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Facultad de Ciencias de la Educación y Psicología – Departamento de Psicología



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Programa de Doctorado de Ciencias Sociales y Jurídicas

**Bienestar psicológico en enfermedades crónicas desde una perspectiva de género: variables psicosociales e intervenciones psicológicas breves**

**Psychological wellbeing in chronic disease from a gender perspective: psychosocial variables and brief psychological interventions**

TESIS DOCTORAL

Doctoranda

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CÓRDOBA, NOVIEMBRE DE 2022

**TITULO:** *Bienestar psicológico en enfermedades crónicas desde una perspectiva de género: variables psicosociales e intervenciones psicológicas breves*

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**TÍTULO DE LA TESIS:** Bienestar psicológico en enfermedades crónicas desde una perspectiva de género: variables psicosociales e intervenciones psicológicas breves

**DOCTORANDA:** Naima Zahra Farhane Medina

#### **INFORME RAZONADO DE LAS DIRECTORAS DE LA TESIS**

La tesis doctoral realizada por Dña. Naima Zahra Farhane Medina ha seguido un desarrollo sobresaliente en cada una de sus fases. La doctoranda ha realizado una pormenorizada revisión sobre la influencia de variables psicosociales y motivacionales implicadas en el manejo de la enfermedad crónica dentro de un marco biopsicosocial y partiendo de la perspectiva de género. Además, ha diseñado e implementado programas de intervención psicológica basados en la promoción de la salud basándose en la evidencia científica más reciente, así como en la personalización de las intervenciones y el uso de tecnología *mHealth*.

Los objetivos de esta tesis doctoral aparecen correctamente estructurados y poseen una coherencia interna, habiéndose desarrollado mediante tres estudios. El trabajo de investigación presenta una metodología cuidada y variada, incluyendo la revisión sistemática, el uso de cuestionarios y la implementación de ensayos controlados no aleatorizados. De este modo, los resultados ofrecidos por los diferentes estudios han permitido profundizar en los objetivos iniciales desde diferentes perspectivas y han sido publicados en tres artículos científicos en revistas de impacto indexadas en el *Journal Citation Reports*. Es por ello que esta tesis doctoral se presenta en la modalidad de *compendio de artículos*.

Los artículos publicados que han derivado del trabajo original de investigación realizado son:

- Farhane-Medina, N. Z., Luque, B., Tabernero, C., & Castillo-Mayén, R. (2022). Factors associated with gender and sex differences in anxiety prevalence and comorbidity: A systematic review. *Science Progress*, 105. <https://doi.org/10.1177/00368504221135469>. Impact Factor JCR (2021): 1.512 (Q3).
- Farhane-Medina, N. Z., Castillo-Mayén, R., Luque, B., Rubio, S. J., Gutiérrez-Domingo, T., Cuadrado, E., Arenas, A., & Tabernero, C. (2022). A brief mHealth-based psychological intervention in emotion regulation to promote positive subjective well-being in cardiovascular disease patients: a non-randomized controlled trial. *Healthcare*, 10(9), 1640. <https://doi.org/10.3390/healthcare10091640>. Impact Factor JCR (2021): 3.160 (Q2).
- Farhane-Medina, N. Z., Castillo-Mayén, R., Tabernero, C., Rubio, S. J., Gutiérrez-Domingo, T., Cuadrado, E., Arenas, A., & Luque, B. (2022). Effectiveness of an eHealth intervention to improve subjective well-being and self-efficacy in cardiovascular disease patients: A pilot non-randomized controlled trial. *Nursing Open*, 1-14. <https://doi.org/10.1002/nop2.1400>. Impact Factor JCR (2021): 1.942 (Q3).

Teniendo en cuenta la conocida influencia del estrés y la ansiedad en el origen, curso y pronóstico de diversas enfermedades crónicas, así como la brecha de género en estas variables psicológicas, en el primer estudio se realizó una revisión sistemática para conocer qué factores psicosociales y biológicos se han analizado para explicar las diferencias en ansiedad entre mujeres y hombres. Este trabajo supone un primer paso para profundizar en la relación entre bienestar psicológico y salud.

