podrían destacar la mejora de las estrategias de difusión de los resultados de la investigación y el incremento de la comunicación bidireccional entre investigadores y clínicos. Por lo tanto, con el propósito de aunar los resultados de la investigación con la práctica clínica, investigadores, clínicos y otros agentes implicados se deberían involucrar para implementar estas y otras medidas.

## Capítulo 4

# La adecuación de los tratamientos psicológicos a las situaciones reales de aplicación

### 4.1. Introducción

Debido a que muchos de los TBEs publicados en revistas científicas tienen una aplicabilidad baja o nula en la realidad (Kazdin, 2008), desde hace unos años se está reivindicando una mejor adecuación de los tratamientos psicológicos a situaciones reales de aplicación, lo cual podría dar lugar a una mejora de la diseminación de los TBEs entre los profesionales aplicados. Esta adecuación podría conllevar la flexibilización de los tratamientos y su utilización en diferentes contextos (p. ej. atención primaria y atención especializada), su adaptación a formatos breves de tiempo limitado y la generalización de las terapias a otros “problemas” psicológicos (no necesariamente trastornos) o circunstancias psicosociales en las que pueda cobrar sentido la participación de psicólogos (Moriana y Martínez, 2011).

En España, el coste medio por sesión de tratamiento psicológico en el sector privado suele oscilar entre 40 € y 90 €, por lo que las personas de bajos recursos económicos no pueden beneficiarse de dicho tratamiento, teniendo que ser atendidos por los servicios públicos de salud. En este sentido, se deberían desarrollar modalidades de intervención psicológica basadas en la evidencia que se ajusten a la dinámica de funcionamiento de los servicios de salud pública.

El uso de terapias breves podría ser una alternativa razonable para adecuar los tratamientos a la dinámica real del servicio público de salud. Esta modalidad de intervención responde de manera efectiva y ética a los recursos económicos y las necesidades psicológicas de las personas (Lyons y Low, 2009), ya que, debido a su duración y bajo coste, podrían beneficiarse muchos usuarios de los servicios públicos de salud. Además, si tenemos en cuenta que la mayoría de las personas interrumpen la psicoterapia cuando únicamente han realizado unas pocas sesiones (Alcázar, 2007; Rondón et al., 2009), cobra sentido organizar la terapia en torno al número de sesiones a las que acude el grueso de los pacientes. Igualmente, las terapias breves podrían utilizarse para ofrecer terapia psicológica inmediata a aquellos pacientes que están en listas de espera para acceder a programas de tratamiento especializados, como tratamiento inicial para pacientes en riesgo y como un complemento a tratamientos psicológicos más extensos (Sánchez y Gradolí, 2002), incluso para aquellos que están recibiendo tratamiento farmacológico.

Adicionalmente al uso de la terapia breve, el abordaje psicológico desde una perspectiva transdiagnóstica enfocada en un conjunto de principios terapéuticos comunes facilitaría la diseminación y el entrenamiento del tratamiento, al contrario de lo que ocurre con los numerosos y complejos protocolos manualizados de tratamiento tradicionales (Barlow et al., 2004).

#### **4.2. El abordaje de los trastornos mentales desde los sistemas públicos de salud**

Los problemas de salud mental tienen una incidencia muy elevada en las consultas de atención primaria (AP), ya que una de cada cinco está relacionada con este tipo de problemáticas (Latorre, López-Torres, Montañés y Parra, 2005), siendo el tercer motivo de consulta más común en AP (Shah, 1992). Concretamente, varios estudios sugieren que el número de pacientes que acuden a AP con trastornos emocionales es muy elevado (Kroenke, Spitzer, Williams, Monahan y Lowe, 2007; Laufer et al., 2013; Lejtzen, Sundquist, Sundquist y Li 2014; Roca et al., 2009). Además, estudios recientes indican que este tipo de trastornos, que engloban a los trastornos depresivos y los distintos trastornos de ansiedad, han aumentado exponencialmente en las últimas décadas (Chisholm et al., 2016., Vos et al., 2015).

En nuestro país, el abordaje de los trastornos mentales dentro de los servicios públicos de salud se realiza mediante una colaboración entre los niveles de AP y atención especializada (AE), siendo los facultativos de AP los responsables de su detección,

derivación o intervención en aquellos casos que no necesiten un tratamiento especializado (Moreno y Moriana, 2012). Sin embargo, numerosas investigaciones indican que los médicos de AP presentan dificultades para diagnosticar y tratar los trastornos mentales (Aragónés, Piñol y Labad, 2006; Collins, 2005, DeVicente y Berdullas, 2009; Fernández et al., 2006; Gerrits, van Marwijk, van Oppen, van der Horst y Penninx, 2013; Jacka, et al., 2013; Latorre et al., 2005; Ortiz, González y Rodríguez, 2006), manifestando que no disponen de técnicas ni de tiempo necesario para abordar este tipo de problemas adecuadamente (Moreno y Moriana, 2012).

Debido a estas dificultades, los pacientes con trastornos emocionales que acuden a los servicios públicos de salud suelen ser tratados únicamente desde AP, lo que implica un uso excesivo de medicación psicotrópica (Secades et al., 2003). Además, en otras muchas ocasiones, los pacientes son derivados a AE sin que presenten un trastorno mental diagnosticable, al mismo tiempo que les recetan psicofármacos, ocasionando una sobrecarga en los servicios de AE y un aumento del gasto sanitario farmacológico y asistencial (Ortiz et al., 2006).

Respecto al abordaje psicológico de los trastornos mentales desde los servicios de AE, se calcula que cada año surgen alrededor de 200 casos nuevos por profesional, a lo que hay que añadir los casos en tratamiento y en seguimiento ya registrados (Valero y Ruiz, 2003). Esto supone una carga de trabajo muy elevada que provoca que el tratamiento se alargue en el tiempo. Un estudio llevado a cabo por Labrador, Estupiñá y García (2010) encontró que el proceso de evaluación psicológica en AE es bastante largo, con una media de cuatro sesiones antes de poder comenzar el tratamiento. Además, debido a que las listas de espera se suelen prolongar entre dos y tres meses, el 31 % de los pacientes abandonó el tratamiento antes de su finalización, acudiendo la mayoría de ellos a ocho sesiones de tratamiento.

### **4.3. Las terapias breves**

Las terapias breves, también conocidas como terapias de tiempo limitado, surgen para responder a las exigencias de los sistemas públicos de salud acerca del uso de terapias psicológicas de corta duración que generen resultados favorables en la práctica clínica (Hewitt y Gantiva, 2009). Este tipo de terapias es utilizado por numerosos modelos teóricos que reducen su método tradicional de tratamiento a formatos de tiempo limitado (Epstein y Brown, 2002), entre los que se encuentran la terapia psicodinámica breve, la terapia breve cognitivo-conductual, la psicoterapia expresiva de apoyo, la terapia de

solución de problemas, la terapia centrada en la realización de tareas, la intervención en crisis, la terapia breve de familia o la terapia breve de grupo.

Concretamente, dentro de la perspectiva cognitivo-conductual, la intervención breve se centra en animar al paciente a que contraste empíricamente sus ideas y creencias, identificando los antecedentes y reforzadores de la conducta desadaptativa con el objetivo de que este desarrolle y potencie habilidades para afrontar y prevenir situaciones de riesgo de forma exitosa (Hewitt y Gantiva, 2009). Estos autores plantean que el modelo de terapia breve cognitivo-conductual se centra en el presente más que en la historia lejana del paciente, pretende incrementar la motivación y la autoeficacia hacia el cambio, trabaja los pensamientos y las emociones para lograr el cambio y tiene como objetivo la toma de decisiones y el inicio del cambio comportamental.

Siguiendo a Cape, Whittington, Buszewicz, Wallace y Underwood (2010), para que una terapia se considere breve debe tener más de dos sesiones y menos de diez, partiendo de la idea de que la intervención es flexible a las características y síntomas del paciente. Aunque no existe un acuerdo entre diferentes autores acerca de cuántas sesiones comprenden las terapias de tiempo limitado, todos coinciden en la importancia del tiempo como herramienta terapéutica (Bedics, Henry y Atkins, 2005; Hewitt y Gantiva, 2009; Lyons y Low, 2009; MacNeil, 2001; Miller, 2000). La limitación del número de sesiones ayuda a que tanto terapeuta como paciente se centren por completo en la terapia, aumenta la motivación del paciente y requiere que el terapeuta sea activo en el establecimiento de metas alcanzables, planteando cada sesión como una intervención con un resultado particular con el objetivo de que el paciente experimente el cambio lo antes posible (Fosha, 2004).

Como ya se comentó al inicio de este capítulo, varios estudios señalan que la mayoría de los pacientes abandonan la terapia cuando únicamente se han llevado a cabo unas pocas sesiones. Aunque las sesiones a las que acuden el grueso de los pacientes varían en función del estudio (Alcázar, 2007; Chen, 1991; Haynes, 1979; Reyes, Weldt, Mateluna y Almarza, 2005), todos coinciden en que la mayoría de los pacientes abandonan la terapia antes de las diez primeras sesiones. Por lo tanto, el establecimiento de un protocolo de intervención de menos de diez sesiones permitiría que la mayoría de los pacientes completasen la terapia.

En los últimos años se está planteando que la adaptación de las terapias psicológicas tradicionales a un formato breve de tiempo limitado podría mejorar el tratamiento de los trastornos emocionales (Shepardson, Funderburk y Weisberg, 2016), ajustándose más al funcionamiento de los servicios de salud y dando lugar a una mayor accesibilidad para los pacientes. Estas terapias están especialmente indicadas para los trastornos adaptativos y emocionales leves o moderados, por lo que deberían ser el primer paso para la intervención terapéutica en este tipo de pacientes (Collings et al., 2015).

Las terapias breves permiten que la mayoría de los pacientes con problemas emocionales de gravedad leve o moderada puedan ser ayudados con relativa rapidez, ya que algunas investigaciones sobre la eficacia de estas terapias han mostrado que obtienen resultados similares a las terapias convencionales (Cape et al., 2010; Lyons y Low, 2009). Por tanto, las terapias de tiempo limitado son igualmente eficaces, pero más eficientes, que las terapias tradicionales (Churchill et al., 2001; Nieuwsma et al., 2012).

Esta modalidad terapéutica ha demostrado su eficacia en la reducción de síntomas ansiosodepresivos (Amaya, Cardona, Ramírez, Sánchez y Gantiva, 2008; Arco, López, Heilborn y Fernández, 2005; Bernhardsdottir, Vilhjalmsson y Champion, 2013; Koutra, Katsiadrami y Diakogiannis 2010, Saravanan, Alias y Mohamad, 2017), en la mejora de las habilidades de solución de problemas (Bannink, 2007), en la disminución de síntomas de estrés postraumático (Kip et al., 2016; Labrador, Fernández y Rincón, 2006), o en el descenso de la ingesta de alcohol en personas que presentaban un consumo excesivo (Gantiva, Gómez y Flórez, 2003). Además, la mejoría en el paciente tratado con terapias breves permanece tiempo después de finalizar la intervención (Hamdan-Mansour, Puskar y Bandak, 2009; Vázquez et al., 2012).

Las terapias de tiempo limitado también han mostrado sus beneficios en contextos de AP. Los resultados del metaanálisis realizado por Cape et al. (2010) señalaron la eficacia de varias terapias en formato breve (terapia cognitivo conductual, counselling y terapia de solución de problemas) para el abordaje de los trastornos emocionales en este nivel asistencial, sugiriendo la necesidad de ampliar su nivel de evidencia y depurar los procedimientos para implementar este tipo de intervenciones. Además, como indican Dath, Dong, Stewart y Sables (2014), el uso de terapias breves en AP para el tratamiento de los trastornos emocionales no solo es beneficioso para los pacientes, sino también para el desempeño de los médicos de familia. Así mismo, utilizadas desde un enfoque transdiagnóstico, las terapias breves han demostrado ser eficaces para la reducción de la



sintomatología en pacientes con características y trastornos comórbidos distintos (McManus, Shafran y Cooper, 2011; Norton, 2008).

#### **4.4. El tratamiento transdiagnóstico**

Tradicionalmente han existido controversias entre la concepción categorial de la psicopatología y la concepción dimensional. El enfoque categorial clasifica a los individuos dentro de categorías clínicas cualitativamente diferenciadas, mientras que el enfoque dimensional sitúa al individuo a lo largo de una dimensión o continuo (p. ej. neuroticismo-estabilidad) (Castro, 2011).

Uno de los principales problemas asociados al enfoque categorial de los trastornos mentales es la elevada comorbilidad existente entre ellos, con tasas que van desde el 40 al 96 % en algunos trastornos (Clark, Watson y Reynolds, 1995; Kessler et al., 2005; Mineka, Watson y Clark, 1998; Sandín, Chorot, Valiente y Chorpita, 2010; Wittchen et al., 2010). Esta evidencia sugiere que la aparición de varios trastornos de forma conjunta “suele ser la norma más que la excepción” (Sandín, Chorot y Valiente, 2012, p. 186).

El predominio de un enfoque psicopatológico categorial ha dado lugar a la aparición de numerosos tratamientos con apoyo empírico para trastornos específicos, pero que no suelen tener en cuenta la concurrencia de trastornos. Por este motivo, resultaría de gran importancia para la práctica clínica el surgimiento de tratamientos que no estuvieran centrados en trastornos concretos y que pudieran ser utilizados para tratar los síntomas comunes de varios trastornos psicológicos (Belloch, 2012; Sandín et al., 2012). Esta nueva perspectiva, conocida como transdiagnóstica, plantea que los trastornos mentales comparten una amplia gama de procesos cognitivos y conductuales que contribuyen de forma causal al desarrollo y/o mantenimiento de los síntomas (Harvey, Watkins, Mansell y Shafran, 2004). Así, el tratamiento transdiagnóstico es definido como aquel “que está disponible para personas con una amplia variedad de diagnósticos y que no depende del conocimiento de estos diagnósticos para operar de manera efectiva” (Mansell, Harvey, Watkins y Shafran, 2009, p.14).

El término “transdiagnóstico” fue usado por primera vez por Fairburn, Cooper y Shafran (2003), quienes plantearon que los trastornos alimentarios compartían ciertos síntomas nucleares que eran mantenidos por procesos psicopatológicos similares (perfeccionismo clínico, baja autoestima, intolerancia emocional y dificultades interpersonales). Desde entonces, han surgido numerosos planteamientos que han intentado explicar la psicopatología desde una perspectiva transdiagnóstica (Aldao, Nolen

y Schweizer, 2010; Barlow et al., 2004, Carleton et al., 2012; Egan, Wade y Shafran, 2011; Harvey et al., 2004).

El abordaje psicológico desde un enfoque transdiagnóstico es especialmente apropiado para los trastornos emocionales, ya que varias investigaciones han mostrado que la depresión y los distintos tipos de ansiedad tienen importantes características en común (Barlow, 2002; Barlow et al., 2004; Brown y Barlow, 2009; Roca et al., 2009; Rossellini, Boettcher, Brown y Barlow, 2015).

Para intervenir sobre este tipo de trastornos, el equipo de David H. Barlow ha desarrollado el “Protocolo unificado para el tratamiento transdiagnóstico de los trastornos emocionales” (PU; Barlow et al., 2011; Ellard, Fairholme, Boisseau, Farchione y Barlow, 2010). Este protocolo ha sido llevado a cabo para abordar los síntomas subyacentes a los trastornos de ansiedad, trastornos del estado de ánimo y otros trastornos relacionados en los que la ansiedad y la desregulación emocional ejercen un papel importante (Ellard et al., 2010). Este protocolo se puede aplicar simultáneamente a pacientes con variedad de trastornos y puede ser desarrollado fácilmente en formato grupal, por lo que podría reducir las listas de espera y el coste del tratamiento individual (Osma et al., 2018).

El PU está compuesto por cinco módulos de tratamiento centrales, que se enfocan en aspectos clave del procesamiento emocional y la regulación de las experiencias emocionales, y por tres módulos que forman parte de los protocolos cognitivo-conductuales más tradicionales, como son la psicoeducación, la mejora motivacional y la prevención de recaídas (Farchione et al., 2012). Los módulos centrales del protocolo pretenden incrementar la conciencia emocional, modificar las evaluaciones cognitivas erróneas, prevenir la evitación emocional y exponer al paciente a situaciones internas y externas que le producen reacciones emocionales intensas (Sandin et al., 2012). En la tabla 4.1 se muestran los ocho módulos que conforman el PU.

Este protocolo suele llevarse a cabo a lo largo de un periodo comprendido entre 12 y 18 sesiones, permitiendo que el número de sesiones empleadas en cada módulo sea variable en función de las necesidades del paciente. De este modo, por ejemplo, los pacientes con preocupaciones excesivas podrían beneficiarse de un entrenamiento más profundo en conciencia emocional, mientras que las personas con conductas compulsivas se beneficiarían de una práctica prolongada del módulo en el que se trabaja la prevención de la evitación emocional (Boisseau, Farchione, Fairholme, Ellard y Barlow, 2010).

**Tabla 4.1. Protocolo Unificado para el tratamiento transdiagnóstico de los trastornos emocionales**

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- Módulo 1. Mejora de la motivación y el compromiso con el tratamiento
  - Módulo 2. Psicoeducación emocional
  - Módulo 3. Concienciación emocional
  - Módulo 4. Evaluación cognitiva y reevaluación
  - Módulo 5. Prevención de la evitación emocional y conductas impulsadas por la emoción
  - Módulo 6. Incremento de la conciencia y la tolerancia a las sensaciones físicas
  - Módulo 7. Exposición interoceptiva y situacional
  - Módulo 8. Conclusión y prevención de recaídas
- 

Adaptado de “Unified protocol for transdiagnostic treatment of emotional disorders: Therapist guide”, por D. H. Barlow et al., 2011, New York, NY: Oxford University Press.

La eficacia del PU ha sido demostrada en diferentes formatos y contextos, ya sea formato individual (Barlow et al., 2017; Farchione et al., 2012), formato grupal (Bullis et al., 2015), de forma online (Titov, 2011) o en población infantil y adolescente (Allen, Tsao, Sidman, Ehrenreich-May y Zeltzer, 2012). En España, el estudio preliminar de Osma, Castellano, Crespo y García-Palacios (2015) obtuvo como resultado que, tras la aplicación del PU en formato grupal en una unidad de salud mental pública, la mayoría de los participantes dejaron de cumplir los criterios diagnósticos por los cuáles habían sido incluidos en el estudio, manteniéndose los beneficios del tratamiento a los 12 meses.

Actualmente se están llevando a cabo en nuestro país varios ECAs para determinar la eficacia de este protocolo en diferentes contextos (García-Escalera et al., 2017; Osma et al., 2018). Así mismo, desde el año 2013 se está realizando un ECA a nivel nacional bajo el nombre de “Proyecto PsicAP”, en el que se lleva a cabo un tratamiento transdiagnóstico grupal para pacientes con trastornos emocionales de gravedad leve o moderada. Concretamente, este proyecto pretende determinar si el tratamiento transdiagnóstico cognitivo-conductual, en formato grupal, es más eficaz y eficiente que el tratamiento habitual para los trastornos emocionales en los centros de AP españoles, así como comparar el efecto de ambos tratamientos en funcionalidad, calidad de vida, factores cognitivo-emocionales y satisfacción con el tratamiento (Cano-Vindel et al., 2016). Además, desde el año 2017 se está desarrollando un ECA multicéntrico en la provincia de Córdoba que tiene como objetivo conocer la eficacia del PU en un formato de ocho sesiones para el tratamiento individual de los trastornos emocionales. El protocolo de dicho ECA será expuesto en el capítulo 9 de esta tesis doctoral (estudio 4).

#### **4.5. Conclusión**

El uso de una modalidad de intervención psicológica breve podría ser una alternativa razonable para adecuar el tratamiento a las situaciones reales de aplicación, ya que son varios los estudios que sugieren que la mayoría de los pacientes abandonan la terapia en las diez primeras sesiones. Por lo tanto, el establecimiento de un protocolo de tratamiento de menos de diez sesiones permitiría que la mayoría de los pacientes finalizaran la terapia.

Debido a su duración y bajo coste, este tipo de terapias se podrían adecuar a la dinámica de los servicios públicos de salud. Además, las terapias breves están especialmente indicadas para los trastornos emocionales de gravedad leve-moderada, cuya prevalencia en las consultas de AP es muy elevada. Por lo tanto, la inclusión de las terapias breves dentro de la sanidad pública podría contribuir a su descongestión.

Adicionalmente al uso de una modalidad de intervención breve, sería especialmente apropiado abordar los trastornos emocionales desde una perspectiva transdiagnóstica, ya que varios estudios han mostrado que la depresión y los distintos tipos de ansiedad tienen importantes características en común. El tratamiento desde este enfoque, además de permitir abordar los síntomas comunes de varios trastornos, podría facilitar la diseminación y el entrenamiento de los tratamientos.

Por lo tanto, el diseño de ECAs que evalúen la eficacia de protocolos de tratamiento breve desde una perspectiva transdiagnóstica podría contribuir al uso de intervenciones avaladas por la evidencia científica por parte de los profesionales aplicados.



## SEGUNDA PARTE

### Metodología y estudios



## Capítulo 5

# Presentación de los estudios que componen la tesis doctoral

Esta tesis doctoral ha surgido del planteamiento de una serie de objetivos para cuyo cumplimiento se han diseñado los diferentes estudios interrelacionados que la componen. Los dos primeros estudios pretenden determinar el acuerdo existente entre varias instituciones respecto a los tratamientos recomendados para los trastornos mentales en niños, adolescentes y adultos. El tercero de ellos busca conocer el impacto que los TBEs ejercen sobre la práctica clínica. Por último, el cuarto estudio tiene como objetivo diseñar el protocolo de un ECA que examinará la eficacia de la terapia breve para el tratamiento de los trastornos emocionales en los servicios públicos de salud.

Además de los dos primeros estudios, en un principio se planteó la posibilidad de realizar un trabajo adicional que revisara los tratamientos recomendados para las adicciones, ya que, por su amplitud y particularidad, estos trastornos se excluyeron de los estudios anteriores. Esto motivó una estancia de tres meses en el *Institutional Scientific Research Center* de la *Albizu University* de Miami (EEUU), dirigido por el Dr. Steven Proctor, experto internacional en este ámbito. Sin embargo, debido a la existencia de dificultades metodológicas, de otras cuestiones a las que se pretende responder en esta tesis doctoral y a la excesiva extensión de esta si se hubiera incluido dicho estudio, finalmente se optó por realizar esta revisión como un estudio posterior que no ha sido incluido en esta tesis.



En los siguientes apartados se presentan los objetivos e hipótesis que han motivado el desarrollo de cada uno de los estudios, las diferentes metodológicas utilizadas, así como una serie de consideraciones respecto a su estructura.

### **5.1. Objetivos e hipótesis de los estudios**

**Estudio 1.** *Psychological treatments for mental disorders in adults: A review of the evidence of leading international organizations.*

**Objetivo 1.** Analizar y compilar listados de TBEs para los trastornos mentales en adultos usando las recomendaciones de diferentes instituciones, así como determinar el grado de acuerdo existente entre ellas. Para ello se revisarán cuatro instituciones internacionales de reconocido prestigio [División 12 (*Society of Clinical Psychology*) de la *American Psychological Association* (APA), *National Institute for Health and Care Excellence* (NICE), *Cochrane Collaboration* y *Australian Psychological Society* (APS)].

**Hipótesis 1.** Debido a que estas instituciones suelen usar diferentes criterios y niveles para graduar la calidad de la evidencia, las recomendaciones acerca de los tratamientos psicológicos eficaces para los trastornos mentales en adultos pueden diferir de una organización a otra.

**Estudio 2.** *Psychological treatments for mental disorders in children and adolescents: a review of the evidence of leading international organizations.*

**Objetivo 2.** Analizar y compilar listados de TBEs para los trastornos mentales en niños y adolescentes usando las recomendaciones de diferentes instituciones, así como determinar el grado de acuerdo existente entre ellas. Para ello se revisarán cuatro instituciones internacionales de reconocido prestigio [División 53 (*Society of Clinical Child and Adolescent Psychology*) de la *American Psychological Association* (APA), *National Institute for Health and Care Excellence* (NICE), *Cochrane Collaboration* y *Australian Psychological Society* (APS)].

**Hipótesis 2.** Debido a que estas instituciones suelen usar diferentes criterios y niveles para graduar la calidad de la evidencia, las recomendaciones acerca de los tratamientos psicológicos eficaces para los trastornos mentales en población infantojuvenil pueden diferir de una organización a otra.

**Estudio 3.** *El impacto de los tratamientos psicológicos basados en la evidencia sobre la práctica clínica.*

**Objetivo 3.** Examinar el uso que los psicólogos formados en España hacen de los tratamientos basados en la evidencia para los diferentes trastornos mentales.

**Hipótesis 3.** El uso que los psicólogos formados en España hacen de este tipo de tratamientos es limitado, siendo mayor en el caso de las terapias de corte cognitivo-conductual.

**Objetivo 4.** Analizar los factores personales que puedan estar influenciando la integración de la evidencia científica dentro de la práctica clínica.

**Hipótesis 4.** Factores como la edad, el año de finalización de los estudios de grado o licenciatura, el nivel educativo, la acreditación profesional, los años de experiencia clínica, la orientación terapéutica o el ámbito laboral podrían estar mediando en la integración de los TBEs dentro de la práctica clínica.

**Estudio 4.** *Evidence-based brief psychological treatment for emotional disorders in primary and specialized care: study protocol of a randomized controlled trial.*

**Objetivo 5.** Diseñar el protocolo de un ensayo controlado aleatorizado en el que se examine la eficacia de una adaptación a terapia breve del Protocolo Unificado para el tratamiento transdiagnóstico de los trastornos emocionales y la compare con la de otras intervenciones habituales para el abordaje de estos trastornos en Atención Primaria y Especializada. A continuación se muestran las hipótesis derivadas del diseño del protocolo:

**Hipótesis 5.1.** La intervención que incluye terapia psicológica convencional más tratamiento farmacológico será la más eficaz, mientras que la terapia psicológica breve será la más eficiente.

**Hipótesis 5.2.** Las modalidades de tratamiento psicológico breve y convencional, así como la intervención mínima basada en psicoeducación y biblioterapia, serán más eficaces que el tratamiento farmacológico.

**Hipótesis 5.3.** El tratamiento psicológico breve será tan eficaz como el tratamiento psicológico convencional.

**Hipótesis 5.4.** La intervención mínima basada en biblioterapia será menos eficaz que el resto de las modalidades de intervención psicológica.

## 5.2. Método

Debido a que esta tesis doctoral está estructurada por compendio de publicaciones, los diversos estudios que la componen siguen diferentes métodos y diseños de investigación.

### 5.2.1. Metodología empleada en los estudios 1 y 2

La metodología usada en los estudios 1 y 2 se ajusta a la declaración PRISMA - *Preferred Reporting Items for Systematic Reviews and Meta-Analyses*- (Moher, Liberati, Tetzlaff y Altman, 2009) para revisiones sistemáticas, identificándose de manera pormenorizada la estrategia de búsqueda y los criterios de inclusión y exclusión. Se consultaron las páginas webs de las organizaciones incluidas en la revisión para compilar los tratamientos que recomendaban para cada trastorno y sus niveles de evidencia. Además, se recopilaron los RCTs, revisiones y metaanálisis utilizados por las organizaciones para dar soporte a sus recomendaciones.

Para analizar el acuerdo entre las organizaciones, se clasificaron los diferentes niveles de evidencia propuestos por cada organización en un esquema ordinal: sin evidencia, escasa evidencia, moderada evidencia y fuerte evidencia. Partiendo de esa clasificación, el coeficiente de correlación intraclass (*intra-class correlation*; ICC) fue usado como medida de fiabilidad entre evaluadores (*inter-rater reliability*; IRR), teniendo en cuenta solo aquellas terapias que eran consideradas efectivas por, al menos, una organización y asumiendo que todas las terapias incluidas fueron evaluadas por las cuatro instituciones. Esta decisión fue tomada debido a que consideramos que los resultados de la evidencia empírica pueden ser consultados y tenidos en cuenta por cualquier organización, por lo que el hecho de no incluir información acerca de una determinada terapia fue interpretado como ausencia de apoyo hacia la terapia.

Según Hallgren (2012), el ICC es uno de los estadísticos más usados para analizar la IRR para variables ordinales y es válido para estudios con más de dos evaluadores. Su cálculo puede ser realizado de diferentes formas en función de las características del estudio (Hallgren, 2012; McGraw y Wong, 1996), considerando más apropiado para nuestros estudios un modelo de dos vías, de efectos mixtos, de consistencia y de medidas promedio.

### **5.2.2. Metodología empleada en el estudio 3**

El estudio 3 sigue un diseño *ex post-facto* retrospectivo de grupo único. Para analizar el impacto que los TBEs tenían en una muestra de psicólogos formados en España, se desarrolló un instrumento *ad-hoc* (ver anexo 1) que fue aplicado de forma *online* a una muestra de 242 graduados o licenciados en psicología por universidades españolas. El cuestionario estaba compuesto por dos secciones diferenciadas: a) variables sociodemográficas y b) autoinforme acerca del uso de determinadas terapias psicológicas para los trastornos mentales en población adulta. Este último apartado incluía 97 tratamientos, para los cuáles debían marcar una de las siguientes opciones: *lo conozco y lo utilizo habitualmente para este trastorno; lo conozco, pero no considero oportuno utilizarlo para este trastorno; lo conozco, pero no tengo las competencias necesarias para utilizarlo; no lo conozco*. La puntuación total del autoinforme estaba compuesta por el número de veces que se indica que un tratamiento es usado habitualmente, tomándose esta puntuación como medida relativa del impacto de estos tratamientos sobre la práctica clínica. La influencia de determinadas variables en el uso de los tratamientos psicológicos con apoyo empírico fue analizada mediante el coeficiente de correlación de Pearson y las pruebas *t* de Student y ANOVA.

### **5.2.3. Metodología empleada en el estudio 4**

En el estudio 4 se diseñó el protocolo de un ECA multicéntrico con cinco grupos (terapia breve basada en el Protocolo Unificado; tratamiento psicológico convencional; tratamiento psicológico convencional más terapia farmacológica; intervención mínima basada psicoeducación y biblioterapia; y tratamiento farmacológico habitual) que está siendo llevado a cabo en centros de atención primaria y especializada de la provincia de Córdoba (España). En caso de baja respuesta al tratamiento ofertado, según consideraciones éticas, el paciente sería derivado al tratamiento habitual. El ensayo ha sido autorizado por el Comité de Ética de la Investigación Biomédica de la Consejería de Salud de la Junta de Andalucía (ver anexo 2) y ha sido registrado en la plataforma [clinicaltrials.gov](http://clinicaltrials.gov) con el número NCT03286881. El protocolo cumple con las recomendaciones para ensayos de intervención planteadas en la declaración SPIRIT - *Standard Protocol Item: Recommendations for Interventional Trials*- (Chan, Tetzlaff, Altman et al., 2013; Chan, Tetzlaff, Gøtzsche et al., 2013), así como con las normas consolidadas para la comunicación de los ensayos planteadas en la declaración CONSORT -*Consolidated Standards of Reporting Trials*- (Moher et al., 2010; Schulz et

La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

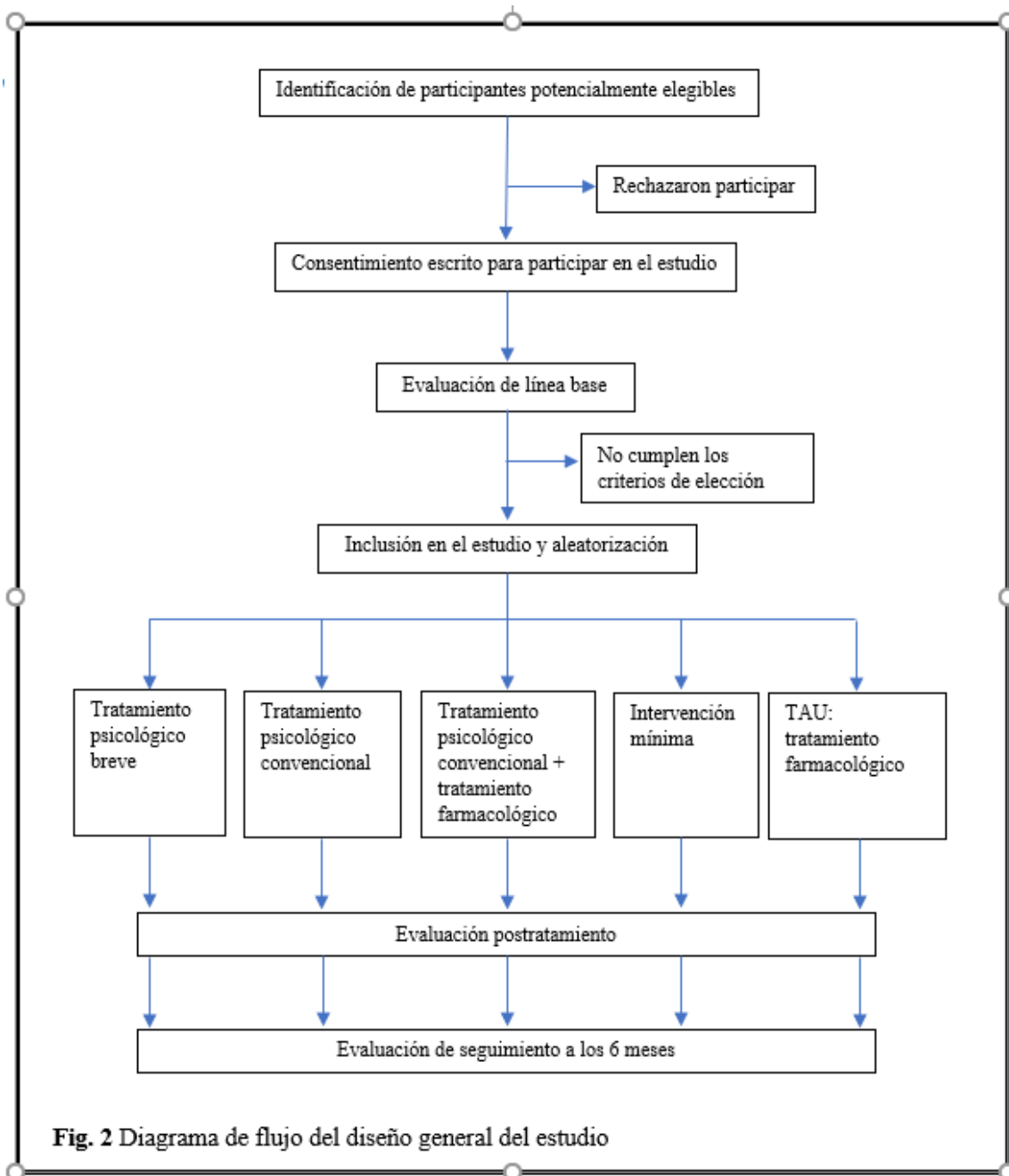
al., 2010). En el anexo 3 se incluye la hoja de información al paciente y el modelo de consentimiento informado. La lista de comprobación SPIRIT en la que se informa del número de página en el que aparecen los distintos elementos que conforman el protocolo se incluye en el anexo 4. La figura 1 incluye el esquema de asignación, intervenciones y evaluaciones del estudio según las recomendaciones de la declaración SPIRIT. La figura 2 muestra el diagrama para ilustrar el flujo de participantes a lo largo del ensayo.

Los datos serán analizados siguiendo el método por intención de tratar (*intention-to-treat*; ITT) y el método por protocolo. El método ITT es considerado la manera más válida y fiable de reducir el sesgo de selección a la hora de estimar la magnitud del efecto de la intervención en los ECAs (Newell, 1992) y consiste en incluir en el análisis de los datos a todos los pacientes aleatorizados en el estudio, incluyendo a los que abandonaron el tratamiento. Por otro lado, aunque el método de análisis por protocolo, consistente en incluir los datos de los pacientes que concluyeron el tratamiento, puede verse afectado por el sesgo de selección, nos ayudará a conocer la eficacia del tratamiento en aquellos pacientes que lo completaron en su totalidad (Higgins y Green, 2011).

Para analizar los cambios debidos a las intervenciones a lo largo del tiempo (línea base, postratamiento y seguimiento) y las diferencias entre los diferentes tratamientos se usarán modelos lineales mixtos, ya que estos modelos de análisis son más precisos que los ANOVAs de medidas repetidas (Gueorguieva y Krystal, 2004). Por último, debido a que el método ITT incluirá pacientes con datos perdidos o incompletos, se utilizará el método de estimación de máxima verosimilitud para tratar dichos datos.

TIMEPOINT	PERIODO DE ESTUDIO							
	Inscripción	Asignación	Intervención				Postratamiento	Seguimiento
	$-t_1$	0	S1	S5	S8	$S_n...24$ u 8 meses	Después de finalizar el tratamiento	6 meses después de finalizar el tratamiento
<b>INSCRIPCIÓN:</b>								
Criterios de elección	X							
Consentimiento informado	X							
Asignación		X						
<b>INTERVENCIONES:</b>								
<i>Terapia breve</i>			←————→					
<i>Terapia psicológica convencional</i>			←————→					
<i>Terapia psicológica convencional + fármacos</i>			←————→					
<i>Intervención psicológica mínima</i>			←——→					
<i>Tratamiento farmacológico</i>			←————→					
<b>EVALUACIONES</b>								
<b>GAD-7</b>	X						X	X
<b>STAI</b>	X						X	X
<b>PHQ-9</b>	X						X	X
<b>BDI-II</b>	X						X	X
<b>PHQ-15</b>	X						X	X
<b>PHQ-PD</b>	X						X	X
<b>BSI-18</b>	X						X	X

**Figura 1.** Esquema de asignación, intervenciones y evaluaciones (Figura SPIRIT). *GAD-7*= GAD-7 scale; *STAI*= State-Trait Anxiety Inventory; *PHQ-9*= Patient Health Questionnaire-9; *BDI-II*= Beck Depression Inventory-Second Edition; *PHQ-15*= Patient Health Questionnaire-15; *PHQ-PD*= Patient Health Questionnaire-Panic Disorder; *BSI-18*= Brief Symptom Inventory 18



### 5.3. Consideraciones sobre la presentación de los estudios

En los siguientes capítulos aparecerán los estudios que componen esta tesis doctoral. Al tratarse de una tesis por compendio de artículos (tres de ellos ya publicados), la estructura, los epígrafes, así como la forma de citar y referenciar siguen las particularidades de la revista en la que cada uno ha sido publicado. Por este motivo, con el objetivo de hacer homogénea toda la estructura de la tesis, se ha unificado el formato de las tablas y los epígrafes incluidos en los diferentes estudios.

