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Vanessa Ferreres Galán

Mejora de la asistencia psicológica en Unidades de Salud Mental Públicas: aplicación del Protocolo Unificado para la prevención y tratamiento de trastornos emocionales en mujeres

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Tesis Doctoral [Extracto]

MEJORA DE LA ASISTENCIA PSICOLÓGICA EN UNIDADES DE SALUD MENTAL PÚBLICAS: APLICACIÓN DEL PROTOCOLO UNIFICADO PARA LA PREVENCIÓN Y TRATAMIENTO DE TRASTORNOS EMOCIONALES EN MUJERES

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TÍTULO: Mejora de la asistencia psicológica en Unidades de Salud Mental Públicas: aplicación del Protocolo Unificado para la prevención y tratamiento de trastornos emocionales en mujeres.

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A mi hermano, por lo que fuimos y siempre seremos,

por muchos universos que nos separen.

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A la vida, porque me ha hecho sentir mucho. Y de eso se trata vivir. Seguiré tratando de vivir, nunca sobrevivir.

"La atención a la Salud Mental es condición indispensable para el desarrollo de calidad de vida y el ejercicio pleno de una ciudadanía en la que se conjuguen los derechos y deberes"

(Estrategia Salud Mental, 2022-2026)

LISTADO DE PUBLICACIONES DE LA TESIS

Artículo 1 (Capítulo 2):

Osma, J., Quilez, A., **Ferreres, V**., Meseguer, M., & Ariza, S. (2022). Feasibility and clinical usefulness of the Unified Protocol in women survivors of violence. *Journal of Child and Family Studies.* https://doi.org/10.1007/s10826-022-02226-z

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Quilez-Orden, A., **Ferreres-Galán, V.,** & Osma, J. (2020). Feasibility and clinical usefulness of the Unified Protocol in online group format for bariatric surgery candidates: study protocol for a multiple baseline experimental design. *International Journal of Environmental Research and Public Health, 17,* 6155. https://doi.org/10.3390/ijerph17176155

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Artículo 3 (Capítulo 4):

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Artículo 4 (Capítulo 5):

Ferreres-Galan, V., Navarro-Haro, MV., Peris-Baquero, O., Guillen-Marín, S., DeLuna-Hermoso, J., Osma, J. (2022). Assessment of Acceptability and Initial Effectiveness of a Unified Protocol Prevention Program to Train Emotional Regulation Skills in Female Nursing Professional during the COVID-19 Pandemic. *International Journal of Environmental Research and Public Health, 19,* 5715.https://doi.org/10.3390/ijerph19095715

Factor de impacto (JCR 2021): 4.614 (Q1)

Artículo 5 (Capítulo 6):(enviado)

Ferreres-Galan, V., Peris-Baquero, O., Moreno, J.D. & Osma, J. (2023). Is the Unified Protocol for transdiagnostic treatment of emotional disorders equally effective for men and women? *Journal of Psychiatric Research*

Factor de impacto (JCR 2021): 5.250 (Q2)

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PRESENTACIÓN

El presente trabajo responde a la necesidad asistencial, y también personal, de mí día a día. Éste, es un trabajo que pretende acercar la **investigación** a la **práctica clínica**, con el objetivo de hacer intervenciones coste-efectivas, eficaces y eficientes en Unidades de Salud Mental (USM en adelante) para adultos como en la que yo trabajo desde hace más de 10 años. En respuesta a la demanda y al interés personal por poder ofrecer una atención más efectiva, surge el propósito de este proyecto.

El presente trabajo supone una contribución, original e innovadora, en la línea de los trabajos que en distintos países se han llevado a cabo para estudiar la eficacia y coste-efectividad del PU para el abordaje de los TEs en distintos contextos (públicos, privados, universitarios, comunitarios, etc.). A través de cinco estudios distintos ofreceremos resultados sobre la utilidad clínica, preventiva y/o terapéutica, del PU aplicado a mujeres en diferentes contextos y circunstancias, pero todos ellos con un nexo común, la intervención desde una USM de nuestro Sistema Nacional de Salud (SNS en adelante).

El primero de los estudios versa sobre la aplicación del PU en un contexto social, fruto del trabajo en red entre Universidad, Sanidad y Servicios Sociales Municipales. Es un estudio piloto con seguimiento a 12 meses cuyo objetivo fue comprobar la viabilidad y utilidad clínica del PU en formato grupal para mejorar la regulación emocional de mujeres con TEs que han sido víctimas de violencia en el entorno familiar.

El segundo de los trabajos es un protocolo de estudio centrado en analizar la viabilidad y utilidad clínica del PU en formato grupal en una condición específica de salud, pacientes candidatos a la cirugía bariátrica que presentan un TE o sintomatología emocional. El protocolo describe un diseño experimental de línea de base múltiple con seguimiento hasta los 24 meses.

En el tercer artículo se presentan los resultados sobre la aplicación del PU en formato grupal para mujeres que han sido intervenidas de cirugía bariátrica y que presentan un TE o sintomatología emocional. Es un estudio piloto en el que se adaptó el PU atendiendo a la condición de salud de estas participantes y se realizó una intervención grupal con seguimiento a los 6 meses.

El cuarto estudio responde a una necesidad asistencial consecuencia de la crisis sanitaria acontecida por la COVID-19. En este artículo se presentan datos referidos a la aplicación del PU en personal sanitario. Se trata de un estudio que evalúa la efectividad y aceptabilidad de la adaptación del PU en un programa preventivo para entrenar en habilidades de regulación emocional a profesionales sanitarias durante la pandemia por COVID-19. El estudio utilizó un diseño de ensayo clínico aleatorizado, con una condición activa de intervención (el PU) y una condición control lista de espera. Se realizó una intervención grupal de 5 sesiones adaptada del

PU en personal de enfermería y auxiliares (27 mujeres) con seguimientos al mes, a los 3 y a los 6 meses.

Destacamos que 3 de los 4 artículos mencionados incluyen la implementación del PU y la recogida de datos. Estos estudios comparten además una serie de características. Por una parte, en todos se aplica el PU, con las adaptaciones convenientes según objetivo y condición. Por otro, en todos, la población atendida son mujeres con trastornos o sintomatología emocional. En el primer estudio, era esperable que la muestra estuviera formada únicamente por mujeres dado que la violencia intrafamiliar es ejercida principalmente hacia la mujer en el núcleo familiar y, además son, en su gran mayoría, las que demandan ayuda. En el tercero y cuarto estudio, a pesar de ofrecerse la intervención tanto a hombres como a mujeres, solo mujeres aceptaron participar. La literatura hasta la fecha es contundente y deja claro que los TEs son mucho más prevalentes en mujeres y que éstas solicitan ayuda y reciben tratamiento en mayor proporción.

Existen pocos estudios que analicen si existen diferencias entre hombres y mujeres en la respuesta a las intervenciones psicológicas. Esta particularidad ha orientado el último de los estudios presentados (en evaluación). En él se analiza si el PU es efectivo de forma similar en hombres y mujeres, ya que la literatura muestra que existen diferencias en función del género en la prevalencia de los TEs, la clínica, la búsqueda de ayuda y también en la respuesta al tratamiento. Es un estudio secundario que forma parte de un ensayo clínico aleatorizado multicéntrico que se ha realizado en el SNS y que compara la eficacia del PU en formato grupal con el tratamiento habitual en distintas USM españolas. Para este estudio se analizó la respuesta al tratamiento (solo en la condición PU en grupo) en función del género de una muestra compuesta por 277 pacientes (217 mujeres) que presentaban un diagnóstico de TE. Se realizó una evaluación pre-tratamiento, así como seguimientos a los 3, 6 y 12 meses.

Los resultados de esta serie de estudios que integran la presente tesis doctoral nos muestran que, por una parte, el PU es una intervención versátil y adaptable al contexto del SNS y clínicamente eficaz para el tratamiento de los TEs o sintomatología emocional. Por otra parte, hemos podido comprobar que el PU no requiere adaptaciones específicas cuando se aplica a mujeres, pese a las diferencias en función de género en prevalencia y otras características reflejadas en la literatura.

Podemos concluir, que atendiendo a la necesidad de ofrecer tratamientos eficaces y costo-efectivos en el SNS por la elevada demanda asistencial, especialmente de mujeres, y la carencia de recursos, el PU responde a esta realidad y nos brinda la posibilidad de ofrecer una intervención psicológica, válida, útil y adaptable a las diferentes condiciones asistenciales actuales.

En la siguiente tabla se pueden observar el listado de artículos que integran este trabajo de tesis doctoral por compendio de publicaciones:

Tabla 1 Tesis doctoral como compendio de publicaciones

	ARTÍCULOS
1	Osma, J., Quilez, A., **Ferreres, V**., Meseguer, M., & Ariza, S. (2022). Feasibility and clinical usefulness of the Unified Protocol in women survivors of violence. *Journal of Child and Family Studies.* https://doi.org/10.1007/s10826-022-02226-z
2	Quilez-Orden, A., **Ferreres-Galán, V.,** & Osma, J. (2020). Feasibility and clinical usefulness of the Unified Protocol in online group format for bariatric surgery candidates: study protocol for a multiple baseline experimental design. *International Journal of Environmental Research and Public Health, 17*, 6155. https://doi.org/10.3390/ijerph17176155
3	**Ferreres-Galan, V.**, Quilez-Orden, & Osma, J. (2022) Application of the unified protocol for transdiagnostic treatment of emotional disorders in post-bariatric surgery patients: an effectiveness and feasibility study in group format. *Anales de Psicología, 38*, 219-231. https://doi.org/10.6018/analesps.482301
4	**Ferreres-Galan, V.**, Navarro-Haro, MV., Peris-Baquero, O., Guillen-Marín, S., DeLuna-Hermoso, J., Osma, J. (2022). Assessment of Acceptability and Initial Effectiveness of a Unified Protocol Prevention Program to Train Emotional Regulation Skills in Female Nursing Professional during the COVID-19 Pandemic. *International Journal of Environmental Research and Public Health, 19*, 5715.https://doi.org/10.3390/ijerph19095715
5	**Ferreres-Galan, V.**, Peris-Baquero, O., Moreno, J.D. & Osma, J. (2023) Is the Unified Protocol for transdiagnostic treatment of emotional disorders equally effective for men and women? *Journal of Psychiatry Research* (enviado)

Esta tesis ha sido aceptada por los coautores de las publicaciones mencionadas anteriormente que han renunciado al derecho de presentarlas como parte de otra tesis doctoral.

RESUMEN

Nuestro SNS presenta una serie de limitaciones que imposibilita una atención adecuada a la Salud Mental (SM) de las personas afectadas.

La principal demanda asistencial en las USM Públicas de adultos proviene de mujeres con trastornos emocionales (TEs; ansiedad, depresión y relacionados). Además, una característica clínica importante a tener en cuenta es la alta comorbilidad entre los TEs, lo que dificulta la elección de tratamientos y su implementación.

Existen tratamientos psicológicos basados en la evidencia (TPBE) para abordar los TEs, pero dichos tratamientos son específicos para cada trastorno, no tienen en cuenta la comorbilidad entre trastornos y, por ello, no resultan coste-efectivos ni costo-eficientes para ser aplicados en el contexto del SNS, principalmente por la carencia de recursos y las largas listas de espera que existen.

El Protocolo Unificado para el Tratamiento Transdiagnóstico de los Trastornos Emocionales (PU), desarrollado por el equipo del Dr. David H. Barlow en la Universidad de Boston, es una intervención cognitivo-conductual centrada en trabajar las dificultades en la regulación emocional compartidas por las personas con TEs. El PU permite utilizar un único tratamiento en formato grupal para abordar todos los TEs, incluyendo la comorbilidad y, como consecuencia, facilita a los clínicos del SNS la creación de grupos heterogéneos de pacientes con TEs en menos tiempo, ofreciendo así atención a un mayor número de personas. Además, al ser una intervención protocolizada, permite programar la intervención en un número concreto de sesiones, permitiendo así que los pacientes reciban una intervención completa de manera intensiva y breve. El PU es una intervención psicológica transdiagnóstica coste-efectiva, con evidencia empírica tanto para la prevención como para el tratamiento de los TEs.

El objetivo general de la presente tesis doctoral es estudiar la eficacia y coste-efectividad del PU para el abordaje de los TEs. Concretamente, nuestro trabajo se basa en estudiar la aplicabilidad y utilidad de esta intervención sobre trastornos y/o sintomatología emocional de mujeres demandantes de asistencia psicológica en la Sanidad Pública y entorno relacionado (servicios sociales). Los diferentes trabajos presentados se unen a la literatura ya publicada sobre la utilidad del PU para la práctica clínica de los psicólogos clínicos del SNS.

CAPÍTULO I: INTRODUCCIÓN GENERAL

1.1 INTRODUCCIÓN

1.1.1 Asistencia psicológica en la salud mental pública española

La atención a la Salud Mental (SM) se describe como una necesidad y se plantea como un objetivo primordial ya desde 2005 con la Declaración de Helsinki de la Conferencia Ministerial de la Organización Mundial de la Salud "No hay salud sin salud mental" (Organización Mundial de la Salud [OMS], 2005). Lamentablemente, la realidad nos muestra que esta atención "imprescindible" no siempre es posible desde los recursos asistenciales de los que dispone el Sistema Nacional de Salud (SNS). El número de Psicólogos/as Clínicos/as en nuestro Sistema Público de Salud es muy inferior a la media europea (Duro Martínez, 2021). En España la ratio general es de 5,58 profesionales por 100000 habitantes, aunque existen grandes diferencias según Comunidades y las ratios oscilan desde los 10.13 en Navarra a los 3.22 en Andalucía (Fernández-García, 2021). En la Comunidad Valenciana, en un informe del Defensor del Pueblo en 2018 se notifica que la ratio en esta comunidad es de 4,38 profesionales por 100000 habitantes (Duro Martínez, 2021). Sin embargo, cabe destacar que los datos referidos a las ratios pueden diferir mucho de unos estudios a otros, dependiendo de la clasificación que se hace de los/las profesionales clínicos según comunidades y países. En cualquier caso, de todos los informes se concluye que los profesionales de la SM son insuficientes para atender a las demandas asistenciales.

La carencia de personal especializado supone el aumento de la lista de espera para ser atendido y la dificultad para implementar tratamientos bien establecidos, dada la demora también en las posibilidades de visitas de seguimiento. Esto supone una merma en el éxito de las intervenciones ya que según las guías NICE (National Institute for Health and Care Excellence) se recomiendan 8 sesiones de media y de frecuencia semanal, para que pueda considerarse efectivo un tratamiento psicológico (NICE, 2011). El portavoz de Sanidad del Grupo parlamentario Popular, José Juan Zaplana, aportaba en una comparecencia parlamentaria en 2021 los datos referidos a las listas de espera en el ámbito de la SM en la Comunidad Valenciana e informaba que, de media, hay que esperar 50 días para ser atendido por un especialista de la SM. Y en departamentos como el de Castellón, las demoras pueden extenderse hasta 180 días (Guindo, 2022).

Como decíamos, la limitación de profesionales especialistas en SM que imposibilita la opción de hacer tratamientos basados en la evidencia en el Sistema Público de Salud se confronta con una demanda asistencial cada vez mayor. En España, en 2019, un 5,2% de la población había sido diagnosticada de depresión y un 5,8% de ansiedad (INE, 2020). Además, el aumento de la visibilidad de los problemas de SM derivados de la pandemia por COVID-19 acontecida desde 2020 ha puesto aún más en evidencia la necesidad de fortalecer la atención a la SM (Dirección General de Salud Pública, 2022). Los datos aportados por la OMS informan de

un aumento de más del 25% de problemas de ansiedad y depresión en el primer año de pandemia, siendo las mujeres las más afectadas por este incremento (OMS, 2022). En una reciente revisión sobre el impacto de la pandemia por COVID-19 en la prevalencia de sintomatología ansiosa y depresiva se concluye que es de vital urgencia fortalecer el sistema sanitario en materia de SM en la mayoría de los países, sobre todo en aquellos donde la pandemia ha sido más devastadora, ya que a nivel global se ha observado un aumento de los trastornos depresivos y ansiosos (27,6% y 25,6% de aumento, respectivamente) con incremento estadísticamente más significativo para las mujeres (Santomauro et al., 2021). En esta línea, y atendiendo a estas necesidades, en el reciente Plan de Acción Valenciano de Salud Mental se especifica como objetivo "mejorar las ratios en atención primaria y atención psiquiátrica, acercar más la atención a quien lo necesite, esté donde esté, y ganar eficiencia con racionalización carga de trabajo para el personal sanitario" (Comisionado de la Presidencia de la Generalitat para el Plan Valenciano de Acción para la Salud Mental, Drogodependencias y Conductas Adictivas, 2023).

En resumen, encontramos que la atención pública a la SM presenta serias dificultades para mantener una atención adecuada y especializada. En los sistemas públicos de salud se evidencia la necesidad de intervenir sobre las largas listas de espera y las demandas asistenciales, cada vez mayores, con formatos de intervención costo-efectivos.

1.1.2 Mapa asistencial en la Comunidad Valenciana

En la Comunidad Valenciana, la organización territorial de la Sanidad y Salud Pública se estructura en base a 24 departamentos de Salud distribuidos por todo el territorio valenciano (BOE, 2018). Cada departamento cuenta con una o varias USM, consideradas como unidades de apoyo (Decreto 74/2007 de 18 de mayo del Consell por el que se aprueba el Reglamento sobre estructura, organización y funcionamiento de la atención sanitaria en la Comunitat Valenciana). Estas unidades actúan de forma integrada y coordinada con otros recursos especializados del departamento. El objetivo de las USM es ofrecer un abordaje psicoterapéutico integral, teniendo como eje al paciente y cuidador principal, utilizando terapia psicofarmacológica y técnicas psicoterapéuticas, individuales y grupales, basadas en la evidencia científica (se excluyen la hipnosis y el psicoanálisis) (Conselleria de Sanitat de la Comunitat Valenciana, 2023). El departamento de Vinaròs, donde está ubicada la USM a la que pertenezco, comprende el territorio norte de la provincia de Castellón y abarca una población de unos 900000 habitantes (con igual proporción de hombres y mujeres) (INE, 2021) distribuidos en torno a 2 comarcas del interior y costa norte de la provincia (Els Ports y el Baix Maestrat). En las siguientes figuras se

muestran la distribución de los municipios del departamento y la distribución de la población en función del género.

Figura 1.1 Mapa municipios Departamento de Salud de Vinaròs (https://vinaros.san.gva.es/portada0)

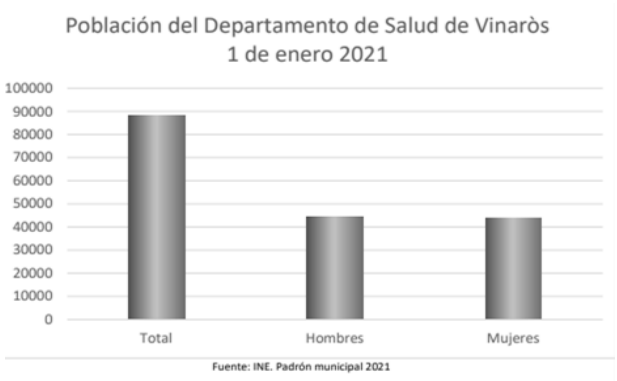

Figura 1.2 Distribución poblacional Departamento de Salud de Vinaròs (INE, 2021)

Para atender a la SM de la población, este departamento cuenta con una USM para adultos ubicada en el Hospital Comarcal de Vinaròs dotada de 6 psiquiatras, 3 psicólogos/as clínicos y una enfermera especialista en SM; una USM Infantil/Adolescencia que cuenta con 2 psicólogas clínicas, una psiquiatra y una enfermera; y para todo el departamento se cuenta también con una auxiliar administrativa, un trabajador social y una terapeuta ocupacional que

responden a las necesidades asistenciales de la población atendida en SM. Como vemos, la dotación de psicólogos/as clínicas se aproxima a la media general, muy por debajo de la europea (Duro Martínez, 2021).

La principal demanda asistencial que ofrece el servicio de SM de nuestro departamento es atender en consultas externas las interconsultas realizadas por nuestros compañeros/as de Atención Primaria. También disponemos de asistencia a urgencias 24 horas por parte de los/as psiquiatras de la USM que realizan guardias localizadas.

En un análisis descriptivo de la población atendida, vemos que la principal demanda asistencial por parte de psicología clínica de la USM de adultos de mi departamento es el trastorno mental común, que incluye cuadros ansiosos, depresivos y relacionados de gravedad leve/moderada. Si analizamos características demográficas concretas, como por ejemplo el género, vemos que las mujeres son la principal población atendida en las USM Adultos. Así, y a modo descriptivo, en los 10 años que llevo ocupando el puesto de facultativa en este departamento, he realizado unas 15000 visitas (tanto evaluación como tratamiento) y más del 70% de la población atendida han sido mujeres, siendo el principal motivo de la derivación un trastorno ansioso y/o depresivo o relacionado.

1.2 LOS TRASTORNOS EMOCIONALES

De todos los trastornos mentales, los trastornos depresivos y ansiosos son los más prevalentes a nivel mundial (OMS,2017) y los que más han aumentado en los últimos años (OMS, 2022). A nivel nacional, el 5,84% de la población de 15 o más años declara haber sido diagnosticada de ansiedad crónica y el 5,28% de depresión, siendo más del doble de frecuentes dichos diagnósticos en mujeres que en hombres (Instituto Nacional de Estadística [INE], 2020). Según el "Institute for Health Metrics and Evaluation" (IHME), en España, el porcentaje de cuadros ansiosos, depresivos o relacionados ha aumentado hasta un 12,69%, de modo que se constata que aproximadamente 5 millones de personas sufre un trastorno de este tipo a nivel nacional (IHME, 2023). Y llama la atención que, en numerosos estudios sobre sintomatología de ansiedad y depresión, se constata que las mujeres adultas presentan peor salud "emocional" que los hombres (OMS, 2022; Sáenz-Herrero, 2019).

Vamos a definir y describir brevemente estos diagnósticos principales:

Los **trastornos depresivos** tienen en común la presencia de un ánimo triste, vacío o irritable, acompañado de cambios somáticos y cognitivos que afectan significativamente a la capacidad funcional del individuo. Engloban según la última edición del Manual Diagnóstico y Estadístico de Trastornos Mentales, el DSM-5-TR (American Psychiatric Association [APA]

2022), el trastorno de desregulación disruptiva del estado de ánimo, el trastorno de depresión mayor, el trastorno depresivo persistente, el trastorno disfórico premenstrual, el trastorno depresivo inducido por una sustancia/medicamento, el trastorno depresivo debido a otra afección médica, otro trastorno depresivo especificado y otro trastorno depresivo no especificado. Los trastornos depresivos tienen una elevada prevalencia. En 2019, 280 millones de personas en todo el mundo presentaban un trastorno depresivo y en 2020, con la pandemia, estos números aumentaron significativamente (OMS, 2022).

Los **trastornos de ansiedad**, por su parte, comparten características de miedo y ansiedad excesivos, así como alteraciones conductuales asociadas. Engloban el trastorno de ansiedad por separación, mutismo selectivo, fobia específica, trastorno de ansiedad social, trastorno de pánico, agorafobia, trastorno de ansiedad generalizada, trastorno de ansiedad inducido por sustancia/medicamento, trastorno de ansiedad debido a otra afección médica, otro trastorno de ansiedad especificado y otro trastorno de ansiedad no especificado (APA,2022). En 2019, 301 millones de personas en todo el mundo presentaban un trastorno de ansiedad. Y tras la pandemia, y al igual que pasó con los trastornos depresivos, estos números aumentaron significativamente (OMS, 2022).

Otros trastornos relacionados y que comparten características con los cuadros ansiosos y depresivos son los trastornos relacionados con el espectro obsesivo y los relacionados con traumas y factores de estrés (anteriormente incluidos en la categoría de trastornos de ansiedad) (APA, 2022):

Los **trastornos relacionados con el espectro obsesivo** difieren del desarrollo evolutivo normal en que las preocupaciones y rituales son más excesivos o persistentes que lo normal para esta etapa de desarrollo e incluyen el trastorno obsesivo-compulsivo, el trastorno dismórfico corporal, el trastorno de acumulación, la tricotilomanía, el trastorno de excoriación, el trastorno obsesivo-compulsivo y relacionados inducidos por sustancia/medicamento, el trastorno obsesivo-compulsivo y relacionados debidos a otra afección médica, otros trastorno obsesivo-compulsivo y relacionados especificados y otros trastorno obsesivo-compulsivo y relacionados no especificados (APA, 2022).

Los **trastornos relacionados con traumas y factores de estrés** incluyen aquellos en que la exposición a un evento traumático o estresante aparece, de manera explícita, como un criterio diagnóstico. Incluyen el trastorno de apego reactivo, trastorno de relación social desinhibida, trastorno de estrés postraumático, trastorno de estrés agudo y trastornos de adaptación (APA, 2022). A continuación, se detalla una tabla resumen de los diagnósticos recogidos en el DSM-5-TR (APA, 2022):

Tabla 1.1 Listado de trastornos emocionales más prevalentes en la sociedad (APA, 2022).

	Trastorno de desregulación disruptiva del estado de ánimo
TRASTORNOS DEPRESIVOS	Trastorno de depresión mayor
	Trastorno depresivo persistente
	Trastorno disfórico premenstrual
	Trastorno depresivo inducido por una sustancia/medicamento
	Trastorno depresivo debido a otra afección médica
	Otro trastorno depresivo especificado
	Otro trastorno depresivo no especificado
TRASTORNOS DE ANSIEDAD	Trastorno de ansiedad por separación
	Mutismo selectivo
	Fobia específica
	Trastorno de ansiedad social
	Trastorno de pánico
	Agorafobia
	Trastorno de ansiedad generalizada
	Trastorno de ansiedad inducido por sustancia/medicamento
	Trastorno de ansiedad debido a otra afección médica
	Otro trastorno de ansiedad especificado
	Otro trastorno de ansiedad no especificado
TRASTORNOS RELACIONADOS CON EL ESPECTRO OBSESIVO	Trastorno obsesivo-compulsivo
	Trastorno dismórfico corporal
	Trastorno de acumulación
	Tricotilomanía
	Trastorno de excoriación
	Trastorno obsesivo-compulsivo y relacionados inducidos por sustancia/medicamento
	Trastorno obsesivo-compulsivo y relacionados debidos a otra afección médica
	Otros trastorno obsesivo-compulsivo y relacionados especificados
	Otros trastorno obsesivo-compulsivo y relacionados no especificados
TRASTORNOS RELACIONADOS CON TRAUMAS Y FACTORES DE ESTRÉS	Trastorno de apego reactivo
	Trastorno de relación social desinhibida
	Trastorno de estrés postraumático
	Trastorno de estrés agudo
	Trastornos de adaptación

En los últimos años, ha aumentado la evidencia científica acerca de la existencia de factores etiológicos comunes en todas estas categorías diagnósticas (Fonseca-Pedrero, 2021). Varios hallazgos han contribuido a este planteamiento "transdiagnóstico": [a] el gran

solapamiento de la sintomatología ansiosa y depresiva (comorbilidad); [b] la base común de diátesis y factores de vulnerabilidad para su desarrollo; y [c] la generalización de la respuesta al tratamiento principal a otros comórbidos (Brown & Barlow, 2009). Se estima que existe una comorbilidad del 19,1% entre los trastornos de ansiedad y los depresivos (Roca et al., 2009). En cuanto a factores etiológicos comunes, se ha propuesto al neuroticismo (tendencia a experimentar emociones de valencia negativa junto con la sensación de incontrolabilidad e impredicibilidad sobre el mundo), como un factor de vulnerabilidad para el desarrollo tanto de los trastornos ansiosos como de los depresivos y relacionados (Barlow et al., 2014). Precisamente por el importante papel que desempeñan las emociones de valencia negativa en el desarrollo de estos trastornos se utiliza el término Trastornos Emocionales (TEs), para referirse de forma global a la sintomatología ansiosa, depresiva y cuadros relacionados, destacando de este modo la similitud de estas categorías diagnósticas (Bullis et al., 2019). Por último, la investigación ha puesto de manifiesto que tratar un trastorno específico de forma principal repercute en la mejora de la sintomatología comórbida no tratada directamente, lo cual también apoya el planteamiento de abordar de forma conjunta la sintomatología emocional (Brown et al., 1995)

Otro factor común asociado a la sintomatología emocional y ya comentado es que tanto la ansiedad como la depresión, tienen una prevalencia mayor en las mujeres (Sáenz-Herrero, 2019; Santomauro et al., 2021). Una reciente revisión sobre las diferencias de género en sintomatología depresiva apunta a la necesidad de valorar la necesidad de hacer intervenciones personalizadas, sobretodo en mujeres con sintomatología depresiva (Hyde & Mezulis, 2020). El único trastorno relacionado con factores emocionales que no presenta mayor prevalencia en las mujeres es el trastorno obsesivo-compulsivo, cuya prevalencia parece similar en ambos géneros, pero sí se describen diferencias intergénero en otras variables como el inicio, el curso, la expresión y la respuesta al tratamiento de dicho trastorno (Arenas & Puigcerver, 2009).

En conclusión, los TEs presentan una alta prevalencia, sobretodo en mujeres y precisamente por esta elevada prevalencia, la principal demanda asistencial en el SNS proviene de mujeres con TEs. Varios estudios que analizan la asistencia a los problemas psicológicos comparten la conclusión que tanto en atención primaria como especializada la demanda asistencial principal es por sintomatología emocional. Acorde a la literatura publicada, en mi práctica clínica como facultativa a lo largo de 10 años, he realizado más de 15000 consultas, el 80% de las mismas con TEs y el 70% mujeres. Esta realidad pone en evidencia la necesidad de plantearnos intervenciones acordes a dicha demanda, objetivo principal del presente trabajo de tesis doctoral.

1.3 MODELOS BIO-PSICO-SOCIALES EXPLICATIVOS SOBRE LA MAYOR PREVALENCIA DE LOS TRASTORNOS EMOCIONALES EN MUJERES

El análisis de género es un campo de investigación en expansión. De hecho, el enfoque de género es uno de los principios rectores de la reciente Estrategia de Salud Mental del Sistema Nacional de Salud periodo 2022-2026 (Ministerio de Sanidad, 2022).Supone estudiar las desigualdades que se pueden dar en la salud provenientes de diferencias que han sido construidas socialmente, distribución de roles y relaciones de poder entre hombres y mujeres, así como otros factores como el nivel socioeconómico y educacional (Mujeres, 2020). También se especifica como un objetivo general ya en la Estrategia Autonómica de Salud Mental 2016-2020 de la Comunitat Valenciana (Figura 1.3)

OBJETIVO GENERAL 11: POTENCIAR LA INVESTIGACIÓN EN SALUD MENTAL.

OBJETIVOS ESPECÍFICOS	ACCIONES
11.1. Elaborar un plan de investigación acorde a las líneas de la Estrategia	11.1.1. Crear y mantener comisión de investigación en materia de salud mental
	11.1 2.. Incluir la perspectiva de género en la investigación
	11.1.3. Desarrollar líneas de investigación en calidad y gestión y evaluación de servicios de salud mental.
	11.1.4. Disponer de bases de datos accesibles a diferentes líneas de investigación
11.2. Promover la innovación en el proceso de la investigación	11.2.1. Incluir las TICs dentro de las líneas de investigación en salud mental
11.3. Fomentar la difusión del conocimiento	11.3.1. Difundir la información de las investigaciones de salud mental.
	11.3.2. Potenciar la participación de profesionales en espacios científicos de interés.

Figura 1.3 Objetivo general 11 de la Estrategia Autonómica de Salud Mental. Extraído de la Estrategia Autonómica de Salud Mental de la Comunitat Valenciana

Se señala al género como un factor determinante en la salud de las personas dado que interactúa con las diferencias biológicas y factores sociales determinando la forma en que se desarrollen las patologías de hombres y mujeres (OMS,2008).

La literatura nos muestra amplias diferencias entre mujeres y hombres en aspectos de SM. Se han planteado diferentes hipótesis para explicar estas diferencias según género, desde aspectos más biológicos hasta factores psicosociales. Es más, se apunta a que ambos factores,

biológicos y sociales, están interrelacionados, postulando que los determinantes sociales (que incluyen el género en sí) interactúan entre sí y exacerban las vulnerabilidades biológicas (Afifi, 2007).

Así pues, aunque todavía hace falta mucha investigación para clarificar la relación entre género y psicopatología, se ha identificado una serie de factores que pueden explicar el predominio de los TEs en las mujeres. Estos factores pueden dividirse en factores biológicos y psicosociales.

En cuanto a los biológicos, se han identificado varios aspectos relacionados con la predisposición genética, con factores hormonales y con características neuroanatómicas y neuroquímicas implicados en la variabilidad intergénero encontrada en los diferentes TEs (Gaviria-Arbeláez, 2009). Pero las teorías biologicistas por sí solas no pueden explicar la gran desigualdad en la prevalencia de los TEs en función de género por lo que es imprescindible atender a factores psicosociales para entender las diferencias encontradas.

En relación con los factores psicosociales, se apunta a que ser mujer es un factor de riesgo para la SM porque vivimos en una sociedad patriarcal y androgénica que deriva en desigualdades sociales desfavorables para las mujeres. Se señalan múltiples condicionantes sociales como la división sexual del trabajo, los ideales de belleza, la violencia de género, la economía de mercado y la contaminación ambiental, condiciones que provocan mayores consecuencias negativas para la salud de las mujeres (Sánchez, 2018). En concordancia con estos datos, una revisión sistemática sobre la prevalencia de los trastornos depresivos y ansiosos tras la pandemia por COVID-19 apunta a un mayor impacto de ésta en las mujeres ya que se ven más afectadas por las consecuencias sociales y económicas de la crisis acontecida por la pandemia (más carga en el cuidado del hogar por el cierre de colegios, más riesgo de violencia en el hogar, menos empleo y peores salarios, entre otros) (Santomauro, 2021). Así pues, esta reciente revisión refleja cómo los factores psicosociales influyen en la mayor prevalencia de la sintomatología emocional en la mujer, por el hecho de ser mujer.

Con todo, las teorías psicosociales parecen complementar las biológicas y la interrelación de ambas explica de forma más consistente la variabilidad según género en patologías emocionales. Así pues, queda claro que las diferencias de género en TEs deben evaluarse atendiendo a factores biológicos, psicológicos y socioculturales, factores que no siempre se han tenido en cuenta en la investigación sobre SM.

La falta de investigación e información ha supuesto que no se haya tenido en cuenta la posibilidad de que existieran diferencias entre hombres y mujeres, no sólo en la prevalencia de los problemas de salud, sino también en el modo de enfermar, a la hora de diagnosticar o incluso a la hora de responder al tratamiento (Valls-Llobet, 2020). La morbilidad femenina diferencial supone tener en cuenta las enfermedades, motivos de consulta y factores de riesgo

que merecen una atención específica a las mujeres, bien sea por su mayor prevalencia o por su exclusividad para este género (Llobet et al., 2008).

A este respecto, varias líneas de investigación se dirigen a estudiar las patologías desde este enfoque y destacan que teniendo en cuenta dicha morbilidad diferencial, los datos de prevalencia podrían no ser tan dispares. La hipótesis del artefacto (o errores metodológicos) destaca la idea que las mujeres solicitan más demanda y sobre informan más de los problemas emocionales pero ello no implica mayor prevalencia, sino mayor demanda asistencial por cuadros emocionales (Gaviria Arbeláez, 2009). Además, se apunta que esta mayor prevalencia de TEs en mujeres puede deberse también a que es más probable que las mujeres sean diagnosticadas de un cuadro ansioso o depresivo que los hombres cuando acuden por primera vez a recibir asistencia sanitaria (Valls-Llobet, 2020). Vemos pues que es un campo todavía reciente que requiere mayor investigación.