Los dos siguientes estudios se han centrado en factores psicosociales y motivacionales que intervienen en la enfermedad cardiovascular, profundizando a nivel terapéutico y con el objetivo de contribuir al bienestar psicológico y el manejo de esta condición de salud. Para ello, se han diseñado y llevado a cabo dos intervenciones psicológicas para promover variables tan importantes como la autoeficacia y la regulación

emocional en pacientes con enfermedad cardiovascular, valiéndonos de las ventajas del formato *mHealth*. Con estos estudios se ha podido evaluar la eficacia de las intervenciones desarrolladas y los beneficios de la intervención personalizada. Además, en uno de ellos se han podido analizar las diferencias entre mujeres y hombres en la eficacia de la intervención.

Los trabajos realizados tienen un carácter aplicado al ámbito de la salud, aportando evidencia científica, tanto a nivel teórico como práctico, en esta área de estudio que vincula el bienestar psicológico y la salud física desde la perspectiva de género. Las intervenciones psicológicas breves llevadas a cabo a través de un formato *mHealth* permiten avanzar en el conocimiento sobre las ventajas y los beneficios para la salud que ofrece este formato.

Esta tesis doctoral opta a la *mención internacional*, ya que la doctoranda ha realizado una estancia de investigación en la Università degli Studi di Milano-Bicocca (Italia) y, a juicio de las directoras, cumple también con el resto de requisitos para obtener la citada mención. Además, la doctoranda ha realizado diferentes actividades formativas durante su periodo de formación, incluyendo el aprendizaje de diferentes metodologías y técnicas de análisis de datos, así como de contenidos teóricos vinculados con la temática de la tesis. También ha realizado varias presentaciones orales y escritas en diferentes congresos de ámbito nacional e internacional.

En resumen, consideramos que esta tesis doctoral reúne todas las condiciones exigidas para optar al grado de Doctora por la Universidad de Córdoba.

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

Córdoba, 11 de noviembre de 2022

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Esta tesis doctoral ha sido presentada por compendio de artículos, optando al doctorado con mención internacional por la estancia realizada en la Università degli Studi di Milano-Bicocca (Italia). Su realización ha sido posible gracias a la beca de movilidad internacional para estudiantes de doctorado de la Universidad de Córdoba del curso 2021/2022.

*on days i could not move  
it was women  
who came to water my feet  
until i was strong enough  
to stand  
it was women  
who nourished me  
back to life*

*sisters - rupi kaur*

*A mi madre,  
Todo es siempre por y para ti*

*A mi hermana,  
Por el tiempo que te debo y la suerte que he tenido de crecer contigo*

*A Ana,  
Porque cuando veo la ilusión en tus ojos todo esfuerzo merece la pena*

*A mi abuela Pepa,  
Porque sé que estarías orgullosa de mí*

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Con esta tesis se cierra una etapa muy importante, un periodo lleno de trabajo, esfuerzo y sacrificio, pero también lleno de aprendizaje, autoconocimiento y superación. No puedo continuar sin agradecer a todas aquellas personas que me han facilitado el camino, que me han apoyado y que me han acompañado en estos últimos años.

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A todas las personas que han participado en los estudios que en esta tesis se presentan, que quisieron aportar su granito de arena a la investigación con su tiempo, paciencia y amabilidad. Sin vosotras y vosotros esto no habría sido posible.