## Capítulo 6

### Estudio 1

**Moriana, J. A., Gálvez-Lara, M. y Corpas, J. (2017). Psychological treatments for mental disorders in adults: A review of the evidence of leading international organizations. *Clinical Psychology Review*, 54, 29-43. doi: 10.1016/j.cpr.2017.03.008**

#### **Abstract**

Most mental health services throughout the world currently regard evidence-based psychological treatments as best practice for the treatment of mental disorders. The aim of this study was to analyze evidence-based treatments drawn from RCTs, reviews, meta-analyses, guides, and lists provided by the National Institute for Health and Care Excellence (NICE), Division 12 (Clinical Psychology) of the American Psychological Association (APA), Cochrane and the Australian Psychological Society (APS) in relation to mental disorders in adults. A total of 135 treatments were analyzed for 23 mental disorders and compared to determine the level of agreement among the organizations. The results indicate that, in most cases, there is little agreement among organizations and that there are several discrepancies within certain disorders. These results require reflection on the meaning attributed to evidence-based practice with regard to psychological treatments. The possible reasons for these differences are discussed. Based on these findings, proposals to unify the criteria that reconcile the realities of clinical practice with a scientific perspective were analyzed.

**Keywords:** Psychological treatments; Adult mental disorders; Evidence-based psychology; RCTs; Meta-analysis; Review article



## **6.1. Introduction**

Scientific psychology is a discipline that seeks to legitimize its theories by using evidence-based research to support its findings. The study of the efficacy of different psychological treatments based on the assumption that “only science can distinguish good interventions from bad ones” (Westen, Novotny, & Thompson-Brenner, 2004a, p. 632), represents one of the most important advances in clinical psychology. However, the impact of scientific advances on clinical practice and public health is still very small (Barlow, Bullis, Comer, & Ametaj, 2013). Many areas of psychology (cognitive science, perception, emotion, etc.) have used scientific methods to perform research with excellent results. However, both clinical and applied contexts present major complications in relation to experimental control, which hinders the scientific study of psychological treatments.

The principal objective of evidence-based practice in psychology is to use the best available scientific evidence by integrating data obtained from basic and applied research with clinical expertise to enhance patient care (American Psychological Association, 2006; Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996).

### ***6.1.1. History and evolution of the empirical supported treatment concept***

Interest and concern for the scientific assessment of the effects of psychological treatments began to increase in the twentieth century following the publication of an important article by Hans Eysenck in 1952. The author reviewed a series of studies published up to that moment and concluded that approximately 60% of patients treated with psychotherapy experienced some improvement. In contrast, approximately 70% of untreated patients showed spontaneous improvement (Eysenck, 1952). Thus, according to this study, psychotherapy would have no curative effect. However, later studies contradicted Eysenck’s work, which apparently overestimated spontaneous improvement in untreated patients (Andrews & Harvey, 1981; Landman & Dawes, 1982; Smith & Glass, 1977; Smith, Glass, & Miller, 1980). Specifically, the meta-analysis conducted by Smith & Glass (1977), which involved 375 studies, concluded that the average patient receiving psychotherapy is better off at the end of treatment than 75% of patients who do not receive treatment and that the different varieties of therapy do not produce differential effects.

These studies served as a prelude to the development of effective psychological treatments in the 1990s. The proliferation of randomized clinical trials (RCTs) and meta-

analyses led the University of Oxford to create Cochrane, which was dedicated to reviewing, summarizing and disseminating all evidence-based studies that met predetermined requirements and involved the demonstration of evidence from a scientific approach. Later on, the National Institute for Clinical Excellence, known today as the National Institute for Health and Care Excellence (NICE), was created in the UK as an autonomous body whose main objective was to ensure that the National Health Service (NHS) administered treatments based on the best available empirical evidence. Subsequently, the American Psychological Association (APA), and more gradually other public and private institutions, became increasingly interested in incorporating methods for the design and assessment of evidence-based treatments to inform professionals and users of the best therapeutic options available.

In 1993, Division 12 (Clinical Psychology) of the APA coordinated the Task Force on Promotion and Dissemination of Psychological Procedures, which included professionals from the private health sector, the public health system, researchers and users. The task force published several reports (Chambless & Hollon, 1998; Chambless et al., 1996; Chambless et al., 1998; Chambless & Ollendick, 2001; Woody, Weisz, & McLean, 2005) with lists of evidence-based treatments based on criteria to assess RCTs using control groups following standardized treatment guidelines (APA, 2006). Criteria began to be developed to clearly define empirically supported treatments (ESTs) so that health insurance companies could include them in the lists of services they offered to users (Barlow, 1996; Seligman, 1995; Shapiro, 1996).

Possibly one of the major contributions of the list of ESTs has involved the creation of institutions that act as mediators between research and clinical practice, as well as the establishment of explicit criteria for judging the quality of evidence of the different interventions. On the one hand, this mediation involves the evaluation of evidence (through selective reviews guided by criteria), and on the other hand, the transfer of information (through publications, books, manuals, training courses, etc.) to the different stakeholders involved (psychologists, patients, health institutions, the general public). However, the institutions that evaluate the evidence often use different criteria and degrees of assessment, which suggests that the reliability among lists in terms of how they are constructed and analyzed is significantly different (Primerio & Moriana, 2011).

This clearly economic approach not only aimed to highlight the fact that a psychological intervention might be effective for a specific problem, but that it might also

be better than other alternatives and could be employed in more advantageous conditions (shorter term, less expensive). It stands to reason that if over 250 different psychological therapies (Herink, 1980) and more than 400 techniques with their associated variations (Kazdin, 1986) have been documented, considering all of them equally effective might seem rather utopian. Therefore, which treatments are really effective, which are not (or have not yet been demonstrated to be so) and even those that may be harmful would have to be verified from a scientific approach.

Such issues currently represent some of the most important and relevant approaches to the study of mental disorders in clinical psychology today (Barlow et al., 2013). Irrefutably, this methodological approach yields the best results and ensures greater reliability in the choice of psychological treatments, although unlike the evidence-based approach used in medicine and other disciplines, there are important limitations and methodological difficulties associated with the complexity of human behavior.

### ***6.1.2. The present research***

Our main objective was to analyze and compile lists of evidence-based psychological treatments by disorder using data provided by RCTs, meta-analyses, guidelines and systematic reviews of NICE, Cochrane, the Division 12 of the APA (D12) and the Australian Psychological Society. The data was then reviewed to compare the criteria, levels of evidence and lists of these organizations with the aim of analyzing the level of agreement among them for each diagnosis and for each treatment within disorders. Although these organizations differ from each other in terms of their type and overall goals, all of them share a common objective, which is to provide information about the efficacy of available psychological treatments for mental disorders.

### ***6.1.3. Description of the organizations included in the study***

#### ***6.1.3.1. Society of Clinical Psychology (Division 12) of the APA***

The APA is the leading scientific and professional organization representing psychology in the United States. APA's 54 divisions are interest groups organized by members. Some represent subdisciplines of psychology (e.g., experimental, social or clinical psychology), while others focus on topic areas such as aging, ethnic minorities or trauma. The Society of Clinical Psychology (Division 12) includes APA members who are active in practice, research, teaching, administration and/or conduct studies in the field of clinical psychology. Division 12 of the APA (D12) pioneered a wide range of

initiatives aimed at disseminating and identifying “best research evidence” as a major component of evidence-based practice (APA, 2006).

The website of the Society of Clinical Psychology describes the research evidence on effective treatments for psychological disorders. Basic descriptions are provided for each psychological disorder and treatment. Data can be searched by disorder and treatment type, and general information is provided about treatment manuals, training resources, measures, handouts and worksheets, self-help books, Smartphone apps, video demonstrations and descriptions, information on clinical trials, meta-analyses and systematic reviews and other treatment resources. However, inclusive information on the above-mentioned resources is not provided for every treatment. The website is an updated, online version of the original list of ESTs that was first published in 1995 as part of a D12 Task Force report. In 2008, the Committee on Science and Practice of D12 developed this online version of the research-supported treatments list to facilitate dissemination and to be easily revised in response to new research findings. In 2015, D12 undertook an initiative to revise the recommendation status of ESTs using existing systematic reviews and meta-analyses.

Based on the criteria proposed by Chambless et al. (1998) (well-established treatment and probably efficacious treatment), D12 classifies levels of evidence as strong (if criteria are met for well-established treatments), modest (if criteria are met for probably efficacious treatments), controversial research support (if studies of a given treatment yield conflicting results or if a treatment is efficacious but claims about why the treatment works are at odds with the research evidence), no research support and potentially harmful. Recently, D12 has begun to adapt its levels of evidence to the recommendations of Tolin, McKay, Forman, Klonsky and Thombs (2015) (i.e., very strong, strong, weak and insufficient evidence).

#### 6.1.3.2. *National Institute for Health and Care Excellence (NICE)*

NICE is an organization that is responsible for providing evidence-based guidance on health and social care to the National Health Services (NHS) in the UK, which works closely with other organizations such as NHS England, Public Health England or Health Education England. NICE publishes clinical guidelines, technology appraisal guidance, interventional procedures guidance and public health guidelines that make evidence-based recommendations on a wide range of health, public health and social care topics. Its competences range from providing information, education and advice to launching

campaigns and prevention programs for specific treatments for primary, secondary and specialized services, covering all medical specialties.

Every NICE guideline is developed by a different committee of experts, which includes members from clinical practice, public health and social care. In addition, all committees include at least two lay members, who can be patients, caregivers, service users or the general public. The committees conduct systematic reviews and network meta-analyses for evaluating and comparing the benefits and cost effectiveness of the different forms of treatment included in each guideline. The process to develop each guideline usually takes between 18 and 24 months, although there are “short clinical guidelines” that take between 11 and 13 months to produce and are generally used in cases where the development of a guide on an emerging problem is considered urgent. NICE classifies evidence by level in a hierarchy which is similar to that of D12, although different criteria are used. Level I includes the type of evidence obtained from meta-analyses and RCTs (at least one) and corresponds to recommendation grade “A”; level II includes evidence from at least one RCT without randomized groups, or a quasi study, and corresponds to grade “B”; level III, which includes descriptive studies (or those which do not fully meet the criteria in levels I and II), also corresponds to grade “B”; and level IV, which includes evidence obtained from expert committee reports or opinions and/or clinical experiences, corresponds to grade “C”.

More recently, the NICE guidelines were incorporated to the GRADE system for rating clinical guidelines (Atkins et al., 2004). The GRADE system classifies levels of evidence as high quality (further research is very unlikely to change our confidence in the estimate of the effect); moderate quality (further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate); low quality (further research is likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate) and very low quality (any estimate of effect is very uncertain).

#### *6.1.3.3. Cochrane Collaboration*

This organization comprises a network of researchers, practitioners, patients and caregivers from over 130 countries working cooperatively to provide evidence-based data in order to facilitate decision making about which treatment to choose for a particular disorder or health problem. The Cochrane collaborators are affiliated to the organization through Cochrane groups, which are review groups related to health topics, thematic

networks, groups involved in the methodology of systematic reviews and regional centers. These groups are established around the world and most of their work is done online. Each group is a “mini-organization” in itself, with its own funding, website and workload. Based on their interests, experience or geographical location, collaborators join a group or, in some cases, various groups.

The Cochrane groups perform systematic reviews and meta-analyses of specific health topics on all kinds of diseases. These reviews provide a summary of the results of available studies, mainly RCTs, which present information about the effectiveness of interventions in a specific health topic. Cochrane reports on evidence for and against treatments, treatment efficacy and treatment comparison studies to facilitate decision making in health care. Like NICE, Cochrane has also recently incorporated the GRADE model (Atkins et al., 2004) as criteria to determine the quality of evidence.

#### *6.1.3.4. The Australian Psychological Society (APS)*

The Australian Psychological Society (APS) is the premier professional organization for psychologists in Australia. The functions of the APS are conducted through more than 201 active member groups within the society. Each group consists of an elected committee that meets regularly and organizes activities, such as professional development. Evidence-based practice has become a central issue in the delivery of health care in Australia and, as such, government-sponsored health programs require the use of treatment interventions that are evidence-based as a means of discerning the allocation of funding.

The National Health and Medical Research Council (NHMRC) of Australia has published a guide for evaluating evidence and developing clinical practice guidelines. The NHMRC guide informs public health policy in Australia and has been adopted as a protocol for evidence reports by the APS. The NHMRC has developed a rating scale to designate the level of evidence of clinical studies: Level I – systematic review of all relevant randomized controlled trials; Level II – at least one properly designed randomized controlled trial; Level III-1 – well-designed pseudo-randomized controlled trials (alternate allocation or some other method); Level III-2 – comparative studies with concurrent controls and allocation not randomized (cohort studies) or interrupted time series with a control group; Level III-3 – comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group; and Level IV – case series, either post-test or pre-test and post-test.

APS has published a comprehensive review of the available evidence up to January 2010, which examines the efficacy of a broad range of psychological interventions across mental disorders affecting adults, adolescents and children (APS, 2010). This review of the literature examining the efficacy of a broad range of psychological interventions for the ICD-10 mental disorders has been undertaken to support the delivery of psychological services under government mental health initiatives. To determine the level of evidence of the treatments included in the review, APS uses the criteria developed by NHMRC mentioned above.

## **6.2. Method**

The methodology in this review is compliant with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) (Moher, Liberati, Tetzlaff, & Altman, 2009).

### **6.2.1. Search strategy**

We first consulted the websites of the organizations described above (APA, Division 12, [www.div12.org](http://www.div12.org); the Society of Clinical Psychology, [www.psychologicaltreatments.org](http://www.psychologicaltreatments.org); NICE, [www.nice.org.uk](http://www.nice.org.uk); Cochrane, [www.cochrane.org](http://www.cochrane.org); and the APS, [www.psychology.org.au](http://www.psychology.org.au)) to gather all the treatments, disorders and levels of evidence they report. In a second stage, we collected the RCTs, reviews and meta-analyses presented by each organization. The last date of access and updated information uploaded by the organization was July 2016.

As much of the data and studies were uploaded over five years ago and therefore may not be sufficiently up-to-date, the data were completed and updated with the research from the Web of Science-Social Science Citation Index, PsycInfo, Scopus, and Medline databases by introducing the name of the disorder AND RCT *or* meta-analysis *or* systematic review as search criteria.

### **6.2.2. Inclusion and exclusion criteria**

Owing to the sheer number of related disorders and treatments, we selected as our inclusion criteria only those investigated for mental disorders in adults. As a result, mental disorders in children and adolescents, dementia or cognitive impairment, problems related to health psychology, addictions, drug therapies and alternative therapies (art therapy, dance therapy, etc.) were excluded. In the case of Cochrane, the following were also excluded: reviews of specific population sectors (e.g., law enforcement agents, adults aged 60+), the reviews assessment tools, systematic reviews of studies on specific non-

psychological procedures (i.e., cranial magnetic stimulation or electroconvulsive therapy), systematic reviews of studies assessing diagnostic test accuracy and the protocol for a review.

### **6.2.3. Data collection process**

Treatment recommendations for the disorders included in this study can be found in the tables in the Results section. For each treatment, we specify the information on the evidence provided by the different organizations, while leaving the box corresponding to treatments for which there is no reference to evidence blank. We use the term “Insufficient Evidence” for those treatments in which an organization deems that there are not enough studies to consider the treatment effective. In addition, next to the level of evidence we specify the number of RCTs and meta-analyses or systematic reviews that each organization has used to reach their conclusions.

As a result, in the row corresponding to D12 we classify the quality of the evidence of a particular treatment as strong, modest, controversial, no research support or potentially harmful. Only for exposure and response prevention for the treatment of obsessive-compulsive disorder we classify the quality of the evidence as very strong, strong, weak or insufficient evidence. In the row corresponding to NICE we specify the grade of recommendation (A, B, C) for panic disorder, eating disorders, post-traumatic stress disorder, obsessive-compulsive disorder and body dysmorphic disorder, or level of evidence according to the GRADE criteria (high, moderate, low and very low) for generalized anxiety disorder, depression, bipolar disorder, schizophrenia, borderline personality disorder, and attention deficit hyperactivity disorder. Moreover, the guidelines for schizophrenia, social anxiety and specific phobias do not report the level of evidence; consequently, we only indicate whether a particular treatment is considered effective or non-effective for these disorders, without specifying their level of effectiveness in the tables. Finally, some treatments are accompanied by the indication “no evidence” or, when appropriate advised against using. In the case of Cochrane, we opted to show the data exactly as it appears in the systematic reviews we obtained from the system. Specifically, for all the reviews prior to 2010 and that of Fisher, Hetrick and Rushford (2010) we indicate whether a particular treatment is effective or non-effective, while for other reviews we indicate the level of evidence according to the GRADE criteria. Regarding APS, we specify the levels of evidence according to the criteria used



by the organization itself, which are described above (Level I, Level II, Level III-1, Level III-2, Level III-3 and Level IV).

Finally, the total number of organizations that report a given therapy as being effective is shown in the tables. For this purpose, we have considered that a therapy is deemed effective by an organization in the following cases: APA: strong, modest or controversial; NICE: A, B, C, high, moderate, low, very low or effective; Cochrane: high, moderate, low, very low or effective; APS: level I, level II, level III-1, level III-2, level III-3 or level IV.

#### **6.2.4. Statistical analysis**

To analyze agreement among organizations, we have classified the different levels of evidence proposed by each organization into an ordinal scheme: no evidence, weak evidence, moderate evidence and strong evidence (see Table 6.1). In the case of NICE for depression and D12 for bipolar disorder, where two different levels of evidence may appear for a treatment (see Table 6.5 and Table 6.7, respectively), we have used the higher level of evidence.

The intra-class correlation (ICC) is one of the most commonly-used statistics for assessing inter-rater reliability (IRR) for ordinal, interval and ratio variables (Hallgren, 2012). IRR was performed using a two-way mixed, consistency, average-measures ICC to assess the level of agreement among organizations for each diagnosis, taking into account only those therapies considered effective by at least one institution.

According to Hallgren (2012), higher ICC values suggest a greater IRR, with an ICC estimate of 1 indicating perfect agreement and 0 indicating only random agreement. Moreover, this author states that negative ICC estimates indicate systematic disagreement, and some ICCs may be less than  $-1$  when there are three or more coders. The cutoffs proposed by Cicchetti (1994) for the qualitative rating of agreement based on ICC values were used, with IRR being poor for ICC values less than .40, fair for values between .40 and .59, good for values between .60 and .74, and excellent for values between .75 and 1.

**Table 6.1. Ordinal scheme to classify the different levels of evidence**

	<b>D12</b>	<b>NICE</b>	<b>COCHRANE</b>	<b>APS</b>
<b>No evidence</b>	No research support; Potentially harmful	Insufficient evidence; Non effective, Not recommended for use	Insufficient evidence; Non effective	Insufficient evidence
<b>Weak evidence</b>	Controversial	C; Very low; Low	Very low; Low	Level IV; Level III-3; Level III-2
<b>Moderate evidence</b>	Modest; Modest-Controversial	B; Low to moderate; Moderate	Low to moderate; moderate	Level III-1; Level II
<b>Strong evidence</b>	Strong; Strong-Controversial	A; Moderate to high; High; Effective	Moderate to high; High; Effective	Level I

### 6.3. Results

#### 6.3.1. Search results

On the APA Division 12 website, the results presented for disorder or treatments and the level of evidence for each one includes a list of 17 diagnostic categories. In accordance with the inclusion criteria, 13 categories were analyzed, giving rise to a total of 15 mental disorders and 64 psychotherapeutic interventions associated with them.

On the NICE website, we consulted the guidelines relating to mental disorders and reviewed sections corresponding to evidence-based treatments (RCTs and meta-analyses). Of the 33 guidelines belonging to the Mental Health and Behavioral Conditions group, 12 met the criteria for inclusion in our review, providing information on 16 disorders and 73 therapies.

We analyzed the systematic reviews provided by Cochrane for the group of mental disorders in adults and obtained data from the evidence for each of the treatments reviewed. The Cochrane website includes a total of 939 reviews belonging to the Mental Health and Developmental, Psychosocial & Learning Problems group. Of these, 37 met the criteria for inclusion in our analysis, providing evidence of 51 psychological treatments for 16 disorders.

Finally, we incorporated the lists of treatments included in the document published by APS (2010). This guide includes 24 disorders in the interventions in adults section. Consistent with the inclusion criteria, 21 disorders relating to 68 interventions were selected.

### **6.3.2. Agreement for included disorders**

In the tables below we compare whether there is agreement among the four organizations regarding each treatment within the disorders.

#### *6.3.2.1. Anxiety disorders*

##### *Generalized anxiety disorder*

In reviewing the treatments included by the four organizations for generalized anxiety disorder (GAD), we found six different types of treatments supported by some degree of evidence (see Table 6.2). ICC (.889) indicates excellent agreement among organizations for this disorder. Cognitive behavioral therapy (CBT) was the treatment with the highest degree of agreement (four organizations deem it effective). However, the other treatments included on the list were deemed effective by one or two institutions, with some discrepancies as to the effectiveness of psychodynamic therapy (PDT). For example, APS grants a Level II of evidence for PDT, while NICE does not recommend this therapy as a treatment for GAD.

##### *Panic disorder*

We found 11 types of treatments for panic disorder (PD) supported by some degree of evidence when reviewing the treatments included by the organizations (see Table 6.2). ICC (.485) indicates fair agreement among organizations for this disorder. CBT was the treatment that obtained the highest level of agreement (four organizations consider it effective), while the other treatments were regarded as effective by one or two institutions.

##### *Social anxiety disorder*

When analyzing treatments for social anxiety disorder (SAD), we found seven different types of treatments supported by some degree of evidence (see Table 6.2). ICC (.435) indicates fair agreement among organizations for this disorder. CBT was the treatment that obtained the highest degree of agreement (three organizations consider it effective). In contrast, the other treatments analyzed were considered effective by one or two institutions, while discrepancies in interpersonal psychotherapy (IPT) were also observed, given that this therapy is deemed effective by APS (2010), while NICE (2013a) considers it to be non-effective.

**Table 6.2. Anxiety Disorders. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	ACT	AR	BT	CBT	CCBT	CT	ET	IPT	MDFN	PDT	PE	SHT	SST	ST
<i>Generalized Anxiety Disorder</i>														
<b>D12</b>	---	---	---	Strong 10/5	---	---	---	---	---	---	---	---	---	---
<b>NICE (2011)</b>	---	Moderate 4/0	---	Moderate to High 21/0	---	---	---	---	---	NR 2/0	Low to moderate 2/0	Low 10/0	---	NR 3/0
<b>Cochrane (Hunot et al., 2007)</b>	---	---	---	Effective 22/0	---	---	---	---	---	IE 1/0	---	---	---	IE 7/0
<b>APS (2010)</b>	---	---	---	Level I 1/1	---	---	---	---	Level IV 0/0	Level II 1/0	---	Level IV 0/0	---	---
<b>No. of organizations in agreement</b>	---	1	---	4	---	---	---	---	1	1	1	2	---	---
<i>Panic Disorder</i>														
<b>D12</b>	---	Modest 2/0	---	Strong 6/7	---	---	---	---	---	Modest 1/1	---	---	---	---
<b>NICE (2011)</b>	---	---	---	A 19/1	Moderate to High 6/0	---	---	---	---	---	---	A 3/0	---	---
<b>Cochrane (Furukawa et al., 2007; Pompoli et al., 2016; Watanabe et al. 2009)</b>	Low 2/0	Low 12/0	Effective-Low 27/0	Effective-Low 52/0	---	Low 6/0	---	---	Low 2/0	Low 2/0	Low 1/0	---	---	Low 3/0
<b>APS (2010)</b>	---	---	---	Level I 3/2	---	---	---	IE 0/1	---	IE 1/2	Level II 0/0	Level II 2/1	---	---
<b>No. of organizations in agreement</b>	1	2	1	4	1	1	---	---	1	2	2	2	---	1
<i>Social Anxiety Disorder</i>														
<b>D12</b>	---	---	---	Strong 8/7	---	---	---	---	---	---	---	---	---	---
<b>NICE (2013a)</b>	---	---	---	Effective 42/0	---	---	Effective 8/0	Non effective 2/0	Non effective 3/0	Effective 3/0	---	Effective 16/0	Effective 8/0	---
<b>Cochrane</b>	---	---	---	---	---	---	---	---	---	---	---	---	---	---
<b>APS (2010)</b>	Level IV 0/0	---	---	Level I 0/1	---	---	---	Level III-1 1/0	---	Level II <sup>a</sup> 2/0	---	Level II 3/0	---	---
<b>No. of organizations in agreement</b>	1	---	---	3	---	---	1	1	---	2	---	2	1	---
<i>Specific Phobias</i>														
<b>D12</b>	---	---	---	---	---	---	Strong 28/3	---	---	---	---	---	---	---
<b>NICE (2013a)</b>	---	---	---	---	---	---	Effective 4/0	---	---	---	---	---	---	---
<b>Cochrane</b>	---	---	---	---	---	---	---	---	---	---	---	---	---	---
<b>APS (2010)</b>	---	---	---	---	---	---	Level I <sup>b</sup> 1/1	---	---	---	---	Level II 1/0	---	---
<b>No. of organizations in agreement</b>	---	---	---	---	---	---	3	---	---	---	---	1	---	---

Note: ACT = Acceptance and Commitment Therapy; AR = Applied Relaxation; BT = Behavioral Therapy; CBT = Cognitive Behavioral Therapy; ET = Exposure Therapies; IPT = Interpersonal Therapy; MDFN = Mindfulness; PDT = Psychodynamic Therapy; PE = Psychoeducation; SHT = Self-Help Therapy; SST = Social Skill Training; ST = Supportive Therapy  
 NR= Not recommended for use; IE = Insufficient Evidence; <sup>a</sup> As adjunct to medication; <sup>b</sup> Exposure-based CBT

### *Specific phobias*

We found two different types of treatments supported by some degree of evidence when reviewing treatments for specific phobias (see Table 6.2). ICC (.816) indicates excellent agreement among organizations for this disorder. Exposure therapies were the treatments that obtained the highest level of agreement (three organizations regard it as effective).

#### *6.3.2.2. Eating disorders*

##### *Anorexia nervosa*

When reviewing the treatments documented for anorexia nervosa (AN), we found five different treatments supported by some degree of evidence (see Table 6.3). ICC (.741) indicates good agreement among organizations for this disorder. Family-based treatment (FBT) and CBT obtained the highest levels of agreement (four and three organizations, respectively, deem it effective). However, other types of treatments were considered effective by one or two institutions.

##### *Bulimia nervosa*

We found six treatments supported by some degree of evidence when reviewing treatments for bulimia nervosa (see Table 6.3). ICC (.819) indicates excellent agreement among organizations for this disorder. CBT and IPT both obtained the maximum degree of agreement (four organizations consider it effective), while self-help therapy was regarded as effective by three institutions. Although CBT and IPT both obtained the maximum degree of agreement, all the organizations conferred CBT the highest level of evidence, while NICE (2004) and APS (2010) report a level of evidence B and Level III-3 for IPT, respectively.

##### *Binge eating disorder*

When analyzing the treatments that the four organizations included for binge eating disorder (BED), we found four different treatments supported by some degree of evidence (see Table 6.3). ICC (.396) indicates poor agreement among organizations for this disorder. The therapy that obtained the highest level of agreement was CBT (four organizations consider it effective), while IPT and self-help therapy were deemed effective by three organizations and dialectical behavior therapy (DBT) was considered effective by two of them.

**Table 6.3. Eating disorders. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	CAT	CBT	DBT	FBT	HWP	IPT	PDT	SHT
<b>Anorexia Nervosa</b>								
<b>D12</b>	---	Modest - Controversial 4/0	---	Strong 9/2	---	---	---	---
<b>NICE</b> (2004)	C 2/0	C 3/0	---	C 4/0	---	C 1/0	C 2/0	---
<b>Cochrane</b> (Fisher et al., 2010)	---	---	---	Effective 13/0	---	---	---	---
<b>APS</b> (2010)	---	Level III-2 1/1	---	Level II 1/1	---	---	Level II 1/0	---
<b>No. of organizations in agreement</b>	1	3	---	4	---	1	2	---
<b>Bulimia Nervosa</b>								
<b>D12</b>	---	Strong 6/0	---	Modest 2/0	Controversial 3/0	Strong 7/0	---	---
<b>NICE</b> (2004)	---	A 23/0	---	---	---	B 3/0	---	B 5/0
<b>Cochrane</b> (Hay et al., 2009; Perkins et al., 2006)	---	Effective 26/0	---	---	---	Effective 2/0	---	Effective 9/0
<b>APS</b> (2010)	---	Level I 0/1	Level II 0/1	---	---	Level III- 3 0/0	---	Level II 1/0
<b>No. of organizations in agreement</b>	---	4	1	1	1	4	---	3
<b>Binge Eating Disorder</b>								
<b>D12</b>	---	Strong 5/0	---	---	---	Strong 3/0	---	---
<b>NICE</b> (2004)	---	A 6/0	B 1/0	---	---	B 2/0	---	B 2/0
<b>Cochrane</b> (Hay et al., 2009; Perkins et al., 2006)	---	Effective 3/0	---	---	---	Effective 3/0	---	Effective 9/0
<b>APS</b> (2010)	---	Level I 1/1	Level II 0/1	---	---	---	---	Level I 0/1
<b>No. of organizations in agreement</b>	---	4	2	---	---	3	---	3

Note: CAT = Cognitive analytic therapy; CBT = Cognitive behavioral therapy; DBT = Dialectical behavior therapy; FBT = Family-based treatment; HWP = Healthy weight program; IPT = Interpersonal therapy; PDT = Psychodynamic therapy; SHT= Self-help therapy

### 6.3.2.3. Posttraumatic stress disorder

In examining treatments for posttraumatic stress disorder (PTSD), we found seven different types of treatments supported by some degree of evidence (see Table 6.4). ICC (.435) indicates fair agreement among organizations for this disorder. Eye movement desensitization and reprocessing (EMDR) was the treatment that obtained the highest degree of agreement (four organizations consider it effective), although there is some controversy regarding its use. CBT was regarded effective by three organizations, while the other treatments were considered effective by only one institution.

**Table 6.4. Post-traumatic Stress Disorder. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	CBT	CPT	Debriefing	EMDR	PCT	PEX	SIT	SS
<b>D12</b>	---	Strong 16/0	No research support - Potentially harmful 1/2	Strong - Controversial 4/0	Strong 3/0	Strong 8/3	Modes t 2/0	Strong 3/0
<b>NICE</b> (2005)	A <sup>1</sup> or B <sup>2</sup> 24/0	---	Non effective 7/0	A 11/0	---	---	---	---
<b>Cochrane</b> (Bisson et al. 2013; Roberts et al., 2010; Rose et al. 2002)	Very low 64/0	---	Non effective 15/0	Very low 16/0	---	---	---	---
<b>APS</b> (2010)	Level I 6/2	---	---	Level I (This intervention was not included in the review)	---	---	---	---
<b>No. of organizations in agreement</b>	3	1	---	4	1	1	1	1

Note: CBT = Cognitive Behavioral Therapy; CPT = Cognitive Processing Therapy; EMDR = Eye Movement Desensitization and Reprocessing; PCT = Present-Centered Therapy; PEX = Prolonged Exposure; SIT = Stress Inoculation Therapy; SS = Seeking Safety (for PTSD with co-morbid Substance Use Disorder)

<sup>1</sup>Before three months; <sup>2</sup>After three months

#### 6.3.2.4. Adjustment disorder

The only organizations that document effective psychological treatments for adjustment disorders are Cochrane and APS, which provided three different treatments supported by some degree of evidence. ICC (-8.0) indicates systematic disagreement among organizations for this disorder. APS (2010) confers Level III-1 evidence to CBT (one RCT) and Level IV (one non-experimental study) to mindfulness-based cognitive therapy (MBCT). In contrast, the Cochrane database contains a review which indicates that CBT is not effective for adjustment disorders since only moderate-quality evidence (three RCTs) was found to demonstrate that this therapy does not reduce the return-to-work period compared to no treatment (Arends et al., 2012). The authors also found moderate-quality evidence (five RCTs) to support the use of problem-solving therapy (PST) as an effective treatment for this disorder.

#### 6.3.2.5. Depression

When analyzing the therapies for depression, we found 23 different types of treatments supported by some degree of evidence (see Table 6.5). ICC (.022) indicates poor agreement among organizations for this disorder. Several therapies were deemed effective by three institutions (behavior activation therapy, CBT, IPT, PST, ACT, PDT and couples therapy), but none of them obtained the consensus of the four organizations. The other treatments studied were regarded as effective by less than three institutions, 12 of which are considered effective by only one organization.

**Table 6.5. Depression. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	ACT	AR	BAT	CBASP	CBT	CCBT	COMET	COT	CT	Counselling	DBT	EFT
<b>D12</b>	Modest 2/2	---	Strong 5/4	Strong 5/0	---	---	---	Modest 5/1	Strong 14/9	---	---	Modest 4/0
<b>NICE (2010b)</b>	<i>SRM</i> ---	---	Low <sup>a</sup> 2/0	---	High <sup>b</sup> 2/0	Low <sup>g</sup> 7/0	---	High <sup>i</sup> 2/0	---	Low <sup>j</sup> 1/0	---	---
	<i>CRM</i> ---	---	Low <sup>a</sup> 2/0	---	Low <sup>b</sup> 1/0	---	---	---	---	---	---	---
<b>Cochrane *</b>	Very low 4/0	Effective 15/0	Very low 2/0	---	Very low 3/0	---	Very low 1/0	Effective 8/0	---	---	---	---
<b>APS (2010)</b>	Level III-1 1/0	---	---	---	Level I 7/3	---	---	---	---	---	Level II 1/0	Level II 2/0
<b>No. of organizations in agreement</b>	3	1	3	1	3	1	1	3	1	1	1	2
	IPT	FT	MBCT	PA	PDT	PE	PST	REBT	RT	SCT	SHT	SST
<b>D12</b>	Strong 17/4	---	---	---	Modest 1/6	---	Strong 15/7	Modest 1/0	Modest 6/2	Strong 10/0	---	Modest 2/0
<b>NICE (2010b)</b>	<i>SRM</i> Low <sup>c</sup> 1/0	---	---	Moderate <sup>h</sup> 7/0	---	---	Moderate <sup>d</sup> 1/0	Low <sup>e</sup> 1/0	---	---	Low <sup>f</sup> 2/0	---
	<i>CRM</i> Moderate <sup>c</sup> 1/0	---	---	Moderate <sup>h</sup> 5/0	Moderate <sup>k</sup> 1/0	---	Moderate <sup>d</sup> 1/0	Low <sup>e</sup> 1/0	---	---	---	---
<b>Cochrane **</b>	---	IE 6/0	---	Moderate 37/0	---	---	---	---	---	---	---	---
<b>APS (2010)</b>	Level I 2/2	---	Level III-2 0/1	---	Level I 2/2	Level II 2/0	Level II 1/0	---	---	---	Level I 4/2	---
<b>No. of organizations in agreement</b>	3	---	1	2	3	1	3	2	1	1	2	1

Note: ACT = Acceptance and Commitment Therapy; AR = Applied Relaxation; BAT = Behavior Activation Therapy; CBASP = Cognitive Behavioral Analysis System of Psychotherapy; CBT = Cognitive Behavioral Therapy; CCBT = Computerized Cognitive Behavioral Therapy; COMET = Competitive Memory Training; COT = Couples Therapy; CT = Cognitive Therapy; DBT = Dialectical Behavior Therapy; EFT = Emotion-Focused Therapy; IPT = Interpersonal Therapy; FT = Family Therapy; MBCT = Mindfulness-Based Cognitive Therapy; PA = Physical Activity; PDT = Psychodynamic Therapy; PE = Psychoeducation; PST = Problem-Solving Therapy; REBT = Rational Emotive Behavior Therapy; RT: Reminiscence Therapy; SCT = Self-Control Therapy; SHT = Self-Help Therapy; SST = Self-System Therapy

IE = Insufficient Evidence; SRM = Self-report measures supervised; CRM = Clinician-report measures supervised

<sup>a</sup> BAT versus antidepressants; <sup>b</sup> CBT versus waitlist control; <sup>c</sup> IPT versus placebo; <sup>d</sup> PST versus placebo; <sup>e</sup> REBT versus antidepressants; <sup>f</sup> Individual guided self-help with support; <sup>g</sup> CCBT versus waitlist control; <sup>h</sup> Physical activity supervised; <sup>i</sup> COT versus waitlist control; <sup>j</sup> Counselling versus antidepressants; <sup>k</sup> PDT versus waitlist

\* Barbato & Avanzo, 2006; Churchill et al., 2013; Hunot, Moore, Caldwell, Furukawa, Davies, Jones, Honyashiki, Chen, Lewis, & Churchill, 2013

\*\*Cooney et al., 2013; Henken, Huibers, Churchill, Restifo, & Roelofs, 2007; Jorm, Morgan, & Hetrick, 2008



### 6.3.2.6. Obsessive-compulsive disorder

We found four different treatments supported by some degree of evidence when reviewing those relating to obsessive-compulsive disorder (OCD) (see Table 6.6). ICC (.809) indicates excellent agreement among organizations for this disorder. CBT was the treatment that obtained the highest degree of agreement (four organizations regard it to be effective). Although the other therapies were deemed effective by one or two institutions, there was some discrepancies among the organizations. D12 is the only organization that differentiates exposure and response prevention (ERP) from CBT, rating both therapies as having strong level of evidence. In contrast, ERP is included within the concept of CBT by NICE (2006), Cochrane (Gava et al., 2007) and APS (2010). On the other hand, ACT is considered effective by D12 and APS (2010), while NICE (2013b), although suggesting that ACT can improve the symptoms of OCD, does not specifically recommend its use because it is unaware of the relative effectiveness of ACT in relation to CBT with ERP.