Podemos concluir que, aunque la prevalencia de los TEs es mayor en mujeres de forma muy significativa y parece que existen factores biológicos y psicosociales implicados en esta diferencia, podemos considerar también que existen otros factores implicados en tal disparidad, como pueden ser los sesgos de la propia investigación, donde no se ha tenido en cuenta la morbilidad diferencial. Hará falta mayor investigación al respecto para poder sacar conclusiones más concretas y averiguar cuáles son las diferencias según género existentes y qué implicaciones tiene a la hora de desarrollar tratamientos para los TEs.

1.4 TRATAMIENTO PSICOLÓGICO DE LOS TRASTORNOS EMOCIONALES

Los sistemas de clasificación imperantes de los trastornos mentales son los establecidos por la Asociación Americana de Psiquiatría (APA por sus siglas en inglés) y la Organización Mundial de la Salud (OMS) que siguen un enfoque de clasificación categorial (Belloch et al., 2020). Este enfoque supone la agrupación de la psicopatología en categorías discretas basadas en signos y síntomas que caracterizan cada trastorno mental. Paralelamente, los tratamientos psicoterapéuticos formulados se han ido adaptando con el fin de ofrecer tratamientos específicos para cada trastorno mental descrito en dichos sistemas de clasificación. Como resultado de dicho planteamiento, se han desarrollado numerosas intervenciones con eficacia demostrada para una gran variedad de trastornos mentales (p.ej., Treatments that Work series, Oxford University Press). Así pues, se han desarrollado tratamientos psicológicos basados en la

evidencia para prácticamente todas las categorías diagnósticas descritas en los manuales de referencia y ello ha supuesto un hito en la historia de la psicoterapia.

Estudios recientes sobre la eficacia de las intervenciones para los trastornos depresivos describen como terapias basadas en la evidencia la terapia cognitivo-conductual (TCC), la activación conductual, la terapia interpersonal y la terapia cognitiva basada en mindfulness (Barracas, 2021). Para los trastornos de ansiedad, el tratamiento de elección según las principales guías clínicas es la TCC y se han desarrollado tratamientos específicos para cada uno de los trastornos ansiosos descritos: trastorno de ansiedad generalizada, trastorno de pánico, fobia social o fobia específica (Moriana et al., 2017). Para el Trastorno obsesivo-compulsivo y los trastornos relacionados con traumas también se han desarrollado tratamientos específicos con demostrada eficacia, y que incluyen diferentes técnicas de orientación cognitivo conductual también, como por ejemplo la exposición con prevención de respuesta para el trastorno obsesivo-compulsivo (Vallejo et al, 2021) y la exposición prolongada y la flexibilidad cognitiva para los trastornos relacionados con traumas (Pastor & García, 2021).

Pese a la eficacia de los tratamientos descritos, el aumento de las categorías diagnósticas, de poco más de 100 en DSM-I a más de 300 en DSM-5-TR,ha supuesto un aumento de la comorbilidad diagnóstica, sobretodo en trastornos depresivos, ansiosos y relacionados, lo que cuestiona el sistema categorial predominante hasta la fecha y también la eficacia de hacer tratamientos específicos para cada uno de los trastornos. Se estima que más de la mitad de los pacientes con un diagnóstico principal de ansiedad o depresión, presentan un trastorno adicional ansioso o depresivo en el momento de la evaluación, y estas cifras son mayores si analizamos la comorbilidad a lo largo de la vida y no sólo en el momento de la evaluación (Brown et al., 2001).Es evidente que el reduccionismo del enfoque categorial está siendo cada vez más cuestionado y también la utilidad de los tratamientos específicos para cada una de dichas categorías.

Así pues, en referencia a los TEs, como ya hemos comentado, existen algunas limitaciones a la hora de poder ofrecer tratamientos costo-efectivos y eficaces: la alta prevalencia (Depression,2017), la comorbilidad entre los TEs (Minekaet al., 1998), la cuestionable eficacia de algunos de los tratamientos empíricamente validados (Costas &Álvarez, 2018) y el coste económico y en recursos que supone la formación e implantación de cada uno de estos protocolos en las carteras de servicios en SM. Por consiguiente, escoger un tratamiento para dichos trastornos se está convirtiendo en un gran problema para los profesionales de la psicología clínica actual.

Podemos concluir pues, que existen tratamientos psicológicos basados en la evidencia para los diferentes trastornos descritos en los sistemas clasificatorios predominantes, pero éstos presentan dificultades para su uso generalizado en el SNS. La elevada prevalencia de los TEs y las largas listas de espera para ser tratados plantean la necesidad de buscar nuevos tratamientos psicológicos y formatos de intervención más coste-efectivos y adaptables a la población clínica. A este respecto cabe mencionar que la investigación sobre la eficacia de los tratamientos se hace en entornos altamente controlados (p. ej., laboratorios universitarios o unidades asistenciales especializadas), en lugar de, demostrar la eficacia de los tratamientos en entornos naturalísticos, es decir, en el lugar natural donde los pacientes acuden y los terapeutas aplican el tratamiento, en nuestro caso, en el SNS. Para conseguir esto último, muchas veces las intervenciones deben adaptarse (en contenidos, formatos, dosis, frecuencia, etc.) y se debe demostrar que estas adaptaciones siguen siendo eficaces.

1.5 ENFOQUE TRASNDIAGNÓSTICO PARA EL ABORDAJE DE LOS TRASTORNOS EMOCIONALES: PROTOCOLO UNIFICADO

Dada la crisis justificada del enfoque categorial, han ido surgiendo propuestas alternativas para diagnosticar y clasificar los trastornos mentales basándose en criterios dimensionales como la Hierarchical Taxonomy of Psychopatology (HiTOP; Kotov et al, 2017) o los Research Domain Criteria (RDoC; Cuthbert & Insel, 2013). El enfoque dimensional asume que no existen categorías cuantitativamente diferentes, sino que entiende la conducta como una dimensión o continuo (Belloch et al., 2020). Desde una aproximación científica más integradora y convergente, surge el enfoque transdiagnóstico, que aún basándose en una conceptualización dimensional de base, asume algún sistema categorial (Sandín et al., 2012). La base de este planteamiento es que las diferentes categorías diagnósticas planteadas comparten síntomas, evolución clínica, antecedentes temperamentales y respuesta a los tratamientos, por lo que pueden tener un abordaje común atendiendo a estos factores (McEvoy et al., 2009). Esta propuesta integradora/híbrida transdiagnóstica parece responder mejor a los hallazgos empíricos más recientes. Los procesos causales comunes a diferentes categorías diagnósticas, la elevada comorbilidad y los resultados positivos de los mismos esquemas de tratamiento para cada trastorno, señalan la necesidad de centrar la investigación de la psicopatología y la ciencia

clínica en los procesos causales más que en los síntomas o trastornos en sí mismos (Caballoet al., 2016).

La perspectiva integradora transdiagnóstica no es novedosa, pues ya encontramos este enfoque en modelos como el psicodinámico, el humanista, el conductual y el sistémico, entre otros (Pérez-Álvarez, 2017). Sauer-Zavala et al. (2017) plantean que existen tres amplias categorías para referirse y entender el enfoque transdiagnóstico cuando hablamos de tratamientos psicológicos. La primera plantea que las intervenciones pueden aplicarse a una amplia gama de trastornos, basándose en principios terapéuticos de aplicación universal, como es el caso de los modelos psicodinámico, humanista y conductual, entre otros. El segundo planteamiento se basa en un enfoque modular, entendiendo el tratamiento como transdiagnóstico porque el terapeuta escoge un conjunto de intervenciones adaptadas a la sintomatología del paciente independientemente del diagnóstico. Por último, la tercera categoría implica intervenciones que se centran explícitamente en los mecanismos compartidos implicados en el desarrollo y mantenimiento de la psicopatología común (Sauer-Zavala et al, 2017).

Entendiendo el transdiagnóstico desde esta tercera categoría, el equipo del Dr. David H. Barlow plantea un enfoque transdiagnóstico centrado en la posibilidad de diseñar un único tratamiento para todos los TEs, dirigido a los mecanismos etiológicos y de mantenimiento compartidos por los mismos (Brown & Barlow, 2009). Estos autores proponen el neuroticismo como dimensión central en la etiología, curso y mantenimiento de los TEs. En base a su modelo de triple vulnerabilidad (Suárez et al, 2009), es mucho más probable desarrollar este tipo de trastornos si se da una combinación entre la vulnerabilidad biológica y psicológica. Los altos niveles de neuroticismo componen la vulnerabilidad biológica generalizada (hiperexcitabilidad de las estructuras límbicas y control inhibitorio limitado de las estructuras corticales). La vulnerabilidad psicológica puede ser generalizada o específica. La generalizada, hace referencia a experiencias tempranas caracterizadas por ambientes estresantes e impredecibles, o estilos de crianza que conducen a un sentimiento general de incontrolabilidad e impredictibilidad sobre los eventos de la vida. Estas circunstancias impiden el aprendizaje de estrategias de regulación emocional y predisponen al individuo al desarrollo de alteraciones emocionales ante estresores futuros. La específica, supone experiencias adversas (estresores) vividas por la persona, a través de las cuales se asocia la respuesta emocional intensa (y reactividad fisiológica) con ciertos estímulos internos (p.ej., recuerdos o pensamientos) o externos (p.ej., un lugar o persona concreta) (Allen et al., 2008; Suárez et al, 2009).

Considerando lo expuesto previamente, el equipo del Dr. Barlow ha desarrollado un tratamiento para los TEs que pone el énfasis en lo que tienen en común, en lugar de en sus diferencias (Barlow, 2019) . Este tratamiento, que recibe el nombre de “Protocolo Unificado para el Tratamiento Transdiagnóstico de los Trastornos Emocionales” (PU en adelante), hace

hincapié en los déficits de regulación emocional ya que las respuestas emocionales intensas, la reacción aversiva a las experiencias emocionales y las conductas de evitación son comunes a las personas con estos diagnósticos. El PU incorpora técnicas psicológicas que han demostrado su eficacia como la conciencia emocional plena, flexibilidad cognitiva o la exposición (Ellard et al., 2010) y que forman parte de los siguientes módulos terapéuticos (Barlow, 2019):

- Estableciendo objetivos y manteniendo la motivación
- Comprendiendo las emociones
- Conciencia emocional plena
- Flexibilización cognitiva
- Oponiéndose a las conductas emocionales
- Comprender y afrontar las sensaciones físicas
- Exposiciones emocionales
- Reconocer tus logros y mirar hacia el futuro

Para ilustrar de modo gráfico el proceso terapéutico basado en el PU, se utiliza la metáfora de la construcción de una nueva relación más sana con tus propias emociones basándose en la construcción de una casa, desde los cimientos hasta el tejado (Figura 1.4).

Figura 1.4 Figura módulos PU [Imagen de Belén García de Mateos extraída de Barlow et al. (2019)]

Pese a la reciente publicación del PU, contamos ya con datos sobre su eficacia. Las revisiones sistemáticas, dos de ellas metanálisis (Carlucci et al., 2021; Cassiello et al., 2020 & Saliros et al., 2019) muestran que el PU mejora significativamente los síntomas de ansiedad y depresión después de su implementación, con tamaños del efecto que son al menos comparables con los obtenidos por intervenciones específicas para cada trastorno. Además de ser eficaz para la reducción significativa de síntomas ansiosos y depresivos, también ha demostrado eficacia en la reducción en dimensiones de vulnerabilidad como el neuroticismo y en aumentos en calidad de vida y la regulación emocional (Carlucci et al., 2021; Elhusseini et al., 2022).

En nuestro país, contamos también con datos sobre la eficacia del PU para el tratamiento de TEs en formato grupal en USM públicas (Osma et al., 2018). Nuestro grupo de investigación ha liderado en España una línea de investigación centrada en estudiar la coste-efectividad del PU aplicado con distintos formatos, grupal e híbrido, en nuestro SNS. Uno de los estudios ya realizado se ha centrado en estudiar la eficacia, efectividad y eficiencia del PU para el tratamiento transdiagnóstico de los TE en formato grupal a través de un ensayo clínico aleatorizado multicéntrico en el contexto de la SM Pública Española. A través de este estudio se ha puesto de manifiesto que la intervención grupal basada en el PU es eficaz (Osma et al., 2022) y altamente costo-efectiva para nuestro SNS (Peris et al., 2022) en comparación con el tratamiento habitual y, además, es ampliamente aceptada tanto por pacientes que reciben este tratamiento como por profesionales que lo aplican (p.ej., Osma et al., 2021; Peris et al., 2021;).

A su vez, contamos con datos de eficacia en su aplicación preventiva en poblaciones no clínicas como, por ejemplo, estudiantes universitarios (Bentley et al., 2018) o mujeres con infertilidad (Martínez-Borba et al., 2022).

Apenas contamos, por el contrario, con estudios que utilizando el PU hayan tenido en cuenta la variable género y los pocos que existen no han encontrado diferencias significativas en la respuesta al tratamiento entre mujeres y hombres (Carlucci et al., 2021). Por tanto, la hipótesis de que existen diferencias de género en la respuesta al tratamiento con el PU para el abordaje de los TEs no está totalmente confirmada.

Así pues, el enfoque transdiagnóstico se centra en identificar los factores etiológicos y de mantenimiento compartidos entre diferentes categorías diagnósticas. La principal ventaja de este enfoque es que permite desarrollar intervenciones que son efectivas para diferentes trastornos, lo que facilita la posibilidad de intervención en contextos donde hay carencia de recursos, como nuestro SNS. El PU es un tratamiento transdiagnóstico para los TEs que ha mostrado su eficacia no solo en formato individual, sino también grupal, lo que supone que además de eficaz, es eficiente y coste-efectivo y, por tanto, adecuado para ser utilizado en entornos como nuestro SNS

1.6 JUSTIFICACIÓN DE LOS ESTUDIOS QUE INCLUYE LA TESIS POR COMPENDIO

Caballo et al. (2016) señalan que las prioridades de investigadores y clínicos son diferentes: los primeros están más interesados por la validez de las intervenciones, mientras que los segundos son más pragmáticos y buscan el cambio conductual, sin estar tan preocupados por la validez. Sin embargo, ambos enfoques pueden coordinarse si queremos disponer de tratamientos eficaces que puedan responder a las demandas asistenciales. Así pues, es esencial poder coordinar el trabajo investigador con la práctica clínica.

Para una buena práctica clínica, es importantísimo contar con tratamientos basados en la evidencia costo-efectivos. La ya descrita falta de recursos y la demanda cada vez mayor de atención psicológica por problemas emocionales requieren de soluciones prácticas y adaptadas a las necesidades de la población.

La Estrategia de Salud Mental del SNS 2002-2026 (Ministerio de Sanidad, 2022), plantea como objetivo general *"Mejorar la salud mental de la población en todos los niveles y ámbitos de atención del Sistema Nacional de Salud"* y se asienta en una serie de principios entre los que se encuentra un enfoque de género (tener en cuenta las diferentes necesidades de mujeres y hombres en todo el proceso de planificación y prestación de servicios de SM) y una atención personalizada y segura.

Teniendo en cuenta estos objetivos y necesidades asistenciales, el presente trabajo pretende acercar la investigación a la práctica clínica y estudiar la viabilidad de aplicar intervenciones costo-efectivas que puedan atender a la demanda asistencial de la práctica clínica habitual. Por los ya comentados beneficios del PU para el abordaje de los TEs, hemos desarrollado varias adaptaciones del PU para aplicarlo a diferentes contextos y circunstancias que se dan en la práctica habitual. Ello ha supuesto adaptarlo para su aplicación, en primer lugar, en un contexto social, con mujeres con TEs en contexto de violencia intrafamiliar. En segundo lugar, en una condición de salud específica, mujeres con obesidad que han sido sometidas a cirugía bariátrica y, en tercer lugar, se ha desarrollado una adaptación del PU en contexto preventivo para ser aplicado a mujeres sanitarias en situación de riesgo por la crisis sanitaria por COVID-19.

Dado que la principal demanda asistencial proviene, como la literatura ya recoge, de sintomatología emocional en mujeres, cerramos este compendio de publicaciones con un estudio secundario a otro multicéntrico en el que anteriormente hemos trabajado, en el que analizamos si existen diferencias en la respuesta al tratamiento basado en el PU en función del género.

En resumen, el presente trabajo se justifica sobre la necesidad de acercar la investigación a la práctica clínica y analizar la utilidad clínica del PU en mujeres con TEs o factores de riesgo para desarrollarlos y determinar si cabría hacer adaptaciones en función del género atendiendo a las diferencias encontradas en diferentes parámetros relacionados con los TEs en hombres y mujeres.

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CAPÍTULO II: "FEASIBILITY AND CLINICAL USEFULNESS OF THE UNIFIED PROTOCOL IN WOMAN SURVIVORS OFVIOLENCE"

Osma, J., Quilez, A., Ferreres, V., Meseguer, M., Ariza, S., (2022). Feasibility and clinical usefulness of the Unified Protocol in women survivors of violence. *Journal of Child and Family Studies.* https://doi.org/10.1007/s10826-022-0226-z

2.1 ABSTRACT

Violence against women is a serious public health problem. Worldwide, one in three women experiences violence throughout their lives. According to the triple vulnerability theory, being a survivor of violence could constitute a psychological vulnerability that would favor the appearance of emotional disorders, affecting their health, their style of parenting, and family well-being. The objective of this study is to verify the feasibility and usefulness of Unified Protocol (UP) in a group format for improving emotion regulation in women survivors of violence attended in the Specific Child and Adolescent Intervention Team (SCAIT), a social community service. The sample consists of 11 women who have experienced different types of violence who received the UP through 11 weekly, two-hour long and in group format sessions. Assessments were conducted at pre and post intervention and at 3, 6, and 12 months follow-up. The results of the Multivariate Analysis of Variance (MANOVA) show an increase in quality of life (including family relationships), self-esteem and extraversion scores, and a reduction in interference (including family life), neuroticism, somatization, anxiety, emotional lack of control, negative affect, depression, and emotional rejection scores. This evolution of the scores with the MANOVA takes into account all the evaluation time points (post, and follow-up at 3, 6 and 12 months). The results were statistically significant ($p < 0.05$), and had large effect sizes ($\eta 2$ $p > 0.14$). In addition, the reliable change index was calculated to assess the change at an individual level of each of the participants for the different outcomes. 90.9% of the participants rated the quality of the program received as “excellent” and we obtained a high rate of session attendance (82.64%). These results justify the need for randomized controlled clinical studies to demonstrate the feasibility and clinical efficacy of the UP in this context. This intervention would allow to address the needs of this population, by offering them comprehensive care and improving their mental health from a biopsychosocial model. Likewise, it might indirectly improve the well-being of the rest of the family members.

Keywords Emotional disorders; Unified Protocol; Social services; Violence against women; Family well-being

Highlights

● Being a survivor of violence increases the probability of developing an emotional disorder.

● Poor health status in mothers is associated with poorer parenting styles and family well-being.

● The Unified Protocol is an emotional-based CBT intervention that could improve mothers' mental health and family well-being.

● Unified Protocol shows preliminary viability and clinical utility for women who have experienced violence and have emotional disorders.

2.2 INTRODUCTION

Emotional Disorders (hereinafter EDs) encompass anxiety, mood and related disorders (Brown & Barlow, 2009) and are the most prevalent mental disorders worldwide (World Health Organization [WHO], 2017a). Focusing on the world's female population, 178.7 million women suffer from at least one anxiety disorder (4.8 %), and 161.6 million from a mood disorder (4.4 %). In Spain, 1.8 million women suffer from at least one anxiety disorder (7.8 %), and 1.2 million from a mood disorder (5.4 %) (Institute for Health Metrics and Evaluation, 2017).

Brown and Barlow (2009) propose neuroticism (one of the "Big 5 personality traits") as a central dimension in the etiology, course, and maintenance of EDs and, in their triple vulnerability model, this variable conforms generalized biological vulnerability. In addition, the model includes two types of psychological vulnerability, one generalized (early experiences or parenting styles that contribute to a feeling of uncontrollability and unpredictability of events) and a specific one (adverse experiences undergone by the person, causing them to associate an intense emotional response with external or internal stimuli). For women, one of the main traumatic experiences they may undergo throughout their lives is the different types of violence against women, which can lead to generalized (e.g., family violence during childhood) or specific (e.g., intimate partner violence) psychological vulnerability. In addition, it has been shown how neuroticism scores are higher in women suffering violence than in control women (Brown et al., 2016), also increasing generalized biological vulnerability.

In Article 1 of the United Nations' "Declaration on the Elimination of Violence against Women", such violence is defined as "any act of violence based on female membership that results or may result in harm to women." Thus, different types of violence, such as intrafamilial, domestic, sexual, or gender violence, can be encompassed within this general definition (WHO, 2017b). In this article, we focus on women who have experienced different types of domestic violence. Domestic violence is defined as "physical, psychological, sexual or other abuse or aggression, inflicted by people in the family environment and generally directed at the most vulnerable members of the family: children, women and the elderly" (Ministerio de Sanidad y Consumo, 2003).

Due to the ambiguity of the definitions and the variability of concepts, it is difficult to clarify the extent of the issue (Larizgoitia, 2006), so that on many occasions the rates of violence vary depending on the definition adopted (Overstreet, 2000). Despite this, the figures show that violence against women is a serious public health problem that must be addressed. Worldwide, one in three women experience violence throughout their lives. In Spain, 55 female suffering violence died in 2019 alone; 125,936 complaints were filed; and 68,714 phone calls were made to the telephone information and legal advice service on violence against women (Gobierno de España [Spanish Govt.], 2019).

The numbers of moderating variables that can contribute to the impact of violence are immense (Galovski et al., 2021). There is a wide variety of sociocultural, historical, victim and specific factors of trauma, which means that the impact of violence can vary substantially between individuals (Briere & Jordan, 2004). One of the main consequences of experiencing violence is the development of mental health disorders, increasing their functional impairments and affecting their work, school, and social functioning (Helfrich et al., 2008).Some examples of functional impairment indicated by these authors include difficulties in finding or keeping a job, difficulties in continuing to attend work, problems concentrating, difficulties in maintaining friendships and interacting with other people, or difficulties in participating effectively in a group (Helfrich et al., 2008). In fact, women who experience violence are 2.3 times more likely to develop Post-traumatic Stress Disorder than those who do not experience violence (Galovski et al., 2021). Also, the likelihood of experiencing symptoms like depression and anxiety (although anxiety and depressive responses can be sometimes an adaptative response to the environment) is higher in people exposed to violence compared to the normal population (e.g., Graham-Bermann, 2011) because, in the former, these disorders range between 30% and 60% (Larizgoitia, 2006).But violence not only directly impacts the person who experiences it, but indirectly affects all family members and can result in a wide variety of negative consequences for children and family well-being (Herschell et al., 2016). As we have mentioned before, exposure to violence has an impact on the mental health of women who suffer it, and poor mental health in mothers is associated with an increase in the probability of developing behavioral difficulties in their children (D'Souza et al., 2019). In addition, being a survivor of violence tends to change parenting styles, increasing the probability of women survivors of violence adopting an overprotective style compared to other mothers (Boeckel et al., 2014), and this style is associated with poor self-regulation processes in children and adolescents (Christopher et al., 2013; Mak et al., 2020). Moreover, being a victim of violence is associated with difficulties in communicating with children, since mothers avoid talking about certain topics with them with the intention of protecting them (Kamody et al., 2019). Because of all of these consequences, the treatment of EDs in mothers with risk factors (e.g., history of violence)

can be a very positive way to improve parenting styles and family well-being (Carreras et al., 2019).

To better understand the etiology and maintenance of EDs, Bullis et al. (2019) describe the Functional Model of EDs. This model is composed of three related components: 1) the tendency to experience negative emotions (e.g., anxiety and depression); 2) aversive reactions to emotional experiences when they occur, and 3) efforts to suppress emotional experiences or, if these don't work, avoid them. What this model explains is that EDs are characterized by aversive reactions to emotional experiences, which generally implies avoidant coping (Bullis et al., 2019). It is suggested that all these components are triggered by a personality dimension called neuroticism (Barlow et al., 2014).

As in the general population (Brown et al., 2001), in female survivors of violence, EDs also present with high levels of comorbidity, that is, more than one psychological disorder at a time, reaching 84.2% for post-traumatic stress disorder and depression (Paz et al., 2004). This comorbidity makes it difficult to choose the most appropriate psychological intervention. Although there is evidence of the effectiveness of Cognitive Behavioral Therapy (hereinafter CBT) for the specific treatment of EDs (Trabold et al., 2018), there is still a limitation regarding the most appropriate treatment when there is comorbidity. In addition, some females that have experienced violence have unspecified anxiety or mood disorders, or subclinical symptoms, further complicating treatment choice. In this sense, the Unified Protocol for the Transdiagnostic Treatment of EDs (hereinafter, UP) is a CBT-based intervention designed to treat the etiological and maintenance mechanisms of EDs (Boettcher & Conklin, 2017; Kennedy & Barlow, 2017). Different studies suggest the importance of etiological and transdiagnostic framing for intervention with violence-exposed populations (e.g., Miller-Graff & Howell, 2016). The UP consists of 8 treatment modules, 5 of which are considered core modules because are used to train a specific emotional regulation skill (Sauer-Zavala et al., 2017). Despite the UP being a protocolized intervention, it is also flexible, which allows clinicians to be able to use only some of the modules or to change their order to personalize the UP to their patients (Sauer-Zavala et al., 2019). The UP aims to provide adaptive emotion regulation strategies so that individuals can accept, tolerate and respond effectively to intense emotions without giving up their personal goals and objectives (Barlow et al., 2018).

This intervention focuses on a wide range of emotional psychopathology and subclinical or unspecified symptoms, thus reducing treatment times and costs, and enhancing response to treatment (Barlow et al., 2017). In addition, the UP can be applied in group format (e.g., Osma et al., 2015), promoting social support among the participants, an aspect that has proven to be a protective factor for a good prognosis in female survivors of violence (Buesa & Calvete, 2013), and that has obtained better results of efficiency than the individual format (Echeburúa et al., 2014). To date, the UP has shown significant improvement in pre-treatment symptoms and has

obtained effect sizes that are at least comparable to existing specific CBT protocols, in face-to-face, group, and online format (e.g., Sakiris & Berle, 2019).

It is important to highlight that the majority of the positive outcomes on the feasibility and efficacy of the UP for the treatment of EDs have been achieved in clinical and healthcare settings, not in community settings. This fact is an important gap because when women go to healthcare settings they do not usually declare themselves as having experienced violence (Bradley, 2002). Moreover, less stigma regarding psychological disorders have been detected in community settings (Muñoz et al., 2009). In addition, we have found no studies on the clinical usefulness of the UP for improving anxiety and depressive symptoms in women who have experienced or currently experience violence.

Considering the three-axis analysis described by Ferro and Vives (2004), we need evidence-based interventions not only regarding their clinical effectiveness, changes in the expected direction and maintenance over time (axis of efficacy), but also interventions that are cost-effective for the resource that applies to them (i.e., group interventions; axis of efficiency). Finally, we also need interventions accepted and positively valued by the users who receive them (axis of effectiveness). Therefore, the general objective of this study is to explore the feasibility and clinical usefulness of a group adaptation of the UP, applied in a community context to a group of women who had experienced violence. The specific objectives pursued are: [1] to obtain a statistically significant reduction in the scores of depression, anxiety, neuroticism, negative affect, somatization, panic, emotional lack of control, emotional rejection, lack of emotional attention, emotional confusion and interference of symptoms in the participants' lives after the intervention; [2] to obtain a statistically significant increase in scores in participants' extraversion, positive affect, self-esteem, and quality of life after the intervention; [3] and to confirm that the changes in both directions are maintained over time, at three temporal moments that involve follow-up at three, six, and twelve months. In addition, we intend [4] to obtain data that show the participants' acceptance and satisfaction with the intervention (high rates of session attendance and high scores in satisfaction with treatment).

Based on these objectives, we established the following study as a single-arm pilot study to explore the feasibility and clinical usefulness of a group application of the UP in a social services context.

2.3 METHOD

2.3.1 Participants

The total sample of this study consisted of 11 participants, all women, with a mean age of 49.64 years (*SD* = 5.52, range = 40-59), users of the "Equipo Específico de Intervención con Infancia y Adolescencia" [Specific Child and Adolescent Intervention Team (hereinafter, SCAIT)] at Social Services Center of Benicarló (Castellón, Spain). Ten of the participants have Spanish nationality and 1 has Moroccan nationality; 6 participants are divorced and 5 are in a couple; and all of them have children, between 1 and 3. At the clinical level, 5 participants presented subclinical anxious-depressive symptoms without medication, 1 of them had an unspecified depressive condition with medication, and 5 had an unspecified anxiety-depression condition with medication. One of the participants (Participant 2) suffers from fibromyalgia. She is the only participant with a significant medical condition. The main conflicts that the women refer to are problems in managing the behavior of the children in the case of 7 participants, filio-parental violence in the case of 3 of them, and a history of intimate partner violence in the case of 1 participant. Regardless of the conflict addressed by the SCAIT, all the participants have experienced domestic violence, by their husbands (6 participants) or their children (4 participants). It should be noted that most of the participants highlight the management of their children's behavior as the main problem, something to be expected considering that they are users of a social service program whose aim is to address the needs of children and families, serving families with high risk factors to improve their well-being.

2.3.2 Procedure

The sample of this study was a convenience sample obtained from the SCAIT service at Social Services Center of Benicarló (Castellón, Spain).The SCAIT is a municipal service, included within the social care network as a resource directed at the sectors of family and children. It has interdisciplinary, specific, and specialized teams, whose goal is the prevention, care, and treatment of situations of crisis and family destructuring (Sospedra et al., 2010). This service offers psychosocial counseling, therapy, and family mediation services (Consellería de Bienestar Social [Ministry of Social Welfare], 2014).

The SCAIT psychologist (M.C.M.) was responsible for informing the users of the existence of this study, and of the characteristics of the intervention to be performed. She was also responsible for carrying out the initial evaluation of the users at the Social Services Center of Benicarló (Castellón, Spain). Participation in the study was voluntary (participants' intention to treat) and without financial compensation. The inclusion criteria were being of legal age; speaking Catalan or Spanish fluently; committing to attend the sessions; presenting anxious or

depressive symptomatology or meeting the criteria for at least one ED, and understanding and accepting the contents of the informed consent, expressed by signing it. Exclusion criteria were presenting a serious mental disorder (bipolar disorder, schizophrenia, or organic mental disorder); a personality disorder; being in the process of grieving; substance abuse, or presenting a suicide risk at the time of evaluation. After selection according to the inclusion criteria, the participants were assigned to two different intervention shifts (morning and afternoon) depending on their availability. In total, five evaluations were performed at different times: pre-intervention, post-intervention, and follow-ups at three, six and twelve months.

To ensure the proper implementation of the UP, the psychologists of the morning and afternoon intervention groups (V.F.G. and M.C.M.) received a 20-hour training course given by a psychologist accredited by the Unified Protocol Institute as UP trainer (J.O.) and were continuously supervised by him during treatment. The study was approved by the Ethics and Research Committee of the Hospital Comarcal de Vinaròs (Castellón, Spain).

2.3.3 Intervention

The intervention consisted of 11 weekly, two-hour sessions and in group format to address seven UP modules. For module 1, “Setting goals and maintaining motivation”, a single session was used; two sessions were used for module 2, “Understanding emotions”; a single session was used for module 3, “Mindful emotional awareness”; three session were used for module 4, “Cognitive flexibility”, which was the most difficult to understand for the participants; a single session was used for module 5, “Opposing emotional behaviors”. Module 6, “Understanding and coping with physical sensations”, was eliminated because the participants manifested on several occasions that physical sensations were not associated with anxiety/fear or other overwhelming emotions. Although the content about the relationship between physical sensations, thoughts and behaviours was explained, the interceptive exposure exercises were not practiced in this case. It is important to note that, although the interceptive exposure was not practiced in this group, it is necessary to assess whether these associations exist, because they are quite frequent. If they exist, this module should be developed, as it can be very beneficial for the participants.

Two sessions were used for module 7, “Emotional exposure”; and, finally, a single session was used for module 8, “Recognize achievements and look to the future”. In this study we provided a special emphasis on the validation of the participants' emotional experience, as they had been exposed to constant situations of invisibilization and invalidation. Some examples of these situations of invalidation described by the participants are: lack of respect on the part of their children or partners; feelings of not being good mothers or not having known how to educate their children well, blaming themselves for the behavior of their children; hiding

situations of violence experienced in the family context to protect their family or due to fear of the consequences; etc. In addition, their emotions are congruent with the situation of violence they are experiencing (anxiety and sadness), but their closest environment invalidates them (e.g., you should not feel anxious or sad or you should be happy with your family).

2.3.4 Instruments

Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998; Spanish version by Ferrando et al., 2000). It contains structured questions that evaluate major psychiatric disorders and it is divided into 16 modules, each with structured questions corresponding to the different diagnostic categories. In the validation study, it had a value of .75 for Cohen's Kappa, showing good interjudge reliability.

Rosenberg Self-Esteem Scale; (RSES; Rosenberg, 1965; Spanish version by Vázquez et al., 2004). It contains 10 items in the form of sentences with a 4-point Likert scale ranging from 1 (*strongly agree*) to *4* (*strongly disagree*). Higher scores indicate a higher level of self-esteem. In the present study, we obtained a Cronbach alpha of .69.

Quality of Life Index (QLI; Mezzich et al., 2000). It contains 10 items that are rated on a 10-point Likert scale ranging from 1(*Poor*) to10 (*Excellent*). Those items are: physical well-being, emotional well-being, self-care and independent functioning, occupational functioning, interpersonal functioning (it includes family functioning), social emotional support, community and services support, personal fulfillment, spiritual fulfillment, and overall quality of life. The higher the score, the higher the quality of life. In the present study, we obtained a Cronbach alpha of .88.

Maladjustment Scale (MS; Echeburúa et al., 2000). This scale reflects the extent to which the person's current problems are affecting the different areas of their daily life, which are scored on a 6-point Likert scale ranging from 0(*not at all*) to 5 (*Very severe*). These areas are: work, social life, free time, relationship with partner, family life, and overall maladjustment in everyday life. The higher the score, the greater the interference of current problems in the person's life. We found a Cronbach alpha of .80 in this study.

Positive and Negative Affect Scale (*PANAS*; Watson et al., 1988; Spanish version by Sandín et al., 1999). It consists of 20 items that measure both positive and negative affect, 10 items for each dimension. Each item is rated on a 5-point Likert scale ranging from 1 (*Not at all, very slightly*) to 5 (*Extremely*). The higher the score in each of the dimensions, the greater the affect evaluated. In the present study, we found a Cronbach alpha of .90 for Positive Affect and of .96 for Negative Affect.

Brief Symptom Inventory (BSI-18; Derogatis, 2001;Spanish version by Andreu et al., 2008).It is made up of 18 items and screens psychiatric symptoms by means of a 5-point Likert

scale ranging from 0 (*Not at all*) to 4 (*Very much*). The higher the score in each of the subscales (Somatization, Depression, Anxiety, and Panic), the greater the severity of the symptomatology. Cronbach alpha scores in the present study were .63 for the Somatization, .88 for Depression, .78 for Anxiety, and .69 for Panic subscales.