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# Índice de contenidos

<b>Resumen extendido.....</b>	<b>18</b>
<b>Prólogo.....</b>	<b>28</b>
<b>Marco teórico .....</b>	<b>34</b>
<b>Capítulo 1. Evolución en la conceptualización de la salud y enfermedad.....</b>	<b>36</b>
Introducción .....	36
Modelo biopsicosocial .....	39
La Psicología de la Salud.....	43
Resumen .....	48
Summary.....	49
<b>Capítulo 2. Enfermedades crónicas y modelo biopsicosocial.....</b>	<b>51</b>
Introducción .....	51
Enfermedades no transmisibles.....	51
Enfermedades cardiovasculares .....	59
Resumen .....	74
Summary.....	75
<b>Capítulo 3. Bienestar psicológico, bienestar subjetivo y enfermedad cardiovascular ....</b>	<b>76</b>
Introducción .....	76
Variables psicológicas como determinantes del bienestar psicológico y comportamiento saludable ..	78
Sexo, género y salud .....	84
Resumen .....	91
Summary.....	92
<b>Capítulo 4. Nuevas estrategias terapéuticas – Intervenciones mHealth .....</b>	<b>94</b>
Introducción .....	94
Intervenciones mHealth .....	94
Ventajas de las intervenciones mHealth .....	95
Eficacia de las intervenciones mHealth - Resultados relacionados con la salud y ECV.....	96
Futuras líneas y principales desafíos de las intervenciones mHealth.....	98
Otras consideraciones .....	100
Resumen .....	102
Summary.....	103
<b>Método y resultados .....</b>	<b>104</b>
<b>Capítulo 5. Methods.....</b>	<b>106</b>
General objectives of the thesis .....	106
Specific objectives and hypotheses of each study.....	106
<b>Capítulo 6. Study 1.....</b>	<b>112</b>
Abstract.....	112
Introduction.....	113
Methods .....	116
Results.....	118
Discussion.....	134
References.....	142
<b>Capítulo 7. Study 2.....</b>	<b>156</b>

Abstract.....	156
Introduction.....	157
Methods .....	161
Results.....	167
Discussion.....	172
Conclusions.....	176
References.....	178
<b>Capítulo 8. Study 3.....</b>	<b>190</b>
Abstract.....	190
Introduction.....	191
Background.....	191
The study .....	194
Results.....	200
Discussion.....	211
References.....	217
<b>Discusión y conclusiones generales .....</b>	<b>226</b>
<b>Capítulo 9. Discussion.....</b>	<b>228</b>
Practical implications and future lines of research.....	233
Strengths and Limitations .....	236
<b>Capítulo 10. Conclusiones generales .....</b>	<b>240</b>
General conclusions .....	240
<b>Publicaciones derivadas de la tesis doctoral .....</b>	<b>246</b>
<b>Referencias .....</b>	<b>252</b>



# **RESUMEN EXTENDIDO**

*EXTENDED ABSTRACT*

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La transición epidemiológica en occidente ha supuesto grandes cambios en los patrones de morbi-mortalidad, con un aumento exponencial de las enfermedades no transmisibles (ENT). Esto provocó un cambio en la concepción de salud hacia una perspectiva más integradora, en la que los factores biopsicosociales eran necesarios para explicar los procesos de salud-enfermedad y las personas por tanto se convertían en agentes activos, en responsables más que meros sujetos pasivos a la espera de recibir medicación.

Las enfermedades cardiovasculares (ECV) son el conjunto de ENT más prevalente y con una mayor tasa de mortalidad a nivel mundial. Históricamente han sido consideradas enfermedades masculinas, aunque las estadísticas muestran una mayor mortalidad en mujeres. Esta brecha de sexo en las ECV parece venir determinada por un sesgo de género que afecta al diagnóstico e intervención y hace necesaria una perspectiva de género a la hora de abordarlas. Estas enfermedades son el claro ejemplo de la necesidad de entender la salud de manera integral, ya que los principales factores de riesgo cardiovascular son modificables y, por tanto, prevenibles. Uno de los objetivos de la Psicología de la Salud es precisamente conocer los factores subyacentes que influyen en el comportamiento saludable de este tipo de pacientes con el fin de promoverlo. En esta dirección, numerosas investigaciones han relacionado las conductas saludables con variables psicológicas como la autoeficacia, una regulación emocional adecuada o el bienestar psicológico, que se vinculan con un mayor compromiso terapéutico y cambios saludables en el estilo de vida. A su vez, las ECV se han encontrado relacionadas con unos niveles altos de ansiedad, estrés y depresión, y estas se relacionan asimismo con un peor pronóstico de la enfermedad y una peor calidad de vida en estos pacientes. Por esta relación entre factores psicológicos y determinantes de salud cardiovascular, se necesitan intervenciones dirigidas a intentar promover estas variables psicológicas con el objetivo de mejorar su ajuste a la enfermedad y la reducción del riesgo cardiovascular. En esta