**Table 6.6. Obsessive-Compulsive Disorder. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	ACT	CBT	ERP	SHT
<b>D12</b>	Modest 1/0	Strong 6/6	Strong 7/1	---
<b>NICE</b> (2006; 2013b)	IE 1/0	B 29/0	---	---
<b>Cochrane</b> (Gava et al., 2007)	---	Effective 8/0	---	---
<b>APS</b> (2010)	Level IV 0/0	Level I 3/1	---	Level II 0/1
<b>No. of organizations in agreement</b>	2	4	1	1

Note: ACT = Acceptance and Commitment Therapy; CBT =Cognitive Behavioral Therapy; ERP = Exposure and Response Prevention; SHT = Self-Help Therapy  
IE = Insufficient Evidence

### 6.3.2.7. Bipolar disorder

In our review of the treatments associated with bipolar disorder, we found 10 different treatments supported by some degree of evidence (see Table 6.7). ICC (.075) indicates poor agreement among organizations for this disorder. Family-focused therapy (FFT) and interpersonal and social rhythm therapy (IPSRT) were the treatments that obtained the highest level of agreement (three organizations consider them effective), while the other treatments were regarded as effective by less than three institutions.

**Table 6.7. Bipolar Disorder. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	<b>CBT</b>	<b>CT</b>	<b>FFT</b>	<b>FP</b>	<b>GT</b>	<b>ICIT</b>	<b>IPSRT</b>	<b>MBCT</b>	<b>PE</b>	<b>SC</b>
<b>D12 Support for mania</b>	---	Modest 6/0	NRS 7/0	---	---	---	NRS 2/2	---	Strong 4/0	Strong 3/0
<b>D12 Support for depression</b>	---	Modest 6/0	Strong 7/0	---	---	---	Modest 2/2	---	Modest 4/0	NRS 3/0
<b>NICE (2014a)</b>	Low <sup>a</sup> 1/0	---	Low <sup>a</sup> 1/0	Low <sup>a</sup> 1/0	Very low <sup>a</sup> 8/0	Low <sup>a</sup> 1/0	Very Low <sup>a</sup> 1/0	---	---	Low <sup>a</sup> 2/0
<b>Cochrane (Justo et al. 2007)</b>	---	---	IE 7/0	---	---	---	---	---	---	---
<b>APS (2010)</b>	Level II <sup>b</sup> 0/1	---	Level II <sup>b</sup> 0/1	---	---	---	Level II <sup>b</sup> 0/1	Level II <sup>b</sup> 1/0	Level II <sup>b</sup> 2/1	---
<b>No. of organizations in agreement</b>	2	1	3	1	1	1	3	1	2	2

Note: CBT = Cognitive Behavioral Therapy; CT = Cognitive Therapy; FFT = Family-Focused Therapy; FP =Family Psychoeducation; GT = Group Therapy; ICIT = Integrated Cognitive and Interpersonal Therapy; IPSRT = Interpersonal and Social Rhythm Therapy; MBCT = Mindfulness-Based Cognitive Therapy; PE = Psychoeducation; SC = Systematic Care

NRS = No Research Support; IE = Insufficient Evidence

<sup>a</sup> Quality of evidence for depression symptoms at post-treatment; <sup>b</sup> Adjunct to medication

#### 6.3.2.8. *Schizophrenia*

An analysis of the treatments for schizophrenia revealed 11 treatments supported by some degree of evidence (see Table 6.8). ICC (.704) indicates good agreement among organizations for this disorder. CBT and FFT obtained the highest degree of agreement (four organizations consider them effective). However, the remaining nine treatments were deemed effective by one or two institutions, with some discrepancies among the organizations for various therapies (i.e., social skills training, cognitive remediation).

#### 6.3.2.9. *Personality disorders*

##### *Borderline personality disorder*

Twelve treatments supported by some degree of evidence were found with regard to borderline personality disorder (BPD) (see Table 6.9). ICC (.53) indicates fair agreement among organizations for this disorder. DBT was the treatment that obtained the highest level of agreement (four organizations deem it effective), followed by mentalization-based treatment (MBT) and schema-focused therapy (SFT), which were considered effective by three institutions.

##### *Antisocial personality disorder*

Few psychological interventions have been developed specifically for the treatment of antisocial personality disorder (ASPD) (NICE, 2010a), which might explain why this disorder is only documented in NICE and Cochrane. NICE (2010a) indicates that the evidence for the treatment of ASPD in the community is limited to one trial (Davidson et al., 2009). The authors compared CBT with treatment as usual for people with ASPD living in the community and did not find an effect for CBT on anger or verbal aggression compared with treatment as usual, however they found a small, non-significant effect for social functioning and physical aggression compared with treatment as usual. As a result, they conclude that further research is likely to have an impact on the effect estimate of CBT in the community for people with ASPD (NICE, 2010a). In contrast, Cochrane includes a review by Gibbon and colleagues (2010) on 11 RCTs, in which they assess the benefits of psychological treatments in adults with ASPD. The results suggest that there is insufficient evidence to justify the use of any psychological intervention in adults with this disorder.

**Table 6.8. Schizophrenia. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	<b>ACT</b>	<b>ASCT</b>	<b>AT</b>	<b>CAT</b>	<b>CBT</b>	<b>CR</b>	<b>FFT</b>	<b>IMR</b>	<b>PDT</b>	<b>PE</b>	<b>PSS</b>	<b>SE</b>	<b>SST</b>	<b>ST</b>	<b>TEP</b>
<b>D12</b>	Modest 4/0	Strong 3/3	---	Modest 2/0	Strong 6/3	Strong 7/3	Strong 5/1	Modest 1/1	---	---	---	Strong 7/0	Strong 5/2	---	Strong 1/3
<b>NICE (2014b)</b>	---	---	IE 5/0	---	Effective 31/0	IE 17/0	Effective 32/0	---	IE 2/0	IE 16/0	---	---	IE - Non Effective 20/0	IE 17/0	---
<b>Cochrane *</b>	---	---	IE 1/0	---	Very low to low 20/0	IE 3/0	Low 53/0	---	Non Effective 4/0	Very low to moderate 64/0	IE 3/0	Very low 14/0	Very low 13/0	IE 24/0	IE
<b>APS (2010)</b>	---	---	---	---	Level I 3/3	---	Level I 1/1	---	IE 0/1	IE 0/1	IE 0/0	---	---	---	---
<b>No. of organizations in agreement</b>	1	1	---	1	4	1	4	1	---	1	---	2	2	---	1

Note: ACT = Acceptance and Commitment Therapy; ASCT = Assertive Community Treatment; AT = Adherence Therapy; CAT = Cognitive Adaptation Training; CBT = Cognitive Behavioral Therapy; CR = Cognitive Remediation; FFT = Family-Focused Therapy; IMR = Illness Management and Recovery; PDT = Psychodynamic Therapy; PE = Psychoeducation; PSS = Problem Solving Skills; SE = Supported Employment; SST = Social Skills Training; ST = Supportive Therapy; TEP = Token Economy Programs

IE = Insufficient Evidence

\* Almerie et al., 2015; Buckley, Maayan, Soares-Weiser, & Adams, 2015; Jones, Hacker, Cormac, Meaden, & Irving, 2012; Kinoshita et al., 2013; Malmberg, Fenton, & Rathbone, 2001; McGrath & Hayes, 2000; McIntosh, Conlon, Lawrie, & Stanfield, 2006; McMonagle, & Sultana, 2000; Pharoah, Mari, Rathbone, & Wong, 2010; Xia & Li, 2007; Xia, Merinder, & Belgamwar, 2011; Zhao, Sampson, Xia, & Jayaram, 2015

**Table 6.9. Borderline Personality Disorder. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	CAT	CBT	DBT	ERG	IPT	MACT	MBT	PDT	PE	SFT	STEPSS	TFT
<b>D12</b>	---	---	Strong 6/4	---	---	---	Modest 3/0	---	---	Modest 1/0	---	Strong - Controversial 3/0
<b>NICE</b> (2009a)	Very low to Moderate 1/0	Very low to Moderate 1/0	Very low to Moderate 9/0	---	---	Very low 2/0	Very low to Moderate 1/0	IE 1/0	---	IE 1/0	Very low to Moderate 1/0	IE 1/0
<b>Cochrane</b> (Stoffers et al., 2012)	---	Moderate 3/0	Low to Moderate 8/0	Low 1/0	Low 2/0	Low 2/0	Low to Moderate 2/0	Low 1/0	Low 1/0	Low 3/0	Moderate 2/0	Moderate 2/0
<b>APS</b> (2010)	---	IE 1/0	Level I 3/1	---	---	---	---	Level II 3/0	---	Level II 3/0	---	---
<b>No. of organizations in agreement</b>	1	2	4	1	1	2	3	2	1	3	2	2

Note: CAT = Cognitive Analytic Therapy; CBT = Cognitive Behavioral Therapy; DBT = Dialectical Behavior Therapy; ERG = Emotion Regulation Group Training; IPT = Interpersonal Therapy; MACT = Manual-Assisted Cognitive Therapy; MBT = Mentalization-Based Treatment; PDT = Psychodynamic Therapy; PE = Psychoeducation SFT = Schema-Focused Therapy; STEPSS = Systems training for emotional predictability and problem solving; TFT = Transference-Focused Therapy  
IE = Insufficient Evidence

### 6.3.2.10. *Other disorders*

#### *Insomnia*

Psychological treatment for insomnia has only been documented by D12 and APS (2010), which found eight different interventions supported by some degree of evidence. ICC (-.112) indicates systematic disagreement among organizations for this disorder. D12 reports a strong level of evidence for CBT (3 RCTs/1 meta-analysis or systematic reviews), sleep restriction therapy (2/1), stimulus control therapy (4/2), relaxation therapy (3/2) and paradoxical intention (1/3), and a modest level of evidence for electromyographic biofeedback (4/1). In turn, APS (2010) confers a Level I to CBT (1/4) and self-help therapy (0/1) and a Level IV to MBCT (0/1). Consequently, of all the therapies included in the study, only CBT is considered effective by the two organizations.

#### *Attention deficit hyperactivity disorder (adults)*

Psychological treatment for attention deficit hyperactivity disorder in adults has been studied by D12, NICE and APS, who report three different types of treatments supported by some degree of evidence. ICC (.731) indicates good agreement among organizations for this disorder. The only treatment that D12 and NICE (2009b) consider effective for this disorder is CBT, which was rated as having strong (four RCTs) and moderate (one RCT) levels of evidence, respectively. However, in addition to considering CBT effective and giving it a Level II (two systematic reviews) rating, APS (2010) also considers MBCT (Level IV; one systematic review) and DBT (Level III-1; one systematic review) to be effective for this disorder. As a result, CBT is the only therapy deemed effective by more than one organization (three organizations consider it effective).

#### *Hypochondriasis*

The only organizations that provide information about effective psychological treatments for hypochondriasis are Cochrane and APS (2010), which present six different types of treatments supported by some degree of evidence. ICC (-1.39) indicates systematic disagreement among organizations for this disorder. Cochrane considers the following treatments effective for this disorder: CBT (three RCTs), cognitive therapy (two RCTs), behavioral therapy (one RCT), and behavioral stress management (one RCT) (Thomson & Page, 2007). In contrast, APS (2010) confers Level I evidence to CBT (two RCTs/one meta-analysis) and psychoeducation (one RCT/one meta-analysis) and Level

III-2 to self-help therapy (one comparative study). Once again, CBT is the only therapy to be considered effective by two organizations.

#### *Body dysmorphic disorder*

For this disorder, which is included by all the organizations except D12, evidence-based support is only available for CBT. Consequently, NICE (2006) gives CBT a level of evidence B (two RCTs). Cochrane (Ipser, Sander, & Stein, 2009) suggests that CBT may be useful in treating patients with this disorder (three RCTs) and APS (2010) confers a Level I of evidence (two meta-analyses and systematic reviews). The ICC for this disorder could not be calculated because there are too few cases.

#### *6.3.2.11. Disorders documented by a single organization*

This section includes sexual disorders, dissociative disorders, somatization disorder and conversion disorder. The ICC obtained for sexual disorders and somatization disorder was 0, thus indicating random agreement among organizations for these diagnoses. The ICC for dissociative disorders could not be calculated because there are too few cases.

Sexual disorders are only documented by APS (2010), which assigns a Level I of evidence to self-help therapy (one RCT and one meta-analysis), and a Level II to CBT (one RCT) and IPT (one RCT). This organization is also the only one documenting evidence for dissociative disorders, for which it confers a Level IV of evidence to CBT (one systematic review), and somatization disorder giving a Level I of evidence to CBT (one systematic review) and a Level II to family therapy (studies not included by APS) and PDT (studies not included). Finally, conversion disorder is documented in only one review by Cochrane (Ruddy & House, 2005), which concludes that the use of psychosocial interventions for conversion disorder require more research and it is not possible to draw any conclusions about their potential benefits or harm from the studies included (three RCTs).

### **6.4. Discussion**

Although the validation of psychological treatments using scientific methods is the predominant approach in clinical psychology today, it is still subject to important limitations, methodological criticisms and proposals for improvement (Allen & Kadden, 1995; Barlow, et al., 2013; Borckardt, Nash, Murphy, Moore, Shaw, & O'Neil, 2008; Garfield, 1996; Hunsley, 2007; Hunsley & Lee, 2007; Kazdin, 1996, 2008; Kratochwill, 2007; Martínez & Moriana, 2009; Rodríguez, 2004; Silverman, 1996; Wampold, 2007).

The objective of this study was to compile a list of evidence-based psychological treatments by disorder. For this purpose, data provided by four international organizations were used to analyze the level of agreement among them regarding each diagnosis and each treatment within the disorders. The results of the analysis showed that agreement is low for most of the disorders, as only seven have achieved an acceptable ICC. Excellent agreement among organizations was found for four disorders (generalized anxiety disorder, specific phobias, bulimia nervosa and obsessive-compulsive disorder), while good agreement was observed for three disorders (anorexia nervosa, schizophrenia and attention deficit hyperactivity disorder). For all other treatments, the agreement among institutions was low.

The main findings of this study highlight the existing discrepancies in the evidence presented by different organizations reporting on the effectiveness of psychological treatments. These organizations differ not only in terms of the level of evidence they provide, but also in term of the treatments of choice and interventions that have no positive effects (Moriana & Martínez, 2011). These discrepancies may be due to several reasons. One of the possible causes may be that the procedures or committees are biased. In the case of D12, for example, it is not clear what constitutes good experimental designs (Kazdin, 2000) and the evidence provided by NICE and Cochrane may be influenced as it relies on the meta-analyses which they commission. The fact that numerous treatments are considered effective by a single organization may support this theory. In most cases, these institutions only provide information on treatments they consider effective with a higher or lower level of evidence. Therefore, we cannot know why they do not recommend certain treatments. This is evident in depression, where 12 out of 23 treatments are considered effective by only one organization, as well as in post-traumatic stress disorder, where five out of seven treatments are considered effective only by D12.

Another possible cause of these discrepancies may be that different RCTs or meta-analyses were reviewed. The analysis of the main discrepancies shows that, in most cases, the institutions use different studies to determine the quality of the evidence. For example, in the case of generalized anxiety disorder, APS (2010) grants a Level II of evidence for psychodynamic therapy based on the RCT of Leichsenring and colleagues (2009) and the non-randomized controlled trial of Ferrero and colleagues (2007), while NICE (2011) does not recommend this therapy as a treatment for GAD based on the RCT of Durham, Murphy, Allan, Richard, Treiving, and Fenton (1994) and the RCT of Crits-Christoph,



Gibbons, Narducci, Schamberger, and Gallop (2005). Regarding adjustment disorder, APS (2010) confers Level III-1 evidence to CBT based on the pseudo-randomized controlled trial of Van der Klink, Blonk, Schene, and Van Dijk (2003), while Cochrane (Arends et al., 2012) indicates that CBT is not effective for adjustment disorders based on the studies of Blonk, Brenninkmeijer, Lagerveld, and Houtman (2006), de Vente, Kamphuis, Emmelkamp, and Blonk (2008) and Willert, Thulstrup, and Bonde (2011). Something similar occurs with bipolar disorder, where D12, NICE (2014a) and APS (2010) consider that family-focused therapy is effective for this disorder, whereas Cochrane (Justo, Soares, & Calil, 2007) indicates that there is insufficient evidence to support the use of family interventions in this disorder. In analyzing the studies on which D12 and Cochrane base their recommendations (seven RCTs each), for example, we observe that only one study is the same, specifically that of Clarkin, Carpenter, Hull, Wilner, and Glick (1998).

Several discrepancies were found for schizophrenia, which may also be due to the fact that different studies were reviewed. For instance, while D12 confers a strong level of evidence to cognitive remediation, NICE (2014b) suggests that there is no consistent evidence for this treatment in schizophrenia. When comparing the 10 studies used by D12 and the 17 studies on which the NICE (2014b) recommendations are based, we note that only two coincide (i.e., Wykes, Reeder, Corner, Williams, & Everitt, 1999; Wykes et al., 2007). The same applies to social skills training (SST). Thus, while D12 reports that the evidence on the effectiveness of SST is strong and two studies by Cochrane (Tungpunkom, Maayan, & Soares-Weiser, 2012; Almerie et al., 2015) conclude that there is strong evidence to suggest that this therapy is effective and that SST may improve the social skills of people with schizophrenia and reduce relapse rates, NICE (2014b) considers that the evidence is insufficient to suggest that SST is effective in schizophrenia and advises against providing this therapy as a specific treatment for the disorder. If we analyze the studies on which D12 and NICE base their recommendations (seven and 20 respectively), for example, we observe that only two are the same (i.e., Eckman et al., 1992; Liberman, Wallace, Blackwell, Kopelowicz, Vaccaro, & Mintz, 1998).

Significant discrepancies have also been found for borderline personality disorder. While Cochrane (Stoffers, Völm, Rücker, Timmer, Huband, & Lieb, 2012) and APS (2010) deem psychodynamic therapy to be effective for this disorder, schema-focused therapy is considered effective by D12, Cochrane (Stoffers et al., 2012) and APS (2010),

and transference-focused therapy is regarded as effective by D12 and Cochrane (Stoffers et al., 2012). In contrast, NICE (2009a) states that there is insufficient evidence to support the use of these therapies for borderline personality disorder. When comparing the studies on which these organizations base their recommendations, we observe that the studies used by NICE (2009a) are different from those used by the rest of the organizations, which are practically the same. Some differences were also observed among the organizations with regard to the use of CBT for this disorder. Specifically, APS (2010) considers there is insufficient evidence to indicate that CBT is effective for this disorder based solely on the RCT of Cottraux and colleagues (2009), while Cochrane (Stoffers et al., 2012) regards CBT to be effective based on the study of Cottraux and colleagues (2009), the RCT of Davidson and colleagues (2006) and the RCT of Bellino, Zizza, Rinaldi, and Bogetto (2007). NICE (2009a) on the other hand deems CBT to be effective for this disorder based solely on the study of Davidson and colleagues (2006).

Another reason that might explain the discrepancies among organizations is the different criteria used by each. A comparison of the organizations showed that the requirements for granting, for example, the highest level of evidence to a certain treatment differed among organizations. D12 requires at least two good experimental designs that demonstrate the efficacy of treatments. The criteria used initially by NICE require at least one meta-analysis or RCT. The GRADE system, used later by NICE and Cochrane, grants the highest level of evidence if further research is very unlikely to change the confidence in the estimate of the effect. Finally, APS requires a systematic review of all relevant RCTs to confer the highest level of evidence. The analysis of these discrepancies also shows that, in some cases, the studies which the institutions base themselves on to determine the quality of the evidence are the same. Therefore, in these cases, the reason for the discrepancies could be the criteria used. This is the case of social anxiety disorder, where interpersonal psychotherapy is deemed non-effective by NICE (2013a) based on the RCT of Lipsitz and colleagues (2008) and the RCT of Stangier, Schramm, Heidenreich, Berger, and Clark (2011), while APS (2010) considers this therapy to be effective based solely on the study of Lipsitz and colleagues (2008). Similar results are found for obsessive-compulsive disorder, where ACT is considered effective by D12 and APS (2010) based on the RCT of Twohig and colleagues (2010) and the case series study of Twohig, Hayes, and Masuda (2006), respectively. However, although NICE (2013b)

suggests that ACT can improve the symptoms of OCD, it does not specifically recommend the use of this therapy based on the study of Twohig and colleagues (2010).

The fact that the reviews of existing evidence are made at different time periods may also explain the discrepancies found. Regular updates of the lists reporting effective psychological treatments are therefore advisable given that a substantial number of these lists, reviews and guides are currently out of date. The APS data are from 2010, but many of the studies state that they actually date from 2005. Cochrane includes the most up-to-date studies, some of which are from 2015, such as the studies on schizophrenia. Nonetheless, others are older, like those on obsessive-compulsive disorder, which date from 2007. NICE has published some updated guidelines, for example the guidelines on bipolar disorder, which were published in 2014, while others are outdated like the guidelines on eating disorders, which date from 2004. Finally, it is difficult to know when the data on the D12 website are updated as it is renewed without displaying any information on the latest update, which can only be guessed at by using the date of the studies themselves. This suggests that the information on some disorders on the D12 website were updated in 2015 and that earlier studies (e.g., panic disorder) have not been updated since 1995. Moreover, the fact that a Cochrane review of the year 2000 (McGrath & Hayes, 2000) suggests there is no consistent evidence to support the use of cognitive remediation in schizophrenia, while D12 confers a strong level of evidence to this therapy based, among others, on five studies after the year 2000 indicate that these discrepancies in the observed evidence may be due to the different time periods in which the reviews were made.

Therefore, we believe that the discrepancies can be explained by a combination of the issues discussed above. As a result, it would be advisable to unify the criteria for assessing evidence and improve the coordination between organizations in order to verify that a treatment is truly effective using high-quality reproducibility studies performed by independent teams.

Although the view in this review is that some treatments are superior to others, and identifying treatments as being research supported will improve the quality of mental health care, there is evidence to support that comparisons of different psychotherapies show non-significant differences (Castonguay & Beutler, 2006; Gibbons et al., 1993; Livesley, 2007; Norcross, 2011). These authors suggest that most structured psychotherapies are fairly equivalent in terms of their effectiveness and that certain

factors, such as patient characteristics, therapist characteristics and therapeutic rapport, contribute to the change more than the psychotherapy practiced.

The lack of reproducibility studies in this field, as in other scientific fields of psychology (Aarts et al., 2015), is considerable in disorders such as schizophrenia, in which treatments such as SST are not considered effective by NICE (NICE, 2014b). This is due to the fact there are no quality studies in the UK that have examined the reproducibility of RCTs, in contrast to many other countries (Moriani et al., 2015). In addition, in the same way that many more reproducibility studies are needed, comparative studies of psychological versus pharmacological versus combination therapy are important because modern medical treatments for various types of mental disorders have begun to be questioned in recent years (Whitaker, 2002) and several studies have reported that drug treatment can be harmful in patients with mental disorders. In this regard, recent evidence indicates that long-term treatment of schizophrenia with antipsychotics may produce poorer treatment results (Harrow, 2007; Jung, Wiesjahn, Wendt, Bock, Rief, & Lincoln, 2016; Moilanen et al., 2013; Wunderink, Nieboer, Wiersma, Sytema, & Nienhuis, 2013). Other studies on people suffering from depression have found that antidepressants may cause the illness to worsen (El-Mallakh, Gao, & Roberts, 2011) and may increase relapse (Andrews, Kornstein, Halberstadt, Gardner, & Neale, 2011).

On a final note, if interventions are already problematic when complex treatment techniques or programs are used, such as a therapy consisting of relaxation training, technical problem solving or cognitive restructuring, it is difficult to determine to what extent which treatment played a part in the individual's improvement. Comprehensive treatment programs have often been evaluated without identifying their causal mechanisms. Because programs are designed prior to being evaluated, we do not know if the design of a chosen program is superior to the multiple possible variants (O'Donohue & Yeater, 2003). The next generation of research could analyze procedures (techniques, strategies) that are simpler units of analysis to determine what is useful, harmful or harmless in each treatment guide and thus make changes that will improve treatment efficacy (Westen, Novotny, & Thompson-Brenner, 2004b).

#### **6.4.1. Limitations**

First, the heterogeneity of levels of evidence adopted by the different organizations greatly hinders a comparative assessment and is contrary to scientific methods. Second, although we have reviewed and compared data provided by four

international organizations, there are many other organizations that confer grades and levels of evidence whose inclusion would have given greater robustness to our review. And lastly, the disorders included in this study only comprise a small part of the spectrum of mental disorders in adults.

#### **6.4.2. Future directions**

Future studies should aim to reach a consensus on the scientific methods used to validate psychological treatments in order to unify the criteria among organizations, researchers and professionals on levels of evidence and methodological approaches for improving the quality of the studies that support them. Moreover, performing studies similar to ours on mental disorders in children and adolescents, addictions, health psychology and other related areas not included in this study is both necessary and of interest.

#### **6.5. Conclusions**

This study is the first to compare evidence provided by four leading international organizations on different psychological treatments for the principal adult mental disorders. From the main findings, it should be highlighted that there is no consensus regarding the evidence presented to support the effectiveness of psychological treatments for most mental disorders in adults. The therapies based on cognitive-behavioral models are those that have shown higher levels of evidence. In addition, although there are numerous treatments for many of the disorders mentioned (e.g., 23 treatments for depression), not all offer the same quality of evidence or studies to support them. As a result, we need to contribute to improving the quality of RCTs through more independent studies that promote and contemplate reproducibility as a much more important criterion than envisaged so far. Finally, as regards the comparison, we found that while similar evidence exists for some disorders (e.g., bulimia nervosa), for others there is a significant number of treatments for which the level of evidence varies greatly depending on the organization (e.g., depression), and some worrying divergences between organizations regarding the evidence presented for treatments for disorders (e.g., for schizophrenia).

The most important conclusion is that which Archibald L. Cochrane already anticipated more than thirty years ago and which is still very relevant for our discipline today:

“It is surely a great criticism of our profession that we have not organized a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomized controlled trials” (Cochrane, 1972, p. 11).

### ***Acknowledgements***

Preparation of this article was supported in part by National Grants (Ministerio de Economía y Competitividad, Spain Government) Ref. PSI2014-56368-R to Juan Antonio Moriana and Grant Semillero de Investigación-UCO to Jorge Corpas.

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## Capítulo 7

### Estudio 2

**Gálvez-Lara, M., Corpas, J., Moreno, E., Venceslá, J. F., Sánchez-Raya, A. y Moriana, J. A. (2018). Psychological treatments for mental disorders in children and adolescents: a review of the evidence of leading international organizations. *Clinical Child & Family Psychology Review*, 21, 366-387. doi: 10.1007/s10567-018-0257-6**

#### **Abstract**

In recent decades, the evidence on psychological treatments for children and adolescents has increased considerably. Several organizations have proposed different criteria to evaluate the evidence of psychological treatment in this age group. The aim of this study was to analyze evidence-based treatments drawn from RCTs, reviews, meta-analyses, guides and lists provided by four leading international organizations. The institutions reviewed were the National Institute for Health and Care Excellence (NICE), the Society of Clinical Child and Adolescent Psychology (Division 53) of the American Psychological Association (APA), Cochrane Collaboration and the Australian Psychological Society (APS) in relation to mental disorders in children and adolescents. A total of 137 treatments were analyzed for 17 mental disorders and compared to determine the level of agreement among the organizations. The results indicate that, in most cases, there is little agreement among organizations and that there are several discrepancies within certain disorders. These results require reflection on the meaning attributed to evidence-based treatments with regard to psychological treatments in children and adolescents. The possible reasons for these differences could be explained by a combination of different issues: the procedures or committees may be biased,

different studies were reviewed, different criteria are used by the organizations or the reviews of existing evidence were conducted in different time periods.

**Keywords:** Psychological treatments; Child and adolescent mental disorders; Evidence-based psychology; Review article

### **7.1. Introduction**

Psychological treatments for children and adolescents have been given less attention than those implemented in the adult population. In many cases, psychological interventions involving children and adolescents were designed as adaptations of those of adults (Jacobs et al. 2008) when in clinical practice it can be verified that, for example, a child suffering from depression has specific characteristics that differ greatly from those of adults in terms of the etiology, symptoms, evolution and treatment of this disorder. In their comprehensive review of the literature on the treatment of adolescents, Weisz and Hawley (2002) examined 25 empirically supported psychotherapies that have been used in children and adolescents. According to these authors, 14 of the 25 therapies have been shown to be effective in adolescents. Interestingly, seven are downward adaptations of treatments originally designed for adults and six are upward adaptations of treatments originally designed for children, leaving only one that was developed specifically for adolescents. In conclusion, few of the 14 empirically supported treatments that have been used in adolescents were designed with a focus on the primary developmental task of adolescence (Holmbeck et al. 2010).

Interest in therapies for children and adolescents began a little later than Eysenk's influential work (1952), which questioned the benefit of psychotherapies, and the subsequent meta-analyses of Smith and Glass (1977) and Shapiro and Shapiro (1982), which supported the beneficial effects of psychotherapy in adults. In this regard, Casey and Berman (1985) published a meta-analysis of child treatment studies, concluding that "the evidence from this review suggests that previous doubts about the overall efficacy of psychotherapy with children can be laid to rest" (p. 388). Later, Weisz and colleagues conducted two meta-analyses of psychotherapy studies with children (Weisz et al. 1987, 1995). These studies were the first to provide empirical evidence that the effects of child psychotherapy appear to differ depending on a variety of factors, including the child's problem and the type of therapy (Southam-Gerow and Prinstein 2014). Recently, Weisz et al. (2017) have performed a new meta-analysis of child and adolescent treatment studies encompassing the last five decades, concluding that youth psychological therapy

has a beneficial effect of moderate magnitude and is relatively durable over time, although this effect depends on the child's problem, the type of therapy used, the control condition employed and who reports the outcome.

The American Psychological Association (APA) Task Force on Promotion and Dissemination of Psychological Procedures made a significant effort to systematically define how psychological treatments should be evaluated, which included professionals from the private health sector, the public health system, researchers and users. The task force published several reports (Chambless and Hollon 1998; Chambless and Ollendick 2001; Chambless et al. 1996, 1998) with lists of evidence-based treatments based on criteria to assess randomized controlled trials (RCTs) using control groups following standardized treatment guidelines (APA 2006). Criteria began to be developed to clearly define empirically supported treatments (ESTs) for mental health disorders (Barlow 1996; Seligman 1995; Shapiro 1996).

Possibly one of the major contributions of the list of ESTs has involved the creation of institutions that act as mediators between research and clinical practice, as well as the establishment of explicit criteria for judging the quality of evidence of the various interventions. This mediation entails both the evaluation of evidence (through selective reviews guided by criteria) and the transfer of information (through publications, books, manuals, training courses, etc.) to the different stakeholders involved (psychologists, patients, health institutions and the general public). However, the institutions that evaluate the evidence often use different criteria and degrees of assessment, thus suggesting that the reliability among lists is significantly different in terms of how they are constructed and analyzed (Primero and Moriana 2011).

The evidence concerning psychosocial treatments for children and adolescents experiencing behavioral health problems is building up at an impressive rate (Southam-Gerow and Prinstein 2014). For the period 1965–2009, Chorpita et al. (2011) identified over 750 treatment protocols from 435 studies on child and adolescent mental health. Moreover, in the last few decades, professionals and stakeholders have shown a growing interest in psychosocial treatments that have been found to ameliorate child and adolescent clinical disorders (Silverman and Hinshaw 2008), and several authors have proposed different criteria to evaluate the evidence of psychological treatments in children and adolescents (Chorpita et al. 2011; Kazdin and Wilson 1978). In addition, the Society of Clinical Child and Adolescent Psychology of the APA (Lonigan et al. 1998;

Silverman and Hinshaw 2008; Southam-Gerow and Prinstein 2014) and other organizations (e.g., National Institute for Health and Care Excellence, Australian Psychological Society, Cochrane Collaboration) have made different proposals in this regard, although agreement among them is not unanimous.

The present study therefore aims to analyze and compile lists of evidence-based psychological treatments in children and adolescents by disorder using data provided by RCTs, meta-analyses, guidelines and systematic reviews of the Society of Clinical Child and Adolescent Psychology of the APA, the National Institute for Health and Care Excellence (NICE), the Australian Psychological Society (APS) and Cochrane Collaboration. The data were then reviewed to compare the criteria, levels of evidence and lists of these organizations with the aim of analyzing the level of agreement among them.

These four organizations were selected for the review for the following reasons. The Society of Clinical Child and Adolescent Psychology of the APA is a leading international organization which promotes evidence-based psychological treatments in children and adolescents. NICE and Cochrane Collaboration are international organizations that provide guidance on all kinds of evidence-based therapies on a wide range of health disorders, and the APS facilitates clear and rigorous information about the efficacy of a broad range of psychological interventions across mental disorders.

## **7.2. Method**

The method used in this review conforms to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement (Moher et al. 2009).

### ***7.2.1. Description of the organizations included in the study***

#### ***7.2.1.1. Society of Clinical Child and Adolescent Psychology (Division 53) of the APA***

APA is the leading scientific and professional organization representing psychology in the United States. APA's 54 divisions are interest groups organized by members. Some represent subdisciplines of psychology (e.g., clinical psychology), while others focus on thematic areas such as aging or ethnic minorities. The Society of Clinical Child and Adolescent Psychology (Division 53) includes APA members who are active in practice, research, teaching, administration and/or conduct studies in the field of clinical child and adolescent psychology. The mission of Division 53 of the APA (D53) is to promote the advancement of clinical child and adolescent psychology by integrating its scientific and professional aspects, and promoting scientific inquiry, training, and

professional practice in clinical child and adolescent psychology as a means of improving the mental health of children, adolescents and families. The D53 website ([www.effectivechildtherapy.com](http://www.effectivechildtherapy.com)) informs the general public about research evidence for psychological treatments in this age group.

Evidence-based treatment reviews have appeared in the *Journal of Clinical Child and Adolescent Psychology (JCCAP)* over the past two decades and have also been disseminated on the D53 website. In 1998, Lonigan et al. (1998) published a special issue on empirical support for specific psychological treatments. Some years later, Silverman and Hinshaw (2008) published a second special issue of evidence-based treatment updates. Due to the large number of new treatment studies, the D53 Board of Directors determined that a decennial review of the evidence base was insufficient to keep up with the rapidly collecting evidence (Shotham-Gerow and Prinstein 2014). Therefore, a new special issue focusing on evidence-based treatments was published in 2014 (Shotham-Gerow and Prinstein 2014) and D53 aimed to publish more updates on evidence-based treatments for various child and adolescent problems more regularly.

D53 currently classifies levels of evidence into five levels. To be considered a Level One treatment (also defined as “Works well” or “Well-established treatments”), at least two large-scale RCTs must have demonstrated the superior efficacy of the treatment to some other treatment and the studies must have been conducted by independent investigatory teams working in different research settings. Level Two therapies (also defined as “Works” or “Probably efficacious therapies”) have strong research support, but may not have been tested by different or independent teams. In Level Three therapies (also defined as “Might work” or “Possibly efficacious therapies”), there may be one study showing that the treatment is better than no treatment, or there may be a number of smaller clinical studies without all of the appropriate procedural controls. Level Four therapies (also defined as “Unknown,” “Untested” or “Experimental therapies”) may be in use, but have not been studied carefully. For some child/adolescent symptoms or disorders with limited therapy options, a treatment at this level could be worth considering. Finally, Level Five therapies (also defined as “Does not work” or “Tested but did not work”) have been tested in well-designed studies and have not yet shown positive results or have been shown to make symptoms or behaviors worse. A therapy currently listed as Level Five would not be a good treatment option.



#### 7.2.1.2. *National Institute for Health and Care Excellence (NICE)*

NICE is an organization that is responsible for providing evidence-based guidance on health and social care to the National Health Services (NHS) in the UK, which works closely with other organizations such as NHS England, Public Health England or Health Education England. NICE publishes clinical guidelines, technology appraisal guidance, interventional procedures guidance and public health guidelines that make evidence-based recommendations on a wide range of health, public health and social care topics. Its competences range from providing information, education and advice to launching campaigns and prevention programs for specific treatments for primary, secondary and specialized services covering all medical specialties.