NEO-FFI Personality Inventory (NEO-FFI; Costa & McCrae, 1999). This contains 60 items that provide a quick and overall measurement of the five major personality factors. The responses are rated on a 5-point Likert scale ranging from 0 (*Strongly agree)* to 4 (*Strongly disagree)*. The higher the score in each of the dimensions, the higher the tendency toward that personality factor. In this study, we only used Neuroticism and Extraversion factors, with Cronbach alpha values of .66 and .86, respectively.

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004; Spanish version by Hervás & Jódar, 2008). This scale includes 28 items rated on a 5-point Likert scale ranging from 1 (*almost never/0-10% of the time*) to 5 (*almost always/90-100% of the time*). The higher the total score, the higher the emotional dysregulation. In this study, the DERS obtained Cronbach alpha values of .92 for Emotional Lack of Control, .94 for Emotional Rejection, .79 for Life Interference, .92 for Lack of Emotional Attention, and .61 for Emotional Confusion.

Questionnaire for the evaluation of the UP components (ad hoc, see "Appendix 1"). It consists of 9 items that evaluate the extent to which the participants considered that the UP in general and each of its components in particular were useful to help them regulate their emotions adaptively, rated on a 10-point Likert scale ranging from 0 (*Not at all*) to 10 (*very much*). The higher the score, the better the UP rating.

Satisfaction with treatment questionnaire (ad hoc). This scale presents 7 items that evaluate participants' overall satisfaction with the treatment, based on its perceived quality, adaptation to their expectations, their recommendation to friends or family, the usefulness of the techniques learned, their joint and general satisfaction with the treatment, the discomfort it generated, and the likelihood that they would choose such a treatment again. Participants rated the items on a 4-point Likert scale ranging from 0 (*Bad/Not at all*) to 4 (*Excellent/Very much*). The higher the score, the greater the satisfaction with the treatment.

Survey about the opinion of the treatment received (ad hoc).Through a survey developed specifically for this study, participants were asked three open questions that they were requested to answer in writing. The first questions refers to the objectives they set out to achieve, the second asked them which objectives they had achieved or were in the process of achieving, and the third refers to their beliefs about the benefits provided by the intervention.

2.3.5 Data analysis

The analyses were carried out with the statistical package IBM SPSS Statistics version 22.0 for Windows (IBM Corp., 2013). First, the sociodemographic characteristics of the total sample (N = 11) were analyzed with descriptive statistics, calculating the mean and standard deviation of the scores in the different questionnaires. Next, a Missing Values Analysis and Little's MCAR test were performed to determine the random distribution of missing values, and after confirming this, the Last Observation Carried Forward (LOCF) was used. Internal consistency was then explored using Cronbach's alpha.

As the sample size is less than 50 (N = 11), the normal distribution of the variables was verified with the Shapiro-Wilk normality test. A Multivariate Analysis of Variance (MANOVA) was then performed to check whether the differences in the scores of the variables measured at different times were statistically significant. Finally, the Reliable Change Index (hereinafter RCI), which evaluates the clinically significant change obtained to determine in which variables the scores approach those of the normative sample, was calculated. The RCI is a procedure that assesses whether the change is reliable, beyond the fluctuation associated with imprecise measurement tools. A clinically significant change will be considered if an RCI score is equal to or greater than 1.96 (Jacobson & Truax, 1991).

Session attendance was also recorded, to calculate the attendance rate and use it as an indicator of feasibility and acceptance of treatment. For the same purpose, quantitative and qualitative analyses were carried out. At the quantitative level, the participants' assessment of and satisfaction with the treatment received was evaluated through two questionnaires. Qualitatively, participants were asked to answer three main questions about the treatment, and their answers were analyzed by selecting and sorting information through a process of segmentation, identifying key topics, and categories of analysis (De Andrés Pizarro, 2000).

2.4 RESULTS

2.4.1 Descriptive analyses

The results of descriptive analyses for the sociodemographic characteristics of the sample are described in the participants section. The mean scores and standard deviations of all the administered instruments are shown in Table 2.1.

Table 2.1 Mean and Standard Deviation (SD) of the Sample Scores on the Instruments.

Variable	PRE		POST		3-MONTH FOLLOW-UP		6-MONTH FOLLOW-UP		12-MONTH FOLLOW-UP		MANOVA	
	N	*M (SD)*	*N*	*M (SD)*	*N*	*M (SD)*	*N*	*M (SD)*	*N*	*M (SD)*	*F*	η^2_p
RSES	11	26.73 (4.60)	11	30.27 (4.08)	11	30.91 (5.07)	11	30.27 (4.24)	10	31.10 (3.98)	4.025**	.309
QLI	11	5.55 (1.53)	11	7.19 (1.48)	11	7.10 (1.24)	11	6.92 (.92)	10	7.23 (1.82)	5.346**	.373
QLI-Interpersonal	11	6.36 (2.11)	11	7.73 (1.27)	11	7.18 (1.89)	11	7.36 (1.57)	10	7.70 (1.83)	2.848*	.240
MS	11	16.09 (6.11)	11	8.45 (6.53)	11	7.73 (5.80)	11	7.55 (6.15)	10	9.40 (6.80)	10.999***	.550
MS-Family Life	11	2.36 (1.03)	11	1.91 (1.38)	11	1.27 (1.01)	11	0.91 (1.04)	10	1.70 (1.06)	5.159**	.364
PANAS-Positive	11	28.73 (8.33)	11	36.64 (6.61)	11	33.36 (8.65)	11	31.10 (8.43)	10	30.40 (9.94)	2.387	.210
PANAS-Negative	11	31.55 (11.40)	11	23.73 (9.34)	11	20.00 (8.66)	11	17.82 (5.76)	10	20.60 (7.00)	5.822**	.393
BSI-18-Somatization	11	10.00 (4.80)	11	5.45 (4.57)	11	2.36 (2.34)	11	1.82 (2.36)	10	4.30 (6.00)	9.839***	.522
BSI-18-Depression	11	10.18 (6.51)	11	5.64 (5.01)	11	3.55 (3.08)	11	2.73 (1.68)	10	3.80 (4.83)	6.002**	.400
BSI-18-Anxiety	11	6.18 (3.19)	11	4.36 (3.04)	11	2.45 (2.07)	11	2.00 (1.95)	10	2.20 (2.39)	7.397***	.451
BSI-18-Panic	11	5.73 (3.32)	11	3.09 (3.48)	11	.45 (.69)	11	.82 (.87)	10	1.30 (2.31)	13.678***	.603
DERS-Total	11	77.27 (20.12)	11	59.55 (19.79)	11	51.27 (12.59)	11	48.82 (9.21)	10	50.30 (15.29)	9.302***	.508
DERS-Lack of Emotional Attention	11	) (4.31)	11	8.91 (3.11)	11	10.00 (4.00)	11	10.00 (3.32)	10	9.80 (3.46)	1.391	.134
DERS-Confusion	11	! (3.22)	11	8.27 (3.44)	11	7.64 (4.76)	11	6.82 (2.44)	10	7.40 (2.99)	2.212	.197
DERS-Rejection	11	20.45 (7.88)	11	15.55 (7.65)	11	11.18 (3.97)	11	13.00 (7.44)	10	12.70 (7.86)	5.317**	.371
DERS-Interference	11	11.27 (3.55)	11	9.00 (4.49)	11	7.91 (2.81)	11	6.73 (1.55)	10	7.10 (3.18)	5.215**	.367
DERS-Lack of Control	11	23.73 (9.34)	11	17.82 (7.15)	11	14.55 (3.98)	11	12.27 (3.64)	10	13.30 (6.22)	7.139**	.442
NEOFFI-Neuroticism	11	29.45 (6.58)	11	23.18 (7.61)	11	22.00 (8.87)	11	19.09 (8.32)	10	19.50 (9.68)	10.340***	.535
NEOFFI-Extraversion	11	26.55 (8.29)	11	30.91 (7.93)	11	30.45 (9.21)	11	31.18 (8.77)	10	29.40 (9.17)	2.849*	.240

Results of the multivariate analysis of variance (MANOVA)

PRE: pre-intervention; POST: post-intervention; RSES: Rosenberg Self-Esteem Scale; QLI: Quality of Life Index; MS: Maladjustment Scale; PANAS: Positive and Negative Affect Scale; BSI-18: Brief Inventory of Symptoms; DERS: Difficulties in Emotion Regulation Scale; NEOFFI: NEOFI Personality Inventory; after the name of the scale, the name of the subscales appears separated by a hyphen; * p < .05; **p< .01; *** p< .001; $.^2_p \simeq$ .01: small effect size; $.^2_p \simeq$ .06: medium effect size; $.^2_p >$ .14: large effect

The Missing Value Analysis showed that 6.24% of the data were missing from the total set of all the variables. Little's MCAR test showed a significance of p = 1.00 (p > .05), which implies a random distribution of the missing values, so LOCF was performed for those missing values. The results of the Shapiro-Wilk normality test showed that the scores of the participants in the different variables were normally distributed (p> .05).

2.4.2 Clinical Utility

In this section, the results directly related to objectives 1, 2 and 3 will be addressed. MANOVA showed that the statistically significant changes were increased scores on the variables of quality of life, including the quality of the interpersonal area (family), self-esteem, extraversion, and decreased scores on the variables of interference (including interference in family life), neuroticism, somatization, anxiety, emotional dysregularion, emotional lack of control, negative affect, depression, and emotional rejection ($p < .05$). The increase in positive affect and the decrease in the variables lack of emotional attention and emotional confusion did not show statistically significant changes ($p > .05$). In all the variables, the effect sizes were large ($n^2_p > .14$). Table 2.1 depicts the mean scores on each variable and assessment time, and the specific value of the statistic, effect size, and significance.

The results of the RCI showed that, after the end of the intervention, ten participants (90.91 %) maintained normalized scores in the variable interference of symptomatology; eight participants (72.73 %) maintained normalized scores in the variable of emotional dysregulation; seven participants (63.64 %) maintained normalized scores in the variables quality of life, positive affect, and negative affect; six participants (54.55 %) did so in the variables quality of the interpersonal area and rejection of emotions; five participants (45.45 %) did so in the variable emotional lack of control; four participants (36.36 %) did so in the variables self-esteem, interference of emotions, neuroticism and depression; three participants (27.27 %) did so in emotional confusion; two participants (18.18 %) maintained normalized scores in interference in family life, emotional lack of attention, somatization and extraversion, and one participant (9.09 %) maintained normalized scores in interference in somatization and anxiety.

The results of the RCI showed that one year after the end of the intervention, eight participants (72.73 %) maintained normalized scores in the variable emotional dysregulation; seven participants (63.64 %) maintained normalized scores in the variables quality of life, emotional lack of control, somatization and anxiety; six participants (54.55 %) did so in the variables quality of the interpersonal area, interference of symptomatology, positive affect, negative affect, rejection and interference of emotions, neuroticism, somatization and depression; five participants (45.45 %) did so in the variable self-esteem; four participants (36.36 %) did so in the variable emotional confusion; three participants (27.27 %) did so in extraversion; two participants (18.18 %) maintained normalized scores in lack of emotional attention, and one participant (9.09 %) maintained normalized scores in interference in family life. Table 2.2 shows the RCI values between pretest and posttest, and between pretest and the 1-year follow-up, respectively.

Table 2.2 Reliable Change Index (RCI) of each Participant between Pre-treatment and Post-treatment (Post) and Pre and 12-month Follow-up (12m).

	Normative data	RCIP1		RCIP2		RCIP3		RCIP4		RCIP5		RCIP6		RCIP7		RCIP8		RCIP9		RCIP10		RCIP11	
	M(SD)	Post	12m	Post	12m	Post	12m	Post	12m	Post	12m	Post	12m	Post	12m	Post	12m	Post	12m	Post	12m	Post	12m
RSES	25.27(5.57)	0.88	0.88	−1.31	−2.19*	5.25**	6.13**	1.31	2.63**	1.75	1.75	1.75	0.00	-0.88	-0.44	1.31	2.19**	2.63**	4.38**	2.19**	2.19**	2.19**	1.31
QLI	6.98(1.11)	0.68	3.41**	−1.87	−1.87	3.23**	4.09**	2.21**	3.58**	6.47**	7.49**	0.19	-0.13	6.13**	2.89**	4.43**	6.30**	5.96**	5.28**	−0.17	−0.17	3.06**	0.34
QLI-Inter	7.68(1.56)	2.27**	2.27**	−1.13	−1.13	1.13	2.27**	1.13	1.13	4.53**	5.67**	0.00	0.00	−2.27*	−2.27*	2.27**	4.53**	5.67**	4.53**	2.27**	2.27**	1.13**	−2.27*
MS	2.22(1.66)	−7.71**	−8.99**	0.64	1.93	−4.50**	1.28	−4.50**	−5.14**	−7.71**	−8.35**	−2.57**	−1.93	−2.57**	−3.85**	−2.57**	−0.64	−5.14**	−3.85**	−11.56**	−11.56**	−5.78**	0.64
MS-Fam	0.30(0.56)	−1.90	−1.90	1.90	1.90	−1.90	−1.90	−1.90	−1.90	−1.90	−1.90	0.00	−1.90	3.81*	−1.90	1.90	1.90	0.00	0.00	−5.71**	−5.71**	−3.81**	0.00
PANAS-P	32.52(8.46)	−2.07*	−1.48	0.00	−5.02*	3.55**	3.55**	1.18	4.73**	4.14**	0.59	1.48	−2.07*	6.50**	5.61**	2.07**	4.14**	3.25**	1.77	2.07**	−2.66*	3.55**	−1.48
PANAS-N	20.61(7.73)	4.23*	0.53	1.32	0.00	−2.90**	−2.90**	−2.11**	−1.85	−3.96**	−5.02**	0.00	0.00	−0.79	−5.28**	−3.43**	−2.90**	−2.64**	−6.07**	−6.07**	−7.13**	−6.34**	0.00
DERS-Total	59.1(17.5)	−2.44**	−5.35**	3.51*	1.37	−3.36**	−3.36**	−2.44**	−4.12**	−7.79**	−6.26**	−0.76	−1.68	−0.76	−6.72**	−3.97**	−4.28**	−3.97**	−8.09**	−4.43**	−4.58**	−3.36**	0.00
DERS-LA	9.60(5.40)	2.00*	3.20*	−2.00	0.80	−1.60	−2.80**	−1.20	−1.60	−3.20**	−4.00**	0.00	0.00	1.60	1.20	−0.40	−0.80	−1.60	−1.60	−2.40**	−1.20	−0.40	0.80
DERS-C	7.90(3.10)	1.95	0.97	0.97	1.95	−2.92**	−2.43**	−0.49	−1.95	−4.38**	−5.35**	−0.97	−0.49	−0.97	−4.38**	−1.95	−1.95	−3.89**	−3.89**	0.97	0.00	−1.95	−0.97
DERS-R	14.90(6.50)	−1.38	−4.82**	2.75*	−1.38	−2.41**	−2.06**	−2.41**	−3.10**	−3.44**	1.38	−0.69	−1.38	−0.69	−4.47**	−2.41**	-0.69	−3.44**	−6.19**	−2.75**	−3.78**	−1.72	−0.34
DERS-I	10.20(3.90)	−1.51	−2.51**	2.01*	2.01*	0.00	0.00	−1.01	−1.51	−3.52**	−3.02**	−0.50	−2.01**	0.00	−5.03**	−4.53**	−4.53**	2.01**	−1.01	−4.02**	−4.02**	−1.51	−0.50
DERS-LC	16.50(7.50)	−5.66**	−8.17**	4.40*	0.94	−1.57	−1.26	−0.94	−2.20**	−5.34**	−5.66**	0.00	−0.63	−1.57	−4.71**	−1.57	−3.46**	−2.51**	−6.60**	−3.46**	−2.51**	−2.83**	0.63
NEOFFI-N	21.58(7.48)	−0.45	−3.79**	0.00	0.89	−3.79**	−3.12**	−0.22	−4.01**	−3.34**	−4.01**	−1.34	−1.56	0.67	0.00	−2.90**	−2.67**	−3.79**	−3.12**	−1.78	−2.45**	−0.89	0.67
NEOFFI-E	32.05(6.64)	−0.49	−0.49	−0.73	−2.69*	0.73	1.47	0.98	2.20**	2.93**	3.42**	0.49	−0.73	1.95	0.00	1.71	2.69**	2.93**	0.98	1.47	−0.24	−0.24	0.24
BSI-18-S	8.14(5.64)	−2.67**	−2.94**	−0.53	2.14*	−1.07	−1.34	−1.07	−1.60	−1.60	−2.94**	−0.27	−0.53	−0.53	−3.21**	−1.60	−2.14**	−1.34	−2.67**	−1.07	−2.14**	−1.60	0.53
BSI-18-D	11.176.46)	−0.32	−0.63	0.63	0.95	−1.58	−1.90	−2.84**	−3.48**	−2.21**	−3.79**	−0.32	−0.63	−1.58	−5.69**	−3.16**	−4.11**	−1.58	−2.53**	−2.53**	−2.21**	−0.32	2.53**
BSI-18-A	6.46(3.01)	−1.31	−2.62**	0.87	−0.87	0.00	−0.44	−1.74	−2.62**	−2.62**	−3.93**	0.44	0.44	0.00	−3.05**	−1.74	−2.18**	−1.31	−2.62**	−1.31	−2.62**	0.00	1.74
BSI-18-P	4.45(3.60)	−2.09**	−2.09**	0.84	−0.84	0.00	−0.42	−1.68	−2.51**	−2.51**	−3.77**	0.42	0.42	0.00	−2.93**	−1.68	−2.09**	−1.26	−2.51**	−1.26	−2.51**	0.00	1.68

Note: P1... P11: Participant 1... Participant 11; RSES: Rosenberg Self-Esteem Scale; QLI: Quality of Life Index; QLI-Inter: Interpersonal Subscale of Quality of Life Index; MS: Maladjustment Scale; MS-Fam: Family Life Subscale of Maladjustment Scale; PANAS: Positive and Negative Affect Scale; PANAS-P: Positive Affect Subscale; PANAS-N: Negative Affect Subscale; DERS-Total: Difficulties in Emotion Regulation Scale; DERS-LA: Lack of Emotional Control Subscale; DERS-C: Confusion Subscale; DERS-R: Rejection Subscale; DERS-I: Interference-Subscale; DERS-LC: Lack of Control Subscale; NEOFFI: NEOFFI Personality Inventory; NEOFFI-N: Neuroticism Subscale; NEOFFI-E: Extraversion Subscale; BSI-18: Brief Inventory of Symptoms; BSI-S: Somatization Subscale; BSI-D: Depression Subscale; BSI-A: Anxiety Subscale; BSI-P: Panic Subscale; * < ±1.96 (significant change in scores but in the undesired direction); ** < ±1.96 (significant change in scores in the desired direction, i.e., improvement of scores until reaching a normalized score

2.4.3 Viability and satisfaction with the intervention

In this section, the results directly related to objective 4 will be addressed. Participants attended a mean number of sessions of 9.09 (*SD* = 1.38, range 8 - 11) of the 11 sessions that made up the treatment, which is 82.64% of the program. In addition, no dropouts were recorded during treatment or at the follow-ups.

In the UP component assessment questionnaire, the mean score obtained was 9 for the UP in general (*SD* = 1.34, range = 6 - 10). Focusing on each of the techniques, the scores varied between 8.18 and 8.91. The "understanding emotion" technique obtained a mean score of 8.73 (*SD* = 1.49, range = 5 - 10); the "mindful emotional awareness" technique a mean score of 8.64 (*SD* = 1.63, range = 6 - 10); the "cognitive flexibility" technique a mean score of 8.32 (*SD* = 1.85, range = 5 - 10); the "opposing emotional behaviors" technique a mean score of 8.55 (*SD* = 1.52, range = 6 - 10); and the "emotional exposure" technique a mean score of 8.55 (*SD* = 1.51, range = 6 - 10).

In the treatment satisfaction questionnaire (N = 11), 90.9 % of the participants (n = 10) rated the quality of the program received as "excellent" and the remaining participant rated it as "good". A 54.5 % (n = 6) stated that the intervention "totally" corresponded to what they expected, while the remaining 5 participants stated that it did but "partially". To the question "If a friend or family member needed similar help, would you recommend this treatment program?", 90.9 % of the participants (n = 10) answered "Yes" and the remaining participant answered "probably yes". Lastly, 81.8 % of the participants (n = 9) reported that the program's content had helped them "a lot" in dealing more effectively with their problems, and the remaining two participants reported that it had helped them "quite a bit".

Finally, the responses to the survey about their opinion of the treatment received were analyzed qualitatively. The selected analysis categories were: the objectives prior to the start of the intervention; the objectives achieved after the intervention; the impact of the group format on the participants; and overall satisfaction with the intervention. Table 2.3 shows the fundamental testimonies of some of the participants, which illustrate how they refer to these points, and the different categories that are framed within each one of them.

Table 2.3 Coding of the participants' responses to the satisfaction survey on the treatment received

What objectives did you set out to achieve during this intervention?
1. Emotional regulation (7 participants): “My main objective was to understand my fear”, “I want to learn to relax”
2. Increased self-esteem and quality of life (6 participants): “I need to strength my self-esteem”, “I need not to feel self-conscious”
3. Improve family well-being (3 participants): “I want to achieve a more positive relationship with my family and with myself”
4. Improve parenting styles (2 participants): “I want to learn to better educate my children, ask them respectfully and that they respect me”
5. Reduction on the interference of intense emotions (5 participants): “Being able to separate all the problems of my daily life, because I only have time to be aware of them”
What objectives have you achieved, or are you in the process of achieving?
1. Greater knowledge about the emotional response (4 participants): “I have learned to identify thoughts, to observe the physical sensations in my body, what behaviors I usually follow to face the intense emotions and also I have learned to identify what factors trigger this fear that I feel and the consequences of my behaviors”, “I have learned to differentiate my emotions”
2. Reduction on the frequency, duration and emotional intensity (9 participants): “It has helped me to feel less anxiety”, “Before, the anxiety lasted for at least an hour, now it doesn't”
3. Learning about anxiety management and mindfulness techniques (8 participants): “Now I am able to calm myself down”, “I always keep in mind not judging”, “Focus on that present moment”
4. Emotional exposure (5 participants): “Now I am able to read the emails that my lawyer asks me too”
5. Generate alternative thoughts and carry out opposite behaviors to those driven by emotions (7 participants): “When I raise the tone of voice I realize it, and I can change it to a softer tone”, “I have managed to think before acting”, “I have learned to not think that everything will always go wrong”, “I have more control of my impulses and this make me not see things so negatively”
6. Increase self-esteem and empowerment (7 participants): “Now I know that if I want to do something, I am able to do it”, “Until now I was always walking and looking behind me, now I don't”
Why would you say that attending these sessions has helped you?
1. Increased self-esteem, self-confidence and motivation (3 participants): “Now I feel that I am a useful and optimistic person”, “I should start loving myself”, “You have to keep working”, “To know that I can achieve my aims has given me the confidence to face the problems in a better way, even if it requires effort”
2. Improvement in general level of health (4 participants): “Now I sleep well”, “Before I felt pain in my body or my hands”, “Before, I always went to the doctor because of my asthma, now I don’t need it”
3. Increased perception of social support (9 participants): “I have always felt very good here”, “When everyone believes you, it is a liberation”, “Here I have been able to tell what I have kept quiet during years”
4. Increase in quality of life (7 participants): “All this has given me my life back”, “I am very grateful, it

has given me my life again"

5. Increase family well-being (6 participants): "Now I am happy, and my family too"

6. Favor a sensitive parenting style (2 participants): "Now I speak to my son in a calmer way, and when I raise the tone of voice, I realize it and I can change it to a softer tone", "My son listens to me, understands me and does what I ask", "My son and I understand each other better and respect each other more", "This therapy has helped me a lot with my parenting skills"

7. Reduce problem behaviors in children (2 participants): "Now my daughter has fewer tantrums and they are less intense", "My daughter takes orders more, that's a great achievement"

2.5 DISCUSSION

This study applies a psychological intervention based on improved emotion regulation, called UP, in a group format to a sample of females surviving domestic violence diagnosed with ED or subclinical symptoms that were users of the SCAIT service, a community service aimed at improve family well-being. We aimed to improve their clinical symptoms after the intervention (objectives 1 and 2), to maintain changes at 12-month follow-up (objective 3) and to obtain data about the feasibility, acceptance, and satisfaction with the UP (objective 4).

Preliminary results underscore the feasibility and clinical usefulness of the UP in group format applied in the social services context.

2.5.1 Preliminary clinical utility data

In this section, the results directly related to objectives 1, 2 and 3 will be addressed. When we assessed the participants' improvement in specific variables after treatment, the statistically significant increase in quality of life and the reduction of interference of symptomatology are promising. This fact is especially relevant in this sample, as the participants are subjected to intense psychosocial stressors, which sometimes do not cease with the passage of time. Despite not intervening directly on these stressors, the UP seems to improve the scores in these variables, being consistent with the results obtained in other studies (e.g., Osma et al., 2015). Specifically, the participants showed an improvement on the quality of life area of interpersonal relationships which includes family relationships, and within the subscales of the interference scale, they also had improved in the area of family life; which means that participants achieved one of their main objectives, which was to improve coexistence and family well-being after the UP intervention.

In addition, participants improved the emotion regulation skills, which is one of the specific aspects targeted by the UP and which is reflected in the statistically significant decrease

in scores in total Difficulties in Emotion Regulation Scale punctuation. Specifically, a statistically significant reduction is observed for the subscales of rejection, interference and emotional lack of control ($p < .001$), but not for the lack of emotion attention and emotional confusion subscales ($p > .05$). The lack of significant results in these two specific subscales could be due to the fact that in the validation into Spanish the authors obtained internal consistency scores lower than the rest of the subscales, an aspect that the authors explain that could be due to the reduction of items for the adaptation and validation into Spanish (Hervás & Jódar, 2008). Despite this, the significant reduction in emotional dysregulation, suggests the effectiveness of the UP to improve this variable (Mazaheri et al., 2014), an aspect that can have very positive consequences on parenting styles, promoting greater sensitivity in mothers and improving family well-being (Carreras et al., 2019). As for affective symptomatology, the results of this study show that the participants improved significantly in symptoms of panic, somatization, anxiety, and depression, thereby confirming the effectiveness of the UP to reduce emotional symptomatology (Sakiris & Berle, 2019). Improving mothers' mental health can consequently decrease the probability that their children develop behavioural difficulties (D'Souza et al., 2019). Additionally, significant changes are also achieved in personality dimensions such as neuroticism and negative affect. These results are in line with those found in previous studies (e.g., Sauer-Zavala et al., 2012). In addition to improvements in negative affect and neuroticism, the application of the UP has achieved changes in extraversion, that is, the tendency to experience positive emotions such as satisfaction or happiness. Previous studies that have used the UP for the treatment of people with EDs have found contradictory results in this regard, as some of them confirm the changes in extraversion (e.g., Osma et al., 2015), and others do not (e.g., Ellard et al., 2010). More studies should be conducted to clarify these results on extraversion and positive affect.

In general, almost all the participants improved their scores after the intervention in the expected direction, and we highlight the overall improvement in some variables such as interference of symptomatology in their daily life, self-esteem, or quality of life. However, there are specific cases where improvement was not so obvious, and which are worth commenting on in more detail. An example is the case of Participant 2, who showed no significant changes. In this case, the fact that she suffers from fibromyalgia, a disease that causes high levels of pain and interferes considerably in her working life, may have influenced the results. Content customization (e.g., what variables influence the intensity of pain) and specific skills (e.g., mindfulness exercises focused on pain observation) in these cases could help improve the results.

Another case is that of Participant 6, who improved in almost all the variables after treatment but showed a significant worsening in positive affect at the 1-year follow-up. A possible explanation is that at the time of the1-year assessment, she had been evicted from her

home, and had to find a new home for herself and her daughter, with few financial resources, which implied a very high level of stress. The last relevant case is that of Participant 11, who, although she showed significant changes in most variables after treatment, barely maintained these changes at the 1-year follow-up. This fact may have been due to problems caused by living with her daughter, who was diagnosed with borderline personality disorder and returned to live at home during that period of time. This daughter had spent some time in a child protection center for child-parental assault.

However, it is important to note that the cases of these three participants tend to be the most common among survivors of violence. As mentioned in the introduction, the number of moderating variables that can contribute to the impact of violence is immense (Galovski et al., 2021), so that an intervention can often result in limited progress due to all these moderating variables. In these cases, medical problems and family dynamics have an important influence and could be framed as factors that impact exposure to the trauma of violence (Helfrich et al., 2008; Herschell et al., 2016).

2.5.2 Preliminary feasibility data

In this section, the results directly related to objective 4 will be addressed. Regarding feasibility, the results of this study show that the users accepted this type of intervention, as the attendance rate was 82.64 %, well above those reported in other studies aimed at treating EDs in this population. For example, the CBT-based intervention for female survivors of violence by Johnson et al. (2011) reported an average attendance at 6.8 sessions out of 12 (*SD* = 4.3), representing an attendance rate of 56.66 %. In addition, no participant dropped out of our treatment. This information contrasts with studies that claim a general problem with adherence to psychological intervention programs in female victims of violence, shown in the high dropout rates, up to 66.98 % (Hansen et al., 2014). We believe that the differential aspect of this group that made adherence so high and led to no dropouts was the fact that they had previously been users of the SCAIT and knew both the service and the staff. They came to this resource voluntarily and had already had positive experiences with other services. In addition, the group format enhanced feeling understood and interpersonal validation. Furthermore, the fact that the intervention was conducted in a community context rather than in a mental health unit might imply less stigma.

Another aspect that reflects the feasibility of the UP are the participants' responses to the satisfaction questionnaire, stating that the quality of the treatment program received is excellent and that it met their expectations, that they would recommend it to a loved one who was in the same situation and would even choose it again if they had to seek help once more. These results are similar to those found with the same instrument by Osma et al. (2019) in their UP

application study for the transdiagnostic treatment of EDs in public mental health units in Spain. In addition, in the component rating questionnaires, the scores are very high for the protocol in general, with a mean score of 9 (score range: 9 out of 10). Psychoeducation about emotions and mindfulness techniques were the most valued components regarding its usefulness. The open answers provided by the participants (Table 2.3) also indicated that they have learned useful emotional strategies, they have achieved meaningful aims and they are satisfied with the intervention.

2.5.3 Strengths and Limitations

One of the strengths of this study is to apply an emotion-regulation based psychological intervention to treat EDs or subclinical affective symptomatology in female survivors of violence who are cared for in a community context to improve family well-being. This idea arises from the current need to resort to contexts in which psychological interventions can reach more people, rather than waiting for the people who are suffering to go to specialized clinical contexts (e.g., Bentley et al., 2017). The dissemination of evidence-based interventions in all sectors and contexts of society is essential if we are to reduce the emotional and economic costs arising from the main public health problems (Osma & Sauer-Zavala, 2019), in this case, violence against women and the consequences of violence for all family members.

However, this study has some limitations. The first refers to the small sample size (N = 11). In this sense, we note that case studies are an advisable cost-effective method to study preliminarily the effectiveness, feasibility, and/or implementation of recent intervention programs in contexts other than those studied previously, but their results should be assessed prudently, and as a preliminary phase. Therefore, it would be interesting to replicate the results with a larger sample of women and through a randomized clinical trial. Another limitation is the lack of the incorporation of partners and/or family into the sessions, either at a specific moment or in a specific parallel intervention. A third limitation is that some of the measures used in the study did not have good internal consistency, which makes it more difficult to fully understand how the intervention has affected the constructs with less consistency. It would be necessary to replicate the analyses with a larger sample, to see if the internal consistency would improve. Given the nature of the violence experienced by women and the community context in which it has taken place, including family interventions could have contributed to an understanding of the participants' emotional problems and the possible reduction of interpersonal problems that can hinder their recovery. Finally, we could not develop some working material (participant's workbook) adapted to the nature and characteristics of the specific problem of violence against women, which would have led to greater customization of the intervention. Despite these limitations, the participants' rate of program attendance was not affected.

As can be seen with this study, we have been able to preliminary explore two of the three axes proposed in the three-axis analysis (Ferro & Vives, 2004). Thus, through objectives 1, 2 and 3, we explore the clinical utility of the intervention and, therefore, the axis of efficacy, and, through objective 4, the acceptability and viability of the intervention, that is, the axis of effectiveness. However, one of the main limitations is that due to the small sample size and the fact that it is a pilot study, no cost-effectiveness analyses have been carried out to explore the effectiveness axis. Therefore, and taking this limitation into account, it will be interesting for future studies to take this approach into account, in order to replicate the results that explore the axes, adding analyses that allow the exploration of effectiveness.

This study is added to the growing literature that supports the effectiveness and versatility of the UP applied in different contexts and for different populations. Having preliminary data on the feasibility and clinical usefulness of the UP for the treatment of EDs in females who have experienced violence, and in a context such as social services, can have countless advantages. The first is to be able to serve this group from a community approach, that is, with an interdisciplinary team that can evaluate and intervene comprehensively in this social problem. The second is the reduction of costs both for female users (e.g., traveling to a single resource) as well as for professionals (e.g., facilitating data collection and management). The third is the group application format, as it favors positive social reinforcement, modeling, and enhanced motivation for change and learning of better coping skills (Echeburúa et al., 2014). Thus, we consider that this type of intervention allows addressing the needs of this population more directly, offering them comprehensive care and improving their mental health from a biopsychosocial model, also having indirect positive consequences on other members of the family or partners of women, and thus improving family well-being.

2.6 CONCLUSIONS

With this study, we have obtained preliminary data showing the clinical utility and the viability and acceptability of UP in group format and with women who have experienced domestic violence. More specifically, the MANOVA results showed an increase in quality of life, self-esteem and extraversion, as well as a reduction in interference, neuroticism, somatization, anxiety, emotional discontent, negative affect, depression, and emotional rejection. Regarding acceptability, a high attendance rate and no dropouts were obtained. However, it must be taken into account that this is a pilot study, and, therefore, it has several limitations that mean that we must be cautious in interpreting the results. Among these limitations, we should include small sample sizes, the fact that some measures did not obtain

high internal consistency, the fact that the efficiency axis could not be analyzed by means of cost-effectiveness analysis, the inability to introduce partners or relatives into the group, the unfeasibility to carry out family intervention sessions, or the failure to develop working material such as a manual for the participants. Taking into account that the results are not promising, the need for randomized controlled clinical studies is justified to overcome the limitations of the present study. In this sense, future lines should fundamentally value introducing partners or families to the intervention, providing material for the participants, and carrying out more controlled analyses with a larger sample. All this to replicate the analyses and establish a greater exploration of the three axes of efficacy, efficiency, and effectiveness. Having data such as the one in this study could make it possible to address the needs of this population in a more direct way, offering them comprehensive care, and improving their mental health from a biopsychosocial model. Likewise, this makes it possible to indirectly improve the well-being of the rest of the family members.

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Conflict of interest

Authors declare no conflict of interest

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APPENDIX 2.1

Questionnaire for the evaluation of the Unified Protocol components

(Osma, Crespo, Fermoselle, Sala and Castellano, 2014)

Name (code): **Date**:
Point of Assessment (Mark with a cross):

Post-treatment	
3-month follow-up	
6-month follow-up	
12-month follow-up	

1. To what extent do you consider that the therapy you received has helped you adaptively regulate your emotions?

0	1	2	3	4	5	6	7	8	9	10
Nothing										A lot

2. Of the techniques and exercises that we practice during therapy, to what extent do you consider that each of them has helped you to regulate your emotions properly?