línea, y partiendo de los prometedores resultados de la telemedicina para promover conductas saludables, es necesario conocer si este tipo de intervenciones serían eficaces para mejorar las variables psicológicas antes mencionadas en pacientes con ECV. De igual modo, la brecha de salud entre mujeres y hombres hace necesaria la implementación de una perspectiva de género en la investigación e intervención sobre la misma.

Por todo lo anterior, la presente Tesis Doctoral tiene como objetivo profundizar en el análisis de los factores psicosociales que afectan a la salud y que se relacionan con la ECV, así como poner a prueba la eficacia de intervenciones *mHealth* para promover las variables psicológicas que se relacionan con los comportamientos saludables y el bienestar psicológico de esta población. Se proponen, por tanto, una serie de investigaciones que se han materializado en la publicación de tres artículos científicos independientes e interrelacionados, los cuales se presentan a continuación.

El primer estudio es una revisión sistemática que tiene como objetivo explorar los factores psicosociales que se han estudiado para explicar la vulnerabilidad diferencial del bienestar psicológico en mujeres y hombres. Partiendo de un modelo biopsicosocial, complementado con la perspectiva de género, se incluyeron estudios que evaluaban las diferencias de sexo y género en la ansiedad y su comorbilidad. Siguiendo la metodología PRISMA, se realizó una búsqueda sistemática en las bases de datos electrónicas PubMed y PsycInfo, incorporando estudios empíricos y revisiones publicadas entre 2008 - 2021. Tras la búsqueda, 44 estudios fueron incluidos, los cuales se analizaron y clasificaron en función del objeto de estudio. Finalmente, se realizó una síntesis narrativa cualitativa de los resultados. Los resultados de los estudios incluidos mostraron que las diferencias en la vulnerabilidad psicológica entre sexos se han analizado históricamente a partir de factores biológicos o factores de corte psicosocial; sin embargo, estudios que abordasen la problemática aludiendo de manera conjunta a ambos factores fueron escasos.

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El segundo estudio tiene como objetivo evaluar la efectividad de una intervención psicológica *mHealth* en regulación emocional para mejorar el afecto positivo y la autoeficacia en personas con ECV. Para ello, se diseñó un ensayo controlado no aleatorizado de dos brazos, en el que la muestra de 69 pacientes cardiovasculares participó en un grupo experimental o un grupo control o de tratamiento habitual. La intervención, basada en el proceso de regulación emocional (Gross, 1998; Leahy, 2011), está conformada por dos fases. La primera consistió en una sesión presencial y la segunda en una intervención basada en *mHealth* de 14 días. Ambos grupos fueron evaluados en múltiples ocasiones en afecto positivo y autoeficacia (crónica y cardíaca), incluyendo dos *follow-ups*, lo que permitió un análisis de medidas repetidas. Los resultados indican que la intervención psicológica *mHealth* fue efectiva para mejorar el afecto positivo y la autoeficacia en pacientes con ECV, encontrándose diferencias intragrupo y entre grupos.