Each NICE guideline is developed by a different committee of experts, which includes members from clinical practice, public health and social care. In addition, all committees include at least two lay members, who can be patients, caregivers, service users or the general public. The committees conduct systematic reviews and network meta-analyses for evaluating and comparing the benefits and cost effectiveness of the different forms of treatment included in each guideline. The process to develop each guideline usually takes between 18 and 24 months, although there are “short clinical guidelines” that take between 11 and 13 months to produce and are generally used in cases where the development of a guide on an emerging problem is considered urgent. NICE classifies evidence by level in a hierarchy which is similar to that of D53, although different criteria are used. Level I includes the type of evidence obtained from meta-analyses and RCTs (at least one) and corresponds to recommendation grade “A”; level II includes evidence from at least one controlled study without randomized groups, or a quasi study, and corresponds to grade “B”; level III, which includes descriptive studies (or those which do not fully meet the criteria in levels I and II), also corresponds to grade “B”; and level IV, which includes evidence obtained from expert committee reports or opinions and/or clinical experiences, corresponds to grade “C”.

More recently, the NICE guidelines were incorporated into the GRADE system for rating clinical guidelines (Atkins et al. 2004). The GRADE system classifies levels of evidence as high quality (further research is very unlikely to change our confidence in the estimate of the effect); moderate quality (further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate); low quality (further research is likely to have an important impact on our confidence in the

estimate of the effect and is likely to change the estimate) and very low quality (any estimate of effect is very uncertain).

#### 7.2.1.3. *Cochrane Collaboration*

This organization comprises a network of researchers, practitioners, patients and caregivers from over 130 countries working cooperatively to provide evidence-based data in order to facilitate decision making about which treatment to choose for a particular disorder or health problem. The Cochrane collaborators are affiliated to the organization through Cochrane groups, which are review groups related to health topics, thematic networks, groups involved in the methodology of systematic reviews and regional centers. These groups are established around the world and most of their work is done online. Each group is a “mini-organization” in itself, with its own funding, website and workload. Based on their interests, experience or geographical location, collaborators join a group or, in some cases, various groups.

The Cochrane groups perform systematic reviews and meta-analyses of specific health topics on all kinds of diseases. The reviews provide a summary of the results of available studies, mainly RCTs, which present information about the effectiveness of interventions in a specific health topic. Cochrane reports on evidence for and against treatments, treatment efficacy and treatment comparison studies to facilitate decision making in health care. Like NICE, Cochrane has also recently incorporated the GRADE model (Atkins et al. 2004) as criteria to determine the quality of evidence.

#### 7.2.1.4. *Australian Psychological Society (APS)*

The APS is the premier professional organization for psychologists in Australia. The functions of the APS are conducted through more than 201 active member groups within the society. Each group consists of an elected committee that meets regularly and organizes activities, such as professional development. Evidence-based practice has become a central issue in the delivery of health care in Australia and, as such, government-sponsored health programs require the use of treatment interventions that are evidence-based as a means of discerning the allocation of funding.

The National Health and Medical Research Council (NHMRC) of Australia has published a guide for evaluating evidence and developing clinical practice guidelines. The NHMRC guide informs public health policy in Australia and has been adopted as a protocol for evidence reports by the APS. The NHMRC has developed a rating scale to designate the level of evidence of clinical studies: Level I – systematic review of all

relevant randomized controlled trials; Level II – at least one properly designed randomized controlled trial; Level III-1 – well-designed pseudo-randomized controlled trials (alternate allocation or some other method); Level III-2 – comparative studies with concurrent controls and allocation of not randomized (cohort studies) or interrupted time series with a control group; Level III-3 – comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group; and Level IV – case series, either post-test or pre-test and post-test.

APS has published a comprehensive review of the available evidence up to January 2010, which examines the efficacy of a broad range of psychological interventions across mental disorders affecting adults, adolescents and children (APS 2010). This review of the literature examining the efficacy of a broad range of psychological interventions for the ICD-10 mental disorders has been undertaken to support the delivery of psychological services under government mental health initiatives. To determine the level of evidence of the treatments included in the review, APS uses the criteria developed by NHMRC mentioned above.

### ***7.2.2. Search strategy***

We first consulted the websites of the organizations described above (APA, Division 53, [www.effectivechildtherapy.org](http://www.effectivechildtherapy.org); NICE, [www.nice.org.uk](http://www.nice.org.uk); Cochrane, [www.cochrane.org](http://www.cochrane.org); and APS, [www.psychology.org.au](http://www.psychology.org.au)) to gather all the treatments, disorders and levels of evidence they report for children and adolescents. In a second stage, we collected the RCTs, reviews and meta-analyses presented by each organization. The last date of access and updated information uploaded by the organization was October 15, 2017.

### ***7.2.3. Inclusion and exclusion criteria***

Owing to the sheer number of related disorders and treatments, we selected as our inclusion criteria only those investigated in children and adolescents. Problems related to health psychology, learning disorders, speech disorders, personality disorders, substance abuse, self-harm, body-focused repetitive behaviors and drug therapies were excluded. In the case of Cochrane, the following types of reviews were also excluded: reviews of specific sectors of the population (e.g., psychological interventions for depression in adolescents and adults with congenital heart disease), prevention reviews, reviews on assessment tools, systematic reviews of studies on specific non-psychological procedures

(i.e., cranial magnetic stimulation or electroconvulsive therapy), systematic reviews of studies assessing diagnostic test accuracy and the protocols for reviews.

#### **7.2.4. Data collection process**

Treatment recommendations for the disorders addressed in this study can be found in the Results section. Information on the evidence provided by the different organizations for each treatment is specified in the tables, while the box corresponding to treatments for which there is no reference to evidence is left blank. When an organization deems that there are not enough studies to consider the treatment effective, we use the term “Insufficient Evidence.” In addition, next to the level of evidence we specify the number of RCTs and meta-analyses or systematic reviews that each organization has used to reach their conclusions.

As a result, in the row corresponding to D53 we classify the quality of the evidence of a particular treatment as Level One, Level Two, Level Three, Level Four or Level Five. In the row corresponding to NICE, we specify the grade of recommendation (A, B, C) for post-traumatic stress disorder and obsessive-compulsive disorder, or the level of evidence according to the GRADE criteria (high, moderate, low and very low) for other disorders included by this organization. Moreover, the update guideline for attention deficit hyperactivity disorder (ADHD) (NICE 2013a) does not report the level of evidence of behavioral classroom management (BCM) and organization training (OT). Consequently, we only indicate whether these treatments are considered effective, non-effective or if there is insufficient evidence, without specifying the level of effectiveness of the treatments in the tables. Finally, some treatments are accompanied by the indication “no research support” or, when appropriate, “advised against using.” For Cochrane, we opted to show the data exactly as it appears in the systematic reviews obtained from the system. Specifically, for all the reviews conducted after 2012 and that of Reichow et al. (2012); Storebø et al. (2011) and Krisanaprakornkit et al. (2010), we indicate the level of evidence according to the GRADE criteria, while for other reviews we indicate whether a particular treatment is effective or non-effective. Regarding APS, we specify the levels of evidence according to the criteria used by the organization itself, which are described above (Level I, Level II, Level III-1, Level III-2, Level III-3 and Level IV).

Finally, the total number of organizations that report a given therapy as being effective is shown in the tables. For this purpose, we have considered that a therapy is deemed effective by an organization in the following cases. D53: Level One, Level Two,

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Level Three and Level Four; NICE: A, B, C, high, moderate, low, very low or effective; Cochrane: high, moderate, low, very low or effective; APS: level I, level II, level III-1, level III-2, level III-3 or level IV.

### 7.2.5. Statistical Analysis

To analyze agreement among organizations, we have classified the different levels of evidence proposed by each organization into an ordinal scheme as no evidence, weak evidence, moderate evidence and strong evidence (see Table 7.1). In the case of NICE for autism and D53 for autism, depression and disruptive disorder, where different levels of evidence may appear for a treatment (see Table 7.3, Table 7.5 and Table 7.6, respectively), we have used the higher level of evidence.

**Table 7.1. Ordinal scheme to classify the different levels of evidence**

	<b>D53</b>	<b>NICE</b>	<b>COCHRANE</b>	<b>APS</b>
<b>No evidence</b>	Level Five	Insufficient evidence; Non-effective; No Research Support; Do not use	Insufficient evidence	Insufficient evidence
<b>Weak evidence</b>	Level Three; Level Four	C; Very low; Low	Very low; Low	Level IV; Level III-3; Level III-2
<b>Moderate evidence</b>	Level Two	B; Low to moderate; Moderate; Low to high	Low to moderate; moderate	Level III-1; Level II
<b>Strong evidence</b>	Level One	A; Moderate to high; High, Effective	Moderate to high; High; Effective	Level I

The intra-class correlation (ICC) is one of the most commonly-used statistics for assessing inter-rater reliability (IRR) for ordinal, interval and ratio variables (Hallgren 2012). The ICC is suitable for this type of measurements since it evaluates the reliability of the obtained qualifications when comparing the variability of the different grades for the same treatment with total variation across all classifications and treatments. As in the previous study of Moriana et al. (2017), IRR has been performed using a two-way mixed, consistency, average-measures ICC to assess the level of agreement among the four organizations for each diagnosis, taking into account only those therapies considered effective by at least one institution.

According to Hallgren (2012), higher ICC values suggest a greater IRR, with an ICC estimate of 1 indicating perfect agreement and 0 indicating only random agreement. Moreover, this author states that negative ICC estimates indicate systematic disagreement, and some ICCs may be less than -1 when there are three or more coders. The cutoffs proposed by Cicchetti (1994) for the qualitative rating of agreement based on

ICC values were used, with IRR being poor for ICC values less than .40, fair for values between .40 and .59, good for values between .60 and .74 and excellent for values between .75 and 1.

### **7.3. Results**

#### ***7.3.1. Search results***

The APA Division 53 website includes a list of 13 diagnostic categories. In accordance with the inclusion criteria, 10 mental disorders were analyzed, giving rise to a total of 91 psychotherapeutic interventions associated with them.

We consulted the guidelines relating to mental disorders published on the NICE website and reviewed sections corresponding to evidence-based treatments. Of the 39 guidelines published by the Mental Health and Behavioral Conditions group, nine met the criteria for inclusion in our review. One set of guidelines on Urological Conditions that provides information on 13 disorders and 63 therapies was also included.

We analyzed the systematic reviews provided by Cochrane for the group of mental disorders in children and adolescents and obtained data from the evidence for each of the treatments reviewed. The Cochrane website includes a total of 935 reviews belonging to the Mental Health and Developmental, Psychosocial & Learning Problems group. Of these, 22 which provide information on 26 psychological treatments for eight disorders met the criteria for inclusion in our analysis.

Finally, we incorporated the lists of treatments included in the document published by APS (2010). This guide includes 17 disorders in the interventions in children and adolescents section. Consistent with the inclusion criteria, 14 disorders relating to 21 interventions were selected.

#### ***7.3.2. Agreement for included disorders***

In what follows, we compare the four organizations to determine whether there is agreement among them regarding treatments for the disorders.

##### ***7.3.2.1. Anxiety disorders***

###### ***General symptoms of anxiety***

The only organizations that provide information about effective psychological treatments for general symptoms of anxiety are D53 and Cochrane, which present 21 different types of treatments supported by some degree of evidence. The ICC (.266) indicates poor agreement among organizations for this disorder. The review presented by

D53 (Higa-McMillan et al. 2016) does not specify the number of studies included in analyses for each treatment family. According to the review, there is Level One evidence for cognitive behavioral therapy (CBT), exposure, modeling, CBT with parents, education and CBT with medication; Level Two evidence for family psychoeducation, relaxation and assertiveness training, attention control, CBT for children and parents, cultural storytelling, hypnosis and stress inoculation; Level Three evidence for contingency management and group therapy; Level Four evidence for biofeedback, CBT with parents only, play therapy, psychodynamic, rational emotive therapy and social skills; and Level Five evidence for assessment/monitoring, attachment therapy, client-centered therapy, eye movement desensitization and reprocessing (EMDR), peer pairing, psychoeducation, relationship counseling and teacher psychotherapy. In turn, Cochrane (James et al. 2015) suggests that CBT is an effective treatment for childhood and adolescent anxiety disorders, with a low to moderate level of evidence (41 RCTs).

#### *Specific Anxiety Disorders*

Psychological treatment for social anxiety disorder (SAD) in children and adolescents has been studied by NICE and APS, which report three different types of treatments supported by some degree of evidence. The ICC (0) indicates random agreement among organizations for this disorder. The only treatment that APS (2010) considers effective for this disorder is CBT, which was rated as Level II evidence (two RCTs). However, in addition to considering CBT effective and assigning it a low level of evidence (eight RCTs), NICE (2013b) also considers CBT with parents (very low to low; three RCTs) and self-help therapy (low; two RCTs) to be effective for this disorder. As a result, CBT is the only therapy considered effective by NICE and APS.

Specific phobias (SP) in children and adolescents are only documented by APS (2010), which assigns CBT a Level II of evidence (one RCT). This organization is also the only one that provides evidence for generalized anxiety disorder in this age group, for which it confers a Level I of evidence to CBT (one RCT). Given that only one organization included treatments for these disorders, the ICC could not be calculated. Finally, no organization provides information regarding empirically supported treatments for panic disorder in this age group.

**Table 7.2. Attention deficit hyperactivity disorder. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	<b>BCM</b>	<b>BPI</b>	<b>BPT</b>	<b>CBMI</b>	<b>CBT</b>	<b>CT</b>	<b>CTI</b>	<b>FT</b>	<b>MT</b>	<b>NT</b>	<b>OT</b>	<b>SST</b>
<b>D53</b> (Evans et al., 2014)	Level One 2/0	Level One 1/0	Level One 6/0	Level One 6/0	---	Level Four 2/0	Level Two 2/0	---	---	Level Three 1/0	Level One 2/0	Level Five
<b>NICE</b> (2009; 2013a)	IE 1/0	---	Moderate 1/0	---	Moderate to High <sup>a</sup> 10/0	---	---	---	---	---	Effective 2/0	---
<b>Cochrane</b> (Bjornstad & Montgomery, 2005; Krisanaprakornkit et al., 2010; Storebø et al., 2011; Zwi et al., 2011)	---	---	Effective 5/0	---	---	---	---	IE 2/0	IE 4/0	---	---	IE 11/0
<b>APS</b> (2010)	---	---	---	---	Level I 1/3	---	---	---	---	---	---	---
<b>No. of organizations in agreement</b>	1	1	3	1	2	1	1	---	---	1	2	---

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

BCM = Behavioral Classroom Management; BPI = Behavioral Peer Interventions; BPT = Behavioral Parent Training; CBMI = Combined Behavior Management Interventions; CBT = Cognitive Behavioral Therapy; CT = Cognitive Training; CTI = Combined Training Interventions; FT = Family Therapy; MT = Meditation Therapies; NT = Neurofeedback Training; OT = Organization Training; SST = Social Skills Training; IE = Insufficient evidence

<sup>a</sup> Some studies include mixed CBT/social skills interventions



**Table 7.3. Autism. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	Animal-based Intervention	Auditory Integration Therapy	Cognitive Interventions	COMPASS	Comprehensive ABA + DSP Classrooms	EIBI / Individual, comprehensive ABA	Family Therapy	Individual, comprehensive ABA + DSP / ESDM	Individual, focused ABA + DSP / RIT / Joint attention intervention
<b>D53</b> (Smith & Iadarola, 2015)	---	---	---	---	Level Four 1/0	Level One 4/0	--	Level Three 1/0	Level Two 4/0
<b>NICE</b> (2013c)									
<b>Overall autistic behaviors</b>	---	---	---	Low 1/0	---	---	---	IE 1/0	---
<b>Impaired reciprocal social communication and interaction</b>	IE 1/0	---	IE 7/0	---	---	---	---	IE 2/0	IE 2/0
<b>Restricted interests and rigid and repetitive behaviors</b>	---	---	IE 1/0	---	---	---	---	IE 2/0	---
<b>Cochrane *</b>	---	IE 6/0	IE 22/0	---	---	---	IE 0/0	---	---
<b>APS</b> (2010)	---	---	---	---	---	---	---	---	---
<b>No. of organizations in agreement</b>	---	---	---	1	1	1	---	1	1
	LEAP / Comprehensive ABA classrooms	Music Therapy	Parent Training	PECS / Individual focused ABA for AAC	PRT – Individual focused ABA for spoken communication	Social-Communication Intervention	Social Skills groups	Teacher implemented focused ABA + DSP	Teacher implemented focused DSP
<b>D53</b> (Smith & Iadarola, 2015)	Level Three 1/0	---	Level Two for DSP <sup>a</sup> 10/0 Level Three for ABA <sup>a</sup> 3/0 Level Four for ABA + DSP <sup>a</sup> 1/0	Level Two 2/0	Level Three 1/0	---	---	Level One 3/0	Level Three 1/0
<b>NICE</b> (2013c)									
<b>Overall autistic behaviors</b>	Low 1/0	---	IE 3/0	---	---	IE 1/0	---	---	---
<b>Impaired reciprocal social communication and interaction</b>	---	IE 1/0	IE 3/0	IE 1/0	---	Low to Moderate <sup>b</sup> 16/0	---	---	---
<b>Restricted interests and rigid and repetitive behaviors</b>	---	---	Low 1/0	---	---	IE 1/0	---	---	---
<b>Cochrane **</b>	---	Low to moderate 10/0	Low 1/0	---	---	---	Low 5/0	---	---
<b>APS</b> (2010)	---	---	---	---	---	---	---	---	---
<b>No. of organizations in agreement</b>	2	1	3	1	1	1	1	1	1

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

AAC = Augmentative and Alternative Communication; ABA = Applied Behavior Analysis; DSP = Developmental Social-Pragmatic; EIBI = Early Intensive Behavioral Intervention; ESDM = Early Start Denver Model; LEAP = Learning Experiences: An Alternative Program for Preschoolers and Parents; PECS = Picture Exchange Communication System; PRT = Pivotal Response Treatment; RIT = Reciprocal Imitation Training; IE = Insufficient Evidence

<sup>a</sup>D53 includes evidence for different types of parent training; <sup>b</sup>Some studies include social skills group interventions

\* Fletcher-Watson, McConnell, Manola, & McConachie, 2014; Sinha, Silove, Hayen, & Williams, 2011; Spain and colleagues, 2017

\*\* Geretsegger, Elefant, Mössler, & Gold, 2014; Oono, Honey, & McConachie, 2013; Reichow, Steiner, & Volkmar, 2012.

7.3.2.2. *Attention Deficit Hyperactivity Disorder*

In reviewing the treatments included by the four organizations for attention deficit hyperactivity disorder (ADHD) in children and adolescents, we found nine different types of treatments supported by some degree of evidence (see Table 7.2). The ICC (.173) indicates poor agreement among organizations for this disorder. Behavioral parent training (BPT) was the treatment with the highest level of agreement (three organizations consider it effective), while the other treatments were regarded as effective by less than three institutions.

7.3.2.3. *Autism*

In examining treatments for autism in children and adolescents, we identified 14 different types of treatments supported by some degree of evidence (see Table 7.3). The ICC (-1.447) indicates systematic disagreement among organizations for this disorder. Parent training was the treatment with the highest level of agreement (three organizations consider it effective). The other treatments were regarded as effective by less than three institutions, 12 of which are considered effective by only one organization.

7.3.2.4. *Bipolar Disorder*

When analyzing treatments for bipolar disorder in children and adolescents, we found four different types of treatments supported by some degree of evidence (see Table 7.4). The ICC (.667) indicates good agreement among organizations for this disorder. Family-focused therapy (FFT) was the treatment that obtained the highest level of agreement (three organizations consider it effective), while the other therapies were deemed effective by only one institution.

**Table 7.4. Bipolar disorder. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	CBT	DBT	FFT	IPSRT
<b>D53*</b> (Fristad & MacPherson, 2014)	---	Level Two 0/0	Level One <sup>a</sup> 5/0	Level Four 0/0
<b>NICE</b> (2014)	---	---	Very low 2/0	---
<b>Cochrane</b>	---	---	---	---
<b>APS</b> (2010)	Level IV <sup>a</sup> 0/0	---	Level II <sup>b</sup> 0/0 [A]	---
<b>No. of organizations in agreement</b>	1	1	3	1

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

CBT = Cognitive Behavioral Therapy; DBT = Dialectical Behavior Therapy; FFT = Family-Focused Therapy; IPSRT = Interpersonal and Social Rhythm Therapy; [A] = Adolescents only

<sup>a</sup>Family Skill Building plus Education; <sup>b</sup> Adjunct to medication

\*Levels of evidence provided by D53 do not exactly match the levels proposed by Fristad & MacPherson (2014)

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**Table 7.5. Depression. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	AR	BT	CBT	CBT group	CCBT	FFT	IPT	IPT group	NDST	PDT	SHT	SM
<b>D53 Support for children</b> (Weersing et al., 2017)	---	Level Three 2/0	Level Four 3/0	Level Three 4/0	Level Three 1/0	Level Four 1/0	---	---	---	Level Four 1/0	---	---
<b>D53 Support for adolescent</b> (Weersing et al., 2017)	---	---	Level One 14/0	Level One 12/0	Level Four 1/0	Level Three 5/0	Level One 4/0	Level Two 3/0	---	---	Level Three 2/0	---
<b>NICE</b> (2015)	Moderate 2/0	---	Very low to moderate 6/0	Very low to moderate 15/0	Moderate to high 2/0	Low 1/0	Low 2/0	---	Low to moderate 1/0	Very low to moderate 1/0	Low 2/0	Low 1/0
<b>Cochrane</b> (Henken et al., 2007; Cox et al., 2014)	---	---	---	---	---	IE 6/0	---	---	---	---	---	---
<b>APS</b> (2010)	---	---	Level I 0/2	---	---	Level I 0/2	Level I[A] 0/2	---	---	---	Level II [A] 0/0	---
<b>No. of organizations in agreement</b>	1	1	3	2	2	3	3	1	1	2	3	1

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

AR = Applied Relaxation; BT = Behavior Therapy; CBT = Cognitive Behavioral Therapy; CCBT = Computerized Cognitive Behavioral Therapy; FFT = Family-Focused Therapy; IPT = Interpersonal Therapy; NDST = Non-Directive Supportive Therapy; PDT = Psychodynamic Therapy; SHT = Self-Help Therapy; SM = Self-Modeling; [A] = Adolescents only

**Table 7.6. Disruptive behavior in children and adolescents. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	CBI	CBT	CHFBT	DBT	FCFI	FFI	MCI	MMI	PFBT	PFBT+CH	PFBT group	Play Therapy	PTBI
<b>D53 Support for younger children</b> (Kaminsky & Claussen, 2017)	---	---	Level Two 6/0	---	---	Level Four <sup>a</sup> 1/0	---	---	Level Two** 17/0	Level One 8/0	Level One 8/0	Level Two 2/0	---
<b>D53 Support for adolescents*</b>	---	---	Level Two	---	---	Level Four <sup>a</sup>	---	---	Level One / Level Two***	---	---	Level Two	---
<b>NICE (2013d)</b>	Low to High 10/0	---	Low to Moderate 27/0	---	High 3/0	Low to Moderate 8/0	Moderate to High 16/0	Low to High 14/0	Moderate to High 54/0	Low to moderate 12/0	---	---	Non-effective 7/0
<b>Cochrane</b> (Armeliuss & Andreassen, 2007; Furlong et al., 2012; Littell et al., 2005; MacDonald & Turner, 2007; Montgomery et al., 2006; Woolfenden et al., 2001)	---	Effective 16/0	---	---	Effective 5/0	Effective 9/0	---	IE <sup>b</sup> 8/0	---	---	Effective 10/0	---	---
<b>APS (2010)</b>	---	Level I 2/1	---	Level IV [A] 0/0	---	---	---	---	Level I 0/2	---	---	---	---
<b>No. of organizations in agreement</b>	1	2	2	1	2	3	1	1	3	2	2	1	---

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

CBI = Classroom-Based Interventions; CBT = Cognitive Behavior Therapy; CHFBT = Child-Focused Behavior Therapy; FCFI = Foster Carer-Focused Interventions; FFI = Family-Focused Interventions; MCI = Multi-component interventions; MMI = Multimodal Interventions; PFBT = Parent-Focused Behavior Therapy; PFBT+CH = Parent-Focused Behavior Therapy with Child Participation; PTBI = Parent-Teacher-Based Interventions; [A] = Adolescents only; IE = Insufficient Evidence

<sup>a</sup> Family Problem-Solving training; <sup>b</sup> Multisystemic Therapy

\*D53 does not inform about the review on which their recommendations in adolescents are based. The information provided by the review included in the D53 website (McCart & Sheidow, 2016) does not match the recommendation provided by D53

\*\*Parent-focused behavior therapy and including any of the following: individual child, child groups, family problem solving training, teacher training or self-directed parent training

\*\*\* Parent-focused behavior therapy and including any of the following: self-directed parent training or teacher training

#### 7.3.2.5. *Depression*

An analysis of the treatments for depression in children and adolescents revealed 12 treatments supported by some degree of evidence (see Table 7.5). The ICC (.286) indicates poor agreement among organizations for this disorder. CBT, interpersonal therapy, FFT and self- help therapy obtained the highest level of agreement (three organizations consider them effective), but none of them obtained the consensus of the four organizations, since Cochrane suggests that there is very limited evidence upon which to base conclusions about the relative effectiveness of psychological interventions for treating depressive disorders in this age group (Cox et al. 2014). The other treatments studied were regarded as effective by less than three institutions, five of which are considered effective by only one organization.

#### 7.3.2.6. *Disruptive Behavior*

In examining treatments for disruptive behavior in children and adolescents, we found 12 different types of treatments supported by some degree of evidence (see Table 7.6). The ICC (-.273) indicates systematic disagreement among organizations for this disorder. Family-focused interventions (FFI) and parent-focused behavior therapy (PFBT) both obtained the highest degree of agreement (three organizations regard them to be effective). The other treatments were considered effective by one or two institutions.

#### 7.3.2.7. *Eating Disorders*

##### *Anorexia nervosa*

When reviewing the treatments documented for anorexia nervosa (AN), five different treatments were found to be supported by some degree of evidence (see Table 7.7). The ICC (.655) indicates good agreement among organizations for this disorder. Family therapy-behavioral (FTB) obtained the highest level of agreement (three organizations consider it effective). However, other types of treatments were regarded as effective by one or two organizations.

##### *Bulimia nervosa*

We found four treatments supported by some degree of evidence when reviewing treatments for bulimia nervosa (see Table 7.8). The ICC (0) indicates random agreement among organizations for this disorder. FTB obtained the highest level of agreement (three organizations consider it effective), while the other treatments were considered effective by one or two institutions.

**Table 7.7. Anorexia Nervosa. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	AFT / IOP	CBT	CT	FTB	FTS
<b>D53</b> (Lock, 2015)	Level Two 1/0	Level Four 1/0	Level Four 1/0	Level One 9/0	Level Two 1/0
<b>NICE</b> (2017)	Low 2/0	Low 1/0	---	Low 13/0	---
<b>Cochrane</b>	---	---	---	---	---
<b>APS</b> (2010)	---	---	---	Level I (0/2)	---
<b>No. of organizations in agreement</b>	2	2	1	3	1

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

AFT= Adolescent Focused Therapy; CBT = Cognitive Behavioral Therapy; CT = Cognitive Training; FTB = Family Therapy-Behavioral; FTS = Family Therapy-Systemic; IOP = Insight-Oriented Psychotherapy

**Table 7.8. Bulimia Nervosa. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	CBT	FTB	SHT	ST
<b>D53</b> (Lock, 2015)	Level Four 0/0	Level Three 2/0	Level Three 1/0	Level Four 1/0
<b>NICE</b> (2017)	Very low to low 2/0	Very low to low 3/0	---	---
<b>Cochrane</b>	---	---	---	---
<b>APS</b> (2010)	---	Level II [A] (2/0)	Level II [A] (1/0)	---
<b>No. of organizations in agreement</b>	2	3	2	1

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

CBT = Cognitive Behavioral Therapy; FTB = Family Therapy-Behavior; SHT= Self-Help Therapy; ST = Supportive Therapy; [A] = Adolescents only

### *Binge eating disorder*

Binge eating disorder (BED) in children and adolescents is only documented by NICE (2017), which assigns a low level of evidence for individual CBT (1RCT/0 meta-analysis or systematic reviews), group CBT (0/0) and self-help therapy (1/0). With regard to other organizations, although D53 states that CBT is somewhat effective in adolescents with BED, according to this division, no child and adolescent therapies for this disorder have been tested for effectiveness. In the case of Cochrane, there are no reviews for this age group. In turn, APS (2010) reports that no recent studies have been found to indicate the effectiveness of any interventions for this disorder. Given that only one organization included treatments for this disorder, the ICC could not be calculated.

**Table 7.9. Enuresis. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	<b>Alarm</b>	<b>BTRCT</b>	<b>CBT</b>	<b>CT</b>	<b>DR</b>	<b>DRYBT</b>	<b>FR</b>	<b>RW</b>	<b>SC</b>	<b>SHT</b>	<b>TSP</b>
<b>D53</b>	---	---	---	---	---	---	---	---	---	---	---
<b>NICE</b> (2010)	Low <sup>a</sup> 6/0	IE 5/0	Low 1/0	---	NRS 1/0	Do not use 5/0	NRS 1/0	Very low 6/0	Very low to low 6/0	---	Very low 1/0
<b>Cochrane</b> (Caldwell et al., 2013)	Low 9/0	Low 6/0	---	Low 1/0	---	Low 1/0	Low 1/0	Low 6/0	Low 5/0	---	---
<b>APS</b> (2010)	---	---	Level I 1/3	---	---	---	---	---	---	Level II 1/0	---
<b>No. of organizations in agreement</b>	2	1	2	1	---	1	1	2	2	1	1

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

BTRCT= Bladder Training and Retention Control Training; CBT = Cognitive Behavioral Therapy; CT = Cognitive Therapy; DR = Diet Restriction; DRYBT = Dry Bed Training; FR = Fluid Restriction; RW = Random Waking; SC = Star Charts; SHT = Self-Help Therapy; TSP = Three Step Program; NRS = No Research Support; IE = Insufficient Evidence

<sup>a</sup> Quality of evidence for alarm compared to no treatment

7.3.2.8. *Enuresis*

In reviewing the treatments included by the four organizations for enuresis, we identified 10 different types of treatments supported by some degree of evidence (see Table 7.9). The ICC (-1.15) indicates systematic disagreement among organizations for this disorder. Enuresis alarm, CBT, random waking and star charts were the treatments with the highest level of agreement (two organizations regard them to be effective). The other six therapies were considered effective by only one organization.

7.3.2.9. *Insomnia*

Insomnia in children and adolescents is only documented by APS (2010), which assigns a Level II of evidence to CBT (one meta-analysis). Given that only one organization included treatments for this disorder, the ICC could not be calculated.

7.3.2.10. *Obsessive-Compulsive Disorder*

We found three treatments supported by some degree of evidence when reviewing treatments for obsessive-compulsive disorder (OCD) (see Table 7.10). The ICC (.955) indicates excellent agreement among organizations for this disorder. Individual CBT obtained the maximum level of agreement (four organizations consider it effective). The other therapies, both variants of CBT, were deemed effective only by D53.

**Table 7.10. Obsessive-compulsive disorder. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	CBT	CBT group	CCBT
<b>D53</b> (Freeman et al., 2014)	Level Two 12/0	Level Three 3/0	Level Four 2/0
<b>NICE</b> (2006; 2013e)	B 21/0	---	---
<b>Cochrane</b> (O’Kearney et al., 2006)	Effective 8/0	---	---
<b>APS</b> (2010)	Level I 0/2	---	---
<b>No. of organizations in agreement</b>	4	1	1

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

CBT = Cognitive Behavioral Therapy; CCBT = Computerized Cognitive Behavioral Therapy

7.3.2.11. *Posttraumatic Stress Disorder*

In examining treatments for posttraumatic stress disorder (PTSD), we found 10 different types of treatments supported by some degree of evidence (see Table 7.11). The ICC (.579) indicates fair agreement among organizations for this disorder. CBT was the treatment that obtained the highest level of agreement (three organizations consider it effective). The other treatments studied were regarded as effective by less than three institutions, eight of which are considered effective by only one organization.



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**Table 7.11. Post-traumatic stress disorder. Level of evidence/RCTs /Meta-analyses or systematic reviews of psychological treatments and number of organizations in agreement**

	<b>CBT</b>	<b>CBT group</b>	<b>CBTP</b>	<b>CBTP group</b>	<b>Debriefing</b>	<b>EMDR</b>	<b>GCE+CBT</b>	<b>ITCT</b>	<b>MBS</b>	<b>MBS group</b>	<b>PDT</b>	<b>PT</b>
<b>D53</b> (Dorsey et al., 2017)	Level One 8/0	Level One 6/0	Level One 11/0	Level Two 2/0	---	Level Two 3/0	Level Five 2/0	Level Three 1/0	Level Four 1/0	Level Three 1/0	Level Four 0/0	Level Four 1/0
<b>NICE</b> (2005)	B 7/0	---	---	---	No research support 7/0	IE 1/0	---	---	---	---	---	---
<b>Cochrane</b> (Guillies et al., 2012)	Effective 5/0	---	---	---	---	---	---	---	---	---	---	---
<b>APS</b> (2010)	---	---	---	---	---	Level I (This intervention was not included in the review)	---	---	---	---	---	---
<b>No. of organizations in agreement</b>	3	1	1	1	---	2	---	1	1	1	1	1

Each box includes information about the level of evidence, the number of RCTs and the number of meta-analyses or systematic reviews that each organization has used to reach their conclusions (level of evidence/RCTs/meta-analyses or systematic reviews)

CBT = Cognitive Behavioral Therapy; CBTP = Cognitive Behavior Therapy with parent involvement; EMDR = Eye Movement Desensitization and Reprocessing; GCE = Group Creative Expressive; ITCT = Integrated Therapy for Complex Trauma; MBS = Mind-Body Skills; PDT = Psychodynamic Therapy; PT = Play Therapy

### 7.3.2.12. *Psychosis and schizophrenia*

Psychosis and schizophrenia in children and adolescents are only documented by NICE (2013f), which assigns a low level of evidence to CBT (12 RCTs), family therapy (two RCTs) and arts therapies (one RCT), including dance movement therapy, body psychotherapy, drama therapy and music therapy. Furthermore, this organization recommends that supportive therapy or social skills training not be routinely provided as specific therapies for children and adolescents with psychosis or schizophrenia. Given that only one organization included treatments for this disorder, the ICC could not be calculated.

## 7.4. Discussion

The goal of the criteria used to evaluate psychological treatment is to help therapists and clients make good choices about the treatments they provide or request (Southam-Gerow and Prinstein 2014). However, recommendations regarding the effectiveness of a given treatment depend on the organization being reviewed (Moriana et al. 2017). These authors analyzed evidence-based treatments provided by Division 12 of the APA, NICE, Cochrane and APS in relation to mental disorders in adults and concluded that, in most cases, there was little agreement among organizations and that there were several discrepancies within certain disorders.

Based on the previous study, the objective of this work was to compile a list of evidence-based psychological treatments by disorder in relation to mental disorders in children and adolescents. For this purpose, data provided by four international organizations were used to analyze the level of agreement among them regarding each diagnosis and each treatment within the disorders. The results of the analysis showed that agreement is low for most of the disorders, as only three of them show an acceptable ICC. Excellent agreement among organizations was found OCD, while good agreement was observed for bipolar disorder and anorexia nervosa. For all other treatments, the agreement among institutions was low.

As in adults, the main findings of this study highlight the existing discrepancies in the evidence presented by different organizations reporting on the effectiveness of psychological treatments in children and adolescents. Moriana et al. (2017) reported that the discrepancies in adults could be explained by a combination of different issues: the procedures or committees may be biased, different studies were reviewed, different

criteria are used by each organization or the reviews of existing evidence were conducted in different time periods.

In analyzing the existing discrepancies in children and adolescents, the fact that numerous treatments are included by a single organization may support the theory that the procedures or committees are biased. In most cases, these institutions only provide information on treatments they consider effective with a higher or lower level of evidence. Therefore, we cannot determine why they do not recommend certain treatments. This is evident in PTSD, where eight out of 10 treatments are considered effective by only one organization. In some cases, however, organizations also provide information about therapies they do not consider effective, but numerous treatments are still included by a single organization. In autism, for example, information is provided for 18 therapies, of which 11 are reported by a single organization. This also occurs with ADHD or depression in seven out of 12 treatments and five out of 12 treatments, respectively. Moreover, the evidence provided by NICE and Cochrane may be biased as it relies on the meta-analyses which they commission, and the recommendations of D53 are based on the reviews that they perform. APS is the only institution that bases part of its recommendations on the reviews or meta-analyses conducted by other organizations or institutions.

As concerns the issue of whether or not different studies were reviewed, the analysis of the main discrepancies regarding therapies for mental disorders in children and adolescents shows that, in some cases, the organizations do indeed use different studies to determine the quality of the evidence. For example, in the case of ADHD, D53 (Evans et al. 2014) considers that behavioral classroom management is a Level One treatment for this disorder based on the RCTs of Fabiano et al. (2010) and Mikami et al. (2013), while NICE (2013a), based solely on Mikami et al. (2013), deem that the evidence on the beneficial effect of this therapy is insufficient. The same applies to bladder training and retention control training (BTRCT) for enuresis, where Cochrane (Caldwell et al. 2013) confers a low level of evidence for this therapy but NICE (2010b) does not believe that the evidence for BTRCT is sufficient to recommend its use over other treatments. When comparing the six studies used by Cochrane (Caldwell et al. 2013) and the five studies on which the NICE (2010b) recommendations are based, we found that only two coincide (i.e., Bennett et al. 1985 and Harris and Purohit 1977).