- Identify the three-component of emotional experience: Thoughts, Physical Sensations and Behavior.

0	1	2	3	4	5	6	7	8	9	10
None										A lot

- Analyze the ARC of emotions: Antecedents, Responses, and Consequences.

0	1	2	3	4	5	6	7	8	9	10
None										A lot

- Emotional awareness, present-focused, nonjudgmental.

0	1	2	3	4	5	6	7	8	9	10
None										A lot

- Identify automatic appraisals (“jumping to conclusions” and “thinking the worst”).

0	1	2	3	4	5	6	7	8	9	10
None										A lot

- Carry out the cognitive re-evaluation and flexibility.

0	1	2	3	4	5	6	7	8	9	10
None										A lot

- Identify emotional avoidance strategies.

0	1	2	3	4	5	6	7	8	9	10
None										A lot

- Generate alternative actions to Emotion-Driven Behaviors (EDB).

0	1	2	3	4	5	6	7	8	9	10
None										A lot

- Induce physical sensations.

0	1	2	3	4	5	6	7	8	9	10
None										A lot

- Carry out emotional exposures.

0	1	2	3	4	5	6	7	8	9	10
None										A lot

CAPÍTULO III: "FEASIBILITY AND CLINICAL USEFULNESS OF THE UNIFIED PROTOCOL IN ONLINE GROUP FORMAT FOR BARIATRIC SURGERY CANDIDATES: STUDY PROTOCOL FOR A MULTIPLE BASELINE EXPERIMENTAL DESIGN"

Quilez-Orden, A., Ferreres-Galán, V., & Osma, J. (2020). Feasibility and clinical usefulness of the Unified Protocol in online group format for bariatric surgery candidates: study protocol for a multiple baseline experimental design. *International Journal of Environmental Research and Public Health, 17*, 6155. https://doi.org/10.3390/ijerph17176155

3.1 ABSTRACT

Obesity is currently becoming a serious global public health problem due to its high prevalence and continuous increase. This condition is associated with different physical and mental health problems. The presence of emotional disorders (anxiety, depression and related disorders) among candidates for bariatric surgery is very high and predicts worse physical and psychological results. The present study aims to explore the feasibility and clinical usefulness of the Unified Protocol, a transdiagnostic emotion regulation-based intervention, delivered in an online group format to patients with emotional disorder diagnosis or symptoms who are waiting for bariatric surgery. We will conduct a pilot study with a repeated single-case experimental design (multiple baseline design) in a public mental health service. The sample will consist of 60participants who will be randomized to three baseline conditions: 8, 12 or 15 evaluation days before the intervention. Diagnostic criteria, symptomatology and body mass index will be the primary outcome measures, and will include affectivity, personality, quality of life, body image, eating behavior and body mass index like secondary measures. An analysis of treatment satisfaction will be also performed. Assessment points include pre-treatment, baseline, treatment, post-treatment, and follow-ups every three months until two years after post-treatment. The results obtained in this study may have important clinical, social and economic implications for public mental health.

Keywords: emotional disorders; transdiagnostic; online group format; Protocol; bariatric surgery; obesity

3.2 INTRODUCTION

Obesity is a chronic disease characterised by an increase of body fatness, which is usually estimated by Body Mass Index (BMI) calculated as measured body weight (kg) divided by measured height squared (m^2)[1]. Obesity is currently becoming a serious global public health problem due to its high prevalence and increase in recent years [2]. In Spain alone, 25% of the population has obese or overweight, and the expectations are alarming. It is expected that in

2030, up to 80% of Spanish men and 55% of women present obesity or overweight, exceeding 27.2 million of people [3].

The causes of obesity are complex and multifactorial [1], and this condition is associated with different health problems, such as myocardial infarction, hypertension, stroke, dyslipidemia, diabetes mellitus, or obstructive sleep apnea[4–6].All these alterations affect the quality of life and can disturb important areas of functioning (e.g. physical function, vitality, social functioning and emotional role)[7,8]. In addition to all of these complications, people with obesity experience significant psychological difficulties [7]. Due to all of these health implications, obesity represents a challenge to the countries' economies [9]. As of 2016 in Spain, the obesity cost meant almost two billion Euros of extra expenses for the National Health System[3].

For all these reasons (high prevalence and associated costs), many efforts have been made to find treatments for obesity and weight loss, which include lifestyle interventions, pharmacological interventions, surgical interventions, and endoscopic bariatric procedures [7]. Bariatric surgery (BS) is the most commonly performed procedure worldwide [10] and the most effective intervention for individuals with severe obesity (BMI greater than 40 kg/m2) [11], and includes a group of surgical procedures performed to facilitate weight loss, such as open or laparoscopic roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding. The most obvious and studied benefits of BS refer to physical issues, specifically weight loss and improvement of obesity-related physical comorbidities; however, between 10 and 25% of patients who undergo BS show a suboptimal weight loss, and it is estimated that they regain approximately 10% of their weight during the first decade after the intervention [12]. Regarding the psychological benefits of BS, limited and inconclusive results have been found [13]. Some systematic reviews have reported improvements after BS, especially in depressive symptoms, but also limited only to the first months after the intervention, and they tend to reappear after the first two years [10].

Some studies have questioned whether previous psychopathology history could influence the results obtained by BS [2]. This topic is especially relevant because the percentage of psychopathology among people waiting for BS (between 20.9% and 55.5%) [12]is much higher than in the general population (between 12.53% and 13.87%) [14]. Specifically, the group of emotional disorders (ED),which includes anxiety and mood disorders, eating disorders, and related disorders [15], are the most prevalent disorders among BS candidates: eating disorders (50%), mood disorders

(31.5%), anxiety disorders (24%), and substance use related disorders (10%) [12]. It has been concluded that the presence of EDs among candidates for BS predicts worse results in the long term [11], furthermore, a meta-analysis states that the prevalence of suicide mortality is up to 1.8%, and the prevalence of suicide is up to 0.3% after bariatric surgery [16].

As we can observe, psychological evaluation and intervention play a fundamental role in the multidisciplinary work performed with these patients before and after BS although, until now, It has not received much attention [12].Improvements in eating psychopathology (e.g., binge eating, emotional eating, body image dissatisfaction)have been reported from psychological interventions using psychoeducation, goal setting, self-monitoring, normalized eating, stimulus control, cognitive restructuring, and relapse prevention [11]. Cognitive-behavioral therapy (CBT) is the one that accumulates the most evidence of the improvement of eating behaviors (e.g., binge eating and emotional eating) and psychological functioning (e.g., quality of life, depression, and anxiety symptoms) [11]. Despite the good outcomes achieved, these CBT interventions have been developed to treat specific disorders (e.g., eating disorders or anxiety disorders), and this fact raises some limitations. First, clinicians' great effort to specialize in a range of different interventions; second, the increased costs for health systems and clinicians in training, and as a consequence, the difficulties in dissemination and implementation of the CBT interventions [17]. Furthermore, if we consider that the most prevalent disorders among patients with obesity are EDs[12], there are additional limitations to specific CBT interventions. This is because in the case of these disorders, comorbidity is very high, and subclinical symptoms or unspecified disorders usually arise[18]. These comorbid conditions make it even more difficult to choose the best specific CBT treatment in each case [19].

To address all the limitations of the specific CBT treatments previously discussed, in recent years, different CBT interventions from a transdiagnostic approach have been developed and tested. In this sense, the Unified Protocol for the Transdiagnostic Treatment of EDs (UP) is a CBT emotion-based intervention designed to treat the etiological and maintenance mechanisms shared by all EDs [20]. This intervention focuses on a wide range of emotional psychopathology, considering comorbid disorders and subclinical or unspecified symptoms, reducing treatment times and costs, and improving response to treatment [17].

The UP is made up of eight treatment modules, five of which are considered core modules because they are focused on training different specific emotion-regulation skills [21]. Despite that the UP is a protocolized intervention, it is also flexible and versatile, allowing clinicians to use some of the modules or to change modules' order to personalize the UP to their patients [22]. Its main objective is to enhance emotion-regulation strategies to all people presenting emotional dysregulation problems [15]. To date, the UP has shown a significant improvement in pre-treatment symptoms and has obtained effect sizes that are at least comparable to existing specific CBT interventions, in on-site and online formats [23]. Beyond the mood or anxiety disorders per se, the UP has been applied to different health problems, such as cancer [24], HIV [25], or irritable bowel syndrome [26]. Despite the positive data on the effectiveness of the UP for the treatment of EDs in different health conditions, we have found no studies about its clinical utility to improve anxiety and depressive symptoms or EDs in patients with obesity who are waiting for BS. As mentioned, the UP can be applied in various formats, such as onsite or online (both individual and group). Regarding online interventions in mental health (e-Health), there is an important amount of evidence over the last 15 years informing that online treatments are effective to treat a wide range of mental health disorders and that they can be as effective as onsite treatments [27]. We also know that online interventions do not negatively affect the therapeutic relationship [28] and that the users generally show high levels of acceptance and satisfaction with this delivery format [29]. The use of Information and Communication Technologies (ICTs) reduces the burden on health professionals and users, facilitating data collection and accessibility to Treatment [30]. In fact, different studies have shown the need to develop technology-based interventions to increase accessibility to treatment for BS candidates because their obesity condition significantly affects their mobility, and that makes it difficult for them to attend weekly sessions on-site [31]. Another practical benefit of delivering online psychological interventions is related to the current situation caused by the Covid-19 pandemic because the online format (e.g., emails, videoconference, etc.) will allow psychologists to continue their interventions and/or the follow-up assessments in case of new mobility restrictions [32]. Finally, the online group format can offer additional advantages to the online format itself, as it facilitates social support among the participants in the therapy and also allows them to share experiences and learn from each other [33].

Therefore, the general objective of this study is to analyze the feasibility and clinical usefulness of the UP, applied in an online group format, in a mental health setting of the National Health System to candidates for BS who have at least one diagnosis of ED or emotional symptoms. The specific objectives pursued are: to evaluate adherence to treatment and clinical improvement in the primary and secondary measures after applying the UP and to study its long term clinical usefulness until two years after the intervention. Thus, the main

hypotheses proposed for this study are: (1) statistically significant differences (reliable change index; RCI) will be obtained between the scores obtained at the pre-treatment, baseline, and post-treatment on the primary and secondary measures; (2) the improvements obtained after the application of the UP will be maintained in the long term (follow-ups of up to two years); (3) participants in the pilot study will report high adherence rates and high satisfaction scores regarding the treatment delivery format and its components.

3.3 MATERIALS AND METHODS

This is a pilot study using a repeated single-case experimental design (multiple baseline design) to explore the feasibility and clinical usefulness of a transdiagnostic emotion-based online group intervention (UP) for BS candidates with EDs or subclinical anxious or depressive symptoms attended to in a public mental health service. We have chosen this design for three reasons: (1) the unit of intervention and unit of data analysis is an individual case, specifically a cluster of participants; (2) the case provides its own control for comparison purposes because a number of variables are measured before the intervention and compared with measures during and after the intervention and (3) the variable is repeatedly measured within and across different conditions or levels of the independent variable. Furthermore, and because our main objective is to answer the question "Is the Unified Protocol able to improve the emotional state of people waiting for BS?", we chose a multiple baseline design to improve experimental control throughout replication, introducing the independent variable at different points in time. The fundamental idea of choosing this type of design is that each of the participants can be their own control group [34].

The multiple baseline design involves the application of the treatment variable in a staggered way over time, through different observational units. This design is suitable for health services research interventions that are focused on changing patient behavior. This methodology facilitates a systematic comparison of pre-intervention and post-intervention measures [35], and conducting a preliminary assessment of a novel intervention [36]. Like RCTs, the multiple baseline design can demonstrate that a significant change in behaviour has occurred and that is result of the intervention. One of the main limitations is that each participant must show changes only when the intervention is applied, and this issue, at a practical level is complicated, can make it difficult for the researcher to draw clear conclusions about the impact of the intervention. In order to reduce this limitation and improve the internal validity, researchers start treatment at different times across settings, behaviors, or people [37]. The multiple baseline design has advantages over the RCTs because this design requires fewer population groups and

communities and they may act as their own controls[35].In this sense, researchers often use this design with several people at once addressing the issue of external validity [37].

In the present investigation, all consecutive patients who are selected to undergo BS and who present anxiety or depressive symptoms or at least one diagnosis of ED, will be asked to participate. Once inclusion criteria are met (see "Inclusion and exclusion criteria" section), each patient will be randomly assigned to one of the multiple baseline conditions: 8, 12, or 15 evaluation days before the intervention. These multiple baseline conditions have been chosen following the current guides for single-case designs [34, 38].

A random assignment will be carried out to reduce the threat of selection, and the fact of choosing three conditions is one of the established standards for this type of designs in order to reduce the threat of ambiguous temporal precedence and maturation [38]. Furthermore, the fact that all three conditions involve evaluation periods of 8, 12 and 15 days is due to the established standard of having a minimum of five data points in each phase to reduce the threat of attrition [38]. By choosing at least eight, we make sure to meet it even considering the probability that participants will forget to fill out the assessment one day. Actually, the reason for choosing those days is the temporal stability of the variables that we measured through the study.

In addition, the intervention will begin in a staggered manner with individual sessions (to reduce the threat of the history) and to reduce the threat of testing, a pre-treatment assessment will be performed prior to starting the baseline, to consider that the assessment process itself can have therapeutic effects on participants [38].

The study includes five assessment moments (pre-treatment, baseline, treatment, post-treatment, and follow-up, one every three months until two years after treatment completion). The flow chart of the study design is shown in Figure 3.1

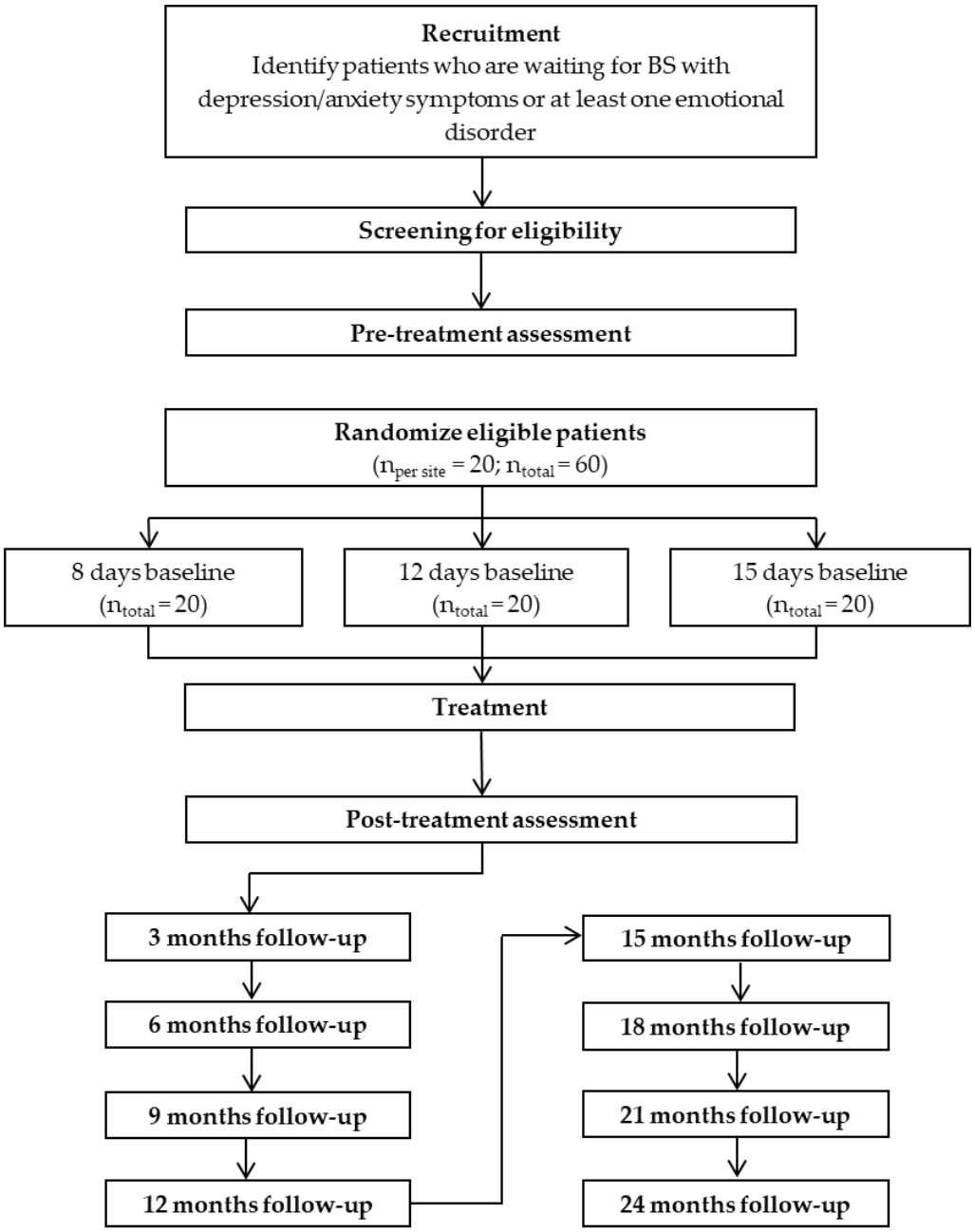

Figure 3.1 Study flow chart. BS: Bariatric surgery

3.3.1 Sample and recruitment

The study recruitment will start in September 2020 until December 2024. The study will be conducted in a public mental health center in Spain (Mental Health Unit of the Regional Hospital of Vinaròs, Castellón). Participants will be people over 18 years of age who have anxious or depressive symptoms, or at least one diagnosis of EDs according to Diagnostic and

Statistical Manual of Mental Disorders five edition criteria [39] and who have been selected for a subsequent BS.

To calculate the sample size, we drew on a study that proposed stepwise rules of thumb for pilot studies based on the target effect size and the size of the future trial [40]. Previous works that study the efficacy of CBT procedures either in person or online have shown large variations in effect sizes, obtaining mainly medium to large effect sizes [41, 42]. Taking these data into account, and expecting a 90% powered main trial and assuming a sample loss of 35% [43] we established a sample size of 20 size of 20 participants per experimental condition for the present study, that is, a total sample of 60 participants.

3.3.2 Procedure

The participants who are referred to the mental health unit for having fulfilled the requirements to be candidates for BS, will be evaluated to see if they meet the rest of the inclusion criteria for this study. In Table 3.1, it can be seen the selection criteria used to choose the appropriate candidates to receive the BS. These criteria are based on the European Guidelines for Obesity Management in Adults, which indicates that a comprehensive obesity management can only be accomplished by a multidisciplinary obesity management team [44].

Table 3.1 Inclusion criteria and main contraindications for BS

Inclusion criteria
BMI> 40 or 35 with associated major comorbidities
Age between 18 and 65 years
Long-standing obesity (3-5 years)
Failure in dietary attempts and treatments under control
Absence of anesthetic contraindication and acceptable surgical risk
Not having endocrine causes of obesity
Understanding of the weight loss process, associated problems and the stated objective
Commitment to adhere to the monitoring standards

Contraindications
Relative
Clearly unfavorable family environment
Personality disorder
Psychogenic vomiting
Hyperphagia in other psychological disorders or other eating disorders
Mild intellectual disability
Psychotic disorders without positive symptoms
Any psychiatric illness that significantly hinders the good follow-up and completion of the guidelines and medical indications for this process and may worsen the patient's state of health
Absolute
Drug dependency
Moderate or severe intellectual disability
Psychotic disorder with positive symptoms
Bulimia nervosa

Participants' evaluation and selection will be carried out by the clinical psychologists and psychiatrists of the mental health unit of (blind note). The clinical psychologists who will participate in this trial will be in charge of collecting all the information from the participants (alphanumeric codes assigned to the participants will be entered to safeguard their anonymity). The coded information will be given to (blind note) to introduce it in the database and then, returned to the center.

Participants who have received the approval for BS by the multidisciplinary health team and also have met the inclusion criteria by the clinician (see "Eligibility criteria" section), will be invited to participate in the study through an informative document. They will also be provided with confidentiality and informed consent documents. After accepting to participate, an email will be sent to participants with a link through which they will be able to complete the pre-treatment evaluation on the Qualtrics survey platform [45]. Then, they will be informed by phone of the experimental condition to which they will have been randomly assigned, which may be 8, 12, or 15 days baseline assessment, and they will then complete online the baseline assessment protocol on the same platform [45]. Randomization to the different baselines will be done with randomizer software (www.randomizer.org). Randomization will be performed by a researcher unrelated to the study using the computer-generated sequence mentioned. In the

program, the researcher will generate one set of 60 numbers, which will have a one to three range. Participants will be randomly assigned to the 8, 12 or 15 baseline days.

The baseline and psychological intervention will be conducted between the period of acceptance for BS and the BS implementation, that last approximately one year in public health settings. The intervention will be carried out in an online group format through the Cisco Webex platform. The UP will be applied in twelve weekly 2-h online group sessions. To comply with the experimental design of the multiple baseline, when each participant completes the baseline evaluation, they will receive the first online session in individual format (to receive the first session in stages), then they will continue with the second session and the rest of the treatment in group format. The content of each session is shown in Table 3.2. Participants will receive the therapy support manual [11]. The online group will consist of five to eight participants, one therapist (V.F.-G.), and one co-therapist (A.Q.-O.). For ethical reasons, if any of the patients feel uncomfortable during the study with the online group format, they may leave the group and receive individual onsite attention (treatment as usual). In this case, the content and estimated number of sessions will be the same, although the frequency will be stipulated by the mental health unit depending on its possibilities.

Table 3.2 Treatment content split by session.

Session number	Content
Sesión 1	Setting Goals and Maintaining Motivation
Session 2	Understanding your Emotions: What is an Emotion?
Session 3	Understanding your Emotions: Following the ARC
Session 4	Mindful Emotion Awareness - I
Session 5	Mindful Emotion Awareness - II
Session 6	Cognitive Flexibility - I
Session 7	Cognitive Flexibility - II
Session 8	Countering Emotional Behaviors
Session 9	Understanding and Confronting Physical Sensations
Session 10	Putting it into Practice: Emotion Exposures - I
Session 11	Putting it into Practice: Emotion Exposures - II
Session 12	Recognizing Accomplishments and Looking towards Your Future

The study plans to conduct a follow-up assessment every three months until two years after treatment completion. All follow-ups will be conducted online. Considering the time interval of the baseline, the psychological intervention and the BS procedure, the two first follow-ups (three and six months after intervention) will be conducted before BS, and the rest will be conducted after BS. In addition, at the baseline and during treatment, the participants

must fill out an online survey made up of 14 questions that will ask about the intensity of the emotions of happiness, sadness, anxiety, other emotions, difficulties in emotion regulation, body image, and emotional eating. Through this weekly evaluation, we expect to observe how the participants evolve in the different variables throughout the different treatment modules.

3.3.3Elegibility criteria

The inclusion criteria for participation in the project will be: (1) being over 18 years of age; (2) being a BS candidate; (3) presenting anxious or depressive symptomatology (moderate scores on the Beck Depression Inventory-II [46,47] and/or Beck Anxiety Inventory [48,49]) or meeting the criteria for at least one ED (anxiety, mood, and related disorders) on the International Neuropsychiatric Interview (MINI; [50]); (4) speaking Spanish or Catalan fluently; (5) committing to attend the sessions; (6) understanding and accepting the contents of the informed consent, expressed by signing it; (7) having Internet to fulfill the protocol assessments and to participate in the online intervention and (8) agreeing to maintain the prescribed medication (including dosage) if any, during the evaluation period and treatment. If medication stability is not possible, the participant's data will be treated separately in the analyses.

The protocol also includes one exclusion criteria that may interfere: (1) having a severe condition that would require being prioritized for treatment, so that an interaction between the two interventions cannot be ruled out. These include a severe mental disorder (bipolar disorder, personality disorder, schizophrenia, or an organic mental disorder), suicide risk at the time of assessment, or substance use in the last three months (excluding cannabis, coffee, and/or nicotine).

3.3.4 Ethics

All participants who meet the inclusion criteria will sign the personal data protection document before randomization so that they have a notion of whom and for what purpose this study's results will be used. Participants will be also informed of what the treatment consists of before starting it, as well as the duration and phases of the study (informed consent). Direct participation in the study will be voluntary. Participants will not obtain any financial or material compensation, and their participation will not imply any risk for them. The UP has already demonstrated its efficacy in previous experimental and quasi-experimental studies with different health problems (see "Introduction" section).

Data management will be carried out following the Spanish Royal Decree 1720/2008, of 19 January, which approves the Regulations for the development of the Organic Law 15/1999, of 13 December, on the protection of personal data [51]. The treatment, communication, and transfer of personal data will follow the provisions of the Declaration of Helsinki [52] in Law 14/2007 on biomedical research. As of 25 May 2018, the new legislation on personal data in the EU is fully applicable, specifically Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, on Data Protection (GDRP; General Data Protection Regulation). Under the aforementioned legislation, participants can exercise their rights of access, modification, opposition, and cancellation of data, for which they must contact their health professional of reference.

The data collected for the study will be identified by an alphanumeric code, and only the health professionals collaborating in the study will be able to relate these data to the participants and their corresponding medical records. Therefore, the identity of the participants in the study will not be revealed to any person, with exceptions in case of a medical emergency or legal requirement. The study already has the approval by the Ethical Research Committee of the General University Hospital of Castellón (CEIm; CI/HIP version 1.0 de 20/07/2019). In addition, the protocol study has been registered at https://clinicaltrials.gov/ (6 March 2020; NCT04421443).

3.3.5 Measures

The evaluation protocol will be administered online by Qualtrics survey [45] at five different moments: pre-treatment, baseline, treatment, post-treatment, and follow-ups every three months until two years after the intervention. Assessment instruments will include demographic characteristics (age, sex, education, marital status, and employment status), a diagnostic interview, and well-established questionnaires for both primary and secondary outcomes. Next, the primary and secondary outcomes that will be evaluated at the pre, post-treatment, and follow-up periods will be described, and later the specific measures that will be used for the baseline evaluation and during the treatment will be specified. Table 3.3 shows the distribution of the measures that will be administered during the study.

Table 3.3 Distribution of the variables administered throughout the intervention.

Measures	Pre-treatment	Baseline	Treatment	Post-treatment	Follow-ups[1]
Demographic characteristics	X				
MINI	X			X	X
BDI-II	X			X	X
BAI	X			X	X
BMI	X	X	X	X	X
PANAS	X			X	X
NEO-FFI	X			X	X
QLI	X			X	X
EuroQol	X			X	X
MI	X			X	X
DERS	X			X	X
BEAQ	X			X	X
PHLMS	X			X	X
ERQ	X			X	X
Surgical Complications	X				
BITE	X			X	X
BSQ	X			X	X
EES	X			X	X
OASIS			X		
ODSIS			X		
OESIS			X		
PESIS			X		
STQ				X	X
Baseline assessment battery[2]		X			
Assessment battery during treatment[3]			X		

Note: MINI: International Neuropsychiatric Interview; BDI-II: Beck Depression Inventory-II; BAI: Beck Anxiety Inventory; BMI: Body Mass Index; PANAS: Positive and Negative Affect Scale; NEO-FFI: NEO Five-Factor Inventory; QLI: Quality of Life Index; MI: Maladjustment Inventory; DERS: Difficulties in Emotion Regulation Scale; BEAQ: Brief Experiential Avoidance Questionnaire; PHLMS: Philadelphia Mindfulness Scale; ERQ: Emotion Regulation Questionnaire; BITE: Bulimic Investigatory Test; BSQ: Body Satisfaction Questionnaire; EES: Emotional Eating Scale; OASIS: Overall Anxiety Severity and Impairment Scales; ODSIS: Overall Depression Severity and Impairment Scales; OESIS: Other Emotions Severity and Impairment Scale; PESIS: Positive Emotion Severity and Impairment Scale; STQ: Satisfaction with Treatment Questionnaire

[1]Quarterly follow-ups up to two years after treatment; [2]For more information about the specific items that make up the baseline assessment battery see section "Baseline assessment"; [3]For more information about the specific items that make up the assessment during treatment battery see section "Assessment during treatment".

3.3.5.1 Primary outcomes

Primary and secondary diagnosis according to the DSM-5 criteria will be evaluated with the International Neuropsychiatric Interview (MINI [50]). Subclinical symptoms of anxiety and depression will be evaluated through the Beck Depression Inventory-II (BDI-II [46, 47]) and the

Beck Anxiety Inventory (BAI [48, 49]). The weight gain or loss of the participants will be evaluated through the Body Mass Index (BMI).

3.3.5.2 Secondary outcomes

Secondary outcomes Secondary outcomes can be grouped around: affectivity, personality traits, quality of life and interference, emotion regulation, aspects related to surgical complications, eating behaviors and body image, and satisfaction with and evaluation of the treatment received.

To assess affectivity, the Positive and Negative Affect Scale (PANAS [53, 54]) will be administered to evaluate positive and negative affect. Personality will be measured with the NEO Five-Factor Inventory (NEO-FFI [55]), which offers a rapid and general measure of the Big Five personality traits of which we will only assess Neuroticism and Extraversion. The Quality of Life Index (QLI [56]) will be used to evaluate several aspects related to quality of life (i.e., physical disability, emotional well-being, self-care and independent functioning, occupational functioning, interpersonal functioning, social–emotional support, community and services support, personal fulfillment, spiritual fulfillment, and overall quality of life). EuroQol [57, 58] is a generic instrument that will be used to measure health-related quality of life. It has five dimensions (mobility, personal care, daily activities, pain, and anxiety/depression), and a general state of health perceived through a visual analog scale. Similarly, the Maladjustment Inventory (MI [59]) will be used to evaluate the extent to which the subject's current problems impact negatively on different areas of daily life, namely, work, social life, leisure time, relationship with the partner, family life, and overall adjustment in daily activities.

Regarding emotion regulation, it will be assessed using the Difficulties in Emotion Regulation Scale (DERS [60, 61]), which presents five dysregulation dimensions: emotional lack of control, emotional rejection, life interference, lack of emotional attention, and emotional confusion. In addition, to assess the different emotion regulation skills that will be trained through the UP, we will use the Brief Experiential Avoidance Questionnaire (BEAQ [62,63]), which is a self-report questionnaire with 15 items that measure experiential avoidance; the Philadelphia Mindfulness Scale (PHLMS [64,65]), which is a 20-item questionnaire that assesses two mindfulness constructs: awareness and acceptance and the Emotion Regulation Questionnaire (ERQ [66,67]), which is a self-report questionnaire commonly used to assess two emotion-regulation strategies: cognitive reappraisal (six items) and expressive suppression (four items).

To assess surgical complications, the professional will be asked to refer the participant to the mental health unit a report describing the course of the operation and the recovery from it. Specific measures related to eating disorders will also be used, such as the Bulimic Investigatory Test (BITE [68,69]), which is a self-report questionnaire used to evaluate the

presence and severity of bulimic symptomatology, and cognitive and emotional signs and symptoms associated with binge eating; the Body Satisfaction Questionnaire (BSQ [70,71]), which is a self-applied scale used to evaluate the fear of gaining weight, feelings of low self-esteem because of one's appearance, the desire to lose weight, and body dissatisfaction, and Emotional Eating Scale (EES [72]), which is a 25-item self-report assessing a person's tendency to cope with negative affect through eating. Participants' weight will be checked monthly to calculate their body mass index (BMI).

Additionally, we created an ad hoc questionnaire to evaluate the participants' evaluation of and satisfaction with the treatment received, the Satisfaction with Treatment Questionnaire (STQ). The Evaluation of the UP Components section consists of nine items that evaluate the extent to which the participants consider that the UP in general, and each of its components in particular, were useful to help them to regulate their emotions adaptively; the Satisfaction with Treatment section presents seven items that evaluate participants' overall satisfaction with the treatment received. In both sections, higher scores show higher levels of positive evaluation and satisfaction. A total of 12 items will also be added to assess the participants' opinion of the online evaluation through Qualtrics and of the Cisco Webex platform used to carry out the online evaluation. At the end of the questionnaire, six open-ended questions appear in which the participants can qualitatively express their opinion of different aspects of the treatment received and the delivery format.

All measures used in the study have been standardized in Spanish. Administration time is between 30 and 40 min for the MINI and approximately 90 min for the primary and secondary outcomes conjointly.

3.3.5.3 Baseline assessment

To facilitate the daily baseline assessment, we have summarized in one item the variable we want to evaluate, for example, the emotion regulation strategies. For this purpose, we have chosen the item with the greatest factor load for each variable [73]. Specifically, participants will answer a battery of 19 questions: six questions about the presence and intensity of specific emotions (e.g., happiness, sadness, anxiety); five questions to assess the five subscales of the Difficulties in Emotion Regulation Scale (DERS [60,61]), which are emotional lack of control, emotional rejection, life interference, lack of emotional attention, and emotional confusion (e.g., "During this day, to what extent have you paid attention to your feelings?"); two questions that refer to the two subscales of the Emotion Regulation Questionnaire (ERQ [66,67]), which are reappraisal and suppression (e.g.," During this day, to what extent have you been able to control your emotions by changing the way you think about the situation you were in?"); two questions that refer to the two subscales of the Philadelphia Mindfulness Scale (PHLMS [64,65]), which are acceptance and awareness (e.g., "During this day, when your emotions have changed, to

what extent have you been aware of it immediately?"); one question to assess experiential avoidance based on the Brief Experiential Avoidance Questionnaire (BEAQ [62,63]) ("During this day, would you say that one of your biggest goals has been to be free of any painful emotion?"); one question from the Emotional Eating Scale (EES [72]) regarding the impulse to eat as a consequence of having experienced an intense emotion ("During this day, to what extent have you felt the urge to eat as a result of experiencing intense emotions?") and one last question from the Body Satisfaction Questionnaire (BSQ [70,71]), which asks about the extent to which the participant has been satisfied with their body image ("During this day, how satisfied have you been with your body image?").

3.3.5.4 Assessment during treatment

The assessment during treatment battery involves continuing to fill in the same baseline questions once a week. In addition, before starting each online session, participants will be asked to fill in an emotional scale to assess its presence, intensity, and interference during the last week. Participants can choose the emotion or emotions that should be assessed. The UP offers four different emotional rating scales: The Overall Anxiety and Depression Severity and Impairment Scales (OASIS; ODSIS [74–76]), Other Emotions Severity and Impairment Scale (e.g., guilt, shame, or anger) (OESIS [77]), and a Positive Emotion Severity and Impairment Scale (e.g., happiness) (PESIS [77]; Supplementary Materials). All of them are used in the UP to help patients to continuously monitor the scores throughout the sessions and their progress over the treatment.

3.3.6 Data Analysis

The analyses will be carried out with the statistical package IBM SPSS Statistics version 22.0 for Windows [78]. First, the sociodemographic characteristics of the sample will be analyzed with descriptive statistics, calculating the mean and standard deviation of the scores in the different questionnaires administered. Next, a missing-value analysis and the Little Missing Completely At Random (MCAR) test will be performed to determine whether or not the distribution of missing values is random, and therefore whether the last observation made (LOCF) can be used. Internal consistency will be explored using Cronbach's alpha.