El tercer estudio es un ensayo clínico piloto no aleatorizado, que tiene como objetivo diseñar y evaluar la efectividad de una intervención *mHealth* multicomponente en autoeficacia para mejorar el bienestar subjetivo y la autoeficacia para el manejo de la enfermedad cardíaca y crónica, analizando además posibles diferencias entre hombres y mujeres. Para este estudio, la muestra estaba compuesta por 42 pacientes cardiovasculares, que participaron equitativamente en un grupo experimental o control. Esta intervención multicomponente fue diseñada en base a la autoeficacia (Bandura, 1986a) e incluye una sesión presencial *personalizada* y una intervención *mHealth* de 14 días. Al igual que en el segundo estudio, ambos grupos fueron evaluados en repetidas ocasiones, con dos evaluaciones *follow-ups* que permitieron hacer comparaciones entre grupos e intragrupo, y ofrecer información más precisa acerca de la efectividad de la intervención. Los resultados mostraron que esta fue efectiva para mejorar el afecto positivo y la autoeficacia para el manejo de la enfermedad en pacientes cardiovasculares.

Sin embargo, cuando se analizaron los datos por sexo, se observó que esta efectividad se daba únicamente en la población masculina.

En conjunto, los resultados derivados de los tres estudios que conforman la presente tesis doctoral ponen de manifiesto la necesidad de incorporar el modelo biopsicosocial, así como la perspectiva de género, para comprender los procesos de salud-enfermedad y abordar el diagnóstico y tratamiento de enfermedades de largo alcance como lo son las ECV, y su relación con la salud mental. Por su parte, los estudios empíricos aportan evidencia en favor de las vertientes terapéuticas que demandan la inclusión de la psicología en la rehabilitación cardíaca, además de la incorporación de nuevas estrategias de intervención que garanticen la accesibilidad de la atención sanitaria a este tipo de pacientes. Se considera que investigaciones futuras, por otro lado, deberían poner el foco en cómo establecer intervenciones *online* sin perder el contacto humano, así como tratar de adentrarse completamente en la personalización de estas intervenciones buscando evitar las diferencias en efectividad para las mujeres y la obtención de mejores resultados terapéuticos.

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The epidemiological transition in Western countries has led to major changes in morbidity and mortality patterns, with an exponential increase in non-communicable diseases (NCDs). This led to a change in the conception of health towards a more integrative perspective, in which biopsychosocial factors were necessary to explain the health-disease processes and people, therefore, became active agents, responsible rather than mere passive subjects waiting to receive medication.

Cardiovascular diseases (CVD) are the most prevalent set of NCDs with the highest mortality rate worldwide. They have historically been considered male diseases, although statistics show a higher mortality in women. This gender gap in CVD seems to be determined by a gender bias that affects diagnosis and intervention and makes a gender perspective necessary when addressing them. These diseases are a clear example of the need for a holistic approach to health, as the main cardiovascular risk factors are modifiable and, therefore, preventable. One of the objectives of Health Psychology is precisely to understand the underlying factors that influence healthy behaviour of these patients in order to promote them. In this direction, numerous investigations have related healthy behaviours to psychological variables, such as self-efficacy, adequate emotional regulation or psychological well-being, which are linked to greater therapeutic commitment and healthy lifestyle changes. In turn, CVD has been found to be associated with high levels of anxiety, stress and depression, which are also related to a worse prognosis of the disease and a poorer quality of life in these patients. Due to this relationship between psychological factors and cardiovascular health determinants, interventions aimed at promoting these psychological variables with the objective of improving their adjustment to the disease and reducing cardiovascular risk are deemed necessary. In this line, and based on the promising results of telemedicine to promote healthy behaviours, it is necessary to know whether this type of intervention would be

effective in improving the aforementioned psychological variables in patients with CVD. Similarly, the health gap between women and men makes it necessary to implement a gender perspective in research and intervention.

For all of the above reasons, the aim of this doctoral thesis is to deepen the analysis of the psychosocial factors that affect health and are related to CVD, as well as to test the effectiveness of mHealth interventions to promote the psychological variables related to healthy behaviours and psychological well-being in these patients. Thus, a series of investigations are proposed. These investigations have materialised in the publication of three independent and interrelated scientific articles, which are presented below.