Several discrepancies were found for autism, which may also be due to the fact that different studies were reviewed. For instance, while NICE (2013a) considers that the evidence for music therapy is inconclusive based solely on the RCT of Gattino et al. (2011), Cochrane (Geretsegger et al. 2014), based on 10 studies (including the RCT of Gattino et al. 2011), supports that music therapy may help children with autism to improve their skills in important areas such as social interaction and communication with a low to moderate level of evidence. The same applies to picture exchange communication system (PECS). Thus, while D53 (Smith and Iadarola 2015) reports a Level Two of evidence on the effectiveness of PECS based on the RCTs of Yoder and Stone (2006a, 2006b), NICE (2013c) considers that it is not possible to draw conclusions about the relative benefit of PECS on reciprocal social communication and interaction in children with autism based on the RCT of Howlin et al. (2007).

As to the different criteria used by each organization, a comparison among them showed that the requirements for granting, for example, the highest level of evidence to a certain treatment differed among institutions. D53 requires at least two large-scale RCTs which have demonstrated the superior efficacy of the treatment to some other treatment. The criteria used initially by NICE require at least one meta-analysis or RCT. The GRADE system, used later by NICE and Cochrane, grants the highest level of evidence if further research is very unlikely to change the confidence in the estimate of the effect. Finally, APS requires a systematic review of all relevant RCTs to confer the highest level of evidence. The analysis of these discrepancies also shows that, in other cases, the studies which the institutions use to determine the quality of the evidence are the same. Therefore, in these cases, the reason for the discrepancies could be the criteria used. This is the case of autism, where, for example, D53 (Smith and Iadarola 2015) confers a Level Three of evidence to the early start Denver model (ESDM) based on the RCT of Dawson et al. (2010), while NICE (2013c), based on the same study, considers that the evidence for ESDM on overall autistic behaviors was inconclusive. The case of family therapy for depression is significant. NICE (2015) considers this therapy to be effective (low level of evidence) based solely on the RCT of Diamond et al. (2002), while D53 (Weersing et al. 2017) grants a Level Three of evidence to this therapy based on Diamond et al. (2002) and Brent et al. (1997), among other studies. In contrast, Cochrane (Henken et al. 2007) suggests that the current evidence base is too heterogeneous and sparse to draw conclusions on the overall effectiveness of family therapy in the treatment

of depression also based on Diamond et al. (2002) and Brent et al. (1997), among others. Lastly, APS (2010) confers a Level I of evidence to family therapy based on this Cochrane review and another review presented by David-Ferndon and Kaslow (2008).

As regards enuresis, we have also found differences among organizations which may be due to the fact that different criteria were used. For instance, while Cochrane (Caldwell et al. 2013) suggests that dry bed training is effective for enuresis based solely on the study of Bennet et al. (1985), NICE (2010b) recommends that dry bed training not be used for the treatment of enuresis in children and young people based on five studies, among them the study of Bennet et al. (1985). The same applies to fluid restriction. Thus, while Cochrane (Caldwell et al. 2013) concludes that there is evidence to suggest that this therapy is effective based on the study of Bhatia et al. (1990), NICE (2010b) concludes that no evidence for fluid restriction was found based on the same study.

The fact that some reviews of existing evidence were conducted in different time periods may also explain the discrepancies found. For this reason, it is advisable to that lists reporting effective psychological treatments be updated on a regular basis since a substantial number of these lists, reviews and guides are currently out of date (Moriani et al. 2017). Moreover, the fact that NICE (2005) suggests that the evidence of EMDR for the treatment of PTSD in children is inconclusive, while D53 (Dorsey et al. 2017) confers a Level Two of evidence to this treatment based on three RCTs after the year 2007 and APS (2010) grants a Level I of evidence to EMDR, indicates that these discrepancies in the observed evidence may be due to the different time periods in which the reviews were conducted.

Hence, as in adults, the discrepancies in the effectiveness of psychological treatments in children and adolescents can be explained by the combination of the issues discussed above. These results reinforce the argument of Moriana et al. (2017) that it would be advisable to unify the criteria for assessing evidence and improve coordination between organizations in order to verify that a treatment is truly effective using high-quality reproducibility studies performed by independent teams.

The four organizations examined in this work are not the only sources that provide information on evidence of psychological treatments for mental disorders in children and adolescents. In many cases, these organizations do not include information contributed by other reviews that have been independently published, such as Davis et al. (2011), who reviewed evidence-based treatments for anxiety and phobias in children and adolescents.

These authors considered that CBT in the form of a one-session treatment (Davis et al. 2009) is the best overall treatment option (well established) for specific phobias, either behavior therapy or group CBT would be optimal (probably efficacious) for SAD, CBT is the treatment of choice (well established) for OCD, CBT is the most efficacious choice (well established) for PTSD and group CBT merits well-established status for childhood anxieties (combined), while individual CBT and family-focused CBT merit probably efficacious status for this last disorder. Additionally, the recent meta-analysis of Öst and Ollendick (2017) has shown that brief, intensive and concentrated CBT is effective for anxiety disorder, and that there is strong support for specific phobia, modest support for PTSD and OCD, and minimal support for panic disorder, SAD, separation anxiety disorder and mixed anxiety disorders. Another recent review of a meta-analysis of CBT in children and adolescents (Crowe and McKay 2017) has obtained overall medium effect sizes for anxiety, small to medium effect sizes for depression, a large effect size for OCD and a small to medium effect size for PTSD. Focusing on PTSD, the recent meta-analysis of Brown et al. (2017) has shown a medium to large effect size for CBT, EMDR, narrative exposure therapy and classroom-based interventions. Another meta-analysis (Gutermann et al. 2016) showed a medium to large effect size for CBT and a small to large effect size for EMDR, concluding that CBT is the most promising treatment for this disorder.

As regards effective treatments for depression, a meta-analysis in pre-adolescent children (12 years and younger) indicated that evidence on the effectiveness of CBT, FFT and psychodynamic therapy is inconclusive for this age group as the number of participants in the trials was relatively small (Forti-Buratti et al. 2016). In contrast, other meta-analyses have shown that CBT is effective in children with depression (Yang et al. 2017) and behavioral activation may be effective for this kind of patients, although this last conclusion should be interpreted with caution (Martin and Oliver 2018; Tindall et al. 2017). In the case of bipolar disorder, a narrative review (Weinstein et al. 2013) considered that FFT, psychoeducational psychotherapy, child- and family-focused CBT, dialectical behavior therapy, interpersonal and social rhythm therapy and CBT are effective treatments for children and adolescents. Although evidence of the effectiveness of psychological treatments in pediatric psychotic disorders is limited, Stevens et al. (2014) suggested in their review that CBT and psychoeducation are available treatments for these patients.

Concerning ADHD, Fabiano et al. (2015) conducted a review of meta-analyses to investigate the degree to which some narrative reviews (Evans et al. 2014; Pelham and Fabiano 2008; Pelham et al. 1998) that use operationalized criteria to graduate the effectiveness of psychological treatments were consistent with the meta-analytic literature. The authors concluded that the recommendations of the narrative reviews about the effectiveness of behavioral parent training and school-based contingency management were consistent with the meta-analytic literature; in turn, no meta-analysis calculated the effect sizes for training- and peer-focused interventions, which the narrative reviews determined to be effective. For disruptive behavior, a recent meta-analysis has pointed out that parent-child interaction therapy, multicomponent intervention and parent-focused intervention are effective treatments, although there is not enough evidence to determine which of them is superior (Bakker et al. 2017). Another meta-analysis suggested that treatments categorized as multicomponent interventions and treatments with only a parent component are similar in their effectiveness, while therapies with only a child component are less effective (Epstein et al. 2015).

Brunner and Seung (2009) conducted a literature review on evidence-based treatments for autism spectrum disorder. The authors concluded that there is solid evidence regarding the efficacy of applied behavior analysis (ABA), milieu teaching, pivotal response treatment (PRT), developmental interventions (including parent training), video modeling and augmentative and alternative communication (PECS and sign language training), and that the evidence on classroom-based treatments, social skill interventions and functional communication treatment remain in an exploratory stage of investigation.

As regards eating disorders, several systematic reviews and meta-analyses consider that CBT is an effective treatment for anorexia nervosa, although it is not superior to other treatments such as dietary counseling, non-specific supportive management, interpersonal therapy or behavioral family therapy (Galsworthy-Francis and Allan 2014), that behavioral family therapy for adolescents with eating disorders is superior to individual therapy at follow-up, while there is no difference at the end of the treatment (Couturier et al. 2013), and that cognitive remediation therapy has potential as a supplementary treatment for young people with anorexia nervosa (Tchanturia et al. 2017). Another recent review also recommends the use of CBT and family-based therapy

to treat eating disorders, anorexia and bulimia in children and adolescents (Herpertz-Dahlmann 2017).

Regarding nocturnal enuresis, Caldwell et al. (2013) affirm that although behavioral therapies (such as fluid restriction or rewards) are superior to no active treatment, they are inferior to alarm training, which is the first-line treatment for this disorder. Another review suggests that alarm training alone or combined with dry bed training increases the number of dry nights compared to no treatment, while the evidence for acupuncture, hypnotherapy and dry bed training alone is weak (Kiddoo 2015). Lastly, a recent meta-analysis on insomnia has provided evidence that CBT is an efficacious treatment for adolescents with sleep and mental health problems (Blake et al. 2017).

The lists of ESTs for different disorders are an important source of consultation, information and guidance for professionals who work with patients, as well as for professors and students in the higher education setting and in the qualification and ongoing training of professionals. The lack of consensus among the list of ESTs provided by the different organizations suggests the need to better identify these treatments. A first step would be to guarantee the quality of all the RCTs included in the systematic reviews and meta-analyses. Currently, several institutions have taken steps to ensure the quality of RCTs through prior registration in a database and subsequent monitoring. This is the case of the U.S. National Library of Medicine and their ClinicalTrials.gov database (<https://clinicaltrials.gov/>). Likewise, it would be advisable to guarantee the quality of the systematic reviews and meta-analyses by registering in the International Prospective Register of Systematic Reviews (PROSPERO; <https://www.crd.york.ac.uk/prospero/>) of the Centre for Reviews and Dissemination of the University of York (UK), which is funded by the UK's National Institute for Health Research. Although RCTs are considered to provide the most reliable evidence on the effectiveness of interventions (Akobeng 2005) and the existence of one or two RCTs with a quality methodological design is usually a requirement to reach the first levels in the different evidence classification systems, it is recommended that the results of individual trials be endorsed by systematic reviews and meta-analyses, taking into account that the samples used in this type of studies in psychology are usually not very large.

Given the importance of scientific research on psychological treatments and its important repercussion on the mental health of the population, international consensus should be promoted through the creation of working groups formed by various



organizations in order to establish common criteria to graduate the quality of the evidence and select RCTs, systematic reviews and other empirical studies that ensure minimum quality standards. In this regard, it seems that the GRADE system for rating clinical guidelines (Atkins et al. 2004) has met with increasing international support. These working groups should establish measures to improve the methodological aspects of RCT design and the inclusion and exclusion criteria of studies in systematic reviews and meta-analyses, in addition to controlling the biases produced by competing theoretical models in order to improve and ensure the objectivity of the scientific method in psychology.

Due to the difficulty of interventions with children or adolescents when complex techniques or proper programs are used (i.e., therapies based on relaxation training or problem solving), it is even harder to determine to what extent each treatment played a part in the individual's improvement. Most ESTs are packages comprising several techniques. In many cases, there are no explanations for the causal mechanism and we cannot know which component of the treatment is responsible for the effect. Comprehensive treatment programs have often been evaluated without identifying their causal mechanisms. Because programs are designed prior to being evaluated, we do not know if the design of a chosen program is superior to the multiple possible variants (O'Donohue and Yeater 2003). This raises doubts concerning the causal mechanisms of the treatment (Primerio and Moriana 2011). The next generation of research could analyze procedures (techniques, strategies) that are simpler units of analysis to determine what is useful, harmful or harmless in each treatment guide and thus make changes that will improve treatment efficacy (Westen et al. 2004). In this line, a recent review of 136 published RCTs of youth CBT treatments by Rith-Najarian et al. (2017) has proposed the need to use multi-parameter filtering in treatment selection and clinical decision making with different types of evidence. However, although we believe that the analysis of techniques or strategies is very positive for research on evidence-based psychological treatments, studies which jointly apply several techniques are recommended. That is, it is equally important to determine the efficacy of both a single technique and the interaction of several techniques packaged into a treatment.

In addition, RCTs with children and adolescents pose an ethical and legal challenge to clinicians and researchers due to several factors (Hoagwood and Cavaleri 2010). One of them involves the informed consent of parents who must authorize experimental therapies with their children or the possibility of being assigned to a control

group or waiting list, which usually involves a higher level of resistance than that normally found in research with adults. Another aspect is the cultural and ethnic diversity of children and their families (Kazdin 2008). It is also necessary to consider the therapist's abilities, the context in which the treatments are developed and the specific characteristics of each developmental stage. Moreover, in the context of child psychology there is a basic differentiating component compared to adult treatments: in many of the interventions the direct or indirect participation of the parents and/or relatives is essential, thus adding complexity to the process.

#### ***7.4.1. Limitations***

First, the heterogeneity of levels of evidence established by the different organizations greatly hinders a comparative assessment. Second, our objective has been to compile and compare the information provided by the four organizations exactly as it is provided by them. Thus, it is possible that some of the treatments included in our review share several components. Third, although we have reviewed and compared data provided by four international organizations, many other organizations confer grades and levels of evidence whose inclusion would have made our review more robust. And lastly, the disorders examined in this study only comprise a small part of the spectrum of mental disorders in children and adolescents.

#### ***7.4.2. Future directions***

Future studies should aim to reach a consensus on the scientific methods used to validate psychological treatments in order to unify the criteria among organizations, researchers and professionals on levels of evidence and methodological approaches for improving the quality of the studies that support them. Moreover, performing studies similar to ours on addictions, health psychology and other related areas not addressed in this study is both necessary and of interest.

### **7.5. Conclusions**

This study is the first to compare evidence provided by four leading international organizations on different psychological treatments for the principal child and adolescent mental disorders. From the main findings, it should be highlighted that there is no consensus regarding the evidence presented to support the effectiveness of psychological treatments for most mental disorders in children and adolescents. In addition, although there are numerous treatments for many of the disorders addressed here, not all provide the same quality of evidence or studies to support them. As a result, we need to contribute

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to improving the quality of RCTs through more independent studies that promote and contemplate reproducibility as a much more important criterion than envisaged so far. Finally, as regards the comparison, we found that while similar evidence exists for some disorders (e.g., OCD), for others there is a significant number of treatments for which the level of evidence varies greatly depending on the organization (e.g., autism), and some notable divergences between organizations regarding the evidence presented for treatments for disorders (e.g., enuresis).

### ***Compliance with Ethical Standards***

*Funding.* This work was supported by a grant from the Government of Spain (Ministerio de Economía y Competitividad) (Grant Number PSI2014-56368-R).

*Conflict of interest.* None of the authors of this review have any conflicts of interest to declare.

*Ethical Approval.* This article does not include any studies with human participants performed by any of the authors.

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## Capítulo 8

### Estudio 3

**Gálvez-Lara, M., Corpas, J., Velasco, J. y Moriana, J. A. El impacto de los tratamientos psicológicos basados en la evidencia sobre la práctica clínica. *En revisión.***

#### **Resumen**

Este trabajo pretende conocer el impacto que los tratamientos basados en la evidencia (TBEs) ejercen sobre la psicología aplicada, así como los factores que podrían estar relacionados con dicho impacto. La muestra estuvo compuesta por 242 psicólogos formados en España, a los que se les administró un cuestionario ad-hoc constituido por preguntas que recogían información acerca de determinadas variables sociodemográficas y sobre el uso de los TBEs para los trastornos mentales en población adulta. Los resultados señalan que, a excepción de las terapias cognitivo-conductuales, el impacto de los tratamientos basados en la evidencia es limitado, pudiendo influir en dicho impacto el tipo de acreditación profesional y los años de experiencia clínica. Los hallazgos de este estudio apoyan la idea de que los resultados de la investigación no se implementan ni consolidan del todo en los ámbitos aplicados.

**Palabras clave:** Tratamientos psicológicos basados en la evidencia; Investigación; Práctica clínica; Divulgación; Terapia cognitivo-conductual

## **Abstract**

This paper aims to know the impact that evidence-based treatments (EBTs) exert on applied psychology, as well as the factors that could be related to this impact. The sample consisted of 242 psychologists trained in Spain, who were administered an ad-hoc questionnaire consisting of questions that gathered information about certain sociodemographic variables and about the use of EBTs for mental disorders in adults. The results indicate that, with the exception of cognitive-behavioral therapies, the impact of EBTs is limited, and the professional accreditation and the years of clinical experience may influence this impact. The findings of this study support the idea that the results of the research are not fully consolidated in the areas applied.

**Keywords:** Evidence-based psychological treatments; Research; Clinical practice; Divulagation; Cognitive-behavioral therapy

## **8.1. Introducción**

La evaluación científica de la eficacia de los tratamientos psicológicos se ha convertido en una cuestión fundamental para la psicología clínica en las últimas décadas, debido, entre otros motivos, a que el avance científico de la psicología en este ámbito pasa por determinar qué terapias son eficaces y al hecho de que la intervención psicológica forma parte de los servicios ofrecidos por los sistemas públicos de salud (Echeburúa, Corral y Salaberría, 2010). Sin embargo, son muchos los autores que plantean que los resultados obtenidos por la investigación científica ejercen poca influencia sobre la psicología aplicada (Barlow, Bullis, Comer y Ametaj, 2013; Kazdin, 2018), habiendo un amplio consenso acerca de la existencia de una brecha entre la investigación y la práctica clínica (Kazdin, 2008; Westen, Novotny y Thompson-Brenner, 2004).

En esta línea, algunos estudios plantean que, en muchas ocasiones, los pacientes no están recibiendo tratamientos basados en la evidencia (TBEs) para el abordaje de sus problemas psicológicos (Dobson y Beshai, 2013; Dozois, 2013). Además, incluso cuando los psicólogos utilizan TBEs, a menudo no son fieles a los manuales de tratamiento, ya que no siempre utilizan todos los elementos de la terapia (Stobie, Taylor, Quigley, Ewing y Salkovskis, 2007). Por lo tanto, esta situación provoca que los pacientes no se beneficien del conocimiento acumulado por décadas de investigación (Tasca et al., 2015), pudiendo incidir negativamente en su bienestar y en su recuperación (Constantino, Coyne y Gomez Penedo, 2017).

Son muchas las razones que se han estudiado para explicar la existencia de las discrepancias entre la investigación científica y la práctica aplicada. En primer lugar, numerosos terapeutas alegan que las muestras de pacientes utilizadas en los ensayos controlados aleatorizados (ECAs) no son representativas de los pacientes que acuden a las consultas de psicología clínica (Gyani, Shafran, Rose y Lee, 2015), planteando además que existen diferencias entre intervenir en condiciones controladas de investigación y hacerlo en el contexto de tratamiento habitual (McLeod et al., 2017). Otros terapeutas mantienen que aprender paso a paso el desarrollo de un tratamiento es más importante que el aprendizaje sobre TBEs, y que aspectos como la alianza terapéutica son más relevantes que la intervención aplicada (Stewart, Stirman y Chambless, 2012).

El hecho de que los resultados de la investigación se divulguen mayoritariamente en revistas científicas puede ocasionar que dichos resultados no lleguen a los profesionales aplicados (Echeburúa et al., 2010). Varias encuestas han demostrado que pocos profesionales de la psicología clínica leen revistas científicas (Stewart y Chambless, 2007; Safran, Abreu, Ogilvie y DeMaria, 2011), tomando las decisiones de tratamiento en base a su experiencia clínica o en la de sus compañeros (Gyani, Sharan, Myles, y Rose 2014; Safran et al., 2011; Stewart y Chambless, 2007; Stewart et al., 2012; Stewart, Chambless y Stirman, 2018). Además, algunos estudios han señalado que factores personales como la edad del profesional (Aarons y Sawizky, 2006), la orientación terapéutica (Gyani et al., 2014; Safran et al., 2011; Stewart y Chambless, 2007), el nivel educativo (Beidas y Kendall, 2010), los años de experiencia clínica (Beidas y Kendall, 2010) y el ámbito laboral (Gyani et al., 2014) pueden influir en el uso de TBEs.

Por lo tanto, el objetivo de este trabajo consiste en determinar el uso que los psicólogos formados en España hacen de los TBEs para los diferentes trastornos mentales, así como analizar los factores personales que puedan estar relacionados con la integración de la evidencia científica dentro de la práctica clínica.

## **8.2. Método**

### **8.2.1. Participantes**

La muestra estuvo compuesta por 242 graduados o licenciados en psicología formados académicamente en universidades españolas, de los cuales el 64 % ( $n = 155$ ) eran mujeres y el 36 % ( $n = 87$ ) hombres, con una media de edad de 39.14 años ( $DT = 10.52$ ).

La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

### **8.2.2. Instrumentos**

Para llevar a cabo este estudio se desarrolló un instrumento *ad-hoc* compuesto por dos secciones diferenciadas: a) variables sociodemográficas (8 ítems) y b) autoinforme acerca del uso de determinados TBEs para los trastornos mentales en población adulta (97 ítems).

Las variables sociodemográficas que se recogieron fueron las siguientes: edad, sexo, nivel educativo, año de finalización de los estudios de grado o licenciatura, acreditación profesional, años de experiencia en evaluación y tratamiento psicológico, ámbito de trabajo y orientación teórica.

El segundo apartado del instrumento fue un cuestionario que incluía 97 de los TBEs recogidos en el estudio de Moriana, Gálvez-Lara y Corpas (2017), agrupados para 12 trastornos en población adulta. Para cada tratamiento los participantes debían marcar una de las siguientes opciones: *lo conozco y lo utilizo habitualmente para este trastorno; lo conozco, pero no considero oportuno utilizarlo para este trastorno; lo conozco, pero no tengo las competencias necesarias para utilizarlo; o no lo conozco*. Aquellos participantes que no desarrollaran práctica clínica o no tuvieran experiencia con un trastorno específico debían responder estas cuestiones en base a su formación académica. Como medida relativa del impacto de estos tratamientos sobre la práctica clínica se utilizó la puntuación total del cuestionario, compuesta por el número de veces que se indica que un tratamiento era utilizado habitualmente, pudiéndose obtener una puntuación entre 0 y 97.

### **8.2.3. Procedimiento**

Se contactó vía email y telefónica con los colegios oficiales y con instituciones científico-profesionales de psicología de nuestro país, preguntándoles por su disposición para difundir nuestro estudio entre sus colegiados o asociados. A aquellos colegios e instituciones que aceptaron colaborar en nuestro estudio se les envió un segundo email que contenía una breve carta de presentación con información sobre el estudio y el link de nuestro cuestionario alojado en *Google Formularios*, con el objetivo de que lo difundieran entre todos sus usuarios.

### **8.2.4. Análisis estadísticos**

En primer lugar, se analizará la presencia de valores *outliers* en la puntuación total del cuestionario mediante un diagrama de caja, dando lugar a la eliminación de los sujetos con estas puntuaciones. En segundo lugar, para determinar la fiabilidad de este

cuestionario se llevará a cabo un alfa de Cronbach como medida de la consistencia interna de los elementos que lo componen. A continuación, para analizar la relación de las variables sociodemográficas con el uso de los TBEs se realizará el coeficiente de correlación de Pearson para la variable “edad”, la prueba *t* de Student para las variables compuestas por dos grupos y el análisis de varianza de un factor (ANOVA) para aquellas que contengan tres o más grupos. La homogeneidad de varianzas será analizada mediante el test de Levene. Para determinar las diferencias específicas entre grupos dentro de cada variable, se realizarán comparaciones múltiples mediante el test de Tukey (si se cumple el supuesto de homogeneidad de varianzas) o mediante la prueba Games-Howell (si no se cumple el supuesto de homogeneidad de varianzas).

### 8.3. Resultados

El diagrama de caja señala la presencia de tres *outliers* con valores iguales o mayores a 91 puntos en el total del cuestionario. Tras la eliminación de los *outliers* se obtuvo un tamaño muestral de 239 participantes con una puntuación media en el cuestionario de 42.92 ( $DT = 18.26$ ). A continuación, las tablas 8.1, 8.2 y 8.3 muestran las frecuencias y porcentajes de respuesta en el cuestionario para los diferentes trastornos.

El análisis de la consistencia interna de los 97 elementos (tratamientos) que componían el cuestionario dio como resultado un alfa de Cronbach muy elevado (.97). La relación de las variables sociodemográficas con el uso de los TBEs fue analizada mediante el coeficiente de correlación de Pearson y las pruebas *t* de Student y ANOVA. El análisis de correlación de Pearson indica que no hay una correlación estadísticamente significativa entre la edad y el uso de dichos tratamientos ( $r = .063, p > .05$ ). La prueba *t* de Student muestra que no existen diferencias significativas en la variable “orientación teórica” en la utilización de los tratamientos consultados. Los ANOVAs realizados indican diferencias estadísticamente significativas en las variables “acreditación profesional” y “años de experiencia clínica”, no observándose diferencias significativas en el resto de las variables (ver tabla 8.4).

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**Tabla 8.1. Frecuencias y porcentajes (n / %) de respuesta en el cuestionario para los trastornos de ansiedad, trastorno obsesivo-compulsivo y trastorno de estrés postraumático**

	Uso habitual	No considera oportuno su uso para este trastorno	No dispone de las competencias necesarias para utilizarlo	No lo conoce
<i>Ansiedad Generalizada</i>				
TCC	208 / 87.0	13 / 5.4	17 / 7.1	1 / 0.4
Terapia de autoayuda	62 / 25.9	84 / 35.1	27 / 11.3	66 / 27.6
Relajación aplicada	193 / 80.8	28 / 11.7	17 / 7.1	1 / 0.4
Mindfulness	94 / 39.3	30 / 12.6	95 / 39.7	20 / 8.4
Terapia psicodinámica	22 / 9.2	79 / 33.1	90 / 37.7	48 / 20.1
Psicoeducación	178 / 74.5	24 / 10.0	18 / 7.5	19 / 7.9
<i>Trastorno de Pánico</i>				
TCC	204 / 85.4	14 / 5.9	20 / 8.4	1 / 0.4
Terapia conductual	171 / 71.5	43 / 18.0	21 / 8.8	4 / 1.7
Terapia de autoayuda	66 / 27.6	73 / 30.5	39 / 16.3	61 / 25.5
Relajación aplicada	181 / 75.7	35 / 14.6	20 / 8.4	3 / 1.3
Terapia psicodinámica	19 / 7.9	81 / 33.9	87 / 36.4	52 / 21.8
Psicoeducación	175 / 73.2	22 / 9.2	21 / 8.8	21 / 8.8
<i>Ansiedad Social</i>				
TCC	208 / 87.0	13 / 5.4	18 / 7.5	---
Terapia de autoayuda	75 / 31.4	71 / 29.7	33 / 13.8	60 / 25.1
Terapia psicodinámica	24 / 10.0	82 / 34.3	90 / 37.7	43 / 18.0
Terapia interpersonal	67 / 28.0	31 / 13.0	79 / 33.1	62 / 25.9
TAC	81 / 33.9	41 / 17.2	94 / 39.3	23 / 9.6
Terapia de exposición	203 / 84.9	12 / 5.0	19 / 7.9	5 / 2.1
Habilidades sociales	211 / 88.3	13 / 5.4	14 / 5.9	1 / 0.4
<i>Fobias específicas</i>				
Terapia de autoayuda	75 / 31.4	71 / 29.7	31 / 13.0	62 / 25.9
Terapia de exposición	213 / 89.1	4 / 1.7	17 / 7.1	5 / 2.1
<i>Trastorno obsesivo-compulsivo</i>				
TAC	102 / 42.7	39 / 16.3	73 / 30.5	25 / 10.5
EPR	199 / 83.3	9 / 3.8	14 / 5.9	17 / 7.1
Terapia de autoayuda	81 / 33.9	57 / 23.8	33 / 13.8	68 / 28.5
<i>Estrés postraumático</i>				
TCC	195 / 81.6	18 / 7.5	22 / 9.2	4 / 1.7
Terapia de procesamiento cognitivo	96 / 40.2	21 / 8.8	50 / 20.9	72 / 30.1
DRMO (EMDR)	25 / 10.5	34 / 14.2	131 / 54.8	49 / 20.5
Terapia centrada en el presente	72 / 30.1	15 / 6.3	57 / 23.8	95 / 39.7
Exposición controlada	153 / 64.0	29 / 12.1	34 / 14.2	23 / 9.6
Terapia de búsqueda de seguridad	29 / 12.1	25 / 10.5	35 / 14.6	150 / 62.8
Terapia de inoculación del estrés	104 / 43.5	51 / 21.3	52 / 21.8	32 / 13.4

Nota: DRMO = Desensibilización y reprocesamiento por medio de movimientos oculares; EPR = Exposición y prevención de respuesta; TAC = Terapia de Aceptación y Compromiso; TCC = Terapia cognitivo-conductual

**Tabla 8.2. Frecuencias y porcentajes (n / %) de respuesta en el cuestionario para la depresión y el trastorno bipolar**

	Uso habitual	No considera oportuno su uso para este trastorno	No dispone de las competencias necesarias para utilizarlo	No lo conoce
<i>Depresión</i>				
TAC	118 / 49.4	24 / 10.0	79 / 33.1	18 / 7.5
Relajación aplicada	132 / 55.2	85 / 35.6	20 / 8.4	2 / 0.8
Terapia de activación conductual	174 / 72.8	12 / 5.0	19 / 7.9	34 / 14.2
CBASP	32 / 13.4	16 / 6.7	40 / 16.7	151 / 63.2
TCC	203 / 84.9	18 / 7.5	17 / 7.1	1 / 0.4
Entrenamiento en memoria competitiva	8 / 3.3	21 / 8.8	29 / 12.1	181 / 75.7
Terapia de pareja	77 / 32.2	82 / 34.3	49 / 20.5	31 / 13.0
Terapia cognitiva	174 / 72.8	30 / 12.6	28 / 11.7	7 / 2.9
Counselling	51 / 21.3	71 / 29.7	52 / 21.8	65 / 27.2
TDC	48 / 20.1	46 / 19.2	66 / 27.6	79 / 33.1
Terapia centrada en la emoción	79 / 33.1	25 / 10.5	56 / 23.4	79 / 33.1
Terapia interpersonal	73 / 30.5	27 / 11.3	69 / 28.9	70 / 29.3
Mindfulness	87 / 36.4	41 / 17.2	89 / 37.2	22 / 9.2
Actividad física	188 / 78.7	15 / 6.3	24 / 10.0	12 / 5.0
Terapia psicodinámica	26 / 10.9	75 / 31.4	89 / 37.2	49 / 20.5
Psicoeducación	167 / 69.9	29 / 12.1	24 / 10.0	19 / 7.9
Terapia de solución de problemas	182 / 76.2	21 / 8.8	20 / 8.4	16 / 6.7
Terapia racional emotiva conductual	141 / 59.0	26 / 10.9	44 / 18.4	28 / 11.7
Terapia de reminiscencia	14 / 5.9	28 / 11.7	41 / 17.2	156 / 65.3
Terapia de autocontrol	85 / 35.6	60 / 25.1	23 / 9.6	71 / 29.7
Terapia de autoayuda	87 / 36.4	60 / 25.1	31 / 13.0	61 / 25.5
Terapia de autosistema	6 / 2.5	17 / 7.1	21 / 8.8	195 / 81.6
<i>Trastorno bipolar</i>				
TCC	184 / 77.0	16 / 6.7	31 / 13.0	8 / 3.3
Terapia cognitiva	153 / 64.0	33 / 13.8	39 / 16.3	14 / 5.9
Terapia centrada en la familia	115 / 48.1	26 / 10.9	55 / 23.0	43 / 18.0
Psicoeducación familiar	158 / 66.1	15 / 6.3	34 / 14.2	32 / 13.4
Terapia grupal	91 / 38.1	38 / 15.9	80 / 33.5	30 / 12.6
TCH	40 / 16.7	15 / 6.3	52 / 21.8	132 / 55.2
Terapia interpersonal y del ritmo social	32 / 13.4	16 / 6.7	50 / 20.9	141 / 59.0
Mindfulness	72 / 30.1	45 / 18.8	94 / 39.3	28 / 11.7
Psicoeducación	160 / 66.9	22 / 9.2	33 / 13.8	24 / 10.0
Cuidados sistemáticos	45 / 18.8	17 / 7.1	37 / 15.5	140 / 58.6

Nota: TAC = Terapia de aceptación y compromiso; CBASP = Sistema de psicoterapia de análisis cognitivo-conductual; TCC = Terapia cognitivo-conductual; TCH = Terapia cognitiva integrada e interpersonal; TDC = Terapia dialéctico-conductual



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**Tabla 8.3. Frecuencias y porcentajes (*n* / %) de respuesta en el cuestionario para los trastornos de alimentación, esquizofrenia y trastorno límite de personalidad**

	Uso habitual	No considera oportuno su uso para este trastorno	No dispone de las competencias necesarias para utilizarlo	No lo conoce
<i>Anorexia nerviosa</i>				
TCC	177 / 74.1	14 / 5.9	41 / 17.2	7 / 2.9
TBF	130 / 54.4	8 / 3.3	68 / 28.5	33 / 13.8
Terapia interpersonal	74 / 31.0	21 / 8.8	83 / 34.7	61 / 25.5
Terapia psicodinámica	23 / 10.9	69 / 28.9	96 / 40.2	48 / 20.1
TCA	35 / 14.6	30 / 12.6	79 / 33.1	95 / 39.7
<i>Bulimia nerviosa</i>				
TCC	181 / 75.7	14 / 5.9	36 / 15.1	8 / 3.3
TBF	121 / 50.6	17 / 7.1	70 / 29.3	31 / 13.0
Terapia interpersonal	75 / 31.4	22 / 9.2	77 / 32.2	65 / 27.2
Programa de peso saludable	85 / 35.6	22 / 9.2	46 / 19.2	86 / 36.0
TDC	66 / 27.6	26 / 10.9	74 / 31.0	73 / 30.5
Terapia de autoayuda	66 / 27.6	63 / 26.4	44 / 18.4	66 / 27.6
<i>Esquizofrenia</i>				
TAC	86 / 36.0	51 / 21.3	72 / 30.1	30 / 12.6
PTAC	98 / 41.0	10 / 4.2	56 / 23.4	75 / 31.4
Entrenamiento en adaptación cognitiva	74 / 31.0	11 / 4.6	47 / 19.7	107 / 44.8
TCC	163 / 68.2	22 / 9.2	40 / 16.7	14 / 5.9
Rehabilitación cognitiva	114 / 47.7	21 / 8.8	52 / 21.8	52 / 21.8
Terapia centrada en la familia	128 / 53.6	10 / 4.2	59 / 24.7	42 / 17.6
Manejo de la enfermedad y la recuperación	134 / 56.1	9 / 3.8	43 / 18.0	53 / 22.2
Terapia psicodinámica	20 / 8.4	88 / 36.8	72 / 30.1	59 / 24.7
Psicoeducación	157 / 65.7	17 / 7.1	36 / 15.1	29 / 12.1
Empleo con apoyo	104 / 43.5	11 / 4.6	60 / 25.1	64 / 26.8
Habilidades sociales	172 / 72.0	13 / 5.4	41 / 17.2	13 / 5.4
Programas de economía de fichas	88 / 36.8	88 / 36.8	43 / 18.0	20 / 8.4
<i>Trastorno límite de la personalidad</i>				
TCA	44 / 18.4	18 / 7.5	79 / 33.1	98 / 41.0
TCC	166 / 69.5	29 / 12.1	33 / 13.8	11 / 4.6
TDC	88 / 36.8	12 / 5.0	66 / 27.6	73 / 30.5
Entrenamiento en regulación de la emoción	134 / 56.1	13 / 5.4	40 / 16.7	52 / 21.8
Terapia interpersonal	75 / 31.4	17 / 7.1	75 / 31.4	72 / 30.1
Mindfulness	83 / 34.7	37 / 15.5	91 / 38.1	28 / 11.7
Terapia psicodinámica	25 / 10.5	79 / 33.1	87 / 36.4	48 / 20.1
Psicoeducación	159 / 66.5	21 / 8.8	34 / 14.2	25 / 10.5
Terapia centrada en esquemas	31 / 13.0	17 / 7.1	66 / 27.6	125 / 52.3
STEPPS	68 / 28.5	15 / 6.3	53 / 22.2	103 / 43.1
TCT	23 / 9.6	20 / 8.4	55 / 23.0	141 / 59.0

Nota: PTAC = Programa de entrenamiento asertivo comunitario; STEPPS = Entrenamiento para la regulación emocional y la solución de problemas; TAC = Terapia de aceptación y compromiso; TCA = Terapia cognitivo-analítica; TBF = Terapia basada en la familia; TCC = Terapia cognitivo-conductual; TDC = Terapia dialectico-conductual; TCT = Terapia centrada en la transferencia

**Tabla 8.4. Variables sociodemográficas y diferencia de medias en el uso de los TBEs**

<i>Variable</i>	<i>n / %</i>	<i>M (DT)</i>	<i>F/t</i>	<i>p</i>
Nivel educativo			.124	.883
Graduado o licenciado	62 / 25.9	43.90 (20.86)		
Máster	133 / 55.6	42.64 (18.11)		
Doctorado	44 / 18.4	42.36 (14.82)		
Año de finalización de los estudios de grado o licenciatura			.470	.625
1995 o anteriores	72 / 30.1	41.18 (19.14)		
1996 a 2005	107 / 44.8	43.77 (18.14)		
2006 a 2017				
Acreditación profesional			4.775*	.011
No acreditado	31 / 13.0	34.25 (22.51)		
Especialista en psicología clínica	75 / 31.4	46.97 (15.28)		
Psicólogo general sanitario o habilitado	133 / 55.6	42.65 (18.12)		
Experiencia clínica			5.628*	.000
Sin experiencia	41 / 17.2	31.12 (23.44)		
1 a 3 años	45 / 18.8	43.53 (17.89)		
4 a 9 años	54 / 22.6	45.92 (15.62)		
10 a 15 años	42 / 17.6	44.59 (15.07)		
16 años o más	57 / 23.8	46.84 (15.75)		
Ámbito de trabajo			1.501	.225
Desempleado o distinto a psicología	31 / 13.0	39.03 (22.21)		
Sector público	101 / 42.2	45.02 (16.52)		
Sector privado	107 / 44.8	42.05 (18.51)		
Orientación teórica			.450**	.653
Cognitivo-Conductual	147 / 61.5	43.36 (16.31)		
Otras corrientes	92 / 38.5	42.20 (21.09)		
Conductual	49 / 20.5			
Cognitiva	5 / 2.1			
Sistémica	11 / 4.6			
Psicodinámica	6 / 2.5			
Ecléctica	9 / 3.8			
Otras	12 / 5.0			

\*F de Brown-Forsythe debido a la desigualdad de varianzas ( $p < .05$ ) entre los grupos

\*\*Valor de *t* asumiendo varianzas desiguales ( $p < .05$ ) entre los grupos

Debido a que el test de Levene mostró desigualdad de varianzas en las variables “acreditación profesional” [ $F(2, 236) = 4.683, p = .010$ ] y “años de experiencia clínica” [ $F(4, 234) = 4.744, p = .001$ ], se utilizó la prueba de Games-Howell para conocer las diferencias entre los grupos dentro de dichas variables. En cuanto a la acreditación profesional, la prueba Games-Howell señala diferencias estadísticamente significativas entre aquellos profesionales de la psicología que no están acreditados y los especialistas en psicología clínica, sin que aparezcan diferencias significativas en el resto de comparaciones (ver tabla 8.5). Por su parte, las comparaciones múltiples en la variable “años de experiencia clínica” muestran diferencias estadísticamente significativas entre los participantes sin experiencia clínica y aquellos con cuatro años o más de experiencia, mientras que en el resto de comparaciones de esta variable no aparecen diferencias (ver tabla 8.5).