As the sample size is expected to be less than 50, the normal distribution of the variables will be verified with the Shapiro–Wilk normality test. Depending on the result of this test, parametric or non-parametric repeated measures analysis will be carried out to verify whether or not the differences in the scores of the variables measured at different times are statistically significant. In case the variables follow a normal distribution, parametric repeated measures analysis will be carried out, specifically the Multivariate Analysis of Variance (ANOVA), and in case the variables do not follow a normal distribution, non-parametric repeated measures

analysis will be carried out, specifically the Friedman test. If the repeated measures analysis show statistically significant differences between the evaluation time points, post-hoc comparisons will be carried out to correct the level of significance to avoid increasing the type I error. Thus, regarding adjustment for multiple comparisons, the Bonferroni correction will be carried out in case of having performed parametric analysis, and the Wilcoxon signed rank test in case of having performed non-parametric analysis in the comparison of means. More detailed information on this has been added in the data analysis section, explaining step by step which statistical analyzes will be carried out.

Finally, the Reliable Change Index (RCI), which assesses the clinically significant change obtained to determine in which variables the scores have approached those of the normative sample, will be calculated. A clinically significant change will be considered if the RCI score obtained is equal to or greater than 1.96 [79].

Another aspect that we consider important to analyze is how the participants change their scores in each of the variables evaluated based on the content addressed each module. For this purpose, a visual analysis of the changes in the scores will be carried out, to see how the slopes change in the different phases of the study (evaluation and treatment), and in the different modules within the treatment. This visual analysis has been used in previous studies [21]. To carry out this visual analysis, the data from 19 questions that the participants will fill in weekly will be used.

Attendance at sessions will also be recorded to calculate the attendance rate, which will be used as an indicator of viability and acceptance of treatment by users. For the same purpose, quantitative and qualitative analyses will be carried out. At the quantitative level, the participants' evaluation of and satisfaction with the treatment received will be evaluated using an ad hoc designed questionnaire (see "Measures" section). Qualitatively, participants will be asked to answer six main questions about treatment, and their answers will be analyzed by selecting and classifying the information through a segmentation process, identifying key themes and categories of analysis [80].

3.4 EXPECTED RESULTS

Based on the reviewed bibliography, the type of design of the present study, the proposed objectives and the characteristics of the intervention that will be carried out, we hope that the results will reveal the feasibility and clinical usefulness of the UP applied in an online group format, in a mental health setting of the national health system for candidates of BS who have at

least one diagnosis of ED or emotional symptoms. The concrete results that are expected to reach this conclusion are shown in more detail in Table 3.4.

Table 3.4 Main expected outcomes. UP: Unified Protocol for the transdiagnostic Treatment of Eds

Clinical usefulness of the UP for bariatric surgery candidates
Group results: Depending on the characteristics of the sample obtained (we will check if the parametric assumptions are met), the results of the parametric / non-parametric tests that allow comparing the group scores between the different time points are expected to show statistically significant differences in the desired direction. **Individual results:** To obtains statistically significant differences (Reliable Change Index; RCI) between the scores obtained at the pre-treatment, baseline, and post-treatment on the primary and secondary measures. A maintaining of improvements obtained after the application of the UP in the long term (follow-ups of up to two years), with statistically significant differences (Reliable Change Index; RCI) between the scores obtained at the pre-treatment/post-treatment and follow-ups on the primary and secondary measures. **In both cases, the expected directions for the different variables are:** An increase for the variables positive affect, extraversion, quality of life and health-related quality of life. A decrease for the variables negative affect, neuroticism, interference of symptoms, emotional dysregulation, bulimic symptomatology, dissatisfaction with body image and emotional eating.
Feasibility of the UP for bariatric surgery candidates High session attendance rates. High scores on the STQ both in the questions that refer to the treatment itself and its different modules, and in the questions that refer to the group and online format.

Reporting of results will follow the Consolidated Standards of Reporting Trials (CONSORT) recommendations, specifically its extension for designs N-of-one Trials [81].

3.5 DISCUSSION

Obesity and being overweight have become a serious public health problem due to their high prevalence and associated costs [2, 9]. EDs are highly present in people with obesity [7], and this can interfere with a commitment to voluntary weight loss [82] and it is also associated with worse post-intervention outcomes [11]. An intervention based on emotion-regulation

training could help those patients to achieve both aims, to lose weight before the BS to prevent surgery problems and the emergence of emotional symptoms after the BS, maintaining their emotional and physical achievements over time. In addition to the clinical implications, the results derived from this study may also have an important economic impact. Thus, health policies and the managing of this health condition in public health settings could be also influenced.

To prove this, longitudinal studies are needed and some limitations regarding the interventions (specific CBT versus transdiagnostic intervention) and the delivery formats (onsite versus online) must be considered. The use of the UP in an online group intervention format in a public mental health setting with people waiting for BS has the following benefits:

1. It can allow clinicians to use a single treatment for those candidates who present different EDs, with comorbidity, and also with subclinical symptoms or unspecified disorders [15].

2. In other public health systems similar to the Spanish one, where onsite specific CBT is the most common delivery format, and therapy sessions occur at long intervals (e.g., more than a month) due to waiting lists, a UP online group intervention can help to increase the frequency of sessions and reduce costs because there are more patients treated simultaneously (five to eight patients in the same group), which can facilitate better patient care.

3. Thanks to the online format, this intervention will facilitate access to psychological interventions in those candidates who face mobility challenges due to their obesity condition [31]. This innovative approach would be in line with the goals of the World Health Organization proposed in the mental health action plan to use electronic technologies to expand the delivery of mental health care [83].

4. The fact of receiving quarterly follow-ups up to two years after treatment allows guaranteeing the prevention of relapses and maintaining the results, especially beyond the year and a half or two years, which is the moment in which the literature recognizes that pre-BS problems tend to reappear [42].

5. Furthermore, this advantage offered by long term relapse prevention follow-ups leads to a condition of reduced healthcare costs that are associated with the care of comorbid health problems in this type of patients [3].

6. And finally, it is known that group therapy provides benefits to the patient that are not obtained with individual treatment, such as reducing isolation, facilitating social support, and learning from the experiences of others [33], which could improve its efficiency.

Our study also has some limitations. First, some people who are going to undergo BS will prefer individual treatment, which could be a barrier to enroll those participants in our study (e.g., abandonment or decrease in UP satisfaction and effectiveness). In this case, it could be explained to the patient that group treatment resulted in greater weight losses than individual

treatment, even for those clients with a preference for individual therapy and that matching clients with their preferences for individual or group therapy did not enhance treatment outcome either in terms of weight loss or improvements in psychological functioning [84]. Furthermore, a study in a sample of people with EDs diagnosis attended to in public mental health settings in Spain found that the majority of participants preferred receiving psychological treatment in an individual format, followed by group format, and, rarely, in an online format, so it will be necessary to explain to patients the advantages and disadvantages of receiving psychotherapy through individual, group, or online format to help them to decide whether or not to participate in this study [85]. In this sense, the arguments that must be strengthened to justify a group application, in addition to those mentioned previously, are the possibility of sharing experiences, the opportunity to learn from others and receive comments and support and for the online format, convenience [85]. The second main limitation, is that, due to this being a pilot study, the results must be interpreted with caution, as further RCT studies with greater rigor will be required. In this sense, it should be noted that this kind of study is an advisable cost-effective method to preliminarily examine the efficacy, feasibility and/or implementation of recent intervention programs or applications with different samples [86].

Despite the aforementioned limitations, the present study may have different implications. At the research level, it will be the first pilot study aimed at evaluating the feasibility and clinical utility of an online group format of a transdiagnostic intervention for the treatment of ED in public settings in Spain with people waiting for BS, allowing us to increase the evidence on UP's effectiveness, flexibility, and versatility. At a clinical level, the results of the study will reveal whether UP can improve emotional symptoms in candidates and, therefore, improve the effects of BS in the long term. This would have important implications for patients, as it could achieve much more notable improvements after the intervention, and would serve to prevent relapses that generally appear in the long term around two years after BS.

3.6 CONCLUSIONS

In sum, the present study supports the idea of the need to test new forms of psychological interventions with patients waiting for BS [12]. This would allow us to improve the previous psychopathology, and, therefore, to potentiate the effects of BS in the short and long term [2].

The UP may be a good treatment option, considering that it is directed at EDs (which are the most prevalent in people with obesity problems) [12], and that it allows addressing comorbidity, subclinical symptoms, and unspecified disorders [15].

In addition, its application through an online group format can provide extra advantages, as it allows access to treatment for people with mobility problems, something very common among candidates for BS [31], and also fosters social support among the members of the group [33].

Based on all this, the results of the development of this study may have important implications for the National Health System, which will be able to meet the psychological needs of patients with obesity problems, improving their quality of life before the intervention, and enhancing its results in the long term, which will mean a reduction in costs to the system and more specialized and multidisciplinary care for patients who are in this situation.

Supplementary Materials:

Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (therapist guide and workbook) are available at https://www.oxfordclinicalpsych.com/view/10.1093/med-psych/9780190685973.001.0001/med-9780190685973; https://www.oxfordclinicalpsych.com/view/10.1093/med-psych/9780190686017.001.0001/med-9780190686017Both Spanish versions are available at https://www.alianzaeditorial.es/libro/manuales/protocolo-unificado-para-el-tratamiento-transdiagnostico-de-los-trastornos-emocionales-manual-del-terapeuta-david-h-barlow-9788491814795/; https://www.alianzaeditorial.es/libro/manuales/protocolo-unificado-para-el-tratamiento-transdiagnostico-de-los-trastornos-emocionales-manual-del-paciente-david-h-barlow-9788491814818/

Author Contributions:

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The authors declare no conflict of interest.

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CAPÍTULO IV: "APPLICATION OF THE UNIFIED PROTOCOL FOR TRANSDIAGNOSTIC TREATMENT OF EMOTIONAL DISORDERS IN POST-BARIATRIC SURGERY PATIENTS: AN EFFECTIVENESS AND FEASIBILITY STUDY IN GROUP FORMAT"

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4.1 ABSTRACT

Obesity is a serious health problem with global implications. Bariatric surgery (BS) is the most used and effective treatment, but there are patients who do not lose a substantial amount of weight, a fact that has been related with the presence of emotional eating, anxiety and depression symptoms. The aim of this study is to analyze the effectiveness sand feasibility of an emotion regulation-based intervention called Unified Protocol (UP), applied in group format to 6post-BS patients presenting emotional disorders/symptoms. Results at post-treatments how nigh attend ancerates and satisfaction with the UP score sand significant improvement son neuroticism, eating disorders symptoms and emotional eating. A t6-month follow-up we found significant reductions on anxiety symptoms, neuroticism, maladjustment and dysregulation (*d*=0.83-1.46) and he body mass index remained stable over time. These preliminary results are encouraging about the effectiveness and feasibility of the UP to treat emotional dysregulation in patients after BS.

Keywords: Bariatric surgery. Emotional disorders. Transdiagnostic. Group format. Unified Protocol.

4.2 INTRODUCTION

Obesity is currently becoming a serious health problem with global economic and social implications (Spirou et al., 2020). In 34 of the 36 member countries of the Organization for Economic Co-operation and Development (OECD), one in four people suffer obesity, and it is expected that in 2050, there will be around 92 million premature deaths from obesity-related diseases in these countries (OECD, 2019). In Spain alone, it is expected that, by the year 2030, more than 27.2 million people will present with overweight or obesity (Hernáez et al., 2019).

Obesity is related to different physical health problems such as myocardial infarction, hypertension, diabetes mellitus, or obstructive sleep apnea (Castaneda et al., 2019), and also with mental health problems, as it is associated with an increase of approximately 25% in the probability of developing mood and anxiety disorders (Simon et al., 2006). These associations have implications for the quality of life and functioning of people with obesity (Spirou et al., 2020), and they imply high costs for the health systems of the different countries, approximately 8.4% of the total cost in medical attention (OECD, 2019).

For all these reasons, research has increased to seek effective treatments for weight loss in patients with obesity. The three general treatment approaches for obesity are behavioral,

pharmacological and surgical (Bean et al., 2008). To date, bariatric surgery (BS), which includes a group of surgical procedures performed to facilitate weight loss, such as open or laparoscopic roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding (Jumbe et al., 2017), is the most used and effective treatment in these cases (Lauren et al., 2020). Despite being the most effective method currently, between 20% to 50% of operated patients begin to regain their weight within the first 1.5 to 2 years following surgery (Cassin et al., 2013), and it seems that the factors that have been most strongly associated with these outcomes are emotional eating, anxiety, and depression (Hjelmesæth et al., 2019).

Due to the multidisciplinary and complex nature of obesity and related problems, the role that mental health providers can play in identifying and intervening on these types of problems is essential (Wilfley et al., 2010). In the specific case of the BS, psychological interventions can make a significant contribution to the management of post-BS patients, enhancing compliance and maximizing weight loss, psycho-social functioning, and quality of life after surgery (Kalarchi-an & Marcus, 2003). A recent systematic review shows that Cognitive Behavioral Therapy (CBT) has accumulated the most evidence to date for the treatment of specific psychological symptoms in these patients (Spirou et al., 2020), and it seems that the optimal time to apply this type of intervention is between the first and the second year after BS, when weight loss tends to stagnate and emotional aspects often appear (Hjelmesæth et al., 2019).

Considering that emotional eating, anxiety, and depression are symptoms that appear to be associated with poor weight loss, it would be interesting to see what these symptoms have in common to find an intervention that can ad-dress all of them at the same time. In this sense, the transdiagnostic treatments aim to address various disorders at the same time, based on the identification of the etiological and maintenance mechanisms they share (Sauer-Zavala et al., 2017). Within this model, Brown and Barlow (2009) focused their study on emotional disorders (EDs), which encompass unipolar mood disorders, anxiety disorders, and related disorders (emotional eating could also be included in this category). These authors proposed neuroticism as a central dimension in the etiology, course, and maintenance of EDs. This personality dimension is responsible for: a) the frequent experience of strong emotions (e.g., anxiety, sadness, guilt), b) the negative reaction to these emotions (e.g., “I shouldn’t be feeling this way”), and c) efforts to avoid them. David H. Barlow and his team developed the Unified Protocol (UP) for the Transdiagnostic Treatment of Emotional Disorders for the treatment of neuroticism (Barlow et al., 2018).

Neuroticism has special relevance for public health due to its high correlation with different physical and mental health problems, and with the high frequency of the use of general and mental health services (Lahey, 2009), so addressing this trait can have numerous advantages for health ser-vices. Furthermore, it has also been associated with worse BS results (Oltmanns et al., 2020), so reducing it may improve BS outcomes.

The UP is an emotion regulation-based CBT intervention that consists of 8 modules, five of which are considered central: mindful emotion awareness, cognitive flexibility, countering emotional behaviors, confronting physical sensations, and emotion exposure. Its objective is to equip people with emotion-regulation strategies so that they can tolerate intense emotions without giving up their personal goals (Bar-low et al., 2018). Although the UP is a structured intervention, it stands out for its flexibility and versatility, which al-lows it to be easily adapted and administered to a wide range of different problems (Sauer-Zavala et al., 2019). For example, the duration of any of its modules can be increased or their order changed to adapt them to each sample and concrete context (Sauer-Zavala et al., 2019). In this sense, one of the main potentials of the UP in public health systems is the possibility of applying it in group format. This format is advantageous both for the health system and the participants because, on the one hand, it allows caring for several patients at the same time, reducing waiting lists and consultation time; on the other, it facilitates social support through the group participants, allowing them to share their experiences and learn from each other (Yalom & Leszcz, 2005).

To date, the UP has shown strong empirical support, significantly improving emotional symptoms after the intervention, obtaining effect sizes that are at least comparable to the specific existing CBT protocols (Barlow et al., 2017). Moreover, it has shown greater efficacy in the treatment of neuroticism, with significantly lower scores for this variable compared to specific CBT protocols (Sauer-Zavala et al., 2020). This support has been obtained for the treatment of distinct EDs when applying UP in different formats (individual and group, onsite and online) and also when comorbid health conditions, such as HIV, cancer, or irritable bowel syndrome, are present (Cassiello-Robbins et al., 2020). In-deed, data from a systematic review explicitly explore preliminary data about the effectiveness and feasibility of UP for treating EDs in people with other comorbid medical conditions (Osma et al., 2021). On a prevention level, UP has recently been applied in Spain in a group of women with fertility problems (Martínez-Borba et al., 2022).

Therefore, the general objective of this study is to verify the preliminary effectiveness and feasibility (acceptance, satisfaction, adherence) of the UP applied in group format in a mental health unit of the Spanish public health system to post-BS patients who present a diagnosis of ED or anxious or depressive symptoms. Specific objectives are: 1) to obtain data that confirm participants' acceptance of the intervention through high rates of session attendance and high scores in satisfaction with treatment; 2) to obtain a statistically significant reduction in the scores of depression, anxiety, neuroticism, maladjustment, emotional dysregulation, dysfunctional eating behaviors, dissatisfaction with body image, emotional eating, and body mass index; 3) to obtain a statistically significant increase in the scores of extraversion and quality of life; and 4) to confirm that the changes achieved after the intervention are maintained at a 6-month follow-up.

4.3 METHODS

4.3.1 Participants

Nine participants were referred to the study, two of whom were discarded for not meeting the inclusion criteria and one could not start the group due to schedule incompatibility. The total sample of this study consisted of 6 participants, all of them Spanish women, with a mean age of 49.57 years (*SD* = 7.74; *range* = 35-57). At the time of the start of the intervention, 5 of them had undergone BS 13.80 months ago on average (*SD* = 7.53; *range* = 6-21), and the other participant was operated on between UP Sessions 1 and 2. The rest of the sociodemographic and clinical characteristics of the participants are shown in the "Detailed description of the cases" section.

The following inclusion criteria in the study were followed: (1) being over 18 years of age; (2) being a BS candidate or being a post-BS patient (for more information see the inclusion criteria and the main contraindications that are evaluated for BS in the Spanish Health System in Martin et al., (2017), a guide written in collaboration with different obesity surgery associations); (3) presenting anxious or depressive symptomatology: moderate scores on the Beck Depression Inventory-II (Beck et al., 1996) and/or Beck Anxiety Inventory (Beck & Steer, 1993) or meeting the criteria for at least one ED on the International Neuropsychiatric Interview (Sheehan, 2015); (4) speaking Spanish or Catalan fluently, (5) committing to attend the sessions, and (6) understanding and accepting the contents of the informed consent, ex-pressed by signing it. In addition, the following exclusion was included: (1) having a severe condition that would re-quire being prioritized for treatment, so that an interaction between the two interventions could not be ruled out. These included a severe mental disorder (bipolar disorder, personality disorder, schizophrenia, or an organic mental disorder), suicide risk at the time of assessment, or substance use in the previous three months (excluding cannabis, coffee, and/or nicotine).

4.3.2 Detailed description of the cases

Participant 1

She is a single 35-year-old, with no children and a professional training qualification. She is currently working in her own hospitality business. She underwent BS in January 2018 (21 months before starting this intervention), and currently, she has a diagnosis of depressive disorder reactive to the intervention.

This participant went to the mental health unit for the first time in October 2018 (9 months after the surgery). No significant psychopathological history appeared and the results of

the BS were satisfactory. The reason for consultation was: constant feelings of tiredness, decreased illusions, discouragement, and internal nervousness. The patient had been under the care of a psychiatrist until December 2018, when she was referred to a psychologist because she still presented with emotional symptoms reactive to the vital change that BS has produced. In May 2019, she undertook life changes on her own initiative, but she did not feel as good as she would like, and she had many doubts about the decisions she had made. It was at this time that she started the group therapy described in this study.

Participant 2

She is a married 56-year-old, with one child and a professional training qualification. Currently, she is unemployed. She underwent BS in April 2019 (6 months before the start of this intervention), with satisfactory results. Currently, she has a diagnosis of adjustment disorder but not directly related to the BS process.

There is no psychopathological history. She was referred to the mental health unit by the family doctor in October 2019 and the clinician considered her as a candidate for the proposed group treatment. The participant presented with hyperphagia (excessive increase in appetite sensation and un-controlled food intake). She felt anxious, with an irritable mood and she had conciliation and maintenance insomnia. The main request was that the current situation and anxiety levels (that she attributed to the bad relationship with her daughter-in-law) should not affect the good results of the BS due to her worsening eating habits. The participant said that all she wanted was to manage her symptoms to maintain the results of the BS, so she was referred to the intervention de-scribed in this study.

Participant 3

She is a single 47-year-old, with no children and a professional training qualification. Currently, she is working actively. She was the only participant who joined the group with-out having undergone BS to continue working on her eating habits and learn about the experiences of people who had already had the operation. She underwent BS in November 2019, after the first UP treatment session, and the results of BS were satisfactory. She currently has a diagnosis of depressive disorder and an unspecified eating disorder.

The first time she attended the mental health unit was in August 2013, although she did not continue attending the sessions. In February 2014, she returned, referred by the endocrinologist for compulsive intake, and she had gained 54 kilos. They began to work on the symptoms of a binge eating disorder, managing food through different techniques. Little by little, she began losing weight and her eating habits were improving. In February 2018, she received a positive psychiatric evaluation for BS but she had to continue with strict controls in

the mental health unit. She continued like this for several months until September 2019, by which time she had lost 16 kilos and began the group intervention developed in this study.

Participant 4

She is a single 57-year-old, with no children and a professional training qualification. She works in her own beauty business. She underwent BS in January 2018 (21 months before the therapeutic group began), and the results of BS were satisfactory. Currently, she has a diagnosis of depressive disorder in remission.

She had not previously visited the mental health unit, but she had visited different private psychiatrists. This participant had presented with obesity throughout her life, with different depressive symptoms that the family doctor and private psychiatrists had treated with medication. She had dysfunctional obsessive personality traits, high levels of impulsiveness, and high emotional reactivity. At the time of the BS, she was psychically stable, but she developed a post-BS depressive disorder, for which she was referred to the mental health unit to begin the present group intervention.

Participant 5

She is a married 55-year-old, with three children and a basic level of education and she is a homemaker. She underwent BS in July 2018 (15 months before the start of this intervention), with satisfactory results. Currently, she has a diagnosis of dysthymia and a secondary diagnosis of unspecified eating disorder.

She was referred to the mental health unit for the first time in June 2014. At that time, she was diagnosed with dysthymia, and she started a pharmacological treatment recommended by the psychiatrist. The specialist reported improvements in mood thanks to the treatment, but also binge episodes that decreased but never disappeared. In January 2016, she was proposed as a candidate for BS but she did not pass the psychiatric evaluation, so she was referred to the psychology unit to work on the intake pattern and to be re-evaluated for BS in the future. In December 2017, the participant continued to present lack of intake control, with continued eating and a permanent feeling of hunger. These variables were addressed by the clinician through different techniques and she began to improve and to lose weight. She was declared BS fit in April 2018, but dysthymia and some maladaptive eating patterns were maintained, so she began the group treatment described in the present study.

Participant 6

She is a 51-year-old with a professional training qualification who lives with her partner and their three children and is currently working actively. She underwent BS in April 2018 (6

months before the start of this intervention), and BS results were satisfactory. Currently, she has a diagnosis of adjustment disorder reactive to BS.

She had no psychopathological history and she had not been treated in the mental health unit before. The endocrinologist referred her, believing that she probably had mood problems. She had emotional symptoms that she described as unexpected anxiety attacks and low mood that were not related to any trigger. She had a stable family, social, personal, and work life. She attributed her symptomatology to the changes associated with BS.

4.3.3 Instruments

The MINI-International Neuropsychiatric Interview: structured diagnostic psychiatric interview for DSM-IV and ICD-10 (MINI; Sheehan et al., 1998; Spanish validation by Ferrando et al., 2000). It is an interview that evaluates the main psychiatric disorders based on the diagnostic criteria of the DSM-IV (American Psychiatric Association, 1994) and ICD-10 (World Health Organization, 1992). It is divided into 16 modules, each of which has structured questions that refer to the different diagnostic categories. It shows a value of .75 for Cohen's kappa, which shows the inter-judge reliability (Sheehan et al., 1998).

Beck Depression Inventory (BDI-II; Beck et al., 1996; Spanish validation by Sanz et al., 2003). It is an instrument that assesses symptoms of depression through 21 items that are answered on a 4-point Likert-type scale between 0 (Not at all) and 3 (Severely, I can hardly bear it). The total score ranges from 0 to 63, and higher scores indicate a higher level of depressive symptoms. In the Spanish validation study with a clinical sample, a score of .89 was obtained for Cronbach's alpha (Sanz et al., 2005). *Beck Anxiety Inventory (BAI*; Beck & Steer, 1993; Spanish validation by Magán et al., 2008). It is a questionnaire that assesses anxiety symptoms through 21 items that are answered on a 4-point Likert scale, between 0 (Not at all) and 3 (Severely). The total score ranges from 0 to 63, and higher scores indicate a higher level of anxiety symptoms. In the Spanish validation study with a clinical sample, .91 was obtained as Cronbach's alpha (Sanz et al., 2012).

Overall Anxiety Severity and Impairment Scale (OASIS; Norman et al., 2013; Spanish validation by Osma et al., 2019). It is a short scale that assesses the frequency, intensity, and interference of anxiety symptoms. It is made up of 5 items that are answered on a 5-point Likert-type scale, between 0 (I did not feel anxious at all) and 4 (Constant anxiety). The total score ranges from 0 to 20, and higher scores indicate greater severity and interference with anxiety symptoms. In the Spanish validation study with clinical sample, .87 was obtained as Cronbach's Alpha (Osma et al., 2019).

Overall Depression Severity and Impairment Scale (ODSIS; Bentley et al., 2014; Spanish validation by Osma et al., 2019). It is a short questionnaire that assesses the frequency,

intensity and interference of depressive symptoms. It is made up of 5 items that are answered on a 5-point Likert-type scale, which ranges from 0 (I did not feel depressed at all) to 4 (Constant depression). The total score can range from 0 to 20, and higher scores indicate greater severity and interference with depressive symptoms. In the Spanish validation with a clinical sample, a Cronbach's alpha score of .96 was obtained (Osma et al., 2019).

NEO-FFI Personality Inventory (NEO-FFI; Costa & McCrae, 1999). It is a scale that assesses the Big Five personality factors in a general way. In the present study, only the Neuroticism and Extraversion subscales have been administered and taken into account. Each subscale is made up of 12 items that are answered on a Likert-type scale from 0 (Totally agree) to 4 (Totally disagree). The total score for each subscale is calculated by adding the items of said subscale, and the higher the score, the greater the presence of the personality trait evaluated. In the Spanish validation study, Cronbach's alpha scores obtained for the different subscales ranged between .82 and .90 (Costa & McCrae, 1999).

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004; Spanish validation by Hervás &Jódar, 2008). It is a scale that evaluates five dimensions of emotional dysregulation: emotional lack of control, emotional rejection, interference from emotions, emotional inattention and emotional confusion. It is made up of 28 items that are answered through a 5-point Likert-type scale, which ranges from 1 (Almost never / 0-10% of the time) to 5 (Almost always / 90-100% of the time). The total score is the sum of the score of the items of each subscale, and the higher the score, the greater the emotional dysregulation. The Cronbach's alpha scores obtained in the Spanish validation study for the different subscales ranged between .73 and .91 (Hervás & Jódar, 2008).

Quality of Life Index (QLI; Mezzich et al., 2000). It is a questionnaire that assesses quality of life through different dimensions of daily life: physical well-being, emotional or psychological well-being, self-care and independent functioning, occupational functioning, interpersonal functioning, social-emotional support, community and service support, personal fulfillment, spiritual fulfillment and global perception of quality of life. The questionnaire is made up of 10 items that are evaluated on a 10-point Likert-type scale ranging from 1 (Bad) to 10 (Excellent). The total score is an average of the item scores, and the higher the score, the higher the quality of life. In the Spanish validation study, a Cronbach's alpha of .89 was obtained (Mezzich et al., 2000).

Maladjustment Inventory (MI; Echeburúa et al., 2000). It is a scale that assesses the extent to which the person's current problems affect different areas of their life: work or studies, social life, free time, relationship with a partner, family life, and day-to-day maladjustment. It is made up of 6 items, one for each dimension, which are answered using a Likert-type scale that ranges from 0 (Not at all) to 6 (Very serious). The total score ranges from 0 to 30 and the higher

the scores, the more interference from problems in everyday life. In the validation study with the Spanish sample, a Cronbach's alpha of .94 was obtained (Echeburúa et al., 2000).

Bulimic Investigatory Test (BITE; Henderson & Freeman, 1987; Spanish validation by Moya et al., 2004). It is a questionnaire that assesses the presence and severity of bulimia symptoms, taking into account cognitive and emotional signs and symptoms associated with bingeing. It is made up of 33 items that are answered on a dichotomous scale (Yes / No). The total score ranges from 0 to 69, and a score from 15 indicates that you have many thoughts and attitudes consistent with an eating disorder. Cronbach's alpha obtained in the validation into Spanish is .81(Moya et al., 2004)

Emotional Eating Scale (EES; Arnow et al., 1995; Spanish validation by Perpiñá, et al., 2011). It is a scale that evaluates the tendency to eat driven by different emotions. It is made up of 25 items, and each of them explores the tendency to eat when faced with a different unpleasant emotion, with a 5-point Likert-type scale that ranges from 0 (No desire to eat) to 4 (An irresistible urge to eat). The internal consistency obtained in the validation study into Spanish ranges between .60 and .75 (Perpiñá et al., 2011).

Body Shape Questionnaire (BSQ; Cooper et al., 1987; Spanish validation by Raich et al., 1996). It is a questionnaire that assesses dissatisfaction with body image, through the exploration of fear of gaining weight, low self-esteem and the desire to lose weight. It is made up of 34 items that are answered on a 6-point Likert-type scale, ranging from 1 (Never) to 6 (Always). In the validation into Spanish, 105 is indicated as a cut-off point, although in the development of the original scale different ranges are established: scores lower than 81, no concern for body image; between 81 and 110 mild concern about body image; between 111 and 140 moderate concern for body image; above 140, extreme concern for body image. The Crobach's alpha value obtained in the validation into Spanish was .97 (Raich et al., 1996).

Satisfaction with Treatment Questionnaire (STQ; an adaptation of Client Satisfaction Questionnaire [CSQ-8] of Larsen et al., 1979). The CSQ-8 is made up of 8 items that evaluate customer satisfaction with the service they have received. Our adaptation includes 6 of the 8 items of the CSQ-8 (perceived quality, suitability to the previous expectations, recommendation of treatment to friends or family, the usefulness of the techniques learned, general satisfaction with the intervention, and the probability that they will choose an intervention of this type again) and one more item regarding the discomfort that the intervention has generated. All 7 items are answered by means of a Likert-type scale that ranges from 0 (Bad / Not at all) to 4 (Excellent / Very much). The higher the total score, the greater the satisfaction with the treatment program received. The CSQ-8 have shown Crobach's alpha ranged between .86 and .94.

4.3.4 Procedure

The study was carried out at the mental health unit of the Hospital Comarcal of Vinaròs within the Spanish public health system. We used a convenience sampling method to conduct this effectiveness and feasibility study.

The participants were informed of the existence of the study by the different specialists that form the multidisciplinary team of care for patients who received the BS, through the information document. Participation was voluntary and without financial reward. If they wanted to participate in the study, they were referred to the clinician of the mental health unit, who gave them the informed consent document and, after they signed it, evaluated them to verify that they met the selection criteria (see "Participants" section). The clinician administered the evaluation battery in pencil and paper format to the participants (all the information was collected using alphanumeric codes to preserve the participants' identity).

Once the pre-treatment evaluation battery was completed, the intervention was carried out (see "Intervention" section). The sessions were carried out by a clinician (V.F.G.) and a co-therapist (A.Q.O.). The clinician was the one who developed most of the session, explaining the theoretical content and resolving the doubts of the participants. The cotherapist, who was a doctoral student, was an observer and she intervened to complement the work of the clinician and to help participants with their in-session exercises. To ensure the proper implementation of the UP, the clinician received a UP training course and clinical supervision by the leading author (J.O.) who has been certified as a UP trainer by the Unified Protocol Institute and had extensive experience in applying the UP. The clinician has extensive experience in the application of cognitive behavioral treatments (14 years of professional practice) and also has completed the UP therapist training. The role of the supervisor was crucial throughout the implementation of the intervention program, since meetings were held prior to each session to analyze how the previous session had gone and to resolve possible doubts or conflicts and are also helpful to prepare the following session. To monitor and improve the training of the participants, throughout the sessions they received different theoretical documentation that summarized the contents of the next session, for example, specific information about emotional eating or a summary of the UP modules from the participants' manual (Barlow et al., 2019). The idea was that the participants read these documents before the following session, to better understand the contents and have time to review them. In addition, at the end of each session the exercises and their own records were delivered, in paper for-mat, so that they could fill them in as homework until the following session, in which they were shared and corrected.

The assessment protocol was administered at pre-treatment, post-treatment, and 6-month follow-up. As previously mentioned, the evaluation batteries at the pre-treatment and post-treatment time were carried out by the participants in pencil and paper format in the mental

health unit itself and in the presence of their clinician, who answered questions and supervised the completion of the questionnaires. However, the evaluation batteries of the follow-up at 3 and 6 months were filled out by means of a survey on the Qualtrics platform (Qualtrics, 2017), so that the participants did not have to travel to their mental health unit.

4.3.5 Intervention

The UP adaptation for the present study consisted of 9 two-hour group sessions, with a weekly frequency, in which 6 of the 8 modules of the original UP (Barlow et al., 2015) were applied. The main adaptation was to grant special relevance to emotional eating and the relationship between food and emotions. Table 4.1 shows the original UP modules, the number of sessions dedicated to each of them, and the main adaptations for this sample.

Table 4.1 Description of the contents of the UP modules, distribution into sessions and specific adaptations carried out to personalize the intervention.

Modules of the original UP (number of sessions in adaptation)	Adaptations of each module
Setting goals and maintaining motivation (0)	Given the high motivation for change of the majority of participants, and the existence of a common objective, which was to regulate their eating habits so as not to channel with food and maintain weight, this module was replaced by on specifically designed to introduce psychoeducation on emotional eating, and also on the relationship between food and emotions. In addition, the participants were told what the intervention would consist of and the logic behind the skills that would be worked on in relation to the main problem was explained. The importance of participating in sessions, group norms and the important role of doing the homework were also highlighted.
Understanding emotions: psychoeducation and recording of emotional experiences (1)	The module's content was applied on the basis of the experiences of the participants that could be related directly or indirectly to food. In this module, the focus was on contextualizing binging or snacking as an emotion-driven behavior, introducing this concept from this session. Part of the session was also used to detect the association between different emotions and binge or pecking episodes, so that each participant established their own association pattern. The importance that positive emotions can also be associated with binge episodes was highlighted.
Mindfulness: Training emotional awareness and experimentation of the present moment (1)	This module was applied following the same guidelines as the original UP, although specific exercises were carried out that focused mindfulness exercises on food-related activities.
Cognitive flexibility: Cognitive reinterpretation and identification of thought	Two sessions were dedicated to this module, because the participants manifested difficulties in understanding its content. The exercises were adapted to the specific experiences that the participants presented in the session. Some of the most

Modules of the original UP (number of sessions in adaptation)	Adaptations of each module
patterns (2)	characteristic irrational automatic thoughts were: "I need to eat to reduce my sorrows", "even though I don't weigh much anymore, I' m still fat".
Opposing Emotional Behaviors: Emotional Avoidance and Emotion Driven/Directed Behaviors (1)	This module was applied following the same guidelines as the original UP, although the emotion-driven behaviors that the participants reported were closely related to emotional eating, so special attention was paid to this topic. Some examples of specific emotional behaviors the participants exhibited were "wearing wide, dark clothes", "not going to the pool", or “not going through certain areas of the supermarket”.
Understanding and dealing with physical sensations: Awareness and tolerance of physical sensations (0)	The participants did not report being afraid of physical sensations associated with moments of high emotional intensity, so this module was not implemented.
Emotional Exposures: Interoceptive and Situational Exposure (2)	The emotional exposures were quite related to emotional eating, but also associated problems that each of the participants brought to session. The emotional exposures were conducted mainly with anxiety due to its relationship with emotional eating but also with depression, guilty and boring emotions.
Acknowledge your accomplishments and look to the future: Relapse Prevention(1)	This module was applied following the same guidelines as the original UP, adapting the implementation for each participant according to their specific objectives.