The first study is a systematic review that aims to explore the psychosocial factors that have been studied to explain the differential vulnerability of psychological well-being in women and men. Based on a biopsychosocial model, complemented by the gender perspective, studies assessing sex and gender differences in anxiety and its comorbidity were included. Following the PRISMA methodology, a systematic search was conducted in the electronic databases PubMed and PsicInfo, incorporating empirical studies and reviews published between 2008 - 2021. Following the search, 44 studies were included, which were analysed and classified according to the object of study. Finally, a qualitative narrative synthesis of the results was conducted. The results of the included studies showed that differences in psychological vulnerability between the sexes have historically been analysed on the basis of biological factors or psychosocial factors, but few studies have addressed the problem by alluding to both factors together.

The second study aims to evaluate the effectiveness of an mHealth psychological intervention in emotional regulation to improve positive affect and self-efficacy in patients with CVD. To this end, a two-arm, non-randomised controlled trial was designed, in which the sample of 69 CVD patients was assigned to either the experimental group or

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the control or treatment-as-usual group. The intervention, based on the emotional regulation process (Gross, 1998; Leahy, 2011), consists of two phases, a face-to-face session and a second 14-day mHealth phase. Both groups were assessed multiple times on positive affect and self-efficacy (chronic and cardiac), including two follow-ups, which allowed for a repeated measures analysis. The results indicate that the mHealth psychological intervention was effective in improving positive affect and self-efficacy in patients with cardiovascular disease, with intra-group and between-group differences found.

The third study is another pilot non-randomised clinical trial, which aims to design and evaluate the effectiveness of a multicomponent mHealth intervention on self-efficacy in improving subjective well-being and self-efficacy for the management of cardiac and chronic disease, also analysing possible differences between men and women. For this study, the sample consisted of 42 cardiovascular patients, who were equally assigned to the control or experimental group. This multicomponent intervention was designed on the basis of self-efficacy (Bandura, 1986a) and included a face-to-face one-to-one session and a 14-day mHealth intervention. As in the second study, both groups were repeatedly evaluated, with two follow-up assessments allowing for between-group and within-group comparisons and providing more accurate information about the effectiveness of the intervention. The results showed that the intervention was effective in improving positive affect and self-efficacy for disease management in cardiovascular patients. However, when the data were analysed by gender, this effectiveness was found to occur only in the male population.

Taken together, the results derived from the three studies that constitute this doctoral thesis highlight the need to incorporate the biopsychosocial model, as well as a gender perspective, in order to understand health-disease processes and to address the

diagnosis and treatment of long-term diseases, such as CVD, and their relation with mental health. With regards to the empirical studies, they provide evidence in favor of the therapeutic aspects that demand the inclusion of psychology in cardiac rehabilitation, as well as the incorporation of new intervention strategies that guarantee the accessibility of health care for these patients. Future research, on the other hand, should focus on how to establish online interventions without losing human contact, as well as try to fully explore the personalization of these interventions in order to avoid differences in effectiveness for women and to obtain better therapeutic results.

# PRÓLOGO

*PROLOGUE*

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La presente tesis doctoral nace de la colaboración entre el Departamento de Psicología de la Universidad de Córdoba y el Instituto Maimónides de Investigación Biomédica de Córdoba (IMIBIC). Más concretamente, se enmarca dentro de la labor investigadora del grupo GE-04 Psicología aplicada del IMIBIC, cuyo principal interés investigador es explorar la influencia de las variables psicosociales y procesos motivacionales implicados en el manejo de la enfermedad crónica dentro de un marco biopsicosocial, así como el diseño de programas de intervención basados en la promoción de la salud a través de la evidencia científica.

El creciente interés por estudiar las variables implicadas y procesos subyacentes en las enfermedades crónicas nace del cambio en los patrones de morbimortalidad y la prolongación de los años de vida, que han dado lugar a nuevas manifestaciones clínicas y, con ello, a nuevos desafíos en el sistema sanitario. Esto ha supuesto, entre otros aspectos, un cambio en la concepción de salud y la aparición de nuevas disciplinas que adoptan modelos integrativos para explicar los procesos de salud-enfermedad. Un ejemplo de estas es la Psicología de la Salud, a partir de la cual se entiende a la persona como agente de cambio y se pone el foco en los condicionantes que influyen en las conductas de salud.