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**Tabla 8.5. Prueba Games-Howell de comparaciones múltiples de las variables “acreditación” y “años de experiencia clínica”**

		<i>Diferencia de medias</i>	<i>Error estándar</i>	<i>p</i>
No acreditado	Clínico	-12.715	4.411	.017
	Sanitario	-8.396	4.338	.142
Clínico	No acreditado	12.715	4.411	.017
	Sanitario	4.319	2.363	.164
Sanitario	No acreditado	8.396	4.338	.142
	Clínico	-4.319	2.363	.164
Sin experiencia	1 a 3 años	-12.411	4.529	.057
	4 a 9 años	-14.803	4.233	.007
	10 a 15 años	-13.473	4.337	.022
	16 años o más	-15.720	4.214	.004
1 a 3 años	Sin experiencia	12.411	4.529	.057
	4 a 9 años	-2.392	3.410	.956
	10 a 15 años	-1.061	3.539	.998
	16 años o más	-3.308	3.387	.865
4 a 9 años	Sin experiencia	14.803	4.233	.007
	1 a 3 años	2.392	3.410	.956
	10 a 15 años	1.330	3.151	.993
	16 años o más	-.916	2.979	.998
10 a 15 años	Sin experiencia	13.473	4.337	.022
	1 a 3 años	1.061	3.539	.998
	4 a 9 años	-1.330	3.151	.993
	16 años o más	-2.246	3.125	.952
16 años o más	Sin experiencia	15.720	4.214	.004
	1 a 3 años	3.308	3.387	.865
	4 a 9 años	.916	2.979	.998
	10 a 15 años	2.246	3.125	.952

#### 8.4. Discusión

Este estudio ha pretendido analizar el uso que los psicólogos formados en España hacían de los TBEs, así como determinar los factores personales que pudieran estar relacionados con la integración de estos tratamientos dentro de la práctica clínica. Los resultados indicaron que el impacto que las intervenciones psicológicas basadas en la evidencia ejercen sobre la práctica clínica es limitado. Así, a pesar de la evidencia demostrada por todas las terapias incluidas en el cuestionario, en numerosas ocasiones los participantes indicaron que no consideraban oportuno su uso, que no tenían las competencias necesarias para llevarlas a cabo o, simplemente, que no las conocían. Sin embargo, podemos afirmar que, para todos los trastornos analizados, las terapias de corte cognitivo-conductual eran ampliamente utilizadas.

En el caso de la terapia psicodinámica, para todos los trastornos en los que ha demostrado ser eficaz, más del 60 % de los encuestados afirmaron no considerar oportuno su uso o no disponer de las competencias necesarias. Algo parecido ocurre con la terapia interpersonal y con la terapia dialéctico conductual, ya que en todos los trastornos en los

que aparecen, alrededor del 60 % de los participantes indicaron que no la conocían o que no disponían de las competencias para utilizarla. Sin embargo, la eficacia de la terapia dialectico conductual ha sido ampliamente demostrada para el trastorno límite de personalidad, al igual que la eficacia de la terapia interpersonal para la depresión (Moriani et al., 2017)

Otro resultado significativo es el elevado número de terapias que han demostrado ser eficaces, pero que, sin embargo, son desconocidas para la mayoría de los participantes en nuestro estudio. Este es el caso de la terapia de búsqueda de seguridad para el trastorno de estrés postraumático (62.8 %), sistema de psicoterapia de análisis cognitivo-conductual para la depresión (63.2 %), entrenamiento en memoria competitiva para la depresión (75.7 %), terapia de reminiscencia para la depresión (65.3 %), terapia de autosistema para la depresión (81.6 %), terapia cognitiva integrada e interpersonal para el trastorno bipolar (55.2 %), terapia interpersonal y del ritmo social para el trastorno bipolar (59.0 %), cuidados sistemáticos para el trastorno bipolar (58.6 %), terapia centrada en esquemas para el trastorno límite de la personalidad (52.3 %) y terapia centrada en la transferencia para el trastorno límite de la personalidad (59.0 %).

Estos resultados demuestran que la divulgación de la eficacia de todos los tratamientos anteriores no ha sido del todo exitosa. El caso opuesto lo tenemos en el mindfulness, ya que a pesar de no haber un amplio consenso internacional acerca de su eficacia (Moriani et al., 2017), para todos los trastornos en los que mostró ser beneficiosa, al menos el 70 % de los participantes afirmaron utilizar la terapia, o bien conocer la terapia pero no disponer de las competencias necesarias para llevarla a cabo.

Tras analizar los factores personales que podrían estar relacionados con la integración de los TBEs dentro de la práctica clínica, tan solo la acreditación profesional y los años de experiencia clínica estaban relacionados con dicha integración. Los resultados mostraron que los psicólogos especialistas en psicología clínica hacían un mayor uso de los TBEs que los psicólogos no acreditados. Sin embargo, no hubo diferencias entre las puntuaciones de los psicólogos sanitarios y aquellos no acreditados. Recientemente se ha realizado una encuesta a psicólogos aplicados con el objetivo de conocer la actualidad de la psicoterapia en nuestro país (Labrador y Berdullas, 2017). Aunque en esta encuesta se les preguntó a los participantes si sus intervenciones seguían las directrices de guías y protocolos de tratamiento basados en la evidencia, este es el primer trabajo que analiza el uso de un amplio listado de TBEs por parte de los psicólogos

formados en España. Por lo tanto, debido a que la distinción entre psicólogo no acreditado, psicólogo sanitario y psicólogo especialista en psicología clínica es propia de nuestro país, no existen estudios que nos permitan comparar estos resultados.

En cuanto a los años de experiencia clínica, los resultados mostraron que los participantes con cuatro años de experiencia o más obtuvieron mayor puntuación en el cuestionario que aquellos que no tenían experiencia clínica. En cambio, no hubo diferencias entre las puntuaciones de los participantes dentro de los distintos grupos que tenían experiencia clínica. Por lo tanto, el uso de TBEs no aumentó a medida que aumentaban los años de experiencia, estancándose a partir de los cuatro años. Aunque algunos estudios sugieren que existe una relación positiva entre los años de experiencia clínica y la aplicación de TBEs (Aarons, 2004; Beidas y Kendall, 2010), nuestros resultados van más en consonancia con los obtenidos por Nelson y Steele (2007), que indican que no existe relación entre los años de experiencia clínica y el uso de TBEs.

Como se ha indicado anteriormente, el resto de los factores personales analizados (edad, año de finalización de los estudios de grado o licenciatura, nivel educativo, ámbito de trabajo y orientación teórica) no estuvieron relacionados con la utilización de TBEs. En el caso de la edad y año de finalización de los estudios de grado o licenciatura, nuestros resultados contradicen trabajos previos que indican que los profesionales más jóvenes suelen utilizar en mayor medida TBEs que aquellos con mayor edad (Aarons y Sawitzky, 2006) y que puede existir una mayor resistencia al uso de este tipo de intervenciones en los psicólogos que se formaron antes de la época de las prácticas basadas en la evidencia (Lilienfeld, Ritschel, Lynn, Cautin y Latzman, 2013).

En relación con el nivel educativo, los resultados de nuestro estudio muestran que no hay diferencias entre graduados o licenciados, másteres y doctorados a nivel respecto al uso de TBEs. Estos resultados van en la línea de los obtenidos por Nelson y Steele (2007), que indicaron que no había diferencias entre distintos tipos de doctorados y másteres en la utilización de este tipo de intervenciones. Sin embargo, otros autores han señalado que el nivel educativo está relacionado positivamente con el uso de estos tratamientos (Aarons, 2004; Beidas y Kendall, 2010).

Son numerosos los estudios que plantean que la orientación teórica puede ser un factor determinante a la hora de utilizar terapias basadas en la evidencia (Gyani et al., 2014; Safran et al., 2011; Stewart y Chambless, 2007). Aunque todos ellos indican que los terapeutas cognitivo-conductuales utilizan los resultados de la investigación científica

en mayor medida que los terapeutas de otras orientaciones, los resultados de nuestro estudio muestran que no hay diferencias entre los psicólogos cognitivo-conductuales y los psicólogos de otras corrientes a la hora de utilizar o conocer los TBEs. Este resultado podría explicarse debido a que, de los 92 psicólogos incluidos dentro del grupo de otras corrientes, 54 de ellos se definían como terapeutas conductuales o cognitivos.

El último de los factores analizados en nuestro estudio ha sido el ámbito laboral, obteniendo como resultado valores similares en el uso de los TBEs a lo largo de los diferentes ámbitos laborales. Sin embargo, estudios previos indican que el ámbito laboral puede influir en la utilización de este tipo de tratamientos. Así, mientras que los terapeutas del *National Health Service* (NHS) de Reino Unido usaban intervenciones basadas en la evidencia en mayor grado que los psicólogos que trabajaban en el ámbito privado (Gyani et al., 2014), un estudio llevado a cabo en Estados Unidos mostró que los psicólogos que trabajaban en instituciones privadas tenían una actitud más positiva a la hora de realizar prácticas psicológicas basadas en la evidencia que sus colegas que trabajaban en instituciones gubernamentales (Aarons, Sommerfeld y Walrath-Greene, 2009).

Como sugiere Kazdin (2008), muchos de los TBEs tienen una aplicabilidad real muy baja, por lo que para mejorar la diseminación de estos tratamientos entre los psicólogos aplicados sería conveniente adecuar las intervenciones a situaciones reales de aplicación. Otra propuesta para facilitar la diseminación de los tratamientos sería el abordaje psicológico desde una perspectiva transdiagnóstica enfocada en un conjunto de principios terapéuticos comunes (Barlow, Allen y Choate, 2004). Además, el desarrollo de tratamientos encaminados a abordar procesos comunes a distintos trastornos mentales podría aumentar los niveles de eficacia de las intervenciones (Tortella-Feliu et al., 2016).

#### **8.4.1. Limitaciones**

Este trabajo presenta varias limitaciones, además de los sesgos asociados al uso de medidas de autoinforme. En primer lugar, la muestra de participantes en nuestro estudio ha sido pequeña. En segundo lugar, los resultados han podido estar desvirtuados debido a que algunos de los participantes no tenían experiencia clínica y a que es posible que no todos los profesionales con experiencia hubieran intervenido en todos los trastornos por los que se ha preguntado. Así, en unas ocasiones habrían respondido en base a su experiencia clínica y en otras en base al conocimiento que tenían acerca de la eficacia de una determinada terapia. Por lo tanto, futuras investigaciones deberían ir

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encaminadas a conocer el uso de los diferentes tratamientos por parte de psicólogos que tengan experiencia en el tratamiento de un determinado trastorno psicológico.

## **8.5. Conclusión**

Este estudio ha evaluado el impacto que un amplio listado de TBEs ejerce sobre la práctica clínica. Los principales resultados han mostrado que la mayoría de los psicólogos encuestados utilizan terapias de corte cognitivo conductual para el tratamiento de los trastornos mentales. Sin embargo, el uso del resto de los TBEs es muy limitado. Por último, el tipo de acreditación profesional y los años de experiencia clínica podrían estar influyendo en la integración de estos tratamientos dentro de la práctica clínica. Por lo tanto, los hallazgos de este estudio apoyan la idea de que los resultados de la investigación no se consolidan del todo en los ámbitos aplicados.

### ***Conflicto de intereses***

Los autores de este artículo declaran que no tienen ningún conflicto de intereses.

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## Capítulo 9

### Estudio 4

**Gálvez-Lara, M., Corpas, J., Venceslá, J. y Moriana, J. A. (2019). Evidence-based brief psychological treatment for emotional disorders in primary and specialized care: study protocol of a randomized controlled trial. *Frontiers in Psychology*, 9, 2674. doi: 10.3389/fpsyg.2018.02674**

#### **Abstract**

Emotional Disorders (EDs) are very prevalent in Primary Care (PC). However, general practitioners (GPs) have difficulties to make the diagnosis and the treatment of this disorders that are usually treated with drugs. Brief psychological therapies may be a new option to treat EDs in a PC context. This article aims to present a study protocol to evaluate the effectiveness and the efficiency of an adaptation to brief format of the “Unified Protocol (UP) for the transdiagnostic treatment of EDs.” This is a single-blinded RCT among 165 patients with EDs. Patients will be randomly assigned to receive brief psychological treatment based on UP, conventional psychological treatment, conventional psychological treatment plus pharmacological treatment, minimum intervention based on basic psychoeducational information, or pharmacological treatment only. Outcome measure will be the following: GAD-7, STAI, PHQ-9, BDI-II, PHQ-15, PHQ-PD, and BSI-18. Assessments will be carried out by blinded raters at baseline, after the treatment and 6-month follow-up. The findings of this RCT may encourage the implementation of brief therapies in the PC context, what would lead to the decongestion of the public health system, the treatment of a greater number of people with EDs in a

shorter time, the reduction of the side effects of pharmacological treatment and a possible economic savings for public purse.

**Clinical trial registration:** ClinicalTrial.gov: NCT03286881. Registered 19 September 2017.

**Keywords:** emotional disorders, brief psychological treatment, transdiagnostic, primary care, randomized controlled trial

## **9.1. Introduction**

### **9.1.1. Background**

Nowadays, concern for mental health disorders and problems has increased significantly worldwide (Mental Health Foundation, 2016). Common mental health disorders, also called emotional disorders (EDs), are growing exponentially in recent decades (Vos et al., 2015; Chisholm et al., 2016). These disorders include DSM-5 (American Psychiatric Association, 2013) diagnostics of depression, generalized anxiety disorder, panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder, social anxiety disorder, and specific phobias (National Institute for Health and Care Excellence [NICE], 2011). EDs are very prevalent in primary care (PC) services (Roca et al., 2009; Lejtzen et al., 2014), since about 40% PC consultations would be direct or indirect related with this kind of problems (Kroenke et al., 2007).

Some researches point out the difficulties presented by general practitioners (GPs) to make the diagnosis and the treatment of EDs (Collings, 2005; Aragonés et al., 2006; Fernández et al., 2006; DeVicente and Berdullas, 2009; Gerrits et al., 2013; Jacka et al., 2013), and warn of the excess in the use of drugs (Secades Villa et al., 2003). Patients with mild-moderate symptoms of EDs are usually treated in PC with drugs as the first therapeutic option (Kovess-Masfety et al., 2007), which contradicts the research and the international clinical guides instructions (NICE, 2011), that suggest psychological therapies as treatment of choice. Although pharmacological treatment is obviously of choice in severe cases, scientific research indicates that many of the patients with mild-moderate symptoms could reduce them with psychological treatments, without medication (Moreno and Moriana, 2012) and that psychological treatment is more effective than medication in these patients in a PC context (Watts et al., 2015). In the same way, it is suggested that, independently of the severity of the case, psychological treatment should always be present (Gonçalves et al., 2003; NICE, 2011). Other studies have concluded that psychological treatment applied in PC for this kind of patients

promotes a greater recovery, improves the quality of care, decreases the prescription of drugs and reduces the hyperfrequency (Wells et al., 2000; Patel et al., 2010). Furthermore, psychological treatment is mostly preferred by patients, since it is in accordance with their conception of the problems they suffer (Prins et al., 2008; Walters et al., 2008).

Despite the importance of evaluating the efficacy of psychological treatments (Moriana et al., 2017; Gálvez-Lara et al., 2018), the knowledge of the empirical research's results and its later integration by the professional in the clinical practice does not get to consolidate completely in the applied fields (Herbert, 2003; Kazdin, 2008, 2011; Barlow et al., 2013). In this line, some studies have evidenced that psychologist, often, do not use evidence-based treatment (Lilienfeld, 2010; Dobson and Beshai, 2013; Dozois, 2013). At other times, psychologists do not use all the key elements of evidence-based treatment (Stobie et al., 2007). For these reasons, some authors have manifested the existence of a gap between the applied psychology and the scientific research (Westen et al., 2004; Kazdin, 2008, 2011; Babione, 2010).

Some surveys have indicated that applied psychologists feel that research's findings do not show the reality of clinical practice (Tasca et al., 2015) and affirm that the manualized treatments are very rigid for the habitual clinical practice (Gyani et al., 2015). This situation has promoted the demand for a better adequacy of the treatments to the real contexts of application (Kazdin, 2008), which entails their flexibility and use in different contexts (primary and specialized care) and their adaptation to brief formats of limited time (Moriana and Martínez, 2011).

### ***9.1.2. Brief therapies. Adaptation of the psychological treatments to the real context of application***

In recent years, the possibility of adapting conventional psychological therapies to an abbreviated format as a possible solution for the correct treatment of EDs has been suggested (Shepardson et al., 2016). Brief therapy or "time limited therapy" emerges as a therapeutic option of low cost to respond to the demands of public health about the use of psychological therapies of short duration that generate favorable results in clinical practice (Hewitt and Gantiva, 2009). To be considered short, a therapy should have more than two sessions and less than ten, establishing an average of six sessions, on the basis of the idea that the guides are flexible to the characteristics and symptoms of the patient (Cape et al., 2010). Although there is no agreement among different authors about how many sessions include limited time therapies, all agree on the importance of the time as a

therapeutic tool (Miller, 2000; MacNeil, 2001; Bedics et al., 2005; Hewitt and Gantiva, 2009; Lyons and Low, 2009). The limitation of the number of sessions helps both therapist and patient to focus fully on the therapy, increases the motivation of the patient and requires the establishment of achievable goals by the professional, considering each session as one intervention with a particular outcome with the aim that the patient undergoes change as soon as possible (Fosha, 2004).

Brief therapy responds adequately to the economic resources and psychological requirements of patients (Lyons and Low, 2009), and could be used to offer psychological therapy to patients who are in waiting lists for access to specialized programs, such as initial treatment for risk users and as a complement to more extensive psychological treatments (Sánchez and Gradolí, 2002). Due to its idiosyncrasy, brief therapies are especially indicated for adaptive and emotional problems of mild or moderate severity and it is suggested that they should be the first step for the therapeutic approach in this patient profile, giving a wide accessibility to patients and an effective response to their symptoms (Collings et al., 2015).

Some works have shown that brief therapies have obtained similar results to conventional therapies (Miller, 2000; Bloom, 2001; Lyons and Low, 2009; Nieuwsma et al., 2012), demonstrating its effectiveness in reducing anxiety and depressive symptoms (Koutra et al., 2010; Bernhardsdottir et al., 2013; Saravanan et al., 2017), on the improvement of problem-solving skills (Bannink, 2007), in reducing symptoms of posttraumatic stress disorder (Kip et al., 2016) or in the decrease in the intake of alcohol in people who had an excessive consumption (Gantiva et al., 2003). In addition, brief therapies have not only proved effective immediately after treatment, but also that the improvement in the patient stays long after the end of the intervention (Hamdan-Mansour et al., 2009; Vázquez et al., 2012).

### ***9.1.3. Unified Protocol for the transdiagnostic treatment of emotional disorders***

One of the main problems of the categorical approach to psychopathology is the high comorbidity among the different mental disorders (Sandín et al., 2012). In last years, a new approach has emerged for the treatment of mental disorders that aims to develop interventions that can be used to treat the common symptoms of various psychological disorders (Belloch, 2012). This approach, known as transdiagnostic, considers that mental disorders share numerous cognitive and behavioral processes that contribute to the development and maintenance of symptoms (Harvey et al., 2004). Thus, the

transdiagnostic treatment is defined as a “therapy that is made available to individuals with a wide range of diagnosis and that does not rely on knowledge of these diagnoses to operate effectively” (Mansell et al., 2009, p. 14).

Psychological treatment from a transdiagnostic approach is especially appropriate for EDs, since accumulated findings have shown important shared characteristics among depression, anxiety, and other emotion-related disorders (Barlow, 2002; Barlow et al., 2004; Brown and Barlow, 2009; Rosellini et al., 2015). David Barlow and their team developed the “Unified Protocol for the transdiagnostic treatment of EDs” to address the underlying symptoms of disorders in which anxiety and emotional deregulation play an important role (Allen et al., 2008; Ellard et al., 2010; Barlow et al., 2011). The efficacy of PU has been widely demonstrated (Reinholt and Krogh, 2014), both in individual format (Farchione et al., 2012) as in group format (Bullis et al., 2015), with the possibility of simultaneous application to patients with a variety of disorders, so it could reduce the waiting lists and the cost of the individual treatment (Osma et al., 2018).

From a transdiagnostic perspective focused on brief therapies (less than ten sessions) for the treatment of the EDs, several studies have shown their effectiveness both for the reduction of symptoms and for the application of treatment to many patients with different characteristics and comorbid disorders (Roy-Byrne et al., 2010; Dear et al., 2011; Titov et al., 2011; Schmidt et al., 2012; Osma et al., 2015). However, these studies present some limitations related to their designs, since some of them lack a control group (single group design), and others use only a waitlist control group or medication (treatment as usual) as a comparator.

Due to the limitations of the previous studies, it is necessary to design a protocol that evaluates the efficacy of brief therapy from a transdiagnostic perspective compared to other treatment modalities that are frequently used in mental health services (e.g., conventional psychological treatment, combined treatment or psychoeducational information).

#### ***9.1.4. The present study***

The aim of this work is to examine the efficacy of several types of interventions, in therapeutic and cost-effectiveness terms, for the treatment of patients with EDs. The different interventions are the following: brief psychological treatment based on UP; conventional psychological treatment; conventional psychological treatment plus



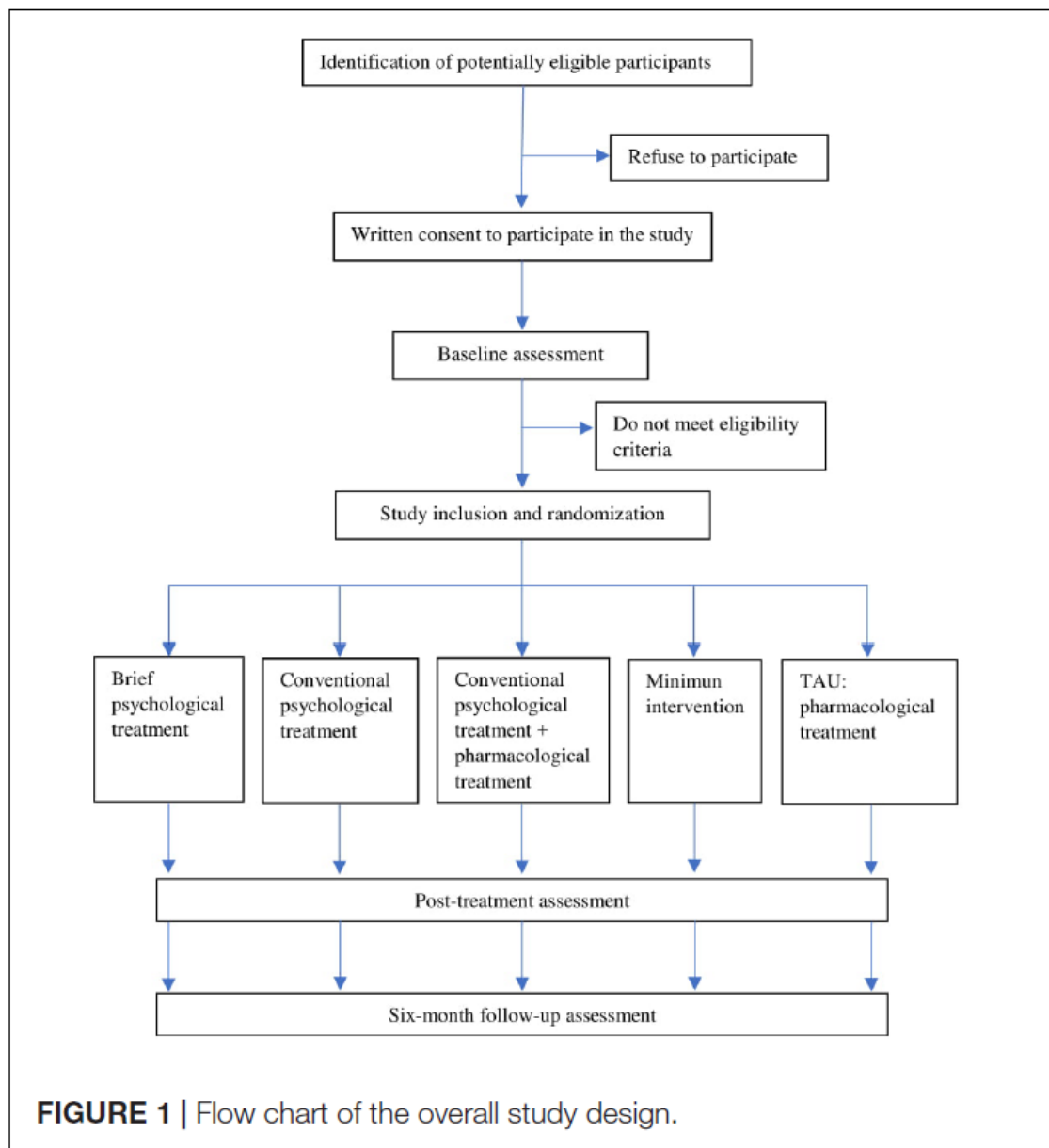
pharmacological treatment; minimum intervention based on basic psychoeducational information, counseling and bibliotherapy; and pharmacological treatment.

We hypothesize that “conventional psychological treatment plus pharmacological treatment” will be the most efficacious treatment, but “brief psychological treatment based on UP” will be the most efficient treatment (cost-effectiveness). Besides, we expect that psychological treatment (brief and conventional) will be more efficacious than pharmacological treatment, but less efficacious than “conventional psychological treatment plus pharmacological treatment,” and that “brief psychological treatment” will be as efficacious as “conventional psychological treatment” but more efficient than this one. Finally, we think that “minimum intervention based on basic psychoeducational information, counseling, and bibliotherapy” will be more efficacious than pharmacological treatment but will get worst results than different versions of psychological treatment.

## **9.2. Materials and Equipment**

### **9.2.1. Study Design**

This will be a multicenter randomized controlled trial (RCT) with five groups that will be realized in primary and specialized care centers from Córdoba (Spain) and its province. Patients will be randomly assigned to receive one of the following interventions: (a) *Brief psychological treatment based on UP*, (b) *Conventional psychological treatment*, (c) *Conventional psychological treatment plus pharmacological treatment*, (d) *Minimum intervention based on basic psychoeducational information, counseling and bibliotherapy*, and (e) *Active comparator treatment as usual (TAU): pharmacological treatment only*. For ethical reasons, in the case of low response to treatment, participants in the *Brief psychological treatment* and *Minimum intervention conditions* will be removed from the trial and will receive the treatment proposed by their GP. Outcome measures will be taken before randomization (baseline assessment), after the intervention (post-treatment assessment) and at 6-month follow-up. The overall study design is summarized in Figure 1. This RCT will be implemented following the SPIRIT guidelines (Chan et al., 2013a,b) and the CONSORT statement (Moher et al., 2010; Schulz et al., 2010).



### 9.2.2. Instruments and Measures

#### *GAD-7 scale*

The GAD-7 scale (Spitzer et al., 2006) is utilized to assess generalized anxiety disorder and other anxiety disorders. In this instrument, participants indicate the presence of anxiety symptoms during the last 2 weeks. The maximum score is 21. The scale has shown high internal consistency ( $\alpha = 0.89\text{--}0.93$ ) (García-Campayo et al., 2010; Zhong et al., 2015).

*State-Trait Anxiety Inventory (STAI)*

The STAI (Spielberger et al., 1983) is a frequently utilized instrument to assess state and trait anxiety. It is composed of 40 items, 20 to assess state anxiety and 20 to assess trait anxiety. A high score indicates the presence of severe anxiety symptoms. This scale has shown excellent internal consistency ( $\alpha = 0.86-0.95$ ) (Spielberger et al., 1983; Fonseca-Pedrero et al., 2012).

*Patient Health Questionnaire-9 (PHQ-9)*

The PHQ-9 (Kroenke et al., 2001) is a specific screening tool for depression in which participants respond to nine items on depressive symptoms during the last 2 week through a 4-point Likert scale. The internal consistency of PHQ-9 ranged from 0.86 to 0.89 (Kroenke et al., 2001).

*Beck Depression Inventory-Second Edition (BDI-II)*

The BDI-II (Beck et al., 1996) is a commonly used scale to assess the presence of depressive symptoms in adolescents and adults. The BDI-II is composed of 21 items that cover the diverse symptoms of major depressive disorder. Each item is scored on a scale from 0 to 3 (from lowest to highest severity), so the maximum score obtained can be 63 points. The internal consistency shown by this inventory has been excellent ( $\alpha = 0.94$ ) (Arnau et al., 2001).

*Patient Health Questionnaire-15 (PHQ-15)*

The PHQ-15 (Kroenke et al., 2002) is frequently used to measure the presence of somatic symptoms. The Spanish version is composed of 15 and the maximum score for this instrument can be 30 points. The PHQ-15 has shown an acceptable internal consistency ( $\alpha = 0.78$ ) (Ros Montalbán et al., 2010).

*Patient Health Questionnaire-Panic Disorder (PHQ-PD)*

The PHQ-PD will be used to measure panic disorder symptoms (Spitzer et al., 1999). It is composed of 15 items. We are facing a probable panic disorder when the patient answers affirmatively to the first four items and presents four or more symptoms related to this disorder.

*Brief Symptom Inventory 18 (BSI-18)*

The BSI-18 (Derogatis, 2000) is the shortest version of the Symptom-Checklist 90-R (Derogatis, 1994). It is composed of 18 items and contains three scales (anxiety, depression, and somatization) and a Global Severity Index (GSI). The internal

consistency showed by this inventory has been good: GSI  $\alpha = 0.93$ , anxiety  $\alpha = 0.84$ , depression  $\alpha = 0.87$ , and somatization  $\alpha = 0.82$  (Franke et al., 2017).

### 9.3. Stepwise procedures

#### 9.3.1. Sample size

To establish the sample size, we considered the effect sizes shown by the previous literature. Due to this study pretends to examine the efficacy of several types of interventions, we collected data from previous findings about brief therapies, transdiagnostic treatment, UP, conventional CBT, and combined therapy for the treatment of anxiety disorders and depression. A meta-analytic study examined the effect of various brief psychological therapies in comparison to usual GP care (Cape et al., 2010). The results of the meta-analysis to brief cognitive behavior therapy showed an effect size (Cohen's  $d$ ) of 1.06 for anxiety, 0.33 for depression and 0.26 for mixed anxiety and depression. In the case of brief counseling, the meta-analysis showed an effect size (Cohen's  $d$ ) of 0.41 to depression and 0.30 to mixed anxiety and depression. Another meta-analysis (Newby et al., 2015) studied the effect of transdiagnostic psychological treatment for depression and anxiety compared to waitlist, TAU and another psychological treatment, showing a large effect size (Hedges'  $g$ ) for both depression ( $g = 0.91$ ) and anxiety ( $g = 0.85$ ). Regarding UP, an RCT obtained an effect size (Hedges'  $g$ ) of 0.56 and 1.11 for anxiety and depression, respectively, using this treatment compared to waitlist (Farchione et al., 2012). Additionally, the findings of a recent meta-analysis about the effect of conventional CBT compared to waitlist, TAU or placebo showed an effect size (Hedges'  $g$ ) of 0.75 for depression, 0.80 for generalized anxiety disorder, 0.81 for panic disorder and 0.88 for social anxiety disorder (Cuijpers et al., 2016). By last, another meta-analysis examined the efficacy of combined therapies (psychotherapy plus pharmacotherapy) in comparison to pharmacotherapy for the treatment of anxiety disorders and depression (Cuijpers et al., 2014). The findings of this study showed an effect size (Hedges'  $g$ ) of 0.51 in favor of the combined therapy using CBT compared to pharmacotherapy only.

Taking into account these results, a generalized medium effect size of 0.6 (Cohen's  $d$ ) was assumed to detect differences between the interventions and TAU. Due to software to calculate the sample size for analysis using mixed linear models is not available, we established the sample size for analysis of variance using the  $f$  index through G\*Power. Therefore, we assumed an effect size of 0.3 ( $f$  index), equivalent to Cohen's  $d$

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= 0.6. Thus, with a statistical power of 0.80 and an alpha level of 0.05, a total sample of 140 participants will be required (28 subjects in each group). With the objective of controlling the lack of participants throughout intervention and evaluation process, based on previous studies (Farchione et al., 2012; Ito et al., 2016), we assumed an abandonment rate of 15%. Consequently, we require to include 165 participants in our study (33 participants per group).

### ***9.3.2. Target population, procedure, randomization and blinding***

We will include in our study patients with depression, anxiety or somatization disorder of mild to moderate severity. The detection of cases will be done from primary care by a GP. Patients that present these characteristics are encouraged to participate in the trial by de GP. Individuals who consent to participate and write the informed consent will receive the baseline assessment. If all eligibility criteria are fulfilled, the patient will be assigned randomly to one of the five groups according to a computer-generated allocation sequence (ratio: 1.1.1.1.1.). The randomization sequence will be generated prior to the recruitment of participants and will be conducted by a researcher uninvolved in the assessments of the study. At the end of treatment, there will be a post-treatment assessment and at 6-month follow-up. A single-blind process will be applied. The researcher in charge of the process of evaluation of the participants at the post-treatment and follow-up assessments are blinded to the intervention condition.

### ***9.3.3. Eligibility criteria***

#### *Inclusion criteria*

In the study may be included any person between 18 and 65 years of age with a DSM-5 diagnosis of generalized anxiety disorder, agoraphobia, panic disorder, specific phobia, social anxiety (social phobia), anxiety disorder not otherwise specified, dysthymia, mayor depressive disorder, depressive disorder not otherwise specified and/or somatic symptom disorder. Besides, patient must meet predetermined cutoff points of mild to moderate severity level in at least one of the following assessment measures utilized: GAD-7  $\geq 10$ ; PHQ-9  $\geq 10$ ; PHQ-15  $\geq 5$ ; PHQ-PD  $\geq 8$ .

#### *Exclusion criteria*

Patients with severe mental disorders (bipolar disorder and/or psychotic disorder), severe depression (PHQ  $\geq 20$ ), recent suicide attempts and/or current suicidal ideation, concurrent substance use disorder (alcohol, cannabis, stimulant, hallucinogen, and/or opioid), personality disorders, suspected or obvious mental retardation, and people who

are taking pharmacological drugs that interferes with the Central Nervous System will be excluded.

#### **9.3.4. Ethical Statement**

The study protocol (PSI2014-56368-R) has been authorized by the Ethics and Clinical Research Committee of the Ministry of Health of the Andalusia Government (Spain) and has been registered at [clinicaltrials.gov](http://clinicaltrials.gov) with the number NCT03286881. This study is compliant with the General Data Protection Regulation (GDPR) of the European Union, potential study participants must provide written informed consent before they can be included in the study. The participants will receive written information regarding the study, including randomization to one of the study groups and the possibility of ending their participation at any time without disadvantages, before obtaining their informed consent. Participation in the study does not entail any danger for the participants except those related with pharmacological intervention. The engagement is voluntary and confidentiality is guaranteed.

#### **9.3.5. Interventions**

##### *9.3.5.1. Brief psychological treatment based on UP*

This intervention protocol consists of eight sessions according to an adaptation to brief format of the UP for the transdiagnostic treatment of EDs (Boisseau et al., 2010; Ellard et al., 2010; Barlow et al., 2011) and the NICE guideline “*Common mental health disorders*” (NICE, 2011). The treatment is developed by clinical psychologists in Specialized Care (SC). Each session has specific objectives:

*S1. Motivation for change and commitment to treatment.* The aim of the first session is to improve motivation for change analyzing the advantages and disadvantages of changing and defining determinants life goals.