4.3.6 Data Analysis

The analyses were carried out using the statistical package IBM SPSS Statistics version 22.0 for Windows (IBM Corp, 2013). First, the sociodemographic characteristics of the total sample (N = 6) were analyzed using descriptive statistics. The mean and standard deviation of the scores in the different questionnaires were calculated. Then, a Missing Values Analysis and Little's MCAR were carried out to test whether or not the distribution of these missing values was random. Once its random distribution was verified, the LOCF (Last Observation Carried Forward) was used for those cases in which some random item from a scale was missing. The Shapiro-Wilk normality test was carried out to verify the normal distribution of the variables.

A record of attendance at the sessions was carried out, to calculate attendance and dropout rates, and to use them as an indicator of feasibility and acceptance of treatment by users. For this same purpose, both quantitative and qualitative analyses were performed. At the quantitative level, descriptive analyses were performed to assess responses to the Satisfaction Treatment Questionnaire (STQ). At a qualitative level, the answers to the four main treatment

questions were analyzed, selecting and ordering the information through a segmentation process, identification of key concepts and categories of analysis (De Andrés Pizarro, 2000).

To explore the effectiveness of this intervention, changes in participants' symptoms were analyzed throughout the different time points. For this purpose, and although the scores followed a normal distribution, we decided to carry out non-parametric tests because the sample did not meet the rest of the parametric assumptions. Therefore, the Wilcoxon-Singed Rank test was conducted to calculate the differences between mean ranks when comparing pre- and post-treatment, and post-treatment and 6-month follow-up. Effect size was calculated with Cohen's *d*, and interpretation of effect sizes was as follows: 0.2 represented a small clinical treatment effect, 0.5 a medium effect and 0.8 or above a large effect (Cohen, 1960). Also, the Friedman test was conducted to assess the change in the scores of the different variables, taking into account the variation at different time points.

Finally, we calculated the Reliable Change Index (RCI), which is defined as a statistical index that evaluates the clinically significant change obtained to determine in which variables each of the participants approaches the scores of a normative sample. A clinically significant change would be considered if the participant obtained scores in the variables that reflect normal functioning, which would imply a score in the RCI of 1.96 or higher (Jacobson & Truax, 1991).

4.4 RESULTS

4.4.1 Descriptive Analysis

The results of the descriptive analysis of the characteristics of the sample are found in the "Participants" section. The mean scores for each of the instruments are shown in Table 4.2. The Missing Values Analysis shows that out of the total set of all variables, 8.75% of the data was lost. In Little's MCAR-test, a significance of $p = 1.00$ ($p > .05$) was obtained, which implies a random distribution of missing values. Based on this, the LOCF was conducted for such missing values. The results of the Shapiro-Wilk normality test showed that the scores of the participants in the different variables were normally distributed ($p > .05$), but the rest of the parametric assumptions were not met.

Table 4.2 Changes after the UP application: mean differences between pre-test and post-test, pre-test and 3-month follow-up and post-test and 3-month follow-up

	MeanPre(SD)	MeanPost(SD)	Mean3-mFU(SD)	Mean6-mFU(SD)	χ^2 Overall	Z(*d*) Pre-post	Z(*d*) Post-6-mFU
OASIS	6.33(3.98)	7.67(5.75)	4.60(4.72)	3.67(2.94)	7.04	-0.94(0.29)	-2.02*(0.88)
ODSIS	6.00(4.24)	6.33(6.62)	3.80(6.10)	1.83(3.60)	5.59	-0.27(0.04)	-1.82(0.84)
NEOFFI							
Neuroticism	33.66(4.41)	29.50(4.81)	27.40(8.08)	23.33(9.33)	13.56**	-2.21*(0.72)	-2.00*(0.83)
Extraversion	22.33(8.50)	21.33(4.55)	21.80(8.53)	25.50(7.23)	3.81	-0.84(0.13)	-2.02*(0.69)
QLI	5.70(1.75)	5.48(1.66)	6.04(1.11)	6.75(1.47)	6.43	-0.31(0.19)	-1.58(0.81)
MI	16.00(9.51)	15.17(4.79)	13.00(9.19)	6.67(6.68)	9.56*	-0.21(0.14)	-2.21*(1.46)
DERS							
Totalscore	87.00(22.57)	80.00(18.38)	62.20(18.28)	59.67(15.96)	10.68*	-0.32(0.34)	-2.21*(1.18)
Lackattention	12.83(3.76)	11.83(4.58)	12.00(2.92)	12.17(3.37)	1.26	-0.95(0.25)	-3.14(0.08)
Confusion	11.83(2.14)	11.50(3.27)	8.60(2.88)	8.00(1.67)	8.41*	-0.14(0.18)	-1.76(1.35)
Rejection	24.33(7.39)	21.00(6.26)	15.20(6.30)	14.00(5.87)	11.13*	-0.94(0.53)	-2.20*(1.15)
Interference	12.17(4.36)	11.83(3.19)	8.80(2.17)	8.17(3.25)	9.63*	-0.11(0.13)	-1.68(1.14)
Lackofcontrol	25.83(8.80)	23.83(8.38)	17.60(5.73)	17.33(7.37)	4.59	-0.41(0.16)	-1.58(0.82)
BSQ	136.67(19.33)	114.83(23.48)	120.20(28.98)	109.17(32.05)	2.52	-1.57(0.89)	-0.31(0.20)
BITE	23.67(6.50)	16.00(9.63)	17.60(11.84)	19.00(12.68)	2.04	-2.00*(0.65)	-1.36(0.27)
EES	44.50(26.30)	36.50(20.71)	34.60(20.09)	35.83(19.75)	4.47	-2.20*(0.64)	0.00(0.03)
BMI	30.75(6.23)	29.82(5.10)	28.91(4.69)	28.27(3.33)	3.74	-0.94(0.14)	-0.94(0.36)

Note:OASIS:OverallAnxietySeverityandImpairmentScale;ODSIS:OverallDepressionSeverityandImpairmentScale;NEOFFI:NEOFiveFactorInventory;QLI:QualityofLifeIndex;MI:MaladjustmentInventory;DERS:DifficultiesinEmotionRegulationScale;BSQ:BodyShapeQuestionnaire;BITE:BulimicInvestigatoryTestEdinburgh;EES:EmotionalEatingScale;BMI:BodyMaxIndex;χ^2:Friedman'stest; Wilcoxon'stest;d:Cohen'sd;Pre:Baseline;Post:Post-treatment;3-mFU:Follow-upat3monthspost-treatment;6-mFU:Follow-upat6monthspost-treatment;*p<.05.;**p<.01.

4.4.2 Feasibility and satisfaction with the intervention

The participants attended a general average of 8 sessions (*SD* = 0.82; *range* = 7-9), representing an attendance rate of 88.89%. In the STQ, 83.3% of the participants rated the quality of the program as good, and 66.7% reported high satisfaction and stated that they would recommend it to a loved one. The same percentage deemed that the contents of the program helped them to deal with their problems and said that they would choose a similar treatment again.

Finally, to analyze the participants' qualitative assessments, their responses to the four questions that were asked at the end of the treatment were coded. To the question "*What did you not like, what did you find difficult or what caused you discomfort?*" three participants answered "nothing," two mentioned "difficulty understanding and putting into practice some concepts," and one participant commented, "I still cannot control the urge to eat very well." To the question "*Do you recognize any obstacle for this type of treatment to continue being applied in the public health system?*" all the participants replied negatively with words like "not at all" or "just the

opposite." To the question "*What positive aspects would you highlight and what did you like or what interested you the most?*" four participants made reference to the social support, with phrases such as "meeting people in the same situation" and "being able to share my experiences." One participant mentioned "interest on the part of the therapists" and another made reference to the improvement in emotion-regulation skills "getting to know myself better, managing my emotions better and not judging". Finally, to the question "*What ideas can you think of to improve the intervention?*" two participants answered “none”, two participants mentioned the need for “more nutritional or physical activity information” related to BS, one participant said expanding the number of sessions, and another mentioned interspersing group sessions with individual sessions.

4.4.3 Effectiveness at group level

Table 4.2 shows the results of the Friedman and Wilcoxon tests (and Cohen’s *d*). Pre- to post-treatment comparisons showed statistically significant improvements in neuroticism (Z = -2.21, p = .027), symptoms related to eating disorders (Z = -2.00, p = .046), and emotional eating (Z = -2.20, p = .028). Post-treatment to 6-month follow-up comparisons showed statistically significant changes in anxiety symptoms (Z = -2.02, p = .043), neuroticism (Z = -2.00, p = .046), extraversion (Z = -2.02, p = .043), maladjustment (Z = -2.21, p = .027), emotional dysregulation (Z = -2.21, p = .027), and DERS’ rejection subscale (Z = -2.20, p = .028); all of them with a medium or large effect size ($0.64 < d > 1.46$).

Taking into account all the temporal moments, the Friedman test showed that the variables with statistically significant changes were neuroticism ($\chi2$ = 13.56, p = .004), maladjustment ($\chi2$ = 9.56, p = .023), emotional dysregulation ($\chi2$ = 10.68, p = .014), and DERS’ confusion ($\chi2$ = 8.41, p = .038), rejection ($\chi2$ = 11.13, p = .011) and interference ($\chi2$ = 9.63, p = .022) subscales.

Thus, the results showed that the main changes occurred in neuroticism and emotional dysregulation (variables directly addressed by the UP), but also in variables directly related to overweight, obesity, and BS. In this sense, although there were only statistically significant changes for the symptoms of eating disorders and emotional eating, there were also reductions in dissatisfaction with body image and BMI (although they were not statistically significant). Finally, the body mass index remained stable over the treatment to 6-month follow-up.

4.4.4 Effectiveness at the individual level

Regarding the Reliable Change Index (RCI) analyses (Table 4.3), the number of participants who normalized their scores at post-treatment on each measure were as follows: 4 for dissatisfaction with body image; 3 for maladjustment and rejection DERS subscale; 2 for

emotional dysregulation; 1 for neuroticism, extraversion, quality of life and lack of attention, confusion, interference and lack of control DERS subscales.

Table 4.3 Reliable Change Index (RCI) of each Participant between Pre- and Post-treatment (Post) and Post- and 6- month Follow-up (6-m FU)

	Normative data	RCIP1		RCIP2		RCIP3		RCIP4		RCIP5		RCIP6	
	M(SD)	Post	6-mFU	Post	6-mFU	Post	6-mFU	Post	6-mFU	Post	3-mFU	Post	6-mFU
BSQ	84.75(30.42)	0.35	-1.16	-6.62[a]	-10.81[a]	-2.32[a]	-13.60[a]	-4.65[a]	-6.51[a]	0.58	-12.44[a]	-2.56[a]	-9.30[a]
NEOFFI													
Neuroticism	21.58(7.48)	-0.89	-0.67	-0.89	-3.12[a]	-2.23[a]	-1.56	-1.11	0.45	-0.22	-0.67	-0.22	-2.67[a]
Extraversion	32.05(6.64)	0.24	0.24	-2.44	3.18[a]	2.20[a]	1.47	-0.49	0.49	-0.24	0.00	-0.73	0.73
QLI	6.98(1.10)	-2.92	2.58[a]	-3.26	7.73[a]	2.41[a]	2.58[a]	-0.52	-1.55	0.86	1.20	1.20	0.52
MI	2.22(1.66)	-0.64	-1.93	-5.14[a]	-7.06[a]	-3.21[a]	-8.35[a]	3.85	-1.93	-3.85[a]	-4.50[a]	5.78	-8.99[a]
DERS													
Total score	59.10(17.50)	2.58	-4.10[a]	-7.14[a]	-3.95[a]	-4.71[a]	-0.61	0.61	-1.06	-0.30	-4.71[a]	2.58	-4.10[a]
Lack attention	9.60(3.40)	0.40	-0.40	0.40	-0.80	-1.60	1.60	-1.20	-2.80[a]	0.40	2.00	-0.80	1.20
Confusion	7.90(3.10)	1.46	-3.89[a]	-2.92[a]	0.49	0.49	-1.95	-1.46	0.00	0.00	-1.95	1.46	-2.92[a]
Rejection	14.90(6.50)	2.75	-3.78[a]	-6.19[a]	-2.75[a]	-4.13[a]	-1.03	2.41	-2.06[a]	-3.10[a]	-1.72	1.38	-3.10[a]
Interference	10.20(3.90)	1.01	-1.51	-4.02[a]	-3.02[a]	-1.51	-1.00	1.51	1.51	0.50	-5.03[a]	1.51	-2.01[a]
Lack of control	16.50(7.50)	0.94	-1.26	-5.03[a]	-3.46[a]	-4.09	0.31	0.00	0.94	1.57	-5.31[a]	2.83	-3.46[a]

Note: P1...P6: Participant1...Participant6; BSQ: Body Shape Questionnaire; NEOFFI: NEO Five Factor Inventory; QLI: Quality of Life Index; MI: Maladjustment Inventory; DERS: Difficulties in Emotion Regulation Scale; [a]<|1.96 | (significant change in scores in the desired direction. i.e. improvement of scores until reaching a normalized score).

The number of participants who normalized their scores from post-treatment to the 6-month follow-up on each measure were: 5 for dissatisfaction with body image; 4 for maladjustment, emotional dysregulation, and rejection DERS subscale; 3 for quality of life, and interference and lack of control DERS subscales; 2 for neuroticism and con-fusion DERS subscale; and 1 for extraversion and lack of attention DERS subscale.

4. 5 DISCUSSION

This is the first study to apply the UP, an emotion-based CBT intervention in a group format in a public mental health unit for a sample of post-BS patients with a diagnosis of an ED or anxious or depressive symptoms. The preliminary results especially highlight the feasibility

and acceptance of this intervention by participants and show preliminary data of its effectiveness for this specific health problem.

The recommendation to conduct an intervention focused on the improvement of emotion-regulation strategies in post-BS patients is based on the presence of emotional symptoms reactive to BS (four participants in our study, 66.67%), and also on that some people in these circumstances have prior psychopathological history (two participants in our study, 33.33%), which has been shown to be a risk factor for poorer or limited BS results, and finally, because of the numerous physical and functional changes produced by BS (e.g., drastic weight loss, body image concerns, mood changes, stress; Jumbe et al., 2017).

Carrying out interventions such as the one described in this study, the UP, allows to care for the psychological wellbeing of post-BS patients, which is one of the main needs of these people to improve their BS results and, thereby, their health (Spirou et al., 2020).

One of the clearest results provided by the present study is the high attendance rate and adherence to the intervention. The attendance rate was very high compared with other studies that have applied other CBT interventions (Cassin et al., 2016; Sockalingam et al., 2017; Sockalingam et al., 2019). The STQ results show high satisfaction with the treatment received, data that generally agree with those obtained in other psychosocial interventions. This shows that post-BS patients generally express high satisfaction with the treatment, and these levels of satisfaction can predict adherence to subsequent follow-up sessions (Lauren et al., 2020).

The qualitative analysis of participants' opinion of the treatment received has shown some positive aspects. None of the participants detected obstacles to the application of this type of intervention in a public health context, confirming its probable feasibility in a naturalistic context. In addition, one of the most positive aspects that the participants highlight is the perception of social support, something previously found in the literature (Yalom & Leszcz, 2005). Through this survey, ideas for future interventions were also detected, such as increasing the information about topics directly related to BS (nutritional information, physical activity, etc.). These ideas are in line with those obtained by Lauren et al. (2020), who recommended incorporating a dietary or physical activity as part of the psychological interventions' focus on these patients. Participants also recommended in-creasing the number of sessions or inserting individual sessions throughout the intervention. This aspect would be crucial to be able to address the specific needs of each participant, dedicating more time to those concepts that take longer to understand, or adding techniques that may be necessary for specific cases.

Regarding the effectiveness, the intervention also shows encouraging preliminary results. At the 6-month follow-up, a generalized decrease or a positive tendency in the expected direction was observed in all study outcomes. Concerning emotional symptoms (assessment with OASIS and ODSIS), in general, there was a rebound at post-treatment, and a new reductionatthe3and6-month follow-up. This rebound at post-treatment can be explained because

the UP, as other psychological interventions, requires becoming aware of emotional responses, and this requires effort and can generate unpleasant emotions at first. With more practice over time, participants are expected to increase their tolerance of unpleasant emotions, thus reducing the frequency and intensity of emotional symptoms (e.g., Osma et al., 2015). This hypothesis is confirmed with the punctuations at the 3 and 6-month follow-up.

Statistically significant changes in neuroticism, emotional dysregulation, and emotional eating are especially relevant, considering that the factors that were most strongly associated with poor weight loss were anxiety and depression (related to neuroticism) and emotional eating (Hjelmesæth et al., 2019). Although no statistically significant differences were found, there were changes in the desired direction in dissatisfaction with body image and BMI, an aspect that is essential in this type of patients. In this sense, furthermore, the statistically significant changes in neuroticism become especially important when considering all their implications for health systems, such as the high frequency of use of general and mental health services (Lahey, 2009).

Changes in maladjustment and quality of life highlight that the intervention provides benefits beyond the emotional dysregulation itself, promoting participants' optimal functioning. These data are also in line with previous psychological interventions carried out with this specific type of sample (Lauren et al., 2020).

Regarding extraversion, we found statistically significant differences, with medium effect size, from post-treatment to 6-month follow-up. The UP focuses on the broad range of emotions, "negative" and "positive" ones, so benefits in both dimensions of personality can be expected. However, mixed results have been found in its efficacy to increase extraversion scores in samples with EDs diagnosis, where some of them confirmed changes in extraversion (e.g., Carl et al., 2014; Tirpak et al., 2019) and others did not (e.g., Ellard et al., 2010). Some factors could explain these discrepancies, such as the small sample sizes of the studies, the different measures used, the population characteristics, or the different formats of delivery and length of the interventions.

Finally, it should be mentioned that the changes obtained on an individual level by each of the participants may have been influenced by personal characteristics or circumstances, notably among them unsatisfactory life changes (Participant 1), dysfunctional obsessive personality traits (Participant 4), or difficulty in understanding and putting into practice the different strategies learned (Participant 6). In this sense, it would be very beneficial to consider these participants' feedback to further personalize the intervention by increasing the number of sessions or inserting individual sessions through-out the intervention.

Based on all the above-mentioned results, it is worth noting the different limitations and strengths of the present effectiveness and feasibility study.

Regarding the limitations of this study, we present data of a group including 6 participants, so the small sample size does not allow the results to be generalized, and they should be considered with caution. However, it is important to highlight that this studies are a recommendable cost-effective method to preliminarily study the effectiveness, feasibility, and/or implementation of novel intervention programs with different samples (e.g., Osma et al., 2018). It would be necessary to carry out more rigorous studies with greater control such as randomized clinical trials that allow to obtain more robust conclusions on the feasibility and effectiveness of the intervention. Furthermore, we wished to study the feasibility and effectiveness of a 9-session UP group intervention to be applied in a public mental health unit where human resources are limited. The aim proposed made it difficult to personalize the intervention to each participant's characteristics (e.g., personality traits, difficulties in understanding the concepts, or lack of practice) and it may have limited the clinical benefits of some participants. As mentioned, the participants recommended the extension of the program sessions and the use of a mixed format, with individual and group sessions, which should be considered in future studies.

A limitation from the clinical approach was not applying modules 1 and 6 as they appear in the original version of UP. Regarding module 1, "Setting goals and maintaining motivation", in this specific case it was not applied because in the sessions prior to the intervention that each of the participants had with the clinician, they reported high motivation for change and a common goal, which was to regulate eating habits to maintain the weight achieved after BS. In these individual sessions, the clinician did explain the fundamentals of the change process, explaining the ambivalence of motivation throughout it. However, it should be noted that although the objective of people who have undergone a BS is usually to maintain weight, it is essential to personalize the objectives for each participant through the exercises in this module, identifying the steps for each of the objectives, and carrying out the exercise of the decisional balance. Furthermore, as mentioned in Table 4.1, it is important to add in this first module information about emotional eating and how the regulation of emotions is essential in this process, in order to understand the logic of the intervention. Regarding module 6, "Understanding and confronting physical sensations". It was not applied because the participants in the pre-sent study did not report fear to physical sensations, however, it is important to emphasize that patients with higher scores on anxiety sensitivity will benefit the most with this module. Hunger is a very relevant physical sensation to work with this kind of participants. It would be interesting to set out adapted exercises to expose them to this sensation, to identify and tolerate it.

Another limitation identified by the participants was that the intervention could have incorporated more specific content regarding the common difficulties for patients with obesity, such as dietary aspects or physical activity. Although in the present study, the material was

delivered to the participants extracted mainly from the original UP manual (Barlow et al., 2015), it would be interesting to design a specific manual, which could intersperse information about emotion-regulation strategies with information related to BS. It would also be interesting to increase the number of follow-up sessions every few months up to a minimum period of two years, as evaluating the maintenance of long-term achievements is especially relevant in this sample (Lauren et al., 2020). Finally, this study took place in a public mental health unit, so the results might not be generalizable to other contexts, such as community or social services, but having been carried out in a naturalistic context is one of the strengths of this study.

In sum, the strengths of the study are: [1] performing an emotion-regulation-based CBT intervention applied after BS, which is the type of intervention that the literature identifies as most appropriate for these patients (Hjelmesæth et al., 2019); [2] using an intervention focused on addressing transdiagnostic mechanisms rather than the specific symptoms of each disorder, allowing us to care for patients with comorbidity, subclinical symptomatology, and unspecified disorders, and overcoming many of the limitations of specific CBT (Barlow et al., 2017); [3] related to the previous points, using an intervention developed specifically to target neuroticism, which is a personality factor that predicts poorer BS results (Oltmanns et al., 2020) and which has been shown to have many implications for health systems (Lahey, 2009); and [4] applying the intervention in group format in a public mental health unit, which provides additional cost-effective advantages such as the reduction of waiting lists, treating more people at the same time, or enhancing social support among the participants (Yalom & Leszcz, 2005).

4.6 CONCLUSIONS

This study joins the literature that supports the versatility of the UP, adding encouraging data on its preliminary effectiveness and feasibility in post-BS patients with emotional dysregulation. In addition, it highlights the importance of psychological work in the multidisciplinary approach that must be considered to address this relevant health problem (National Health and Medical Research Council, 2013).

One of the advantages of applying this intervention is to reduce the costs associated with EDs in post-BS patients, but above all, the main advantage of applying this type of intervention in these patients is to allow a better prognosis and maintenance of the improvements obtained through the intervention (Sarwer & Heinberg, 2020). In this way, we can directly address the needs of this population, responding to the psychosocial variables that revolve around BS, and offer them specialized quality care that allows them to improve their quality of life and functioning. This study is the first step to figure out if the UP applied in group format in the

public Mental Health System in Spain could be a cost-effective intervention to post-BS patients, but researchers must conduct controlled studies in the future to obtain more robust conclusions.

Conflict of interest:

The authors of this article declare no conflict of interest.

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CAPÍTULO V: "ASSESSMENT OF ACCEPTABILITY AND INITIAL EFFECTIVENESS OF A UNIFIED PROTOCOL PREVENTION PROGRAM TO TRAIN EMOTIONAL REGULATION SKILLS IN FEMALE NURSING PROFESSIONALS DURING THE COVID-19 PANDEMIC"

Ferreres-Galan, V., Navarro-Haro, MV., Peris-Baquero, O., Guillen-Marín, S., DeLuna-Hermoso, J., & Osma, J. (2022). Assessment of Acceptability and Initial Effectiveness of a Unified Protocol Prevention Program to Train Emotional Regulation Skills in Female Nursing Professional during the COVID-19 Pandemic. *International Journal of Environmental Research and Public Health*, 19, 5715. https://doi.org/10.3390/ijerph190957

5.1 ABSTRACT

Healthcare professionals, especially women, have shown increases in stress and in anxious-depressive symptoms as a consequence of the COVID-19 pandemic. The aim of the study was to evaluate the acceptability and preliminary effectiveness of the Unified Protocol (UP) prevention program to provide emotional regulation skills to cope with stressful situations. The sample consisted of 27 healthcare professionals (100% women; mean age: 45.67; SD = 7.71) working in a Spanish public hospital, who were randomized to an immediate treatment group (ITG, n=13) or to a delayed treatment group (DTG, n=14). The program consisted of five-weekly, two-hour, UP-based group sessions. The time points assessed were: pre and post intervention and at 1-, 3- and 6-month follow-ups. Statistically significant between-group differences ho wed lower emotional exhaustion, and personal accomplishment in favor of the ITG. Regarding the effect of time for all participants who received the UP, statistically significant reductions were observed in neuroticism, personal accomplishment, and subjective distress caused by traumatic events ($-0.23 \leq d \leq -0.73$). A statistically significant interaction "Time*Condition" was found in anxiety, with increases in anxiety in the DTG. Participants showed high satisfaction with the UP. These findings show good acceptability and preliminary effectiveness of the UP to reduce the emotional impact of the pandemic in female healthcare workers.

Keywords: Prevention; Emotion Regulation Skills; Unified Protocol; Healthcare workers; COVID-19 pandemic.

5.2 INTRODUCTION

The COVID-19 pandemic is and has been a great global health challenge. The populations at greatest risk of suffering mental health problems due to the pandemic consequences include healthcare workers and, more specifically, front-line workers [1]. Healthcare workers are and have been addressing very severe job stressors for many months. For example, they have worked for more hours than usual, faced higher work overload and are at great risk of being infected, have underwent very strict safety protocols, and have been required to be highly concentrated and vigilant [2,3]. In turn, these factors have often placed healthcare workers under great stress [4, 5]. As a

consequence, burnout and fatigue have augmented in this population during the COVID-19 pandemic [6]

In this regard, several systematic meta-analyses and reviews have reported that the first wave of the COVID-19 pandemic was associated with a higher percentage of mental health problems in healthcare personnel, with emotional disorders (EDs; depression, anxiety, and related disorders; ref. [7]) being the most prevalent disorders in this population [8,9]. In fact, a study conducted by Luo et al. [10] that included healthcare personnel from 17 countries around the world reported a prevalence of anxiety and depression in this population group of 33% and 28%, respectively. In Spain, several studies were carried out with healthcare professionals during the first wave of the pandemic [11–13]. Findings are consistent with those obtained internationally in which a high proportion of anxious and depressive symptomatology has been observed, as well as high levels of stress. For example, a study developed by Alonso et al. [14] that included a sample of 9146 healthcare professionals from 18 healthcare institutions reported that 1 in 7 Spanish healthcare workers presented a probable mental disorder during the first wave of COVID-19. Specifically, 28.1% met criteria for a major depressive disorder, 22.2–24% for anxiety disorders (Generalized Anxiety Disorder, Panic Disorder, or Post-Traumatic Stress Disorder), and 6.2% for a substance use disorder. In turn, the risk of having a current mental disorder was higher in healthcare professionals who had been treating patients with COVID-19 more frequently and in those who had been in quarantine or isolation. Another important result was that the healthcare workers with the most risk to develop a mental disorder were those of the female gender and nursing professionals [14]. These findings suggest that there are great mental health needs to be met among healthcare personnel, especially in women, who should be considered a high-risk group for mental disorders. Thus, it is necessary to develop programs for the prevention and treatment of different mental health problems for this population, with EDs being the most prevalent psychological problems, and paying special attention to females.

Although several advances have been made, traditional treatments for EDs have shown some limitations, such as a high prevalence of comorbidity among EDs, with high costs for Public Health Services (direct and indirect), the ineffectiveness of some of the specific treatment protocols for these disorders, the high relapse rates at the end of treatment, and the economic and resource costs involved in the training and implementation of each of these protocols in the mental health services [15]. Based on

these findings, and in order to resolve these problems, Barlow et al. [16] developed a treatment for EDs that emphasizes what the EDs have in common, rather than their differences. This treatment, the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (UP), emphasizes that emotional regulation (ER) deficits (as intense emotional responses and aversive reactivity to emotional experiences) and avoidance behaviors are common to people with EDs [17]. The UP focuses on the common aspects of the different EDs, resulting in numerous advantages such as allowing the approach of people with comorbidity [18] as well as reducing costs related to the training of mental health workers in evidence-based treatment programs [19]. Moreover, because the UP consists of a modular intervention, it is considered more flexible and adaptable to different psychological problems [20,21] and treatment formats such as group, individual, face-to-face, and online [22,23].

Regarding the efficacy of the UP, a meta-analysis by Sakiris and Berle [24] and a recent systematic review by Carlucci et al. [25] showed that the UP, both in individual and group formats, significantly decrease anxiety and depression symptoms after treatment, and the effect sizes are comparable to those resulting from disorder-specific interventions. In addition to the effectiveness in emotional symptoms, the UP enhances overall functioning and quality of life [26,27]. Furthermore, preliminary research shows promising results of the effectiveness of preventive applications of the UP for nonclinical populations, such as students [28–30]. With respect to other psychological programs in Spain during the COVID-19 crisis for healthcare workers, a study showed that the most common component of these interventions in 36 hospitals was emotional regulation, which was implemented by psychoeducational and cognitive-behavioral techniques in individual interventions. Group interventions mainly used psychoeducation and mindfulness. However, no pro- gram effectiveness results were published [31]. Systematic reviews of preliminary studies show that interventions focused on building resilience may decrease perceived stress and burnout [32,33] and that cognitive behavior therapy and mindfulness-based interventions may be effective to treat symptoms of posttraumatic stress disorder (PTSD) due to COVID-19 experiences [34].

Therefore, and given the increases in EDs and the levels of stress and burnout in healthcare personnel after the COVID-19 pandemic, the application of the UP could be a useful psychological program to prevent EDs in this population and enhance coping with stressful situations. To our knowledge, there are no RCTs published that have

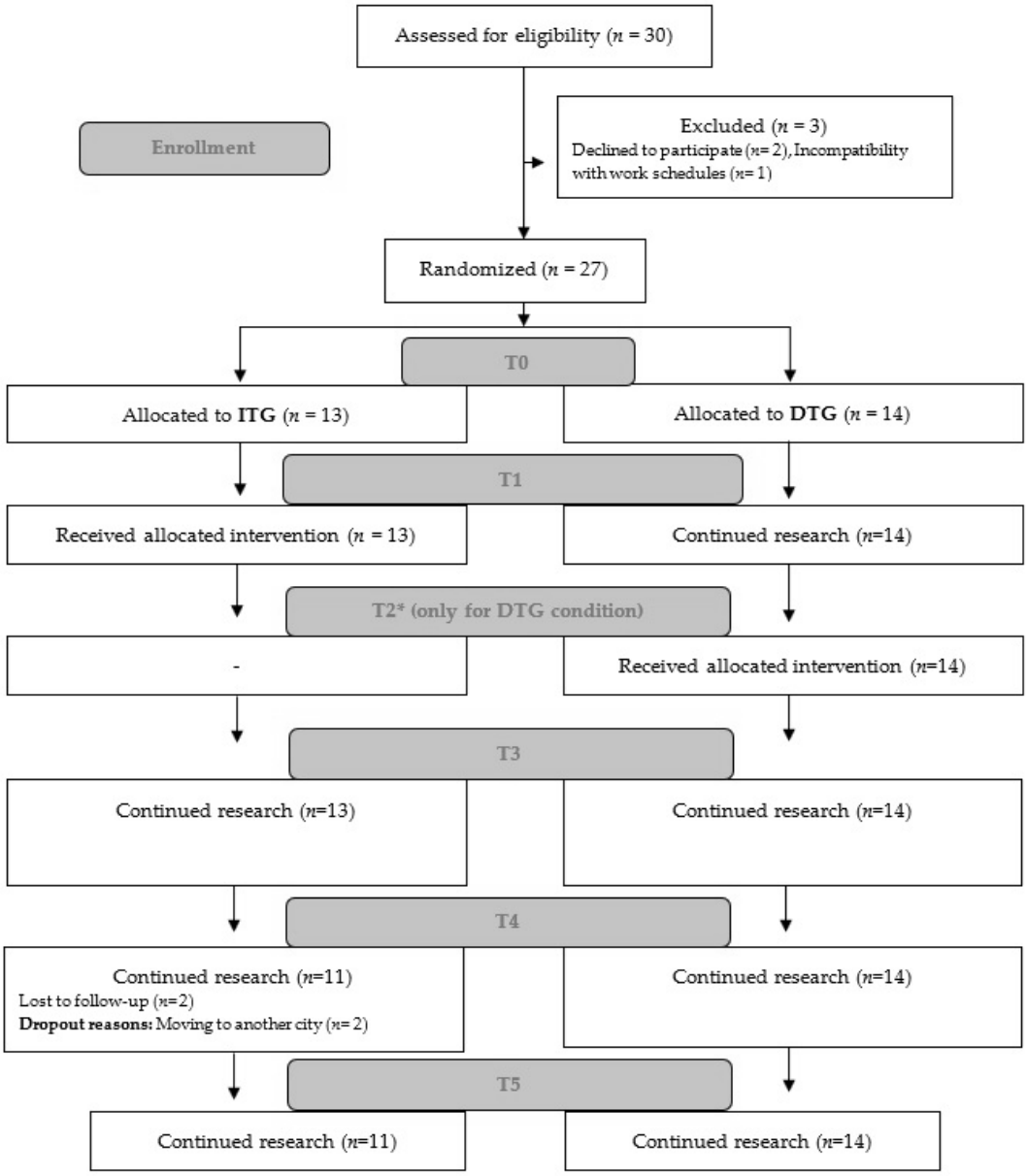
investigated the effectiveness of the UP for healthcare workers and specifically nursing professionals, facing COVID-19. Thus, the main goal of this study was to evaluate the feasibility, acceptability, and preliminary effectiveness of the application of a brief UP prevention program (comparing an immediate treatment group and a delayed treatment group) to provide emotion regulation skills to cope with stressful situations among nursing professionals working in a public hospital in Spain during the health crisis due to the COVID-19 pandemic.

Specifically, our main goal was to evaluate the effectiveness of the UP to improve the severity of stress, anxiety, and depression (the primary EDs-related variables) after the intervention and at one-, three-, and six-month follow-ups. As secondary variables, we aimed to decrease emotional alterations in the context of a health crisis, such as emotional personality dimensions (neuroticism), difficulties in emotion regulation, and the impact of stressful events and professional burnout, as well as to increase quality of life in Spanish nursing professionals. In addition, we evaluated the acceptability of the UP-prevention program by assessing the participants satisfaction with the program. The main hypotheses that we expected were: statistically significant improvements in favor of the immediate treatment group (which received the UP-prevention program first) will be obtained after the intervention in the primary and secondary measures, compared with the delayed intervention group (waiting list). Once both groups have received the preventative program, the improvements obtained after the application of the UP will be maintained at one-, three-, and six-month follow-ups. The study sample will report high satisfaction scores regarding the UP-prevention program received.

5.3 MATERIALS AND METHODS

5.3.1 Participants

The sample consisted of 27 healthcare professionals from (blind note) Hospital, all of them women, with a mean age of 45.67 years (*SD* = 7.71, range 26 - 62). The participants were randomized to an Immediate treatment group (ITG) (*n* = 13) or a Delayed treatment group (DTG) (*n* = 14). The flow chart of the participants can be found in Figure 5.1.