Este enfoque cobra especial relevancia en las enfermedades crónicas y, entre ellas, en las ECV, sobre las cuales influyen de manera relevante aspectos psicosociales y comportamentales, que constituyen determinantes de riesgo modificables. Dentro de estos factores de riesgo para la salud cardiovascular, y partiendo de la disciplina en la que se enmarca la presente tesis, destaca el malestar psicológico, relacionado con la aparición, empeoramiento y fracaso de los tratamientos. Por tanto, analizar los factores psicosociales que están en la base de la alta prevalencia e incidencia de estos malestares se torna esencial en este contexto. Es igualmente prioritario profundizar a nivel terapéutico en

variables que puedan promover transformaciones integrales como las que se necesita llevar a cabo en las enfermedades crónicas y de naturaleza cardiovascular. En este sentido, no menos importante es tener en cuenta las barreras que esta población tiene para el acceso y continuidad en la atención y rehabilitación terapéutica. El crecimiento de la eSalud y las herramientas *mHealth*, gracias a una incorporación de la tecnología a los sistemas de atención sanitaria, permite realizar intervenciones breves y de adecuado coste-beneficio. La naturaleza *online* de este tipo de abordaje terapéutico es un campo prometedor que parece poder hacer posibles y accesibles estas intervenciones para pacientes con ECV.

Por todo lo anterior, para esta tesis se propuso el diseño de una serie de estudios que diesen respuesta a la influencia de las variables psicosociales en el bienestar psicológico y problemáticas crónicas de salud, tanto en su presentación como en los intentos de abordaje terapéutico. Estas motivaciones han resultado en el estudio de los factores explicativos sobre las diferencias en ansiedad entre hombres y mujeres, mediante una revisión sistemática de las mismas. Así mismo, se han llevado a cabo dos intervenciones para el fomento de la autoeficacia y la regulación emocional valiéndonos de las ventajas del formato *mHealth*, con la pretensión de comprender si estas podían contribuir al bienestar y al mejor manejo de la enfermedad de pacientes con ECV.

En cuanto a la estructuración de contenidos, esta tesis se divide en tres grandes secciones. La *primera sección* contiene el marco teórico que precede y sustenta las investigaciones realizadas. Esta consta de cuatro capítulos. El **capítulo uno** hace un recorrido por la evolución en la conceptualización de la salud, a partir de la transición epidemiológica, resaltando la importancia del modelo biopsicosocial y la Psicología de la Salud en el abordaje de los procesos de salud-enfermedad. En el **capítulo dos** se describen las ENT, como problemáticas crónicas y de gran impacto; y dentro de las mismas, las

ECV y los principales factores de riesgo modificable asociados, entre los cuales el estilo de vida y el malestar psicológico, cobran gran relevancia. En el **capítulo tres** se amplía esta última idea, analizando el vínculo entre el bienestar psicológico y la ECV, donde la autoeficacia, la regulación emocional y el sesgo de género se destacan como determinantes en esta relación. El **capítulo cuatro** examina nuevas aproximaciones y herramientas terapéuticas que se sustentan en el creciente uso de la telemedicina, revisando las posibilidades que pueden ofrecer en el abordaje de la salud cardiovascular. Por su parte, la *segunda sección* se refiere a la metodología y los distintos estudios llevados a cabo. Esta sección contiene otros cuatro capítulos. El **capítulo cinco** concierne al método, en el cual se enumeran los objetivos perseguidos en la tesis doctoral junto a las hipótesis que surgen de los mismos. Se ofrece aquí una panorámica breve de las principales características de los estudios que pretenden poner a prueba dichas hipótesis. En los **capítulos seis, siete y ocho**, respectivamente, se recogen los estudios realizados en el marco de la tesis, que dan lugar a tres publicaciones en revistas científicas de impacto. Finalmente, la *tercera sección* concluye con dos últimos capítulos. El **capítulo nueve** presenta la discusión, donde se exponen los hallazgos de las investigaciones propuestas, así como algunas implicaciones prácticas, futuras líneas de investigación a partir de los conocimientos obtenidos en las mismas, las fortalezas y limitaciones del trabajo realizado. Por último, en el **capítulo diez** se establecen las conclusiones generales de la tesis doctoral.