*S2. Understanding the function of emotions.* The second session gives information regarding the adaptive functions of emotions, introduces the concept of Emotion Driven Behaviors (EDBs) and distinguishes between thoughts, physical sensations and behaviors related to emotions.

*S3. Emotional awareness training.* The third session aims to introduce and to practice emotional awareness centered on the present, without judging.

*S4. Cognitive appraisal.* The objective of the fourth session is to teach appropriate thinking patterns, showing how to identify maladaptive ways of thinking and how to modify them.

*S5. Emotional avoidance and EDBs.* The purposes of this session are to teach patients that emotional avoidance strategies favor the development and maintenance of EDs and help them to change their own maladaptive behaviors for others more appropriate and functional.

*S6. Tolerance to physical sensations.* This session aims for the patient to get used to the physical sensations by performing exercises that causes these physical sensations, such as breathing through a straw.

*S7. Interoceptive and situational emotional exposure.* The main of this session is to expose the patient to internal and external triggers that produce intense emotional reactions, in order to improve the habituation to emotions and decrease avoidance behavior.

*S8. Conclusion and relapse prevention.* The objectives are to discuss the skills learned throughout the treatment, to identify the skills that should continue to be practiced in the future and to instruct how to face future situations.

#### *9.3.5.2. Conventional psychological treatment*

Patients in this group will receive the usual psychological treatment established within the healthcare process “Anxiety, Depression, and Somatizations” of the Andalusian Public Health Service (Spain) (Díaz del Peral et al., 2011). This treatment will be conducted in a range between 12 and 24 sessions of traditional CBT applied in a maximum period of eight months. The treatment will be developed by clinical psychologists in Specialized Care (SC).

#### *9.3.5.3. Conventional psychological treatment plus pharmacological treatment*

Patients in this group will receive the conventional psychological treatment based on traditional CBT, commented above, plus pharmacological treatment. The psychological treatment will be implemented by clinical psychologists and the pharmacological treatment will be prescribed by psychiatrist both in SC. This treatment will be carried out in a maximum period of eight months.

#### 9.3.5.4. *Minimum intervention based on basic psychoeducational information, counseling and bibliotherapy*

Patients in this experimental group will receive minimum psychological intervention based on basic psychoeducation, counselling and bibliotherapy by their GPs in PC. Previously, the GPs will have been trained by a clinical psychologist in how to give the patients basic information about their disorders, the use of strategies to face the basic symptoms of EDs without pharmacotherapy, and the use of bibliotherapy as support.

The minimum intervention will be conducted in a range between two to five sessions around 20 to 30 minutes long. Each session will be integrated by three components: a) active listening and counselling; b) psychoeducation about functioning and regulation of emotions; and c) guided bibliotherapy. As a material for bibliotherapy, self-help guides of Andalusian Public Health Service<sup>1</sup> (Spain) will be used considering the main symptoms of each patient.

#### 9.3.5.5. *Treatment as usual*

The participants included in this experimental condition will receive the TAU prescribed by the GP in PC, based on pharmacotherapy exclusively. The GP will prescribe the TAU to the patient in a regular consultation. This consultation will usually consist of a session between five and seven minutes in which the GP will evaluate the psychological and physical symptoms of the patients and will prescribe psychotropic drugs. This treatment will be carried out in a maximum period of eight months.

### 9.4. Proposed analysis

The data will be analyzed following both intention-to-treat (ITT) and per protocol approaches. Firstly, ANOVA or chi-squared will be performed to compare the demographic variables and outcomes measures at baseline. Second, to examine longitudinal changes over time (baseline, posttreatment and follow-up) and between-group differences on these changes we will use linear mixed models, inasmuch as these models are more accurate than repeated-measures ANOVAs (Gueorguieva and Krystal, 2004). In the ITT analysis (all patients randomized are included in the analysis), the

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<sup>1</sup> The self-help guides of Andalusian Health Service can be consulted and downloaded from the following link:

[http://www.juntadeandalucia.es/servicioandaluzdesalud/principal/documentosacc.asp?pagina=gr\\_smental\\_23\\_12\\_gauto](http://www.juntadeandalucia.es/servicioandaluzdesalud/principal/documentosacc.asp?pagina=gr_smental_23_12_gauto)



incomplete or missing data will be considered using the maximum likelihood estimation method. Additionally, Cohen's  $d$  will be calculated to determine the size of between-group effects. Last, we will estimate the Incremental Cost-Effectiveness Ratio (ICER) to compare the relationship between costs and effectiveness of different interventions.

### **9.5. Anticipated results**

This research protocol pretends to highlight the importance of adapting treatments to real contexts of application, and their adjustment to brief formats of limited time that maximize the cost-benefit of implemented care, as other authors suggest (Kazdin, 2008; Moriana and Martínez, 2011), besides contributing to the dissemination of psychological treatments in primary and specialized care.

The principal objective of this work is to examine the efficacious and the efficiency of the brief psychological treatment in a sample of patients with EDs, compared to other four treatments: conventional psychological treatment, conventional psychological treatment plus pharmacological treatment, minimum intervention based on basic psychoeducational information, and pharmacological treatment. Although we think that psychological treatment (brief and conventional) will be more efficacious than pharmacological treatment, as suggested by previous results with patients with EDs (Heuzenroeder et al., 2004; Watts et al., 2015), we expect that “conventional psychological treatment plus pharmacological treatment” will be the most efficacious treatment. These findings will be compliant with other studies that indicate that the combined treatment is superior in efficacy to CBT and pharmacotherapy alone in both anxiety disorders (Furukawa et al., 2007; Van Apeldoorn et al., 2008) and depression (Keller et al., 2000; Pampallona et al., 2004).

Due to brief psychological therapies have obtained similar results to conventional psychological therapies (Miller, 2000; Bloom, 2001; Lyons and Low, 2009; Nieuwsma et al., 2012), proving efficacious in reducing anxious-depressive symptoms (Koutra et al., 2010; Bernhardsdottir et al., 2013; Saravanan et al., 2017), and UP have demonstrated its efficacy to the treatment of EDs (Barlow et al., 2004; Brown and Barlow, 2009; Farchione et al., 2012), we hope that brief psychological treatment based on UP will be the most efficient treatment and as efficacy as conventional psychological treatment. However, although there is evidence suggesting that the patient's improvement, after being treated with brief psychological therapies, remains long after treatment (Hamdan-Mansour et al., 2009; Vázquez et al., 2012), some authors question the maintenance of long-term results

(Seekles et al., 2013). Therefore, the results of this study will be added to the evidence of efficacy for brief psychological treatments for EDs right after the treatment and at 6-month follow-up.

By last, we think that “minimum intervention based on basic psychoeducational information, counseling and bibliotherapy” will be more efficacious than pharmacological treatment for participants included in this study, but will get worst results than different versions of psychological treatment. Due to this kind of interventions are not sufficiently represented in controlled research (Labrador et al., 2000), the results of this work could contribute to the dissemination of minimum psychoeducational interventions to address the treatment of EDs in the PC context.

In last years, new intervention modalities are gaining consensus for the treatment of mental disorders, such as the stepped care approach. This treatment modality consists of apply progressively low and high intensity interventions (Turpin et al., 2008) and is based in two fundamental principles. Firstly, the treatment should produce positive results with the least burden for the patient. Secondly, the results of the patients should be reviewed systematically to decide about the need to move to another level of treatment.

The stepped care model can be implemented in two different ways. Firstly, the purely stepped approach assigns low intensity treatment to all patients and proposes a more intense intervention for patients who do not benefit low intensity treatment. On the other hand, in the stratified approach, patients are initially assigned to different levels of intervention according to an assessment of the symptoms and risks presented (Turpin et al., 2008).

Some recent studies have proved the efficacy of the stepped care model for the treatment of mental disorders. For example, Salomonsson et al. (2018) examined the utility of a purely stepped approach for the treatment of EDs in a primary care setting. These authors showed that the 40% of patients improved with a low intensity treatment. Besides, with this model of treatment less than six sessions were needed per patient, obtaining an overall improve of 63%. Another study (Tasca et al., 2018) tested the usefulness of this approach of intervention for the treatment of binge eating disorder. The findings of this study indicated that the low intensity treatment reduced significantly the symptoms of patients and that a more intensive intervention did not reduce the symptoms more than the low intensity treatment.

In this line, if all the treatments included in our study prove to be effective for addressing EDs, may be used on a stepped care model ordered by the level of intensity. Thus, the minimum intervention based on basic psychoeducational information may be first step of the treatment, followed by brief psychological treatment, conventional psychological treatment and conventional psychological treatment plus pharmacological treatment.

## **9.6. Limitations**

This study presents several limitations. The first one is related to the design of the study, since the interventions included in the protocol are composed by a different number of sessions. Nevertheless, it is necessary to include interventions with different length to determine whether the treatment effect varies depending on the intensity and duration. Besides, except for the “brief psychological treatment based on UP” group, the number of sessions or weeks of interventions within a certain group could vary from one patient to another. However, we will make sure that each patient is evaluated 6 months after the end of the treatment (follow-up assessment).

As a limitation inherent in this type of studies, considerable dropout rate during the intervention process are expected, as well as a substantial missing data to follow-up. Nevertheless, participants will be animated by phone or email to continue with the treatment or to participate in the follow-up assessment. In addition, the anxious-depressive symptoms could be attenuated by the passage of time.

Other limitations may be related to the recruitment difficulties. Due to the participants must be diagnosed with a DSM-5 disorder and must meet predetermined cutoff points, may be recruitment problems related to the difficulty that participants completely met the eligibility criteria. Besides, patients may refuse to be treated by a different intervention than usual.

## **9.7. Conclusion**

This study describes an adaptation to brief format of the UP for the transdiagnostic treatment of EDs. If this RCT proves that brief psychological treatment is as efficacious as conventional psychological treatment and that both treatments are more efficacious than pharmacological treatment, the results of this RCT may encourage the implementation of brief therapies in the PC context. This implementation could lead to the decongestion of the public health system, the treatment of a greater number of people

with EDs in a shorter time, the reduction of the side effects of pharmacological treatment and a possible economic savings for public purse.

### ***Author Contributions***

JM is the principal investigator of the trial and was primarily responsible for the design and development of the RCT. MG-L, JC, and JV contributed to the study design. JV supervised the study therapists. MG-L, JC, and JM drafted the manuscript. JV contributed to editing the manuscript and read and approved the final version of the manuscript.

### ***Funding***

This work has been supported by a Grant from the Government of Spain (Ministerio de Economía y Competitividad) (Grant Number PSI2014-56368-R).

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## Discusión y conclusiones





# Capítulo 10

## Discussion and conclusion

### 10.1. Discussion

This doctoral thesis has sought to achieve a series of objectives for which four interrelated studies were proposed. The results of these studies have confirmed most of the hypotheses proposed. In the first two studies, the recommended treatments by different organizations for mental disorders in children, adolescents and adults were analyzed and compiled to determine the level of agreement among the institutions. The third study tried to establish the impact that evidence-based psychological treatments (EBTs) have on the clinical practice of a sample of psychologist trained in Spain, as well as analyzing the personal factors that may be related to this impact. Finally, in the fourth study, an RCT protocol was designed. This RCT will analyze the efficacy of a brief therapy modality to treat emotional disorders, compared to other habitual interventions in primary and specialized care.

To achieve objectives 1 and 2, two review studies were designed to gather information about the psychological treatments recommended by five international organizations (four organizations in each study). The results showed that, for both adults and children, the level of agreement among the different institutions analyzed was low for most mental disorders, with numerous discrepancies appearing among the recommendations made by the four organizations. Concretely, only seven of the 23 treatments analyzed in the adult population achieved acceptable levels of agreement, whereas only three of the 17 reviewed treatments in the child and adolescent population obtained good levels of agreement. These results corroborate the hypothesis proposed by

Primero and Moriana (2011), assumed in this doctoral thesis, which argued that the recommended treatments could differ from one organization to another due to the different criteria used to evaluate the evidence of the interventions.

The discrepancies among the studied organizations might be due to a combination of different factors: potentially biased procedures or evaluation committees, different studies reviewed, use of different criteria to graduate the level of evidence, and the fact that the reviews of existing evidence were conducted in different time periods. These issues appeared both in the adult population (study 1) and in the child and adolescent population (study 2).

Despite it is frequent that most psychologists claim to use treatments that are supported by the evidence, the divergences found among the analyzed organizations suggest a lack of consensus about what scientific evidence means, so it could be misinterpreted. In this sense, it seems clear that not all the therapies used today for mental disorders are supported by scientific evidence.

In Spain, a controversy has recently arisen following a statement of the *Consejo General de la Psicología* (2019) that stated that “*debe actualizarse lo que se considera fundamentado en evidencia científica, ya que algunas de las que pueden ser consideradas pseudoterapias pueden suponer beneficios contrastados para la salud de los pacientes, cuando son utilizadas correctamente por profesionales psicólogos*” [“what it is considered based on scientific evidence should be updated, since some of the so-called pseudotherapies may have demonstrated benefits on the patient’s health when properly used by trained professionals”]. This statement has been rejected by several professional organizations and numerous psychologists of our country, who requested the rectification of the above-mentioned statement through the so-called “*Carta al COP*” (it can be consulted in this link <https://cartaalcop.wordpress.com/>), in which they affirm that the use of pseudotherapies is against the welfare of patients and the prestige of psychology. This controversy has raised the possible creation of a workgroup to determine what psychological practices should be considered therapeutic and which should be classified as pseudotherapies.

Due to the impact that psychological treatments have on the mental health of the population, international consensus should be promoted through the creation of working groups and international conferences including representatives of various organizations to establish common criteria to assess and grade the quality of the evidence of the different

psychological interventions. In view of the fact that the methodology of evidence-based science is the answer to discerning between therapies and pseudotherapies, these working groups should establish strategies to improve the methodological aspects of RCTs in psychology and to determine the requirements they should meet to be included in systematic reviews and meta-analyses. Furthermore, to ensure the objectivity of the scientific method in psychology, independent RCTs should be promoted. In this RCTs, the biases dependent on the theoretical model of the evaluator should be controlled and the publication bias should not be present.

A first step to optimize the procedure for evaluating the evidence of the treatments would be guaranteeing the quality of the RCTs, systematic reviews and meta-analyses included in the process, establishing as criteria of inclusion their previous registration in databases such as ClinicalTrials.gov (<https://clinicaltrials.gov/>) or PROSPERO (<https://www.crd.york.ac.uk/prospero/>). The registration in these databases would guarantee that the study in question meets minimum standards of methodological quality. In addition, the results obtained in individual trials (RCTs) should be reinforced by the findings of systematic reviews or meta-analyses.

Regarding the system to evaluate and grade the quality of the evidence, GRADE seems to be the most internationally supported one (Atkins et al., 2004, Balshem et al., 2011). As discussed throughout this doctoral thesis, this system is currently used by NICE and Cochrane. In addition, Division 12 of the APA has recently raised the use of a method to evaluate the evidence of psychological treatments based on the GRADE system (Tolin et al., 2015).

Of the different proposals to evaluate and graduate the quality of the evidence described in chapter 2 of this doctoral thesis, the system proposed by Tolin et al. (2015) is the one with the highest methodological rigor, since it proposes to consider all the systematic reviews and meta-analyses existing in the literature meeting a minimum methodological quality, of clinical relevance and are bias-free. After confirming the quality of the systematic review, this system proposes to evaluate the quality of the evidence of the different results present in the review using the GRADE system. Finally, according to the quality of the evidence obtained by the different reviews examined through GRADE, it classifies EBTs into a hierarchical system with four levels of recommendation (very strong recommendation, strong recommendation, weak recommendation, and insufficient evidence). Despite the methodological quality of this

new procedure and although the APA Division 12 starts in 2015 a process of updating its treatment lists using this new system, to date, only the status of one therapy has been updated.

Because many authors have suggested over the past decades that the results obtained by scientific research exert little influence on applied psychology (Barlow et al., 2013; Castonguay et al., 2013; Herbert, 2003; Kazdin, 2008, 2011, 2018; Westen et al., 2004a), the third study aimed to know the impact that EBTs have on the clinical practice of psychologists trained in Spain. The results obtained using an ad-hoc questionnaire confirmed the initial hypothesis, since, with the exception of cognitive-behavioral therapies, the use of EBTs was limited. Hence, despite the demonstrated evidence and the support received by the organizations included in the study 1 of this thesis, many of the therapies included in the questionnaire were used by a low percentage of the participating psychologists.

These results lead to the conclusion that the disclosure of the findings of scientific research in psychological treatments has not been entirely successful. Thus, although the lists of TBEs should be an important source of consultation for applied professionals, university professors and students, the drafters of the "*Carta al COP*" state that "*no contamos -ni hemos contado nunca- con una guía de procedimientos científicamente avalados que guíe nuestra práctica profesional*" ["We do not count on with- nor ever had- a guide of scientific procedures to guide our professional practice"]. As proposed by Echeburúa et al. (2010), the fact that most of the research outcomes are published in scientific journals may cause that advances in psychological treatments do not reach applied professionals, since few psychologists dedicated exclusively to clinical practice read scientific journals (Stewart & Chambless, 2007).

In this sense, it would be necessary that university training programs (undergraduate and postgraduate), as well as those training that accredit or qualify professionally (master's degree in general health psychology or specialist in clinical psychology), include among its contents not only how to perform step by step certain therapies, but should also form about how and where to find updated information on EBTs that is useful to the psychologist in training in the future. Consequently, training in psychology should enable the psychologist to be updated about advances in psychological treatments, emphasizing the benefits that this continuous update would have on patients and on clinical psychology.

With the aim of reducing the gap between research and practice, scientific community should implement the proposals made by Dozois (2013), mainly those aiming to improve the strategies of dissemination of research results and promote bidirectional communication between researchers and applied professionals. In this way, if the results of the research are disseminated in a way that is easy to interpret for non-researchers, probably they may consider these results (Michie & Lester, 2005). In addition, if communication channels where clinicians inform researchers of which interventions work in daily practice were created, collaboration between both sectors may increase and, therefore, the use of EBTs by applied psychologists (Goldfried, 2010).

Another proposal made by Dozois (2013) suggests exploring the mechanisms of change that help us understand why a certain treatment works. In this sense, because most of the EBTs are treatment packages composed of several techniques (Tolin et al., 2015), for some years now, it has been suggested that new research studies should focus on evaluating simpler units of analysis (techniques, strategies) to determine what is useful, harmless or harmful in each treatment (Westen et al., 2004b). However, from a particular point of view, assessing the efficacy of the interaction of several techniques within a treatment package is as important as examining the efficacy of a certain technique.

An additional aim of the third study was to analyze the personal factors that may be related to the integration of the results of the research within the applied practice. The results indicated that, of the analyzed factors, only professional accreditation and years of clinical experience could be related to the use of EBTs. Therefore, these findings differ from those obtained by other studies that indicate that age (Aarons & Sawitzky, 2006), the year of completion of studies (Lilienfeld, Ritschel, Lynn, Cautin, & Latzman, 2013), educational level (Beidas & Kendall, 2010), the scope of work (Aarons, Sommerfeld, & Walrath-Greene, 2009; Gyani et al., 2014) or the theoretical orientation (Gyani et al., 2014) may be influencing the integration of scientific evidence within clinical practice.

Due to the fact that many of the EBTs have a low real applicability (Kazdin, 2008), for some years now, a better adaptation of the treatments to real situations of application (e.g. public health services or brief therapies) has been claimed, thus improving their dissemination. Another alternative that could increase the dissemination of treatments would be to facilitate the training of psychologists in the treatment from a transdiagnostic approach centered on a set of common therapeutic principles, instead of being trained in the numerous and complex specific treatment protocols for each disorder (Barlow et al.,

2004). Thus, as these authors propose, unless psychological treatments move away from complex protocols and become easier to use “it is unlikely that most non-research clinicians will have a sufficient understanding of, or access to, these empirically supported techniques for the emotional disorders” (Barlow et al., 2004, pp. 208-209).

Finally, in study 4, an RCT was designed to evaluate the efficacy of brief psychological therapy from a transdiagnostic perspective for the treatment of emotional disorders, comparing it with other habitual interventions in public health services. For this purpose, the recommendations for intervention trials proposed in the SPIRIT declaration were followed (Chan, Tetzlaff, Altman et al., 2013; Chan, Tetzlaff, Gøtzsche et al., 2013). Thus, among the elements included in the protocol are the registry of the trial in ClinicalTrials.gov, description of the specific objectives and hypotheses, design of the trial, criteria for choosing the participants, specification of the different interventions and the measures of evaluation, trial schedule, explanation of sample size estimation, recruitment strategy and allocation of participants to different groups, specification of blinding, statistical methods to be used, approval of the ethics committee, or the procedure for obtaining informed consent.

Because the SPIRIT statement contains elements that are applicable to the consolidated standards for the communication of the trials (CONSORT statement), the fact of having drafted the protocol following the recommendations of the SPIRIT declaration will facilitate us to be able to report the future results of the trial complying with the guidelines proposed by the CONSORT statement.

Regarding the expected outcomes, based on the findings obtained in previous studies, it is expected that the four treatments in which some type of psychological intervention is performed are more efficacious than pharmacological treatment, being the combined treatment (psychological treatment plus pharmacotherapy) the most efficacious intervention. In addition, it is also expected that brief psychological treatment will be as efficacious as conventional psychological treatment and that the minimum intervention will be the least efficacious psychological treatment.

If these treatments prove their efficacy in addressing emotional disorders in public health services, the implementation of a stepped intervention model that includes the different treatments proposed in this trial, graduated by intensity level, could be promoted. This model of intervention would bring benefits for patients with the lowest

cost for them and for the health system (Turpin et al., 2008), also allowing its decongestion.

## **10.2. Limitations and future directions**

This doctoral thesis present certain limitations that should be acknowledged. Regarding the first two studies, the heterogeneity of levels of evidence established by the different organizations hinders a comparative assessment, having to adapt these levels to an ordinal scheme specifically developed for this aim. In addition, it is possible that some of the treatments reviewed shared some components, since the information has been compiled exactly as it was provided by the institutions. Another limitation was that only five organizations were reviewed, although there are many more around the world. Finally, these two studies have only reviewed a part of the spectrum of mental disorders in children, adolescents, and adults, excluding disorders and mental health problems whose inclusion would have enriched both works. Thus, future studies should review the recommendations of these institutions or others regarding the treatment of addictions or problems related to health psychology, as well as in other areas of psychology such as social intervention or neuropsychology.

Regarding the third study, the results may have been distorted because some of the participants did not have clinical experience and it is possible that not all experienced professionals had conducted interventions with all the disorders for which they were asked. Thus, on some occasions they may have responded based on their clinical experience and on other occasions based on their knowledge about the efficacy of a particular therapy. In this sense, future studies should be aimed to determine the use of different EBTs by psychologists who have experience in the treatment of a certain psychological disorder.

Finally, the fourth study presents a series of limitations that are inherent to RCTs. Thus, a loss of participants during the intervention processes is expected, post-treatment evaluation and follow-up evaluation. In addition, because participants must have certain symptoms with a certain severity, it could be difficult to complete the sample of participants. Besides, some patients may refuse to be included in any different intervention from the usual procedure. Finally, with the exception of the brief therapy group based on the Unified Protocol, the number of intervention sessions within a given group may vary from one patient to another.



### **10.3. Final conclusion**

This doctoral thesis has shown that the recommendations made by different institutions about EBTs differ from each other. This is explained by the use of different methods and criteria to evaluate and grade the evidence of psychological treatments. Thus, after an exhaustive analysis of the treatment guidelines of five reputable organizations for the psychological approach of mental disorders in children, adolescents and adults, it was concluded that there is no consensus about the efficacy of psychological treatments for the most disorders, being present many discrepancies between the evidence presented by the different organizations. This situation suggests necessity to improve the coordination among institutions, as well as the methodology used in the RCTs, in order to optimize the process of identifying EBTs.

A primary aim of the institutions that inform about the evidence of the treatments is to get the results of scientific research to researchers, applied professionals, users, and the general public. This doctoral thesis has sought to corroborate what many authors have pointed out for years, applied psychologists lack a solid knowledge about EBTs. In this sense, the results that emerge from this work confirm the lack of knowledge that Spanish psychologists have about EBTs, which indicates that the disclosure of these treatments has not been entirely successful. This lack of knowledge is present for most therapies, with the exception of cognitive-behavioral therapies, which is an indication of the main psychological current in the educational programs of Spain.

Several proposals to increase the dissemination of the treatments among the applied professionals propose to improve the adequacy of the treatments to real situations of application and to encourage the training of psychologists in the treatment from a transdiagnostic approach. Therefore, the development of brief transdiagnostic therapies would not only allow their inclusion within public health services but would also favor the dissemination of treatment among applied psychologist.

As a final reflection, due to the high prevalence of mental disorders in the general population, researchers, organizations that report the evidence of interventions and applied professionals should optimize their communication, coordination, and their systems of choice of treatments, with the aim of improve the mental health of the population.

# Informe con el factor de impacto de las publicaciones



<b>Estudio 1</b>	<b>Indización</b>	<b>Factor de impacto</b>
Moriana, J. A., Gálvez-Lara, M. y Corpas, J. (2017). Psychological treatments for mental disorders in adults: A review of the evidence of leading international organizations. <i>Clinical Psychology Review</i> , 54, 29-43. doi: 10.1016/j.cpr.2017.03.008	Social Science Citation Index, Journal Citation Reports (Social Sciences Edition), PsycINFO, Current Contents/Social & Behavioral Sciences BIOSIS EMBASE Scopus Google Scholar MEDLINE	Journal Citation Report (JCR) 2017, Impact factor: 9.577 (Q1) Posición 2 de 127 (Psychology, Clinical)

<b>Estudio 2</b>	<b>Indización</b>	<b>Factor de impacto</b>
Gálvez-Lara, M., Corpas, J., Moreno, E., Venceslá, J. F., Sánchez-Raya, A. y Moriana, J. A. (2018). Psychological treatments for mental disorders in children and adolescents: a review of the evidence of leading international organizations. <i>Clinical Child &amp; Family Psychology Review</i> , 21, 366-387. doi: 10.1007/s10567-018-0257-6	Social Science Citation Index, Journal Citation Reports (Social Sciences Edition), Medline, SCOPUS, PsycINFO, Google Scholar, AGRICOLA, CNKI, Current Abstracts, Current Contents / Social & Behavioral Sciences, EBSCO, EMCare, ERIH PLUS, Gale, Gale Academic OneFile, Health Reference Center Academic, OCLC WorldCat Discovery Service, ProQuest	Journal Citation Report (JCR) 2017, Impact factor: 3.600 (Q1) Posición 16 de 127 (Psychology, Clinical)

<b>Estudio 4</b>	<b>Indización</b>	<b>Factor de impacto</b>
Gálvez-Lara, M., Corpas, J., Venceslá, J. F. y Moriana, J. A. (2019). Evidence-based brief psychological treatment for emotional disorders in primary and specialized care: study protocol of a randomized controlled trial. <i>Frontiers in Psychology</i> , 9, 2674. doi: 10.3389/fpsyg.2018.02674	Social Science Citation Index, Journal Citation Reports (Social Sciences Edition), PubMed Central, Scopus, Google Scholar, DOAJ, CrossRef, PsycINFO, Semantic Scholar, Ulrich's Periodicals Directory, CLOCKSS, EBSCO, OpenAIRE, Zetoc	Journal Citation Report (JCR) 2017, Impact factor: 2.089 (Q2) Posición 39 de 135 (Psychology, Multidisciplinary)  Scimago Journal & Country Rank (SJR) 2017, Impact factor: 1.043 (Q1) Posición 52 de 241 (Psychology, Miscellaneous)



Review

Psychological treatments for mental disorders in adults: A review of the evidence of leading international organizations



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ARTICLE INFO

Keywords

Psychological treatments  
Adult mental disorders  
Evidence-based psychology  
RCTs  
Meta-analysis  
Review article

ABSTRACT

Most mental health services throughout the world currently regard evidence-based psychological treatments as best practice for the treatment of mental disorders. The aim of this study was to analyze evidence-based treatments drawn from RCTs, reviews, meta-analyses, guides, and lists provided by the National Institute for Health and Care Excellence (NICE), Division 12 (Clinical Psychology) of the American Psychological Association (APA), Cochrane and the Australian Psychological Society (APS) in relation to mental disorders in adults. A total of 135 treatments were analyzed for 23 mental disorders and compared to determine the level of agreement among the organizations. The results indicate that, in most cases, there is little agreement among organizations and that there are several discrepancies within certain disorders. These results require reflection on the meaning attributed to evidence-based practice with regard to psychological treatments. The possible reasons for these differences are discussed. Based on these findings, proposals to unify the criteria that reconcile the realities of clinical practice with a scientific perspective were analyzed.

1. Introduction

Scientific psychology is a discipline that seeks to legitimize its theories by using evidence-based research to support its findings. The study of the efficacy of different psychological treatments based on the assumption that “only science can distinguish good interventions from bad ones” (Westen, Novotny, & Thompson-Brenner, 2004a, p. 632), represents one of the most important advances in clinical psychology. However, the impact of scientific advances on clinical practice and public health is still very small (Barlow, Bullis, Comer, & Ametaj, 2013). Many areas of psychology (cognitive science, perception, emotion, etc.) have used scientific methods to perform research with excellent results. However, both clinical and applied contexts present major complications in relation to experimental control, which hinders the scientific study of psychological treatments.

The principal objective of evidence-based practice in psychology is to use the best available scientific evidence by integrating data obtained from basic and applied research with clinical expertise to enhance patient care (American Psychological Association, 2006; Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996).

1.1. History and evolution of the empirical supported treatment concept

Interest and concern for the scientific assessment of the effects of psychological treatments began to increase in the twentieth century following the publication of an important article by Hans Eysenck in 1952. The author reviewed a series of studies published up to that moment and concluded that approximately 60% of patients treated with psychotherapy experienced some improvement. In contrast, approximately 70% of untreated patients showed spontaneous improvement (Eysenck, 1952). Thus, according to this study, psychotherapy would have no curative effect. However, later studies contradicted Eysenck's work, which apparently overestimated spontaneous improvement in untreated patients (Andrews & Harvey, 1981; Landman & Dawes, 1982; Smith & Glass, 1977; Smith, Glass, & Miller, 1980). Specifically, the meta-analysis conducted by Smith and Glass (1977), which involved 375 studies, concluded that the average patient receiving psychotherapy is better off at the end of treatment than 75% of patients who do not receive treatment and that the different varieties of therapy do not produce differential effects.

These studies served as a prelude to the development of effective psychological treatments in the 1990s. The proliferation of randomized clinical trials (RCTs) and meta-analyses led the University of Oxford to

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<http://dx.doi.org/10.1016/j.cpr.2017.03.008>


Received 28 July 2016; Received in revised form 24 March 2017; Accepted 27 March 2017

Available online 29 March 2017

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# Psychological Treatments for Mental Disorders in Children and Adolescents: A Review of the Evidence of Leading International Organizations

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Published online: 2 April 2018  
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## Abstract

In recent decades, the evidence on psychological treatments for children and adolescents has increased considerably. Several organizations have proposed different criteria to evaluate the evidence of psychological treatment in this age group. The aim of this study was to analyze evidence-based treatments drawn from RCTs, reviews, meta-analyses, guides and lists provided by four leading international organizations. The institutions reviewed were the National Institute for Health and Care Excellence, the Society of Clinical Child and Adolescent Psychology (Division 53) of the American Psychological Association, Cochrane Collaboration and the Australian Psychological Society in relation to mental disorders in children and adolescents. A total of 137 treatments were analyzed for 17 mental disorders and compared to determine the level of agreement among the organizations. The results indicate that, in most cases, there is little agreement among organizations and that there are several discrepancies within certain disorders. These results require reflection on the meaning attributed to evidence-based treatments with regard to psychological treatments in children and adolescents. The possible reasons for these differences could be explained by a combination of different issues: the procedures or committees may be biased, different studies were reviewed, different criteria are used by the organizations or the reviews of existing evidence were conducted in different time periods.

**Keywords** Psychological treatments · Child and adolescent mental disorders · Evidence-based psychology · Review article

## Introduction

Psychological treatments for children and adolescents have been given less attention than those implemented in the adult population. In many cases, psychological interventions involving children and adolescents were designed as adaptations of those of adults (Jacobs et al. 2008) when in clinical practice it can be verified that, for example, a child suffering from depression has specific characteristics that differ greatly from those of adults in terms of the etiology,

symptoms, evolution and treatment of this disorder. In their comprehensive review of the literature on the treatment of adolescents, Weisz and Hawley (2002) examined 25 empirically supported psychotherapies that have been used in children and adolescents. According to these authors, 14 of the 25 therapies have been shown to be effective in adolescents. Interestingly, seven are downward adaptations of treatments originally designed for adults and six are upward adaptations of treatments originally designed for children, leaving only one that was developed specifically for adolescents. In conclusion, few of the 14 empirically supported treatments that have been used in adolescents were designed with a focus on the primary developmental task of adolescence (Holmbeck et al. 2010).

Interest in therapies for children and adolescents began a little later than Eysenk's influential work (1952), which questioned the benefit of psychotherapies, and the subsequent meta-analyses of Smith and Glass (1977) and Shapiro and Shapiro (1982), which supported the beneficial effects of

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# Evidence-Based Brief Psychological Treatment for Emotional Disorders in Primary and Specialized Care: Study Protocol of a Randomized Controlled Trial

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## OPEN ACCESS

### Edited by:

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United Kingdom

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### Specialty section:

This article was submitted to  
Clinical and Health Psychology,  
a section of the journal  
Frontiers in Psychology

Received: 28 June 2018

Accepted: 12 December 2018

Published: 08 January 2019

### Citation:

Gálvez-Lara M, Corpas J,  
Venceslá JF and Moriana JA (2019)  
Evidence-Based Brief Psychological  
Treatment for Emotional Disorders  
in Primary and Specialized Care:  
Study Protocol of a Randomized  
Controlled Trial.  
Front. Psychol. 9:2674.  
doi: 10.3389/fpsyg.2018.02674

Emotional Disorders (EDs) are very prevalent in Primary Care (PC). However, general practitioners (GPs) have difficulties to make the diagnosis and the treatment of this disorders that are usually treated with drugs. Brief psychological therapies may be a new option to treat EDs in a PC context. This article aims to present a study protocol to evaluate the effectiveness and the efficiency of an adaptation to brief format of the "Unified Protocol (UP) for the transdiagnostic treatment of EDs." This is a single-blinded RCT among 165 patients with EDs. Patients will be randomly assigned to receive brief psychological treatment based on UP, conventional psychological treatment, conventional psychological treatment plus pharmacological treatment, minimum intervention based on basic psychoeducational information, or pharmacological treatment only. Outcome measure will be the following: GAD-7, STAI, PHQ-9, BDI-II, PHQ-15, PHQ-PD, and BSI-18. Assessments will be carried out by blinded raters at baseline, after the treatment and 6-month follow-up. The findings of this RCT may encourage the implementation of brief therapies in the PC context, what would lead to the decongestion of the public health system, the treatment of a greater number of people with EDs in a shorter time, the reduction of the side effects of pharmacological treatment and a possible economic savings for public purse.

**Clinical Trial Registration:** ClinicalTrials.gov, identifier NCT03286881. Registered September 19, 2017.

**Keywords:** emotional disorders, brief psychological treatment, transdiagnostic, primary care, randomized controlled trial

## INTRODUCTION

### Background

Nowadays, concern for mental health disorders and problems has increased significantly worldwide (Mental Health Foundation, 2016). Common mental health disorders, also called emotional disorders (EDs), are growing exponentially in recent decades (Vos et al., 2015; Chisholm et al., 2016). These disorders include DSM-5 (American Psychiatric Association, 2013) diagnostics

Otras contribuciones  
derivadas de la tesis doctoral





### **Artículos en revistas no indexadas**

Gálvez-Lara, M., Corpas, J., Moreno, E., Venceslá, J. F., García-Torres, F. y Moriana, J. A. (2018). Aproximación a un modelo de intervención psicológica en atención primaria basado en la terapia breve. *Informació psicológica*, 115, 25-38.

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Gálvez-Lara, M., Corpas, J., Moreno, E., Venceslá, J. F. y Moriana, J. A. (2018). Introducción a la terapia psicológica breve basada en la evidencia. En F. J. Alós, E. Moreno, F. García-Torres, & R. Castillo-Mayén (Compiladores), *Psicología general sanitaria: textos aplicados para la práctica terapéutica* (pp. 79-100). Cantabria: Mora-Mora.

### **Aportaciones a congresos**

**Comunicación oral presentada en el XI Congreso internacional de psicología clínica** (Granada, 25-28 de octubre de 2018)

Gálvez-Lara, M. Tratamientos psicológicos basados en la evidencia. Un análisis de las diferencias observadas entre organizaciones internacionales.

**Comunicación oral presentada en el XII Congreso internacional de la Sociedad española para el estudio de la ansiedad y el estrés** (Valencia, 20-22 de septiembre de 2018)

Gálvez-Lara, M. Tratamientos psicológicos basados en la evidencia para los trastornos de ansiedad.

**Póster presentado en el XII Congreso internacional de la Sociedad española para el estudio de la ansiedad y el estrés** (Valencia, 20-22 de septiembre de 2018)

Gálvez-Lara, M., Corpas, J., Cuadrado-Hidalgo, F., García-Torres, F., Moreno, E. y Moriana, J. A. Tratamientos psicológicos con apoyo empírico para el trastorno obsesivo compulsivo en niños y adultos.