Note: ITG: Immediate treatment group; DTG: Delayed treatment group; T0: Pre-treatment; T1: Immediate treatment group post-treatment; T2: Delayed treatment group post-treatment; T3: 1-month follow-up; T4: 3-month follow-up; T5: 6-month follow-up.

Figure 5.1 CONSORT diagram illustrating participant flow in the study.

5.3.2 Instruments

5.3.2.1 Primary Instruments

Depression, Anxiety, and Stress Scales (DASS; [35,36]). This evaluates symptoms of depression, anxiety, and stress over the last 7 days, through 21 items with a 4-point Likert response scale ranging from 0 (not applicable to me at all) to 3 (very applicable to me, or applicable most of the time). Cronbach alpha values obtained in the present sample were: 0.90 for Depression, 0.58 for Anxiety, and 0.80 for Stress.

5.3.2.2 Secondary Instruments

Difficulties in Emotion Regulation Scale (DERS; [37,38]). DERS consists of 28 response items ranging from 1 (Rarely) to 5 (Usually) that assess the levels of emotion dysregulation. Higher values reflect larger difficulties in emotion regulation. In this sample, Cronbach's alpha for the DERS was 0.92.

NEO-Five-Factor Personality Inventory (NEO-FFI; [39]). It assesses the personality dimensions of neuroticism, extraversion, openness to experience, agreeableness, and conscientiousness through 60 items. In this study, only the variables of extraversion and neuroticism were measured. Participants answered a 5-point Likert scale scoring from 0 (Strongly disagree) to 4 (Strongly agree). The internal consistency of the NEO-FFI dimensions ranges between 0.82 and 0.90. Cronbach's alpha values in the present sample were 0.82 for Neuroticism and 0.71 for Extraversion.

Maslach Burnout Inventory (MBI; [40,41]). This measure evaluates through 22 items the dimensions of emotional exhaustion, depersonalization, and personal accomplishment. The participants answered using a 7-point Likert response scale ranging from 0 (Never) to 6 (Every day). Cronbach's alpha for the MBI (emotional exhaustion, depersonalization, and personal accomplishment) in the present sample was 0.91, 0.68 and 0.61, respectively.

Impact of Event Scale-Revised (IES-R; [42,43]). This consists of 22 items assessing the subscales of intrusion and avoidance caused by traumatic events. It uses a 5-point Likert-type response scale ranging from 0 (Never) to 4 (Always). Cronbach's alpha for the IES-R in the present sample was 0.94 for the intrusion subscale and 0.89 for the avoidance subscale.

European Quality of Life (EuroQol; [44,45]). This measure is composed of 5 items that assess the subscales of mobility, self-care, activities of daily living, pain/discomfort, and anxiety/depression through a 5-point Likert scale ranging from 0 (no problem) to 4 (serious problems or inability to do anything). It also includes a visual analog scale (VAS) that assesses the overall health status perceived at the present moment and ranges from 0 (worst imaginable health status) to 100 (best imaginable health status). Cronbach's alpha in the present sample is 0.76. In the present study, only the VAS was used in the analysis.

5.3.3 Procedure

This pilot study was conducted at Hospital Comarcal de Vinaròs (Spain), between April 2021 (pre-training of both groups) and December 2021 (6-month follow-up of the DTG group). This prevention program can be considered as the Hospital's 2nd measure aimed at preventing the development of EDs in this professional sector. This program was implemented to offer a

solution to the needs that were discovered through the first measure offered by the Hospital during the pandemic to the healthcare professionals, an over-the-phone psychological assistance service. Based on Hospital internal data, the main requests for the psychological assistance service were made by nursing and auxiliary nursing staff (74%) and mostly women (85%), all of whom were at the front line of intervention in the course of the pandemic. They were a heterogeneous age group, with no significant differences in age. In the first wave of the pandemic, data from the psychological service reported that the psychological impact of COVID-19 was mainly caused by working conditions (lack of protective equipment, workload, continuous reorganizations, lack of knowledge of the virus disease process, etc.) as well as factors related to infected patients (high mortality rates, contact with suffering and death, etc.).However, in the second wave the psychological demands were represented by fear of repetition of situations and physical and emotional exhaustion.

According to this information, the participants were part of the nursing and auxiliary nursing staff of the hospital. The nursing supervisor provided information about the study to all members of the unit and those interested in participating signed the confidentiality, informed consent and personal data protection documents.

No exclusion criteria were established, and the program was offered to all professionals from the nursing department who wished to participate. Of the 304 workers that were part of the nursing department (including nurses, auxiliary nursing care technicians, and anatomic pathology technicians), a total of 27 workers (8.88%) finally participated in the preventive program. Given that this was a service open to all personnel of the nursing department, no minimum number of participants was established. The inclusion criteria were: (a) to be part of the nursing department staff, (b) to be in active service, (c) to be fluent in the language in which the program will be applied (in this case, Spanish and/or Catalan), and (d) to be able to attend all the evaluation and intervention sessions. Subsequently, the two hospital psychologists sent the pre-program evaluation protocol (with codes assigned to each participant) to the supervisor who distributed them to each participant. After filling them out, the psychologists sent to the supervisor the list of participants with the random assignment (carried out through the Randomizer software by an independent researcher) to each condition of the study, as well as the schedule of sessions for both groups.

A delayed treatment control group design study was carried out to determine the effect of the UP-based prevention program. For this purpose, participants were divided into two conditions: Immediate treatment group (ITG) and Delayed treatment group (DTG).

The Immediate treatment group (ITG), formed by 13 participants, received the program consisting of the UP for the transdiagnostic treatment of EDs adapted to a preventive and brief format, which consisted of five weekly sessions of two hours in duration each.

The delayed treatment group (DTG)/waiting list consisted of 14 participants and received the preventive treatment immediately after the end of the intervention in the ITG.

There were two simultaneous evaluations in both groups, which consisted of pretreatment (T0) and one month later (T1, coinciding with the ITG post-treatment, while the DTG had not initiated the intervention). After these simultaneous evaluations, the DGT received the UP intervention and their post-treatment evaluation was carried out (T2) approximately five weeks after the one carried out by the ITG (this extra evaluation was only carried out in the DTG condition). Once both groups received the UP-preventive program and performed their respective post-treatment evaluations, follow-ups were carried out at 1, 3, and 6 months (T3, T4, and T5, respectively). As participants in the DTG condition received treatment 5 weeks later than participants in the ITG condition, their follow-up evaluations also took place 5 weeks later than the follow-up evaluations conducted in the ITG condition.

As for the preventive program based on the UP, an adaptation of 5 sessions was developed in which the following components were taught in each session: (1) "Analysis of emotional experiences", where work was done on the function of all emotions and the emotional experiences analysis (ARC); (2) "Living the present to facilitate emotional management", where emotional awareness and mindfulness were addressed; (3) "Management of worries, uncertainty and fears: What to do or not to do", in which cognitive flexibility and emotional behaviors vs. alternatives were the focus; (4) "Self-care; how to maintain reinforcing and meaningful activities in pandemic", where values were clarified and pleasant activities were programmed; and (5) "Communication skills", in which participants received training on assertiveness in communication with co-workers and patients.

5.3.4 Data Analysis

First, the sociodemographic data were analyzed through descriptive statistical analyses. Next, analyses of variance were carried out through the ANOVA test for continuous variables, and Chi square tests for categorical variables, with the objective of analyzing if there were differences in the study variables between the ITG and the DTG at baseline. Subsequently, a Student's t-test for related samples was performed to evaluate pre-post treatment differences. And finally, again a difference of means ANOVA was performed to compare the scores between the post-treatment of the ITG and at the same time point with the scores of the DTG (without having received the intervention).

Following this, linear mixed model analyses were carried out with all participants (both ITG and DTG) in order to analyze the evolution of the scores over time. For the

DTG condition, the most recent data before the start of treatment (T1) were included as baseline scores, to equalize the number of evaluation moments in the analyses. Given that the treatment, and the 1, 3 and 6-month follow-up evaluations in the DTG were carried out approximately five weeks later than those of the ITG, the variables "Condition" and the interaction "Condition*Time" were included as control variables within the linear mixed model allowing us to analyze possible differences in the scores depending on whether they were immediate or delayed treatment groups.

Finally, post hoc analyses were carried out for those variables in which a statistically significant interaction effect "Condition*Time" was found, which consisted of replicating the linear mixed model but differentiating between the immediate treatment group and the delayed treatment group to analyze whether there were different evolution trajectories in the scores between groups over time. For all statistical analyses, effect sizes were calculated using Cohen's d statistic, whose estimates are usually interpreted as small ($d \approx 0.2$), medium ($d \approx 0.5$), or large ($d \approx 0.8$). All statistical analyses were carried out using SPSS software [46], p-values below 0.05 were considered statistically significant results, and, given that this was a pilot study and following the recommendations of the literature, a minimum of 10 participants per condition was expected in order to achieve a minimum of 80% statistical power, significance level of 0.05, and medium effect sizes ($0.3 \leq d < 0.7$, [47]). In this study, a total of 13 and 14 participants per arm were obtained, so the minimum recommended values of statistical power would have been achieved. Finally, the participants' satisfaction with the preventive program received was analyzed.

5.4 RESULTS

5.4.1 Sociodemographic outcomes and virus exposure of participants.

The sociodemographic information can be found in Table 5.1. Thirty point eight per cent of the participants in the ITG (n = 4) reported a psychological disorder in the past, specifically: depression (n = 2) and mixed anxiety depressive disorder (n = 2). As for the DTG, 35.7% (n = 5) reported a psychological disorder in the past, specifically: depression (n = 3), work stress (n = 1), and post-traumatic stress disorder (n = 1).

Table 5.1 Baseline socio-demographic characteristics of the sample across treatment conditions (N=27).

	ITG (*n* = 13) *n* (%)	**DTG (*n* = 14) *n* (%)**	**TOTAL (N = 27) *n* (%)**
Marital Status			
Married/living with partner	10 (76.9)	11 (78.6)	21 (77.8)
Single	3 (23.1)	2 (14.3)	5 (18.5)
Widowed	0 (0.0)	1 (7.1)	1 (3.7)
Occupation			
Nurse	6 (46.2)	8 (57.1)	14 (51.9)
Nursing Assistant	7 (53.8)	5 (35.7)	12 (44.4)
Anatomic pathology technician	-	1 (7.1)	1 (3.7)
Hospital Unit			
Internal Medicine B	4 (30.8)	4 (28.6)	8 (29.6)
Internal Medicine A	3 (23.1)	3 (21.4)	6 (22.2)
Covid Surgery	3 (23.1)	0 (0.0)	3 (11.1)
Emergencies	0 (0.0)	2 (14.3)	2 (7.4)
Covid plant	1 (7.7)	0 (0.0)	1 (3.7)
Others	2 (15.4)	5 (35.6)	7 (25.9)
Work experience			
More than 5 years	11 (84.6)	13 (92.9)	24 (88.9)
2-5 years	2 (15.4)	1 (7.1)	3 (11.1)
Virus Exposure (0 “no contact” to 10 “close contact”)			
Less than 8	4 (30.8)	4 (28.6)	8 (29.6)
More than 8	9 (69.2)	10 (71.4)	19 (70.4)
8	3 (23.1)	0 (7.1)	3 (11.1)
9	1 (7.7)	1 (7.1)	2 (7.4)
10	5 (38.5)	9 (64.3)	14 (51.9)
Covid infection			
No	10 (76.9)	12 (85.7)	22 (81.5)
Yes	3 (23.1)	2 (14.3)	5 (18.5)
Severity of Symptoms (0 “no symptoms” to 10 “severe symptoms”)			
0	1 (33.3)	1 (50.0)	2 (40.0)
2	1 (33.3)	1 (50.0)	2 (40.0)
3	1 (33.3)	0 (0.0)	1 (20.0)
Family members infected			
No	8 (61.5)	10 (71.4)	18 (66.7)
Yes	5 (38.5)	4 (28.6)	9 (33.3)

Note: ITG: Immediate treatment group; DTG: Delayed treatment group; Internal Medicine (A, B): group of medical specialty focused on the global treatment of diseases.

5.4.2 Immediate treatment group and Delayed treatment group results

First, the results showed no statistically significant differences in the scores at pre-treatment (T0) between the ITG and DTG ($p > .05$). Similarly, the results of the Chi-square test

showed no statistically significant differences between groups in the sociodemographic data (p> .05).

In terms of pre-post treatment differences (T0-T1), the Student's t-test for related samples showed statistically significant reductions in the ITG after receiving the preventive program for the variables DASS_Stress (t = 2.32, p =.039, *Cohen's d* = -0.48), DASS_Depression (t = 2.59, p =.024, *Cohen's d* = -0.40), and MBI_Personal accomplishment (t = 4.96, p=.036, *Cohen's d* = -0.76). With respect to the DTG, no statistically significant differences were found in any of the variables (p> .05) when comparing T0 and T1 scores (coinciding with the post-treatment evaluation of the ITG, and note that the DTG had not yet received the preventive program).

When comparing scores of the ITG and DTG in T1, statistically significant differences were found in MBI_Emotional Exhaustion (F = 4.66, p =.042) and MBI_Personal accomplishment (F = 4.96, p =.036), with lower scores in ITG. The mean variable scores for each of the groups are shown in Table 5.2.

Table 5.2 Means and standard deviations of the variables over time in the immediate and delayed treatment groups. (N = 27).

			T0 M (SD)	T1 M (SD)	T2 M (SD)	T3 M (SD)	T4 M (SD)	T5 M (SD)
Primary outcomes	DASS_Stress	ITG	6.62 (4.52)	4.54 (3.99)	-	4.77 (4.04)	5.18 (4.79)	4.18 (3.19)
		DTG	7.36 (3.59)	5.42 (2.23)	5.29 (2.09)	5.45 (2.66)	5.17 (2.44)	7.17 (3.19)
	DASS_Anxiety	ITG	4.00 (3.56)	2.15 (1.95)	-	1.85 (2.34)	2.27 (3.90)	1.36 (1.96)
		DTG	3.50 (1.7)	2.92 (2.15)	3.00 (2.83)	2.18 (1.72)	1.83 (2.21)	4.17 (2.86)
	DASS_Depression	ITG	5.85 (5.8)	3.69 (5.02)	-	3.08 (3.57)	4.09 (4.61)	4.27 (4.34)
		DTG	5.00 (4.76)	2.67 (1.92)	4.14 (3.7)	2.70 (2.87)	3.08 (2.31)	3.67 (2.77)
Secondary outcomes	DERS	ITG	58.92 (17.54)	54.23 (18.21)	-	51.54 (15.69)	50.55 (14.47)	49.36 (13.84)
		DTG	56.57 (14.85)	55.75 (11.14)	55.23 (12.06)	49.4 (9.99)	55.27 (15.51)	53.83 (12.08)
	Neuroticism	ITG	21.77 (9.64)	21.46 (8.25)	-	18.17 (8.70)	18.00 (9.19)	18.00 (9.30)
		DTG	21.79 (4.64)	19.00 (5.77)	19.36 (5.53)	19.5 (5.10)	19.5 (5.65)	19.25 (4.96)
	Extraversion	ITG	25.46 (5.09)	26.92 (5.92)	-	28.42 (6.99)	28.9 (5.57)	28.00 (6.45)
		DTG	24.21 (6.96)	25.92 (4.89)	26.00 (6.8)	27.67 (7.78)	26.67 (7.02)	27.08 (6.52)
	MBI_Emotional Exhaustion	ITG	11.00 (9.21)	9.69 (6.97)	-	10.15 (7.36)	11.36 (5.73)	13.45 (9.70)
		DTG	16.00 (11.64)	17.17 (10.17)	16.21 (7.68)	15.3 (8.65)	14.18 (8.81)	17.33 (11.11)
	MBI_Depersonalization	ITG	5.85 (4.24)	5.69 (3.84)	-	5.08 (4.09)	5.45 (5.35)	5.55 (4.18)

	DTG	4.79 (5.18)	5.33 (3.87)	4.57 (3.80)	2.91 (2.39)	3.42 (3.32)	3.92 (4.78)
MBI_Personal accomplishment	ITG	40.92 (4.92)	35.15 (6.57)	-	38.23 (6.37)	40.00 (3.9)	36.82 (5.51)
	DTG	38.79 (5.92)	40.42 (5.07)	38.57 (7.90)	40.6 (4.43)	39.18 (6.6)	37.42 (6.69)
IESR_Intrusion	ITG	23.15 (13.63)	19.85 (13.56)	-	15.33 (13.25)	16.73 (12.64)	14.27 (11.88)
	DTG	18.5 (9.59)	20.33 (9.16)	19.85 (8.22)	18.45 (13.02)	15.42 (8.51)	14.5 (6.97)
IESR_Avoidance	ITG	15.08 (7.58)	13.08 (6.60)	-	11 (6.78)	11.36 (6.87)	9.82 (7.21)
	DTG	11.21 (5.94)	13.75 (6.31)	12.79 (4.12)	10.18 (6.21)	11.58 (5.43)	9.75 (4.65)
EuroQol	ITG	74.23 (18.13)	76.54 (17.37)	-	82.67 (13.61)	79.55 (15.92)	81.36 (16.45)
	DTG	77.86 (7.77)	78.00 (7.51)	83.75 (7.72)	86.36 (5.52)	78.17 (24.48)	78.33 (14.51)

Note: ITG: Immediate treatment group; DTG: Delayed treatment group; T0: Pre-treatment; T1: : Immediate treatment group post-treatment; T3: Delayed treatment group post-treatment; T3: 1-month follow-up; T4: 3=month follow-up; T5: 6-month follow-up; DASS_Stress; DASS_Anxiety and DASS_Depression: Depression, Anxiety and Stress Scales dimensions; DERS: Difficulties in Emotion Regulation Scale; Neuroticism and Extraversion: NEO-Five-Factor Personality Inventory dimensions; MBI_Emotional Exhaustion; MBI_Depersonalization and MBI_Personal accomplishment: Maslach Burnout Inventory dimensions; IESR_Intrusion and IESR_Avoidance: Impact of Event Scale - Revised and EuroQol: European Quality of Life

5.4.3 Results of the brief UP preventive program over time for all participants

Regarding the evolution of the variables over time, and considering all participants who had received the preventive UP (both in ITG and DTG conditions), the results of the linear mixed model can be seen in Table 5.3. A statistically significant effect of time was found, with reductions in the variables Neuroticism (F = 2.58, p = .043, *dof* = 84.78, pre-treatment to 6-month follow-up *Cohen's d* = -0.23), MBI_Personal accomplishment (F = 3.95, p = .005, *dof* = 86.25, pre-treatment to 6-month follow-up *Cohen's d* = -0.65), IESR_Intrusion (F = 4. 91, p = .001, *dof* = 86.28, pre-treatment to 6-month follow-up *Cohen's d* = -0.69) and IESR_Avoidance(F = 4.81, p = .001, *dof* = 87.15, pre-treatment to 6-month follow-up *Cohen's d* = -0.73). Additionally, a statistically significant interaction "Time*Condition" was found in the DASS_Anxiety (F = 3.16, p = .018, *dof* = 90.78).

Table 5.3 Main effects of the linear mixed models

	Time			Condition			Time*Condition		
	F	***p***	***Cohen's d***	***F***	***p***	***Cohen's d***	***F***	***p***	***Cohen's d***
DASS_Stress	1.04	.390	0.41	.02	.895	0.18	1.59	.184	0.50
DASS_Anxiety	1.94	.110	0.56	.38	.541	0.25	**3.16**	**.018**	0.71
DASS_Depression	1.26	.290	0.45	.99	.328	0.40	1.94	.110	0.56
DERS	2.36	.060	0.61	.01	.917	0.04	.97	.425	0.39
Neuroticism	**2.58**	**.043**	0.64	.31	.583	0.22	1.61	.179	0.51
Extraversion	2.09	.089	0.58	.00	.992	0.00	.33	.859	0.23
MBI_Emotional Exhaustion	1.19	.321	0.44	3.03	.093	0.70	.62	.653	0.31
MBI_Depersonalization	.80	.527	0.36	1.70	.204	0.52	.20	.939	0.18
MBI_Personal accomplishment	**3.95**	**.005**	0.80	.52	.476	0.29	1.14	.343	0.43
IESR_Intrusion	**4.91**	**.001**	0.89	.29	.597	0.22	1.26	.290	0.45
IESR_Avoidance	**4.81**	**.001**	0.88	.39	.535	0.25	.10	.983	0.13
EuroQol	1.88	.121	0.55	.43	.520	0.26	.64	.638	0.32

Note: OASIS: DASS_Stress; DASS_Anxiety and DASS_Depression: Depression, Anxiety and Stress Scales dimensions; DERS: Difficulties in Emotion Regulation Scale; Neuroticism and Extraversion: NEO-Five-Factor Personality Inventory dimensions; MBI_Emotional Exhaustion; MBI_Depersonalization and MBI_Personal accomplishment: Maslach Burnout Inventory dimensions; IESR_Intrusion and IESR_Avoidance: Impact of Event Scale - Revised and EuroQol: European Quality of Life; *p*-values <0.05 are shown in bold.

Post hoc analyses carried out for the DASS_Anxiety (see Table 5.4), showed a different evolution trajectory between the groups, finding a statistically significant effect of time on the DTG condition, with an increase in anxiety (F = 3.51, p = .014, *dof* = 45.58, pre-treatment to 6-month follow-up *Cohen's d* = 0.49).

5.4.4 Satisfaction results of the brief UP preventive program

Participants showed high satisfaction scores with the UP prevention program received, with a mean of 8.17 out of 10 (SD = 7.71, range = 6.23-9.15). Regarding the qualitative information collected, 59.26% (n=16) of the participants expressed the need for a greater number of sessions and a longer duration of the program, and 44.44% (n=12), showed their satisfaction with the program reporting: "*I found the program very useful, I would recommend it to anyone, I would sign up again*", "*I really liked it, more things like this should be done*", "*It should be offered periodically to health professionals, not only in pandemics*".

5.5 DISCUSSION

Research has shown that the prevalence of EDs has significantly increased in healthcare workers as a consequence of the COVID-19 pandemic [11–14]. The UP is one of the most effective treatments to address EDs by reducing emotional symptomatology and increasing quality of life in different clinical and nonclinical populations [24–27]. Recent studies have shown preliminary evidence of the UP as a preventive program of EDs in the general population [28,29]. However, to our knowledge, this is the first study to evaluate the UP in professionals of a nursing department exposure to COVID-19. Therefore, the general aim of this study was to investigate the acceptability and effectiveness of a brief five-week UP prevention program group in order to help Spanish nursing professionals cope with stressful situations during the COVID-19 pandemic.

We hypothesized to find statistically significant differences in favor of the ITG (the group who first received the UP-prevention program) compared to the DTG (waiting list) in reducing the severity of stress, anxiety, and depression, as well as other related variables such as the impact of stressful situations, burnout, difficulties in emotion regulation, and emotional personality dimensions. In addition to reducing psychopathology, we also expected that the ITG would be superior to the DTG at increasing quality of life in the Spanish nursing workers. Another hypothesis proposed was that once both groups had received the preventative program, the results obtained after the application of the UP will be maintained at one-, three-, and six-month follow-ups.

Regarding the results of our study, first, it is important to highlight that between 15.4% and 21.4% of the nursing workers interviewed for the study reported having at least one ED at baseline, and around 70% of the participants had experienced high COVID-19 exposure at work. Another important issue is that, although the study was open to any nursing worker of the hospital, 100% of the study sample were women. These findings correspond with data of a previous study with similar populations [11–14] and suggest the need to develop programs to reduce EDs in this vulnerable population.

With respect to the findings in the ITG and DTG before and after the treatment (before the DTG had received the program), reductions in anxiety, depression, as well as personal accomplishment were found in ITG but not in DTG. Similar outcomes of other UP preventive programs in reducing depression and anxiety symptoms for adolescents and college students [27,30] have been found. Moreover, although there is little published literature on the effectiveness of psychological interventions for this specific population, several quasi-experimental studies show that programs focused on coping with stress and improving resilience in healthcare professionals during the COVID-19 crisis encountered pre-post

improvements in perceived stress and burnout and were identified as potentially suitable and useful for improving psychological functioning [32,33]. However, although improvements were found in depression and anxiety in our study, a possible explanation for the decrease in the facet of burnout of personal accomplishment (i.e., feelings of competence and successful achievement in our work [40, 41]) after treatment may have to do with a peak increase in COVID-19 in one of the waves, where the pressure of assistance was highest and personal accomplishment could have been difficult to maintain.

Regarding the evolution of the study variables over time, and considering all participants who had received the preventive UP (both in ITG and DTG conditions), a statistically significant effect of time was found to result in reductions in neuroticism and personal accomplishment with medium to large effect sizes. In addition, a significant improvement was found in subjective distress caused by traumatic events (e.g., COVID-19), as measured by intrusion (i.e., nightmares, visual images of the trauma, intrusive thoughts about the traumatic event) and avoidance (i.e., deliberate efforts to not talk about the event, not think about the event, and to avoid reminders of the event) subscales of the IES-R [17,18]. This last finding is interesting as symptoms of post-traumatic stress disorder have been identified as a common symptom directly caused by COVID-19 exposure in healthcare professionals, and the urgent need to develop programs to address this problem has been suggested [48]. To our knowledge, there are no studies that have investigated the effectiveness of the UP to decrease symptoms of post-traumatic stress during COVID-19, and these results show that only by applying a brief UP preventive program was a significant reduction in these severe and disabling symptoms achieved. Regarding other psychological interventions to reduce PTSD symptoms due to COVID-19 experiences, a systematic review found that the most feasible and effective treatment program for healthcare professionals with PTSD is still unclear; however, cognitive behavior therapy and mindfulness-based interventions have shown the most significant effects based on current limited evidence [34].

In addition to these results, post hoc analyses showed a different evolution trajectory between ITG and DTG, finding a statistically significant effect of time on the DTG condition in increasing anxiety over time. If we analyze the results by time points, we can observe that this significant difference becomes much worse at T5, coinciding with the Christmas COVID-19 wave peak. A future research direction would be to conduct longitudinal studies and consider contextual factors (such as peaks of COVID-19) that may influence outcomes of preventive interventions.

On the other hand, contrary to our hypothesis, we did not find significant between group differences in quality of life and emotional regulation over time. Although there was a tendency to increase after treatment, the improvements were not maintained long-term. This is surprising as previous studies of the UP in other populations have shown improvements in both variables

over time [24, 26, 27]. Perhaps this might be due, as suggested by participants, to the brief intervention received and/or to the contents we chose to be included in the program. In this sense, we included the contents of the original UP module numbers 2, 3, 4, and 5 and added two new skills: pleasant activities and assertiveness training, both relevant to enhance stress coping during the pandemic situation. We did not include UP modules 1 (setting goals and maintaining motivation), 6 (understanding and confronting physical sensations), 7 (emotion exposures), and 8 (recognizing accomplishments and looking to the future), because of the nonclinical nature of the participants. It is possible that the other modules and components might have different results in quality of life and emotional regulation variables. Future studies may focus on developing different programs or replicating the one described in the present study to test their effectiveness at improving these specific variables.

A final hypothesis is that the study sample will report high acceptability of the UP prevention program received. Findings showed high satisfaction scores with the UP prevention program received, nonetheless, participants suggested the need to increase the number of sessions and the duration of the program. Another interesting outcome is that no drop-outs happened during the intervention. This was the first evidence-based preventive program conducted at the hospital for workers of the nursing department; therefore, the results of acceptability are promising given the brevity of the program.

Despite these promising findings in reducing emotional symptoms, this study has some limitations. First, all participants were women. This could be explained by the fact that most nurses (84.1% of certificated nurses in Spain in 2020) are women [49]. However, it may be important to replicate these results in men. Secondly, the size of the sample was small. Future studies should conduct RCTs with a bigger sample. In addition to this, some of the measures used in this study have shown Cronbach's alpha values below the recommended values (values below 0.70, [50]), specifically in the anxiety subscale of the DASS (Cronbach's alpha 0.58) and the Depersonalization and Personal accomplishment subscales of the MBI (Cronbach's alpha 0.68 and 0.61,respectively). These sub-dimensions were the ones that presented the lowest Cronbach's alpha indices in the validations (i.e., in the Spanish validation of this instrument, the Anxiety sub-dimension also presented the lowest value with a Cronbach's alpha of 0.70 [36], or the Personal accomplishment in the original validation of the MBI showed a Cronbach's alpha of 0.71 [40]). In addition, the number of observations in this study (n = 27) perhaps has a decisive influence on these low scores, so the results of these instruments should be considered with caution. Finally, given that there were changes in the pressure of assistance during the different waves of COVID-19, a limitation of this study was not to control for this contextual variable. As previously suggested, this may be a future research direction.

5.6 CONCLUSIONS

The results of this study show statistically significant reductions over time in neuroticism and subjective distress caused by traumatic events for all the female workers of the nursing department who received the UP-prevention program with medium to large effect sizes. A statistically significant interaction of time by condition was found in symptoms of anxiety, with greater anxiety in the DTG, which may be due to the changes in care pressure during the different waves of COVID-19. In addition, 100% of participants finished the program and showed high satisfaction with the UP received, highlighting the need to increase the number of sessions and the duration of the program. In conclusion, these findings suggest good acceptability and preliminary effectiveness of the UP to improve emotional symptomatology in female nursing professionals. Studying contextual factors such as the increases in pressure of assistance during COVID-19 waves for future longitudinal studies may be useful to determine the impact of the prevention programs.

Author Contributions

Conceptualization, V.F-G., and J.O.; methodology, V.F.-G, M.N-H., O.P., and J.O.; formal analysis, O.P.; investigation, V.F-G., J.D-H., J.O.; resources, V.F-G. and J.D-H.; data curation, O.P. and S.G-M.; writing—original draft preparation, M.N-H., V.F-G., O.P.; writing—review and editing, J.O., J.D-H..; supervision, J.O. and J.D-H.; project administration, J.O.; funding acquisition, J.O. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee (CEIm) of the Hospital General Universitario de Castelló (6/2021, 04-26-2021) for studies involving humans.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

Not applicable.

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Conflicts of Interest

The authors declare no conflicts of interest.

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CAPÍTULO VI: "IS THE UNIFIED PROTOCOL FOR TRANSDIAGNOSTIC TREATMENT OF EMOTIONAL DISORDERS EQUALLY EFFECTIVE FOR MEN AND WOMEN?"

Este capítulo incluye un manuscrito de la tesis doctoral, que aunque todavía no ha sido publicado, se encuentra en proceso de evaluación

Ferreres-Galan, V., Peris-Baquero, O., Moreno, J.D. & Osma, J. (2023). Is the Unified Protocol for transdiagnostic treatment of emotional disorders equally effective for men and women? (enviado)

Journal of Psychiatric Research

CAPÍTULO VII: DISCUSIÓN GENERAL Y CONCLUSIONES

7.1 DISCUSIÓN

La atención a la SM es un desafío para la Sanidad. Como ya se ha descrito, los TEs (los trastornos más prevalentes a nivel mundial) copan el SNS y ni existen medios ni recursos para poder atenderlos adecuadamente. Son numerosas las publicaciones al respecto y numerosas las políticas sanitarias dirigidas a poder abordar dicha problemática, sobre todo tras la pandemia por COVID-19. Los/Las psicólogos/as clínicos/as, desde los diferentes recursos sanitarios públicos donde ejercemos nuestra práctica clínica, luchamos por poder atender a la demanda existente ofreciendo intervenciones coste-efectivas, coste-eficientes y versátiles para poder aplicarlas en nuestro entorno "limitado". En tal contexto, resulta vital poder disponer de intervenciones que puedan responder a la demanda asistencial y sean aplicables para nosotros, los y las especialistas en psicología clínica. El PU responde a dicha necesidad porque: 1) está dirigido a tratar los TEs, los más prevalentes a nivel mundial; 2) permite su aplicación en un formato coste-efectivo como es el grupal, 3) es un tratamiento basado en la evidencia; y 4) es versátil y permite adaptarse a diferentes contextos y circunstancias (Osma et al, 2022).

El presente trabajo doctoral pretende aportar evidencia científica en la misma línea que la ya publicada sobre la utilidad y efectividad del PU, en concreto en mujeres atendidas en una USM del SNS. A partir del compendio de publicaciones que comprenden esta tesis, queremos reflejar, destacar y discutir sobre varias cuestiones que han ido surgiendo y que resultan imprescindibles, a nuestro parecer, si queremos mejorar las intervenciones psicológicas que desde el SNS realizamos. Estas cuestiones se agrupan en tres unidades temáticas: a) la accesibilidad a los tratamientos psicológicos y que éstos sean tratamientos psicológicos basados en la evidencia (TPBE); b) la coste-efectividad y coste-eficiencia de las intervenciones que desde el sistema público puedan ofrecerse; y c) la personalización de las intervenciones para poder atender a todas las demandas asistenciales. A continuación, profundizaremos en estas cuestiones.

7.1.1 Accesibilidad a los Tratamientos Psicológicos Basados en la Evidencia

El derecho de cualquier ciudadano/a que lo necesite a recibir tratamiento psicológico especializado en la sanidad pública viene amparado en el artículo 43 de la Constitución Española y el Real Decreto 1030/2006, de 15 de septiembre (Prado et al, 2019). Y no sólo eso, como ya hemos mencionado en la introducción del presente trabajo, el tratamiento que debe ofrecerse desde el SNS debe contar con aval científico, es decir, las intervenciones que se ofrecen deben estar basadas en la evidencia (Secretaría Autonómica de Salud Mental, 2023). En

su artículo 18, el Código Deontológico del Psicólogo determina que los/as psicólogos/as no utilizarán medios o procedimientos que no se hallen suficientemente contrastados (Consejo General de Colegios Oficiales de Psicólogos, 2015), y más concretamente, en el artículo 17 del mismo, se establece el deber de los/as profesionales a estar actualizados en su competencia profesional (Consejo General de Colegios Oficiales de Psicólogos, 2015). El objetivo de tales artículos no es más que velar porque las intervenciones sean efectivas para la población. Pero de nuevo la realidad nos muestras que esta necesaria actualización de conocimientos de los y las profesionales sanitarios/as se ve dificultada por la imposibilidad de poder formarse en la intervención de todas y cada uno de los síndromes clínicos descritos en los manuales. Los/Las profesionales no pueden especializarse dado el gran número de trastornos descritos, y la gran proliferación de tratamientos específicos para cada uno de ellos.

Así pues, el SNS debería estar dotado de suficientes profesionales para atender a las demandas asistenciales y, además, los/as profesionales deben estar formados en intervenciones de demostrada evidencia científica. Sin embargo, el mapa asistencial actual nos muestra la incapacidad del sistema para atender a estos "derechos" asistenciales. La demanda de intervención en patologías comunes como los TEs es cada vez mayor, y los recursos son claramente insuficientes. El presente trabajo pretende ofrecer opciones para poder atender a dicha necesidad asistencial. Los artículos presentados en esta tesis responden a esta problemática, ofrecer un TPBE factible desde el SNS que pueda llegar a atender a una de las principales demandas de asistencia en cuanto a SM: mujeres con TEs o en riesgo de sufrirlos. Así pues:

1. La intervención basada en el PU cuenta con evidencia suficiente para poder englobarse dentro de los TPBE, pues contamos ya con más de una decena de ensayos clínicos aleatorizados (ECA) publicados sobre la eficacia del PU en los TEs (Carlucci et al., 2021; Cassielo et al., 2020; Osma et al, 2019; Sakiris et al., 2019)
2. El PU cuenta con datos sobre su viabilidad para ser aplicado en el SNS, lo que permite que todos los pacientes con TEs puedan beneficiarse de una intervención basada en la evidencia aplicada por un psicólogo o psicóloga clínico/a del SNS (Osma et al, 2022).
3. El enfoque transdiagnóstico del PU permite vencer la barrera asociada al hecho que los y las profesionales tengan que estar formados en los diferentes protocolos descritos para cada una de las patologías mentales descritas (Wilamowska et al., 2010). Con una única formación los y las especialistas en psicología clínica pueden intervenir sobra los trastornos más prevalentes en las USM, los TEs y atender y permitir el acceso a un TPBE a todo/a ciudadano/a que lo necesite.

4. El PU es una intervención versátil que permite adaptarse a distintos contextos no sanitarios, como clínicas universitarias (Barlow et al., 2017; Socias-Soler et al., 2022), y a nivel preventivo (García-Escalera et al., 2019; Martínez-Borba et al., 2022).

Nuestro trabajo se une a la evidencia publicada en esta línea. Hemos trabajado en la adaptación del PU a diferentes condiciones y circunstancias de la práctica clínica habitual del entorno de la USM en la que trabajo, con el objetivo de facilitar el acceso a TPBE a toda la sociedad y en diferentes circunstancias acontecidas. Nuestros estudios han versado sobre la aplicación del tratamiento basado en el PU en mujeres con TEs o sintomatología emocional; en contextos sanitarios y no sanitarios; y a nivel clínico y también preventivo.

Cabe destacar en cuanto a la accesibilidad la propuesta de hacer llegar las intervenciones psicológicas incluso a entornos no sanitarios, como el contexto social, ya que es bien conocido el hecho que el estigma sobre la salud mental es mayor en entornos sanitarios que en comunitarios (Muñoz, 2009). En este sentido, uno de los artículos presentados estudia la utilidad y viabilidad de implementar un tratamiento psicológico para TEs en mujeres que han sido víctimas de violencia intrafamiliar. Para facilitar el acceso al mismo, la intervención se hace en un contexto social, favorecido por un trabajo en red e interdisciplinar, lo cual es esencial también si se quiere favorecer atender a la población con patología mental atendiendo a las necesidades sociales actuales. En el contexto de la violencia intrafamiliar, estudios como el de Bradley et al. (2002), ponen de manifiesto que las mujeres que sufren este tipo de violencia no suelen comunicarlo en el entorno sanitario, y dada la elevada comorbilidad de la patología emocional en esta situación, se hace imprescindible poder valorar cómo poder atender los TEs en esta población. Y en este sentido, podemos concluir que el PU es una intervención clínicamente útil y viable para poder atender a este sector de población y mejorar sus recursos emocionales (Osma et al, 2019).

Para atender a la necesidad asistencial y cubrir el derecho de todo ciudadano/a a un TPBE, necesitamos contar con tratamientos de eficacia demostrada que tenga la posibilidad de poder ser aplicados en el SNS por los y las profesionales que lo componen, y que éstos puedan tener la formación que así lo requiera. El PU responde a esta necesidad y permite facilitar el acceso de cualquier ciudadano/a con TEs a recibir un TPBE.

7.1.2 Coste-efectividad/eficiencia de los tratamientos psicológicos para el SNS

Tanto la eficacia como la eficiencia son variables muy relevantes para la mejora y diseminación de los TPBE en el SNS (el PU entre ellos). Como plantea Perez-Alvarez et al. (2003), la eficacia supone que el tratamiento planteado tiene la capacidad de producir mejoras significativas en la dirección esperada y que sea claramente superior a la no intervención o a otras intervenciones. La eficiencia, por su parte, consiste en ofrecer tratamientos psicológicos al menor coste, manteniendo su eficacia, variable imprescindible si queremos optimizar la asistencia sanitaria desde el SNS. Vamos a detenernos en estos aspectos cruciales.

Los servicios de Salud Mental del SNS se encuentran desbordados por la elevada prevalencia de TEs, sobretodo en mujeres (OMS, 2022), y por la falta de recursos a todos los niveles (Riuz-Rodriguez et al, 2017). Esta es una realidad ya reflejada a lo largo del presente trabajo. Por eso, necesitamos poder aplicar formatos y enfoques de intervención costo-efectivos y coste-eficientes a través de:

- **Formato grupal:** La elevada demanda asistencial en la salud mental del SNS genera largas listas de espera e imposibilita poder dedicar el tiempo necesario al tratamiento que necesitan las personas que solicitan atención psicológica. Es por ello por lo que se hace necesario buscar formatos de intervención que permitan poder rentabilizar el tiempo que se dispone en consulta. Osma et al. (2019) realizaron un estudio en el que analizaron las preferencias de intervención en las USM del SNS por parte de pacientes con diagnóstico de TE y los datos concluyeron que la mayoría de los/as pacientes prefieren el formato de intervención individual (85,4%) frente al formato grupal o terapia online. Sin embargo, sabemos que esta intervención no es coste-efectiva si se compara con la intervención grupal (Norton, 2012) y se hace necesario poder instaurar formatos de intervención más coste-efectivos y costo-eficientes si queremos facilitar la disponibilidad de TPBE a todos los/as pacientes que así lo necesiten.

  El PU, dada su versatilidad, es una intervención que se puede aplicar en formato grupal y contamos con estudios que concluyen que este formato de intervención es eficaz y viable en nuestro SNS (Osma et al., 2022) y además eficiente (Peris et al., 2022).Además, el PU en formato grupal ha obtenido buenos resultados de aceptabilidad (Peris et al., 2022) y satisfacción (Osma et al., 2021). Por todo ello, el presente trabajo presenta varios estudios en los que se ha optado por utilizar el PU en formato grupal.

- **Enfoque transdiagnóstico:** Aplicar tratamientos específicos para cada uno de los TEs existentes supone un problema para su aplicación en el SNS. Pese a su eficacia, resulta poco eficiente. El enfoque transdiagnóstico permite aumentar la coste-eficiencia, al permitir implementar el mismo tratamiento a personas con diferente diagnóstico, pero centrándose en los mecanismos comunes de vulnerabilidad (Newby et al., 2015).Esta es la razón por la que, los diferentes estudios que hemos llevado a cabo y que forman parte de esta tesis, han utilizado el PU como intervención psicológica. Utilizar el PU supone, además de aumentar la eficacia, aumentar la eficiencia de la intervención (Norton, 2012) ya que se aborda de forma unificada tanto la sintomatología anímica como la ansiosa y relacionada, lo que supone poder atender con un mismo formato a mayor número de pacientes. Estudios recientes como el de Peris et al. (2022) han puesto de manifiesto la costo-efectividad y coste-eficiencia del PU en nuestro SNS. En su estudio se compara el tratamiento habitual administrado en las USM públicas en formato individual con el PU en formato grupal y se realiza un seguimiento a los 12 meses tras la intervención. Sus resultados muestran que ambos tratamientos consiguen mejoras clínicamente significativas, pero los/as pacientes de la condición de PU, en el mismo periodo temporal, reciben un mayor número de sesiones con menor coste y además consiguen reducciones en el tratamiento farmacológico.

  Recordamos que la intervención grupal y transdagnóstica resulta eficiente para el SNS dado que no es necesario esperar a contar con un número homogéneo de personas en cuanto a su diagnóstico clínico. El PU en formato grupal permite crear grupos de pacientes con TEs con mayor rapidez, reduciendo así las listas de espera.

- **Formato breve e intensivo:** Dado el contexto limitado de recursos tanto humanos como temporales, el hecho de poder aplicar intervenciones breves e intensivas se convierte en una necesidad asistencial.

  Contamos con varios estudios que evidencian la eficacia de aplicar el PU en formato grupal en 12 sesiones de frecuencia semanal (Bullis et al., 2015; Osma et al., 2018; Peris et al., 2022). Así, el PU nos ofrece la posibilidad de hacer una intervención con estas características: eficaz, eficiente, breve e intensiva.

- **Versátil y adaptable:** Las intervenciones disponibles en la cartera de servicios de salud mental tienen que ser versátiles y flexibles si queremos poder atender a toda la población con necesidad de asistencia psicológica y que las intervenciones sean accesibles para todas y cada una de las condiciones que existan. Siguiendo con el análisis de las necesidades asistenciales y la utilidad del PU para atender a dicha necesidad, hemos planteado diferentes condiciones médicas y características sociales

que requieren asistencia psicológica y para las que el PU nos ha resultado viable y útil. Los TEs como ya hemos comentado, son muy prevalentes en la población general, y la sintomatología emocional en general se puede presentar de forma más prevalente aún en determinadas poblaciones, contextos y circunstancias: mujeres, víctimas de violencia, personal sanitario en situaciones de crisis sanitaria o condiciones médicas como la cirugía bariátrica. Así, el PU es un formato de tratamiento que además de las características previas ya descritas, es factible y permite adaptarlo a diferentes circunstancias y condiciones, por lo que resulta una herramienta de gran utilidad para el contexto público de salud mental.

Queremos destacar en este punto uno de los artículos donde se presenta el trabajo realizado en un contexto muy concreto: personal sanitario en pandemia. La eficacia demostrada a nivel preventivo del PU (Bentley et al., 2018; Martínez-Borba et al., 2022), y teniendo en cuenta el objetivo de buscar tratamientos costo-eficientes, ha favorecido la aplicación del PU en este contexto. Diferentes estudios concluyen que trabajar en primera línea durante la crisis sanitaria por COVID-19 (Bohlken et al., 2020; Kisely et al., 2020; Vindegaard y Benros 2020) así como ser profesional sanitario y de género femenino se asocia a mayor afectación emocional (Huang et al., 2020; Lai et al., 2020; Luo et al., 2020). En la Comunidad Valenciana, en uno de los primeros trabajos que evalúa el impacto emocional de la COVID-19 en 228 profesionales sanitarios/as se concluye que existen síntomas emocionales en el personal sanitario evaluado, sobre todo mujeres por lo que resultaría valioso poder incluir intervenciones para el fortalecimiento y optimización de estrategias de regulación interna (Cabedo et al., 2022). En el contexto particular del Hospital en el que yo trabajo, se solicitó al servicio de Psicología Clínica poder hacer esta intervención, dada la sobrecarga y agotamiento emocional detectada en el personal sanitario. Optamos por hacer una adaptación del PU a nivel preventivo (basándonos en los estudios de aplicación de PU a nivel preventivo ya existentes y con buenos resultados) y de nuestra experiencia se concluye que la intervención fue aceptable y efectiva para reducir el impacto emocional de la pandemia en las trabajadoras de enfermería. Esto trabajo aporta evidencia a favor de la importancia de hacer intervenciones que pueden resultar coste-efectiva y también coste-eficientes para el SNS, pues trabajar a nivel preventivo con el personal sanitario puede suponer evitar el desarrollo o instauración de TEs en el personal sanitario y favorecer así el trabajo de los profesionales sanitarios del sistema.

El tratamiento basado en el PU responde a la necesidad asistencial del SNS por ser un tratamiento que: a) facilita la intervención sobre los trastornos psicológicos más prevalentes, permitiendo así el acceso a gran parte de la población que se ve afectada por dichos trastornos; b) es cose-efectivo y coste-eficiente; c) es una intervención breve e intensiva, lo que permite optimizar la posibilidad de intervención; y d) es versátil y permite adaptaciones a diferentes contextos y circunstancias sobre las que es necesario intervenir.

7.1.3 Personalización de los tratamientos psicológicos basados en la evidencia

EL SNS ofrece una intervención universal, pero la heterogeneidad de la población y las circunstancias cambiantes obliga al sistema a ofrecer intervenciones flexibles y adaptables, que puedan atender a las particularidades que se presenten. A una USM pública llegan interconsultas de otros compañeros/as sanitarios/as de Atención Primaria o Especializada, así como de otros recursos asistenciales con los que se trabaja en red, ya que el abordaje de las patologías de salud mental tiene que ser multidisciplinar (educación, servicios sociales…). Además, en condiciones de crisis sanitaria como la acontecida tras la pandemia por COVID-19 de 2020, los y las especialistas en psicología clínica del SNS tuvimos que atender a diferentes condiciones extraordinarias, ya que las necesidades sanitarias supusieron una "herida emocional" importante para los/as profesionales de primera línea de asistencia durante la crisis (Bohlken et al., 2020; Kisely et al., 2020; Vindegaard y Benros 2020). En este contexto y en estas circunstancias, el trabajo doctoral presentado ha ido enfocado a poder atender a estas particularidades y poder adaptar las intervenciones que se pueden ofrecer desde el SNS, teniendo en cuenta poder aplicar TPBE, eficaces y efectivos.

El conjunto de artículos que forman parte de esta tesis doctoral refleja la posibilidad de personalizar los contenidos y ejercicios que incluye el PU a cada una de las circunstancias particulares de los y las participantes en los estudios, desde la adaptación del PU a mujeres víctimas de maltrato (donde se adaptó el trabajo cognitivo del módulo de la flexibilización cognitiva, al que le dedicamos 3 sesiones, ya que las participantes habían estado sometidas a situaciones de gran invisibilización e invalidación que habían condicionado sus interpretaciones cognitivas) a la realizada para trabajar con personas con problemas de obesidad que son candidatas a cirugía bariátrica o la han recibido (donde la principal adaptación se realizó en los

módulos de la flexibilización cognitiva y las conductas emocionales, otorgando especial relevancia al concepto de comer emocional y la relación entre la ingesta y las emociones).

Las personas en espera de recibir la intervención de cirugía bariátrica, presentan porcentajes mayores de TEs que la población general así como trastornos relacionados con la alimentación (Hudson et al., 2007). Aunque la cirugía parece un tratamiento eficaz para abordar la obesidad (Marek et al., 2016), la pérdida de peso inicial no se mantiene a los largo del tiempo para todos los pacientes (Colles et al., 2008) y aunque existen varias causas implicadas en este proceso, parece que los factores emocionales juegan un importante papel, ya que los pacientes sometidos a cirugía bariátrica presentan de forma más prevalente trastornos ansiosos y depresivos, así como trastorno por atracón (Dawes et al., 2016). Así, se plantea que una intervención centrada en tratar la regulación emocional de estos/as pacientes podría generar una mejora a nivel emocional y permitir de este modo aumentar el éxito de la intervención quirúrgica.

En línea con el interés actual por la posible utilidad clínica del PU en el tratamiento de los TEs comórbidos a distintas condiciones médicas, como en casos de dolor crónico (Payne, 2018) o pacientes con VIH (González-Baeza et al., 2023; Parsons et al., 2017), surge el planteamiento de estudiar la posible adaptabilidad del PU en el contexto de la cirugía bariátrica. Aquí se han presentado 2 estudios relacionados: uno donde se presenta el estudio piloto de la aplicación del PU de pacientes en el circuito de la cirugía, y otro estudio en el que se presentan los resultados de una intervención grupal basada en PU aplicada a pacientes que han sido sometidas a la intervención. Estos trabajos nos permiten confirmar la versatilidad del PU para ser aplicado en esta condición médica, lo que permite de este modo poder hacer intervenciones personalizadas en condiciones médicas específicas, en las que las intervenciones psicológicas parecen imprescindibles si queremos abordar el bienestar general de la población.

A destacar en este momento también, analizando la necesidad de hacer intervenciones personalizadas según las necesidades asistenciales que, de forma consistente con la literatura publicada al respecto, la población diana que ha acudido al servicio sanitario por sintomatología emocional ha sido predominantemente de género femenino. Esta realidad clínica nos hizo plantear si es necesario personalizar más las intervenciones y tener en cuenta las diferencias de género a la hora de implementarlas. Por eso nos resultó de interés poder analizar, siguiendo en la línea de estudiar la viabilidad de las intervenciones basadas en PU en el SNS y la personalización de tratamientos, si el PU es igual de efectivo para ambos géneros. El estudio que se presenta en este trabajo describe los resultados del análisis diferencial según la variable sexo de aplicar el PU en una muestra de 277 pacientes (217 mujeres y 60 hombres) y los resultados concluyen que no es necesario personalizar los tratamientos en función del género. Este resultado es de vital importancia, ya que permite concluir que el PU es efectivo para toda la

población, independientemente del género, hecho que facilita las intervenciones desde el SNS, al permitir ofrecer el tratamiento a todos y todas los/as pacientes sin necesidad de adaptaciones que pueden suponer una mayor demanda de recursos.

El presente trabajo se une a la literatura ya publicada sobre la versatilidad del tratamiento basado en el PU para poder ofrecer tratamientos personalizados atendiendo a las necesidades asistenciales.

7.2 LIMITACIONES

El presente compendio de estudios no está exento de limitaciones.

En líneas generales, es destacable el hecho que, en un SNS colapsado y carente de recursos, compaginar la labor asistencial con la investigación se convierte en una tarea tremendamente complicada. Los/Las psicólogos/as clínicos/as del SNS contamos con pocos recursos, poco tiempo y pocas oportunidades para poder dedicarnos a la investigación, ya que la práctica clínica acapara la totalidad de nuestra actividad laboral. A su vez, sabemos de la necesidad de invertir tiempo y esfuerzo en la investigación si queremos optimizar la asistencia que realizamos. Esta limitación es un hándicap que solucionar y el presente trabajo se uno a otros encaminados a abordar esta problemática.

En la reciente Estrategia de Salud Mental del Sistema Nacional de Salud, periodo 2022-2026 (Ministerio de Sanidad, 2022) se especifica como una de las líneas estratégicas la investigación, innovación y conocimiento y concreta que: “La investigación debe constituir un elemento central del quehacer del sistema sanitario”. Esta línea refleja claramente la importancia de incluir la investigación en la práctica clínica. El problema es cómo llevarlo a cabo. En la siguiente tabla se detallan los objetivos elaborados para tal propósito:

Tabla 7.1 Línea estratégica 10. Adaptada de la Estrategia de Salud Mental del Sistema Nacional de Salud, periodo 2022-2026 (Ministerio de Sanidad, 2022).

LÍNEA ESTRATÉGICA 10: INVESTIGACIÓN, INNOVACIÓN Y CONOCIMIENTO	10.1 Objetivo general 1: Impulsar la investigación en todos los ámbitos relacionados con la Salud Mental. 10.2 Objetivo general 2: Establecer líneas de investigación interdisciplinarias en Salud Mental. 10.3 Objetivo general 3: Incorporar la perspectiva de género en todas las líneas de investigación. 10.4 Objetivo general 4: Desarrollar investigaciones sobre los factores socio-familiares de las personas con problemas de Salud Mental. 10.5 Objetivo general 5: Potenciar el uso de las tecnologías de la información en el ámbito asistencial de atención a la Salud Mental en relación con la futura Estrategia de Salud Digital del Sistema Nacional de Salud

El equipo de investigación IPES del Instituto de Investigación Sanitaria de Aragón, cuyo investigador principal es Jorge Osma, y al que pertenezco, hemos centrado nuestra labor investigadora en adaptar el PU en formatos costo-efectivos para las USM del SNS, y fruto de este trabajo conjunto entre clínicos e investigadores intentamos abordar esta limitación asistencial. Son varios los trabajos que se han ido presentando a lo largo de este documento sobre cómo orientar las intervenciones para que resulten más coste-eficientes para el SNS y los artículos presentados aquí cumplen el mismo objetivo.

De modo más concreto, a continuación, se detallan las limitaciones generales encontradas en los diferentes trabajos presentados:

- Una de ellas es que los estudios se han llevado a cabo en un contexto específico, como son las USM del SNS. Esta especificidad implica que los resultados no se pueden generalizar a otros contextos clínicos o comunitarios.
- En la mayoría de los estudios publicados donde se ha adaptado el PU las muestras son pequeñas, por lo que tampoco podemos generalizar los resultados. Además, las

muestras de estos 3 estudios están compuestas exclusivamente por mujeres, y no podemos generalizar los resultados a hombres.

- Las intervenciones que se han propuesto se basan en un formato grupal, lo que excluye a aquellas personas que optan por una intervención individual y rechazan la participación grupal. Esto puede sesgar los resultados.
- Las adaptaciones que se han realizado han podido influenciar en los resultados y mermar la efectividad el PU si se aplica de forma convencional aplicando todos los módulos y sesiones de los mismos.
- Mención especial sobre la que reflexionar, dada la relevancia en la tesis de esta variable, son las diferencias de género. Hemos mencionado la mayor prevalencia de los TEs en mujeres (OMS, 2022; Sáenz Herrero, 2019). También que hay líneas de investigación actuales que analizan esas diferencias y consideran que hay variables relacionadas con dichas diferencias que no se han tenido en cuenta, y que habría que estudiar la morbilidad femenina diferencial (Llobet et al., 2008). En cuanto a limitaciones, podríamos decir que nosotros tampoco hemos tenido en cuenta este enfoque en nuestros estudios y hemos analizado datos de prevalencia sin tener en cuenta dicha morbilidad diferencial. Como señala Valls-Llobet (2020) en su libro "Mujeres invisibles para la medicina" es necesario avanzar en el conocimiento sobre la morbilidad diferencial y sobre los factores de riesgo que determinan las desigualdades de género, y no quedarnos con un enfoque reduccionista.

7.3 IMPLICACIONES PARA FUTURAS INVESTIGACIONES, POLÍTICAS DE SALUD Y PRÁCTICA

7.3.1 Situación actual en investigación sobre la eficacia del Protocolo Unificado en el SNS

Hasta el momento contamos con tres revisiones sistemáticas, dos de ellas meta-análisis (Carlucci et al, 2021; Cassiello-Robbins et al., 2020; Sakiris et al., 2019) así como libros y manuales en castellano (Fonseca-Pedreira 2021; Osma, 2019) que describen la viabilidad, eficacia y efectividad del PU para intervenir sobre los TEs. Además de en nuestro país, a nivel internacional, diferentes equipos investigan sobre la eficacia del PU en los síntomas de salud públicos (Dinamarca, Canadá, Brasil, Japón y Portugal). En España, el equipo de investigación al que pertenezco (IPES) ha centrado su labor investigadora en adaptar el PU en formatos costo-efectivos para las USM del SNS.

7.3.2 Líneas presentes y futuras en desarrollo

7.3.2.1 Protocolo Unificado en Atención Primaria.

Como hemos comentado en la introducción, en el reciente Plan de Acción Valenciano de Salud Mental se especifica como objetivo no sólo mejorar las ratios en atención psiquiátrica, sino también en atención primaria (AP) (Comisionado de la Presidencia de la Generalitat para el Plan Valenciano de Acción para la Salud Mental, Drogodependencias y Conductas Adictivas, 2023).

La AP es la puerta de entrada al SNS español, por lo que es fundamental que la detección y derivación en este primer nivel asistencial se realice adecuadamente (Lobo et al., 2006), para evitar sobrecarga asistencial en AP y en SM Especializada.

En este panorama asistencial, y siguiendo con el objetivo de mejorar la asistencia sanitaria desde el SNS se ha desarrollado toda una línea de investigación en base a la posible utilidad del PU para ser aplicado desde AP. Así, el PU ya se ha aplicado en España en los servicios de AP en un formato de 8 sesiones grupales, de una hora y media y de manera semanal. En el estudio participaron 102 personas con TE y se obtuvieron resultados prometedores con reducciones en la sintomatología emocional siendo superiores a la condición de tratamiento habitual (medicación) (Corpas et al., 2021).

Basándonos en la experiencia clínica e investigadora utilizando el PU para la prevención y tratamiento de TEs en el SNS ya presentada, es crucial subrayar sus potencialidades para su aplicación en AP y plantearnos su viabilidad. Quedan importantes avances por realizar en el contexto de la AP. En este nivel de atención, donde podrían atenderse los TEs leves-moderados, es necesario delimitar los sistemas de evaluación, cribado, derivación e intervención y, en este último caso, la intervención psicológica, debería someterse a prueba la coste-eficacia de intervenciones breves, transdiagnósticas y grupales. Esta es una línea de investigación presente-futura en la que estamos trabajando.

7.3.2.2 Evaluación dimensional de los Trastornos Emocionales

Una línea de investigación relacionada con el tratamiento transdiagnóstico de los TEs está orientada a la evaluación dimensional de los TEs. A partir del desarrollo del modelo transdiagnóstico para los TEs (Brown y Barlow, 2009), han surgido avances en la investigación sobre herramientas de evaluación y programas de tratamiento para los constructos dimensionales subyacentes compartidos por este grupo de categorías y se está trabajando en el desarrollo y validación de instrumentos de evaluación dimensional para los TEs (Osma et al., 2023).

Disponer de un sistema de evaluación dimensional que evalúe las distintas vulnerabilidades transdiagnósticas propias de los TEs ha propiciado la creación del Inventario

Multidimensional para los TEs (MEDI, por sus siglas en inglés), creado por Rosellini y Brown (2019). Y el objetivo principal de este sistema de autorregistro es mitigar la gran cantidad de tiempo y recursos que supone hacer una evaluación psicométrica transdiagnóstica para los profesionales del SNS (Rosellini et al., 2019). El MEDI es un cuestionario breve, que por medio de 49 ítems evalúa 9 de las 10 dimensiones contempladas en el modelo híbrido dimensional-categorial para los TEs (Quílez-Orden et al., 2022).

Así el MEDI a nivel de evaluación es una herramienta desarrollada recientemente, sobre la que todavía se requiere ampliar la investigación. El trabajo en esta línea puede ayudar a mitigarlos tiempos dedicados a las evaluaciones de los TEs y, como consecuencia, mejorar la atención y el tiempo dedicado a la intervención en estos trastornos.

7.3.2.3 Adaptaciones del Protocolo Unificado a otras condiciones médicas

Existe una elevada prevalencia de problemas de salud mental en población con alguna enfermedad orgánica (Naylor et al., 2012). En este sentido, un metanálisis publicado por Daré et al. (2019) revela que existe una prevalencia de trastorno mental del 36% en pacientes que padecen una condición médica crónica. Y concretamente, los TEs se identifican como los trastornos mentales más prevalentes en condiciones médicas (Barlow et al., 2017).Esta situación hace evidente la necesidad de poder ofrecer intervenciones para los TEs en dichas condiciones de salud.

A este respecto, se ha empezado a estudiar la eficacia del PU para abordar los TEs o sintomatología emocional comórbida con condiciones médicas y los resultados parecen alentadores (Cassiello et al., 2020).En una revisión sistemática reciente realizada por Osma et al. (2021) sobre las aplicaciones del PU para los TEs en condiciones médicas se encontraron 9 estudios sobre la adaptación de esta intervención en pacientes con TEs comórbidos a patología médicas como dolor crónico, infertilidad, esclerosis múltiple o cáncer. Los resultados indican que el PU es eficaz en el tratamiento de la sintomatología emocional en población con afectación médica obteniéndose cambios estadísticamente significativos en síntomas ansiosos y depresivos comórbidos a la condición médica con tamaños del efecto grandes.

En esta línea, son varios los trabajos publicados hasta la fecha, y a los que el presente trabajo se une. Dados los prometedores resultados encontrados a lo largo de dichos estudios, se plantea como línea futura de investigación poder seguir analizando la viabilidad y coste-eficacia del PU en dichas condiciones y otras muchas que encontramos en el SNS (p. ej., cáncer, problemas cardíacos o infertilidad).

7.3.2.4 Protocolo Unificado en formato Blended.

En miras de poder seguir trabajando en la mejora de las intervenciones desde el SNS y poder ofrecer servicios sanitarios rentables ante la elevada demanda asistencial por TEs, ha surgido una línea de investigación en torno a la idea de ofrecer tratamientos híbridos, por ejemplo, en formato presencial cara-a-cara y online. De entre las alternativas tecnológicas disponibles, existe un interés creciente por el uso de aplicaciones móviles para ofrecer intervenciones psicológicas (Miralles et al., 2020). Esta alternativa híbrida podría superar algunas de las barreras asistenciales en nuestro SNS ya comentadas, por ejemplo, las aplicaciones móviles, como complemento al tratamiento presencial y dirigidas por un/a terapeuta, aumentan la eficacia de la intervención y reducen la carga de trabajo del clínico (Miralles et al., 2020).

Un metanálisis realizado por Erbe et al. (2017) respecto a los tratamientos en formato híbrido ha revelado que estas intervenciones permiten ahorrar tiempo a los y las clínicos/as y mantener los beneficios de las intervenciones a largo plazo. Además, contamos con evidencia que este formato de intervención es más eficaz que el tratamiento únicamente presencial para la reducción de los síntomas ansiosos y depresivos (Leterme et al., 2020).

Siguiendo esta hipótesis, y con el objetivo central de mejorar las intervenciones que desde el SNS podemos ofrecer, Osma et al. (2021) han presentado un protocolo de estudio para evaluar la eficacia y coste-efectividad de realizar un tratamiento híbrido (combinando visitas presenciales con el uso de una aplicación para teléfonos móviles) comparándolo con el tratamiento habitual que se ofrece en las USM españolas. Esta línea, ya está ofreciendo sus resultados (Osma et al., 2022) y esperamos que en el futuro podamos contar con resultados positivos respecto a las ventajas del formato híbrido en nuestro SNS.

En concreto y atendiendo a los resultados de los estudios presentados en la presente tesis doctoral, se plantean como posibles líneas futuras:

1) Llevar a cabo estudios más rigurosos y con mayor control, como diseños experimentales de línea de base múltiple o ensayos clínicos aleatorizados, para analizar la eficacia del PU para el tratamiento de síntomas emocionales y/o TEs en pacientes en fase de post-cirugía bariátrica.

2) Seguir proponiendo adaptaciones del PU (p.ej., reduciendo el número de sesiones, cambiando el orden de los módulos o añadiendo nuevos, entre otras) para personalizar las intervenciones a las características particulares de las personas atendidas en nuestro SNS con diagnóstico de TEs o relacionados.

3) Mantener la colaboración con otros dispositivos sanitarios y comunitarios para atender de manera integral y multidisciplinar los síntomas o TEs que los usuarios y usuarias de esos

dispositivos puedan presentar. En este sentido, debemos realizar estudios para determinar el grado de implementación, aceptabilidad y eficacia de las intervenciones.

4) Estudiar la utilización de tecnologías en la labor asistencial del especialista en psicología clínica en el contexto del SNS, por ejemplo, aplicaciones para móviles para practicar ejercicios entre sesiones o para monitorizar la evolución de alguna variable, entre otras.

7.4 CONCLUSIONES

A raíz de la evidencia científica encontrada en la presente tesis sobre la eficacia, eficiencia y adaptabilidad del PU para el abordaje de los TEs y sintomatología emocional, podemos extraer las siguientes conclusiones:

El PU en formato grupal es un tratamiento que puede ser implementado en el SNS y que puede responder a las necesidades asistenciales de una USM.

El PU es un tratamiento versátil que permite adaptar los módulos que lo componen para, de esta forma, poder intervenir sobre la sintomatología emocional en condiciones específicas como el caso de mujeres víctimas de violencia intrafamiliar, personas con obesidad en tratamiento con cirugía bariátrica y personal sanitario con elevada carga emocional.

El PU es igualmente efectivo tanto en hombres como en mujeres, por tanto, no es necesario hacer adaptaciones en función del género lo que facilita la intervención en un SNS colapsado y carente de recursos.

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CAPÍTULO VIII: APÉNDICE

8.1 FACTOR IMPACTO REVISTAS, ÁREAS TEMÁTICAS CORRESPONDIENTES A LAS PUBLICACIONES YJUSTIFICACIÓN DE LAS CONTRIBUCIONES

Artículo 1

Osma, J., Quilez, A., Ferreres, V., Meseguer, M., Ariza, S., (2022) Feasibility and clinical usefulness of the Unified Protocol in women survivors of violence. *Journal of Child and Family Studies.* https://doi.org/10.1007/s10826-022-02226-z

Factor de Impacto (JCR 2021): 2.784(Q3)

Área temática: Family Studies

Justificación de la contribución de la doctoranda: Contribución significativa en la investigación, encargándose de llevar a cabo el trabajo de valoración psicológica de las pacientes; adaptación del PU a la condición específica; aplicación de la intervención basada en PU y seguimientos así como colaboración en la redacción del artículo.

Artículo 2

Quilez-Orden, A., Ferreres-Galán, V., & Osma, J. (2020). Feasibility and clinical usefulness of the Unified Protocol in online group format for bariatric surgery candidates: study protocol for a multiple baseline experimental design. *International Journal of Environmental Research and Public Health*, *17*, 6155. https://doi: 10.3390/ijerph17176155

Factor de Impacto (JCR 2021): 4.614 (Q1)

Área temática: Public, environmental and occupational health

Justificación de la contribución de la doctoranda: Contribución significativa en la investigación, encargándose de analizar las posibilidades de realizar el estudio de campo en las USM. Colaboración en los distintos apartados del artículo.

Artículo 3

Ferreres-Galan, V., Quilez-Orden, & Osma, J. (2022) Application of the unified protocol for transdiagnostic treatment of emotional disorders in post-bariatric surgery patients: an effectiveness and feasibility study in group format. *Anales de Psicología, 38* (2), 219-231. https://doi.org/10.6018/analesps.482301

Factor de Impacto (JCR 2021): 2.325 (Q3)

Área temática: Psychology

Justificación de la contribución de la doctoranda: Contribución significativa en la investigación, encargándose de llevar a cabo el trabajo de valoración psicológica de las pacientes; adaptación

del PU a la condición de salud específica; aplicación de la intervención basada en PU y seguimientos así como colaboración en la redacción del artículo.

Artículo 4

Ferreres-Galan, V., Navarro-Haro, MV., Peris-Baquero, O., Guillen-Marín, S., DeLuna-Hermoso, J., Osma, J.(2022) Assessment of Acceptability and Initial Effectiveness of a Unified Protocol Prevention Program to Train Emotional Regulation Skills in Female Nursing Professional during the COVID-19 Pandemic. *International Journal of Environmental Research and Public Health, 19*, (9), 5715

Factor de Impacto (JCR 2021): 4.614 (Q1)

Área temática: Public, environmental, and occupational health

Justificación de la contribución de la doctoranda: Contribución significativa en la investigación, encargándose de llevar a cabo el trabajo de valoración psicológica de las pacientes; adaptación del PU a la condición de salud específica; aplicación de la intervención basada en PU, seguimientos y colaboración en la redacción del artículo.

Artículo 5(enviado)

Ferreres-Galan, V., Peris-Baquero, O., Moreno, J.D. & Osma, J. (en revisión). Is the Unified Protocol for transdiagnostic treatment of emotional disorders equally effective for men and women?

Factor de Impacto (JCR 2021): 5.250 (Q2)

Área temática: Psychiatry

Justificación de la contribución de la doctoranda: Contribución significativa en la investigación, encargándose de llevar a cabo el trabajo de valoración psicológica (y seguimientos) y de la aplicación de la intervención basada en PU de parte de la muestra del estudio; colaboración en la redacción del artículo.

POSDATA

Así empezaba esta historia:

"Me acabo de enterar que he sido aceptada para hacer el Doctorado. ¡Qué ilusión! ¡Qué miedo...!

Pienso: tengo 39 años, he pasado el peor año de mi vida y ya nada es como antes. Me debato entre lo bonito de la vida, y lo cruel de la vida. Pero sonrío ante la noticia. Me ilusiona. Pienso en Jorge, en Alba, en Oscar... ¡Qué bien, trabajar con ellos!

Una no sabe qué le depara la vida, pero intenta remar hacia sus intereses e ilusiones. Y así ha empezado este proyecto. Sin saberlo ni quererlo, me embarco en una aventura que no sé donde me llevará, pero si me arranca una sonrisa y me despierta una ilusión. ¡Creo que valdrá la pena!"

Así acaba:

"Gracias, gracias y mil gracias"

"Las emociones no pueden dimitir"

Inside out