**Póster presentado en el XII Congreso internacional de la Sociedad española para el estudio de la ansiedad y el estrés** (Valencia, 20-22 de septiembre de 2018)

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**Comunicación oral presentada en la IV Jornada de Psicología Clínica en Atención Primaria** (Madrid, 13 de noviembre de 2015)

Moriana, J.A., Gálvez-Lara, M., Moreno, E., Pérez-Dueñas, C., García, F., Sánchez-Raya, A., García Torres, F., Alós, F. y Venceslá, J. F. Los costes del tratamiento de trastornos comunes en Atención Primaria. Una simulación comparativa entre el tratamiento psicológico breve y el convencional.

**Póster presentado en las V Jornadas Emociones y Bienestar** (Madrid, 1 y 2 de octubre de 2015)

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# Anexos



# Anexo 1

## Adaptación del instrumento *ad-hoc* para analizar el impacto de los tratamientos psicológicos basados en la evidencia sobre la práctica clínica

INFORMACIÓN SOCIODEMOGRÁFICA	
<b>Edad</b>	<b>Sexo</b> <input type="checkbox"/> Hombre <input type="checkbox"/> Mujer
<b>Año de finalización de los estudios de grado o licenciatura</b>	<b>Titulación universitaria</b> <input type="checkbox"/> Grado o licenciatura <input type="checkbox"/> Máster <input type="checkbox"/> Doctorado
<p><b>¿Posee alguna de las siguientes acreditaciones profesionales para psicólogos?</b></p> <input type="checkbox"/> No poseo ninguna acreditación profesional <input type="checkbox"/> Especialista en Psicología Clínica <input type="checkbox"/> Psicólogo General Sanitario o habilitado para ejercer en centros sanitarios	
<p><b>¿Cuál de las siguientes opciones describe mejor su situación laboral actual?</b></p> <input type="checkbox"/> Desempleado o realizo una actividad laboral distinta a la psicología <input type="checkbox"/> Trabajo relacionado con la psicología en el ámbito privado <input type="checkbox"/> Trabajo relacionado con la psicología en el ámbito público	
<p><b>¿Tiene experiencia en evaluación y tratamiento psicológico? En caso afirmativo indique el número de años</b></p> <input type="checkbox"/> No <input type="checkbox"/> Sí Número de años _____	
<p><b>En líneas generales, ¿bajo qué corriente psicológica englobaría la mayor parte de los tratamientos que conoce o utiliza?</b></p> <input type="checkbox"/> Conductual <input type="checkbox"/> Cognitiva <input type="checkbox"/> Cognitivo-conductual <input type="checkbox"/> Sistémica <input type="checkbox"/> Psicodinámica <input type="checkbox"/> Ecléctica <input type="checkbox"/> Otro:	

La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

### TRATAMIENTOS PSICOLÓGICOS BASADOS EN LA EVIDENCIA

A continuación presentamos una lista de terapias psicológicas que han mostrado evidencia para ser consideradas efectivas para un determinado trastorno.

Por favor, para cada terapia indica si la conoce y la utiliza habitualmente; si la conoce, pero no considera oportuno utilizarla; si la conoce, pero no tiene competencias para utilizarla; o si no la conoce. En el caso de que usted no desarrolle práctica clínica o no trabaje con ese trastorno, conteste en función de si la utilizaría o no en base a su formación.

#### Trastorno de ansiedad generalizada

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia cognitivo-conductual				
Terapia de autoayuda				
Relajación aplicada				
Mindfulness				
Terapia psicodinámica				
Psicoeducación				

#### Trastorno de pánico

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia cognitivo-conductual				
Terapia conductual				
Terapia de autoayuda				
Relajación aplicada				
Terapia psicodinámica				
Psicoeducación				

#### Trastorno de ansiedad social

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia cognitivo-conductual				
Terapia de autoayuda				
Terapia psicodinámica				
Terapia interpersonal				
Terapia de aceptación y compromiso				
Terapia de exposición				
Entrenamiento en habilidades sociales				

**Fobias específicas**

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia de autoayuda				
Terapia de exposición				

**Trastorno obsesivo-compulsivo**

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia de aceptación y compromiso				
Exposición y prevención de respuesta				
Terapia de autoayuda				

**Trastorno de estrés postraumático**

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia cognitivo conductual				
Terapia de procesamiento cognitivo				
Desensibilización y reprocesamiento por medio de movimientos oculares (EMDR)				
Terapia centrada en el presente				
Exposición controlada				
Terapia de búsqueda de seguridad				
Terapia de inoculación del estrés				

**Trastorno bipolar**

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia cognitivo-conductual				
Terapia cognitiva				
Terapia centrada en la familia				
Psicoeducación familiar				
Terapia grupal				
Terapia cognitiva integrada e interpersonal				
Terapia interpersonal y del ritmo social				
Mindfulness				
Psicoeducación				
Cuidados sistemáticos				



La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

### Depresión

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia de aceptación y compromiso				
Relajación aplicada				
Terapia de activación conductual				
Sistema de Análisis Cognitivo Conductual de la Psicoterapia (CBASP)				
Terapia cognitivo-conductual				
Entrenamiento en memoria competitiva				
Terapia de pareja				
Terapia cognitiva				
Counselling				
Terapia dialéctico-conductual				
Terapia centrada en la emoción				
Terapia interpersonal				
Mindfulness				
Actividad física				
Terapia psicodinámica				
Psicoeducación				
Terapia de solución de problemas				
Terapia racional emotiva conductual				
Terapia de reminiscencia				
Terapia de autocontrol				
Terapia de autoayuda				
Terapia de autosistema				

### Anorexia nerviosa

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia cognitivo-conductual				
Terapia basada en la familia				
Terapia interpersonal				
Terapia psicodinámica				
Terapia cognitivo-analítica				

**Bulimia nerviosa**

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia cognitivo-conductual				
Terapia basada en la familia				
Terapia interpersonal				
Programa de peso saludable				
Terapia dialéctico-conductual				
Terapia de autoayuda				

**Esquizofrenia**

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia de aceptación y compromiso				
Programa de tratamiento asertivo comunitario				
Entrenamiento en adaptación cognitiva				
Terapia cognitivo conductual				
Rehabilitación cognitiva				
Terapia centrada en la familia				
Manejo de la enfermedad y la recuperación				
Terapia psicodinámica				
Psicoeducación				
Empleo con apoyo				
Entrenamiento en habilidades sociales				
Programas de economía de fichas				

La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

### Trastorno límite de la personalidad

	La conozco y la utilizo habitualmente para este trastorno	La conozco, pero no considero oportuno utilizarla para este trastorno	La conozco, pero no tengo las competencias necesarias para utilizarla	No la conozco
Terapia cognitivo-analítica				
Terapia cognitivo-conductual				
Terapia dialéctico-conductual				
Entrenamiento en regulación de la emoción				
Terapia interpersonal				
Mindfulness				
Terapia psicodinámica				
Psicoeducación				
Terapia centrada en esquemas				
Entrenamiento para la regulación emocional y la solución de problemas (STEPPS)				
Terapia centrada en la transferencia				

**Gracias por su colaboración**

## Anexo 2



Servicio Andaluz de Salud  
CONSEJERÍA DE SALUD

Hospital Universitario Reina Sofía



**Gregorio Jurado Cáliz, Secretario del Comité de Ética de la Investigación de Córdoba, comité constituido a tenor de lo establecido en el Decreto 439/2010, de 14 de diciembre, por el que se regulan los órganos de ética asistencial y de la investigación biomédica de Andalucía (BOJA núm. 251 de 27 de diciembre) del que es Presidenta Inmaculada Concepción Herrera Arroyo**

**CERTIFICA**

Que en la reunión del Comité de Ética de Investigación de Córdoba celebrada el día 28 de abril de 2016 (Acta nº 251, ref. 3051), se ha estudiado y evaluado el Proyecto de Investigación, titulado: "Tratamientos psicológicos breves basados en la evidencia para trastornos/problemas comunes. Un ensayo clínico aleatorizado en atención primaria y especializada", Cód. Protocolo PSI2014-56368-R, Protocolo y Hoja de Información al Paciente y Consentimiento informafó versión 1 de 15/01/2016, en el que figura como Investigador principal D. Juan Antonio Moriana Elvira, adscrito a la Universidad de Córdoba, Departamento de Psicología, habiendo considerado los integrantes de dicho Comité que el citado proyecto respeta los principios fundamentales establecidos en la Declaración de Helsinki de 1964, de la Asociación Médica Mundial, y enmiendas posteriores, y en el Convenio del Consejo de Europa de 1996, relativo a los Derechos Humanos y a la Biomedicina, demostrando sus autores conocer suficientemente los antecedentes y el estado actual del tema que proponen investigar, estando bien definidos sus objetivos y siendo adecuada su metodología, por lo que hacen constar la viabilidad en todos sus términos del proyecto de investigación, estimando que los resultados pueden ser de gran interés.

Se hace constar, de acuerdo con el artículo 27,5 de la Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común, que la presente certificación se emite con anterioridad a la aprobación del acta correspondiente.

En Córdoba, a 29 de abril de 2016

**EL SECRETARIO**

**LA PRESIDENTA**

Fdo.: Gregorio Jurado Cáliz



Fdo.: Inmaculada Concepción Herrera Arroyo



Servicio Andaluz de Salud  
**CONSEJERÍA DE SALUD**

Hospital Universitario Reina Sofía



**Gregorio Jurado Cáliz, Secretario del Comité de Ética de la Investigación de Córdoba, comité constituido a tenor de lo establecido en el Decreto 439/2010, de 14 de diciembre, por el que se regulan los órganos de ética asistencial y de la investigación biomédica de Andalucía (BOJA núm. 251 de 27 de diciembre) del que es Presidenta Inmaculada Concepción Herrera Arroyo**

**CERTIFICA**

Que en la reunión del Comité de Ética de Investigación de Córdoba celebrada el día 28 de abril de 2016 (Acta nº 251, ref. 3051), se ha estudiado y evaluado el Proyecto de Investigación, titulado: "Tratamientos psicológicos breves basados en la evidencia para trastornos/problemas comunes. Un ensayo clínico aleatorizado en atención primaria y especializada", Cód. Protocolo PSI2014-56368-R, Protocolo y Hoja de Información al Paciente y Consentimiento informafó versión 1 de 15/01/2016, en el que figura como Investigador principal D. Juan Antonio Moriana Elvira.

Que a dicha sesión asistieron los siguientes miembros:

**PRESIDENTA**

Dña. Inmaculada Concepción Herrera Arroyo. Jefe de Servicio Hematología del HURS.

**SECRETARIO**

D. Gregorio Jurado Cáliz. Técnico de Función Administrativa. Licenciado en Derecho del HURS

**VOCALES**

D. Manuel Jesús Cárdenas Aranzana. Farmacéutico Hospitalario del HURS

Dña. Eva M<sup>a</sup> Rojas Calvo. Auxiliar Administrativo HURS. Licenciada en Derecho

D. Eduardo Morán Fernández. FEA Medicina Intensiva H Infanta Margarita de Cabra

D. Pedro José Rodríguez Fernández. FEA Traumatología de la Agencia Pública Empresarial Sanitaria Alto Guadalquivir. Hospital de Montilla.

Dña. Beatriz García Robredo. Farmacéutica de Atención Primaria del Área Sanitaria Norte

D. José Luis Barranco Quintana. FEA Medicina Preventiva del HURS. Vicepresidente

D. Juan Manuel Parras Rejano. Médico de Familia EBAP, Área Sanitaria Norte de Córdoba

D. Rafael Segura Saint-Gerons. Odontólogo C.S. La Carlota. Distrito Sanitario Guadalquivir

Que dicho Comité está constituido y actúa de acuerdo con la normativa vigente y las directrices de la Conferencia Internacional de Buena Práctica Clínica.

En Córdoba, a 29 de abril de 2016

**EL SECRETARIO**

**COMITÉ DE ÉTICA DE LA INVESTIGACIÓN DE CÓRDOBA**  
CONSEJERÍA DE SALUD  
CÓRDOBA

**LA PRESIDENTA**

Fdo.: Gregorio Jurado Cáliz

Fdo.: Inmaculada Concepción Herrera Arroyo

## Anexo 3

### **HOJA DE INFORMACIÓN AL PACIENTE**

**TÍTULO DEL ENSAYO CLÍNICO:** Tratamiento psicológico breve para trastornos comunes

**PROMOTOR:** FIBICO

**CÓDIGO DE PROTOCOLO:** PSI2014-56368-R

**INVESTIGADOR PRINCIPAL:** Juan Antonio Moriana Elvira Teléfono: 957212093  
E-mail: jamoriana@uco.es  
Centro: Facultad de Ciencias de la Educación. Universidad de Córdoba.

#### **INTRODUCCION**

Nos dirigimos a usted para informarle sobre un ensayo clínico en el que se le invita a participar. El ensayo clínico ha sido aprobado por el Comité Ético de Investigación Clínica correspondiente de acuerdo a la legislación vigente, el Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos.

Nuestra intención es tan solo que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si desea o no participar en este ensayo clínico. Para ello, lea esta hoja informativa con atención y nosotros le aclararemos las dudas que le puedan surgir después de la explicación. Además, puede consultar con las personas que considere oportuno.

#### **PARTICIPACIÓN VOLUNTARIA**

Debe saber que su participación en este ensayo clínico es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con los profesionales sanitarios que le atienden ni se produzca perjuicio alguno en su tratamiento.

#### **DESCRIPCIÓN GENERAL DEL ENSAYO CLÍNICO**

El objetivo de este proyecto es poner en marcha una novedosa iniciativa en nuestro país para acercar las técnicas psicológicas que han demostrado ser eficaces para tratar los desórdenes emocionales (nervios, ansiedad, depresión, dolores, somatizaciones, etc.) en la investigación y en otros entornos clínicos al ámbito nacional tanto de Atención Primaria como de Atención Especializada. En este proyecto piloto se pondrá a prueba un programa de tratamiento psicológico breve y otro psicoeducativo y se compararán los resultados obtenidos con el tratamiento convencional que se utiliza habitualmente con fármacos. El programa se aplicará de forma individual y será dirigido por un psicólogo clínico, médicos de atención primaria y en colaboración con distintos especialistas. El objetivo es el aprendizaje de técnicas y estrategias para manejar el estrés y las emociones (ansiedad, estado de ánimo deprimido, culpa, enfado, etc.).

La elección de tratamientos psicológicos basados en la evidencia. Un análisis para integrar los datos científicos con la realidad asistencial

Las técnicas utilizadas están basadas en la evidencia científica para el manejo correcto de pensamientos y emociones. Las iniciativas previas e investigaciones similares desarrolladas en otros países han obtenido resultados muy positivos y nos sirven de guía y estímulo para la realización de este proyecto.

Todos los participantes en el estudio serán asignados al azar a una de las siguientes condiciones: grupo experimental 1 (que recibirá varias sesiones de tratamiento psicológico breve), grupo experimental 2 (que recibirá varias sesiones de tratamiento psicológico convencional), grupo experimental 3 (que recibirá varias sesiones de tratamiento combinado –farmacológico y psicológico), grupo experimental 4 (que recibirá varias sesiones de tratamiento psicoeducativo) o grupo control (que recibirá el tratamiento convencional, principalmente farmacológico) cuyo objetivo, en todos los casos, será reducir la intensidad y la frecuencia de la ansiedad, la depresión y las somatizaciones.

Cada paciente tendrá la misma probabilidad de recibir el tratamiento tanto de los grupos experimentales como del control. Cabe esperar que todos los tratamientos sean efectivos, aunque pueden existir variaciones respecto al tiempo empleado y a la calidad de sus efectos a medio y largo plazo. Una vez usted acepte participar, cumplimentará una batería de instrumentos de evaluación que indican si cumple el perfil apropiado para el ensayo clínico (esto es, padecer niveles moderados de síntomas emocionales y/o somatizaciones). Cada participante que cumpla el perfil apropiado será asignado a una lista de espera para ser adjudicado más adelante, y de forma aleatoria, a uno de los grupos. Se trata de un ensayo clínico de “doble ciego”. En la evaluación inicial, ni el profesional sanitario ni el paciente sabrán cuál es el tratamiento que va a recibir y en la evaluación final, el evaluador no sabrá qué tipo de tratamiento han recibido los participantes.

Independientemente del grupo al que usted pertenezca, completará dos evaluaciones psicológicas (antes y después del tratamiento), mediante una batería de cuestionarios o tests psicológicos, durante aproximadamente 45 minutos. Ambas evaluaciones incluirán medidas sobre síntomas clínicos (ansiedad, depresión, somatizaciones); preocupaciones, creencias irracionales y errores de pensamiento; funcionamiento a nivel laboral, familiar y social; calidad de vida (psicológica, salud física, social, ambiental); satisfacción con el tratamiento recibido; así como datos sobre frecuentación, consumo de fármacos y otras variables para medir coste-eficacia. Posteriormente a la intervención se le hará un seguimiento a los 6 meses, donde deberá completar las mismas pruebas de evaluación. Los cuestionarios serán respondidos en el centro de salud, bajo la supervisión de un psicólogo clínico. Los evaluadores de la fase de postratamiento en ambos grupos serán “ciegos” a la condición experimental. En otras palabras, no sabrán cuál es el tratamiento que usted ha recibido.

Si usted pertenece al grupo experimental, recibirá un tipo de tratamiento especificado en el Protocolo Código PSI2014-56368-R, en donde es susceptible de recibir las distintas técnicas en él descrito entre las que se encuentran:

- Información científica y psicoeducación sobre la ansiedad, la tristeza, la depresión, el estrés, las somatizaciones
- Identificación y modificación de pensamientos relacionados con las emociones
- Ejercicios de relajación
- Entrenamiento en habilidades sociales y resolución de problemas
- Estrategias de afrontamiento de los problemas cotidianos de cada día

- Prevención de recaídas
- Terapia cognitiva y conductual para la depresión y ansiedad
- Técnicas de terapia de aceptación y compromiso

Todas estas técnicas están recogidas en las guías internacionales de práctica clínica de alta calidad (NICE y NHS EED) que recomiendan la utilización del tratamiento psicológico basado en la evidencia científica (cognitivo conductual) como tratamiento de primera elección para los desórdenes emocionales.

Si usted pertenece al grupo control, recibirá el tratamiento convencional tal y como se viene ofreciendo en Atención Primaria y Especializada (típicamente, tratamiento farmacológico) y volverá a ser evaluado en las mismas fechas que el grupo experimental. El objetivo principal de este ensayo clínico consiste en demostrar que el tratamiento psicológico será más eficaz y eficiente a corto plazo y a largo plazo que el tratamiento habitual seguido por el grupo control, teniendo en cuenta todas las medidas anteriormente mencionadas. Además, los resultados de este ensayo clínico podrán indicar si en el seguimiento a 6 meses los grupos experimentales habrán reducido en mayor medida las tasas de frecuentación a las consultas de Atención Primaria y el consumo de medicamentos (antes y después del tratamiento, así como en el seguimiento), además de otros índices de gasto sanitario, resultando una mejor relación coste-eficacia que la obtenida para el grupo control con tratamiento habitual. Dicha relación se obtendrá con la información facilitada por cada paciente, así como datos objetivos del sistema informático sanitario.

Su responsabilidad como participante en el ensayo clínico consiste en procurar asistir a las sesiones concertadas con el profesional sanitario que se le asigne y a seguir sus indicaciones y prescripciones de tratamiento. También deberá notificar cualquier evento significativo o adverso que le suceda (p. ej., boda, separación o divorcio, accidente, embarazo, pérdida de un ser querido, etc.) o cambios en su medicación (si la hubiera).

## **BENEFICIOS Y RIESGOS DERIVADOS DE SU PARTICIPACIÓN EN EL ENSAYO CLÍNICO**

Se espera que los participantes asignados aleatoriamente a los grupos experimentales (tratamientos psicológicos) obtengan mejores resultados que los asignados al tratamiento habitual (grupo control), en las siguientes variables estudiadas: disminución de sintomatología ansiosa, depresiva y somática, reducción de diagnósticos de trastornos de ansiedad y del estado de ánimo, mejora del funcionamiento a nivel laboral, social y familiar, aumento de la calidad de vida, cambios en los factores cognitivo-emocionales vinculados a los desórdenes emocionales, y menor número de visitas al médico, del consumo de psicofármacos y otros índices de gasto sanitario; además, se espera que estas ganancias se mantengan en el seguimiento.

Otros proyectos piloto parecidos que se han puesto en marcha en otros países han logrado altas tasas de recuperación (76% para la depresión y 74% para la ansiedad), la disminución del riesgo de recaída y el mantenimiento de los resultados positivos a largo plazo. No obstante, es posible que los pacientes de este ensayo clínico no obtengan ningún beneficio para su salud.



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Este ensayo clínico no añade riesgo al tratamiento convencional. Las guías clínicas internacionales (NICE y NHS EED) en las que se sustentan las técnicas psicológicas que serán aplicadas en el grupo experimental muestran que no existe un riesgo destacado de efectos secundarios no deseados tras su aplicación. Adoptar estas técnicas y su empleo de forma correcta comporta beneficio sobre su salud. En cambio, la no aplicación correcta de estas o el no aprendizaje óptimo no acarrea un mayor daño que su no conocimiento o el no uso de las mismas, por tanto, se respeta el principio de proporcionalidad entre los riesgos y los beneficios esperados.

Los beneficios del tratamiento farmacológico para desórdenes emocionales se observan a corto plazo en la reducción de sintomatología ansiosa, depresiva o somática. En cambio se observan riesgos a largo plazo por su uso continuado, los cuales ya son informados por la Agencia Española del Medicamento y Productos Sanitarios y por el médico que los prescribe.

Hacemos constar que el ensayo clínico propuesto respeta y cumplirá la legislación vigente y otras normas reguladoras, pertinentes al proyecto, en materia de ética, experimentación animal o bioseguridad, incluidos los principios fundamentales de la Declaración de Helsinki, del Convenio del Consejo de Europa relativo a los derechos humanos y la biomedicina, de la Declaración Universal de la UNESCO sobre el genoma humano y los derechos humanos, y del Convenio para la protección de los derechos humanos y la dignidad del ser humano con respecto a las aplicaciones de la Biología y la Medicina (Convenio de Oviedo relativo a los derechos humanos y la biomedicina).

## **TRATAMIENTOS ALTERNATIVOS**

El hecho de no participar en este ensayo clínico no tendrá repercusiones negativas en su salud. Los profesionales sanitarios que le atienden le darán información si lo desea.

## **CONFIDENCIALIDAD**

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los participantes se ajustará a lo dispuesto en la Ley Orgánica 15/1999, de 13 de diciembre de protección de datos de carácter personal. De acuerdo a lo que establece la legislación mencionada, usted puede ejercer los derechos de acceso, modificación, oposición y cancelación de datos, para lo cual deberá dirigirse al investigador principal del centro. Los datos recogidos para el ensayo clínico estarán identificados mediante un código y solo el investigador principal del centro y sus colaboradores podrán relacionar dichos datos con usted y con su historia clínica. Por lo tanto, su identidad no será revelada a persona alguna salvo excepciones en caso de urgencia médica o requerimiento legal. Solo se transmitirán a terceros y a otros países los datos recogidos para el ensayo clínico que en ningún caso contendrán información que le pueda identificar directamente, como nombre y apellidos, iniciales, dirección, nº de la seguridad social, etc. En el caso de que se produzca esta cesión, será para los mismos fines del ensayo clínico descrito y garantizando la confidencialidad como mínimo con el nivel de protección de la legislación vigente en nuestro país.

El acceso a su información personal quedará restringido al investigador principal del centro y colaboradores, autoridades sanitarias (Agencia Española del Medicamento y Productos Sanitarios) y a los monitores y auditores contratados por el promotor, cuando

lo precisen para comprobar los datos y procedimientos del ensayo clínico, pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente.

### **COMPENSACIÓN ECONÓMICA**

El promotor del ensayo clínico es el responsable de gestionar la financiación del mismo. Para la realización del ensayo clínico el promotor del mismo ha firmado un contrato con el centro donde se va a realizar y con los profesionales sanitarios del ensayo clínico. No se recompensará ni a los facultativos ni a los pacientes de ninguna manera por el tiempo dedicado al ensayo clínico o por las posibles molestias ocasionadas.

### **OTRA INFORMACIÓN RELEVANTE**

Si usted decide retirar el consentimiento para participar en este ensayo clínico, ningún dato nuevo será añadido a la base de datos, además, puede exigir la destrucción de los resultados de su evaluación.

También debe saber que puede ser excluido del ensayo clínico si el promotor o los investigadores del ensayo clínico lo consideran oportuno, ya sea por motivos de seguridad o porque consideren que no está cumpliendo con los procedimientos establecidos. En cualquiera de los casos, usted recibirá una explicación adecuada del motivo que ha ocasionado su retirada del ensayo clínico.

Al firmar la hoja de consentimiento adjunta, se compromete a cumplir con los procedimientos del ensayo clínico que se le han expuesto.

Cuando acabe su participación recibirá el mejor tratamiento disponible y que su médico considere el más adecuado para su enfermedad, pero es posible que no se le pueda seguir administrando algunos de los tratamientos recibidos. Por lo tanto, ni el investigador ni el promotor adquieren compromiso alguno de mantener dicho tratamiento fuera de este ensayo clínico.

### **FUENTES DE FINANCIACIÓN**

Esta actividad científica forma parte de proyectos de I+D+i financiados en convocatorias competitivas gracias al Ministerio de Economía y Competitividad (Ref. PSI2014-56368-R).

### **DATOS DE CONTACTO DEL INVESTIGADOR PRINCIPAL DEL CENTRO**

En caso de que usted deseara recibir algún tipo de información acerca del ensayo clínico o deseara ejercer sus derechos sobre sus datos de carácter personal debería ponerse en contacto con el investigador principal responsable del ensayo en el Centro de Salud, personal autorizado por el Promotor y responsable de los datos:

#### **INVESTIGADOR PRINCIPAL DEL CENTRO DE SALUD.....**

Nombre..... Apellidos.....

Centro.....

Teléfono.....

E-mail.....

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## CONSENTIMIENTO INFORMADO

Yo (nombre y apellidos)

.....

He leído la hoja de información que se me ha entregado.  
He podido hacer preguntas sobre el estudio.  
He recibido suficiente información sobre el estudio.

He hablado con:  
Comprendo que mi participación es voluntaria.

Comprendo que puedo retirarme del estudio:  
1º Cuando quiera  
2º Sin tener que dar explicaciones.  
3º Sin que esto repercuta en mis cuidados sanitarios

- Presto libremente mi conformidad para participar en el estudio y doy mi consentimiento para el acceso y utilización de mis datos en las condiciones detalladas en la hoja de información.

SI NO

Firma del paciente:  
Nombre:  
Fecha:

Firma del investigador:  
Nombre:  
Fecha

## Anexo 4

### Lista de comprobación SPIRIT (Chan, Tetzlaff, Altman et al., 2013; Chan, Tetzlaff, Gøtzsche et al., 2013)

Sección/Ítem	Nº de ítem	Descripción	Nº de página
<b>Información administrativa</b>			
Título	1	Título descriptivo que indique el diseño, la población, las intervenciones y, cuando corresponda, la sigla o abreviatura del ensayo.	179
Registro del Ensayo	2a	Identificador del estudio y nombre del registro. Si no se lo ha registrado aun, nombre del registro donde se propone inscribirlo.	180
	2b	Todos los elementos del conjunto de datos del registro de ensayos de la Organización Mundial de la Salud.	Comprobado
Versión del protocolo	3	Fecha e identificación de la versión.	180
Financiación	4	Fuentes y tipo de apoyo financiero, material o de otra índole.	195
Funciones y responsabilidades	5a	Nombre, afiliaciones y funciones de quienes contribuyeron con el protocolo.	179 y 195
	5b	Nombre e información de contacto del patrocinador del estudio.	n/a
	5c	Funciones del patrocinador y de los financiadores del estudio, si los hubiera, en el diseño; la recolección, gestión, análisis e interpretación de los datos; la redacción de los informes; y la decisión de someterlo para publicación, especificando si tendrán la última palabra en cualquiera de estas actividades.	n/a
	5d	Composición, funciones y responsabilidades del centro coordinador, el comité directivo, el comité evaluador del criterio de valoración, el equipo de gestión de datos y de cualquier otra persona o grupo que supervise el ensayo, si corresponde (véase el elemento 21a sobre el comité de monitoreo de datos).	n/a
<b>Introducción</b>			
Antecedentes y justificación	6a	Descripción de la pregunta de investigación y justificación para emprender el ensayo, incluido un resumen de los estudios relevantes (publicados y no publicados) que hayan analizado los beneficios y daños de cada intervención.	180-183
	6b	Explicación de la elección del comparador o los comparadores.	183-184
Objetivos	7	Objetivos o hipótesis específicos.	183-184

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Diseño del ensayo	8	Descripción del diseño del ensayo, incluido el tipo de ensayo (por ejemplo, de grupos paralelos, de grupos cruzados, factorial, de un solo grupo), razón de asignación y marco de trabajo (por ejemplo, superioridad, equivalencia, no inferioridad, exploratorio).	184
<b>Métodos: Participantes, intervenciones y resultados</b>			
Ámbito del estudio	9	Descripción de los centros del estudio (por ejemplo, consultorio de atención primaria, hospital académico) y lista de los países donde se recopilarán los datos. Referencia a dónde puede obtenerse la lista de los centros participantes.	184
Criterios de selección	10	Criterios de inclusión y de exclusión de los participantes. Si corresponde, criterios de selección de los centros del estudio y las personas que realizarán las intervenciones (por ejemplo, cirujanos o psicoterapeutas).	188-189
Intervenciones	11a	Intervenciones para cada grupo con detalles suficientes que permitan reproducirlas, incluido cómo y cuándo serán administradas.	189-191
	11b	Criterios para interrumpir o modificar las intervenciones asignadas a cada sujeto en el ensayo (por ejemplo, cambio en la dosis por daños al participante, a petición del participante o debido a una mejoría o a un empeoramiento de la enfermedad).	67
	11c	Estrategias para mejorar el cumplimiento de protocolos de intervención, así como cualquier método para vigilar el cumplimiento (por ejemplo, retorno de la medicación, pruebas de laboratorio).	n/a
	11d	Cuidados concomitantes e intervenciones relevantes permitidos y prohibidos durante el ensayo.	189
Resultados	12	Resultado principal y secundario, y otras valoraciones de la evolución o el desenlace, incluida la variable específica de medición (por ejemplo, presión arterial sistólica), la métrica de análisis (por ejemplo, cambio con respecto al valor inicial o línea de base, valor final, o tiempo hasta el evento), el método de agregación (por ejemplo, mediana, proporción) y el momento de cada variable. Se recomienda especialmente explicar la relevancia clínica de las variables de eficacia y seguridad (daños) seleccionadas.	185-187
Cronograma con respecto a los participantes	13	Cronograma para reclutar, realizar las intervenciones (incluidos períodos de preinclusión y de lavado), evaluar y visitar a los participantes. Se recomienda especialmente incluir un diagrama esquemático.	69
Tamaño de la muestra	14	Número estimado de participantes que se necesitan para alcanzar los objetivos del estudio y explicación sobre cómo se determinó dicho número, incluidas las premisas clínicas y estadísticas que respalden el cálculo del tamaño de la muestra.	187-188
Reclutamiento	15	Estrategias para lograr el reclutamiento adecuado a fin de alcanzar el tamaño de muestra previsto.	188

<b>Método: asignación de las intervenciones</b>			
Asignación generación de la secuencia	16a	Método para generar la secuencia de asignación (por ejemplo, números aleatorios generados por computadora) y lista de cualquier factor utilizado en la estratificación. Para reducir la predictibilidad de la secuencia aleatoria, los detalles de cualquier restricción planificada (por ejemplo, bloques) deberían facilitarse en un documento aparte que no esté disponible para quienes deben reclutar a los participantes o asignar las intervenciones.	188
Mecanismo para ocultar la asignación	16b	Mecanismo para aplicar la secuencia de asignación (por ejemplo, un teléfono central o sobres sellados, opacos y numerados de manera secuencial), con una descripción de toda medida para ocultar la secuencia hasta que se hayan asignado las intervenciones.	188
Ejecución	16c	Quién generará la secuencia de asignación, quién reclutará a los participantes y quién asignará las intervenciones a los participantes.	188
Enmascaramiento (cegamiento)	17a	Quién estará enmascarado después de la asignación de las intervenciones (por ejemplo, los participantes en el ensayo, los prestadores de atención de salud, los evaluadores de los resultados, los analistas de los datos) y cómo se hará el enmascaramiento.	188
	17b	Si hay enmascaramiento, circunstancias bajo las cuales se permite desenmascarar y procedimiento para revelar la intervención asignada a un participante durante el ensayo.	n/a
<b>Método: recolección, gestión y análisis de datos</b>			
Métodos de recolección de datos	18a	Planes para evaluar y recoger las variables iniciales, de evolución y otros datos del estudio, incluido cualquier proceso para mejorar la calidad de los datos (por ejemplo, mediciones por duplicado, capacitación de los evaluadores) y descripción de los instrumentos utilizados en el estudio (por ejemplo, cuestionarios, pruebas de laboratorio) junto con su fiabilidad y validez, si se conocen. Indicar dónde pueden encontrarse los formularios de recolección de datos, si no se encuentran en el protocolo.	184-187
	18b	Planes para promover la retención de los participantes y lograr un seguimiento completo, incluida una lista de los datos que se recopilarán de los participantes que abandonen el ensayo o se desvíen de él.	194
Gestión de datos	19	Planes para ingresar, codificar, proteger y guardar los datos, incluido cualquier proceso para mejorar su calidad (por ejemplo, ingreso por duplicado o revisión del rango de valores). Especificar dónde pueden encontrarse los detalles del procedimiento de gestión de datos que no figuren en el protocolo.	n/a
Métodos estadísticos	20a	Métodos estadísticos para analizar la variable principal y las secundarias. Especificar dónde pueden encontrarse los detalles del plan de análisis estadístico que no figuren en el protocolo.	191-192
	20b	Métodos para cualquier otro análisis adicional (por ejemplo, análisis de subgrupos o análisis ajustados).	n/a

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	20c	Definición de la población de análisis en relación con la falta de cumplimiento del protocolo (por ejemplo, análisis conforme a la aleatorización) y de cualquier método estadístico para tratar los datos faltantes (por ejemplo, imputación múltiple).	191
<b>Método: Monitoreo</b>			
Monitoreo de datos	21a	Composición del comité de monitoreo de datos, resumen de su función y procedimiento de notificación, declaración sobre su independencia con respecto al patrocinador y sobre sus conflictos de intereses. Especificar dónde pueden encontrarse otros detalles sobre sus estatutos que no se hayan incluido en el protocolo. Alternativamente, explicar por qué no se necesita este comité.	n/a
	21b	Descripción de cualquier análisis intermedio y de las reglas de interrupción, incluido quién tendrá acceso a los resultados intermedios y quien tomará la decisión final de terminar el ensayo.	n/a
Daños	22	Planes para recoger, evaluar, informar y gestionar los eventos adversos, tanto los informados espontáneamente como aquellos cuya información se obtuvo al solicitarla, y otros efectos imprevistos de las intervenciones o de la realización del estudio.	n/a
Auditoría	23	Frecuencia y métodos para auditar la realización del estudio, si los hubiera, y si estos procesos son independientes de los investigadores y del patrocinador.	n/a
<b>Ética y diseminación</b>			
Aprobación ética de la investigación	24	Planes para obtener la aprobación del comité de ética o de la junta de revisión institucional.	189
Enmiendas del protocolo	25	Planes para comunicar las enmiendas importantes introducidas en el protocolo (por ejemplo, cambios en los criterios de selección, en las variables de resultados, en el análisis) a las partes pertinentes (por ejemplo, investigadores, comité de ética o junta de revisión institucional, participantes en el ensayo, registros de ensayos, revistas biomédicas, organismos reguladores).	n/a
Consentimiento o conformidad	26a	Quién obtendrá el consentimiento informado o el asentimiento de los participantes en el estudio o de sus representantes autorizados y cómo se hará (véase el elemento 32).	189
	26b	Disposiciones adicionales de consentimiento para la recolección y el uso de datos y muestras biológicas de los participantes de estudios auxiliares, cuando corresponda.	n/a
Confidencialidad	27	Cómo se recopilará, compartirá y guardará la información de carácter personal de los participantes potenciales y reclutados, con el fin de proteger la confidencialidad antes, durante y después del ensayo.	189
Declaración de intereses	28	Conflictos de interés de tipo económico o de otra índole de los investigadores principales tanto para el ensayo en su conjunto como de cada centro.	n/a

Acceso a los datos	29	Declaración de quién tendrá acceso al conjunto de datos finales del ensayo y revelación de los acuerdos contractuales que limiten tal acceso a los investigadores.	n/a
Atención adicional y posterior al estudio	30	Disposiciones, si las hubiera, con respecto a la atención adicional y posterior al ensayo, y para la compensación en el caso de aquellos que sufran algún daño por haber participado en el estudio.	n/a
Política de diseminación	31a	Planes de los investigadores y del patrocinador para comunicar los resultados del ensayo a los participantes, los profesionales de la salud, el público y otros grupos pertinentes (por ejemplo, en una publicación, presentación de información en bases de datos de resultados u otros arreglos para difundir los datos), incluida cualquier restricción de publicación.	214
	31b	Pautas para elegir a los autores y si se pretende usar redactores científicos profesionales.	n/a
	31c	Planes, de haberlos, para hacer público el protocolo completo, el conjunto de datos de los participantes y el código estadístico.	n/a
<b>Apéndices</b>			
Materiales del consentimiento informado	32	Modelo del formulario del consentimiento informado y documentación relacionada que se entregue a los participantes o a sus representantes legales autorizados.	259-264
Muestras biológicas	33	Planes para recoger, estudiar y guardar muestras biológicas para análisis genéticos o moleculares, tanto presentes como futuros, cuando corresponda.	n/a