En suma, se espera que los temas tratados en la presente tesis doctoral supongan un enriquecimiento en el conocimiento y las herramientas que se pueden aplicar para acercarse a la comprensión y mejoría de enfermedades de gran repercusión en la salud y la calidad de vida de las personas.

# **MARCO TEÓRICO**

*THEORETICAL FRAMEWORK*

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## Capítulo 1

### Evolución en la conceptualización de la salud y enfermedad

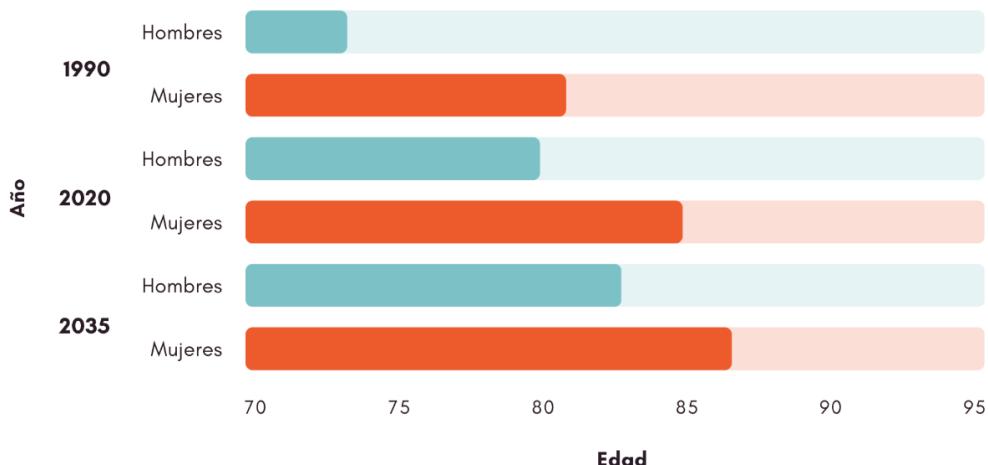
*“But nothing will change unless and until those who control resources have the wisdom to venture off the beaten path of exclusive reliance on biomedicine as the only approach to health care”*

- Engel (1977)

#### Introducción

Desde el pasado siglo se ha podido observar un considerable aumento en la esperanza de vida a nivel mundial, y especialmente en los países industrializados. En concreto, un aumento de más del 60 por ciento ha ocurrido entre 1900-1990 en estas naciones (Kinsella, 1992). En España, por ejemplo, desde los años 90, se ha incrementado esta expectativa de vida en 4,5 años y las proyecciones apuntan a una ganancia de entre 2,3 y 3,2 puntos, en función del sexo, para el año 2035 (Instituto Nacional de Estadística [INE], 2022a) (Figura 1). Por motivos evidentes, la esperanza de vida se considera un indicador fundamental del nivel de desarrollo de una población ya que proporciona información directa y objetiva sobre las condiciones de salud de la misma. Tanto es así, que dentro de la Agenda 2030 establecida por la Asamblea General de Naciones Unidas (2015) la esperanza de vida constituye un indicador dentro del objetivo de desarrollo sostenible “Salud y Bienestar”, más concretamente en el Objetivo 3. Garantizar una vida sana y promover el bienestar de todos a todas las edades. Esta esperanza de vida puede ser el resultado de las mejoras en el Estado de Bienestar, que puede traducirse en diferentes factores como: avances médicos, mejores condiciones de vida, mayor acceso a servicios sanitarios, tasa de personal asistencial, mayor inversión en investigación sanitaria, mejor respuesta a problemas de salud, hábitos de vida saludable, etc., y que repercuten en una

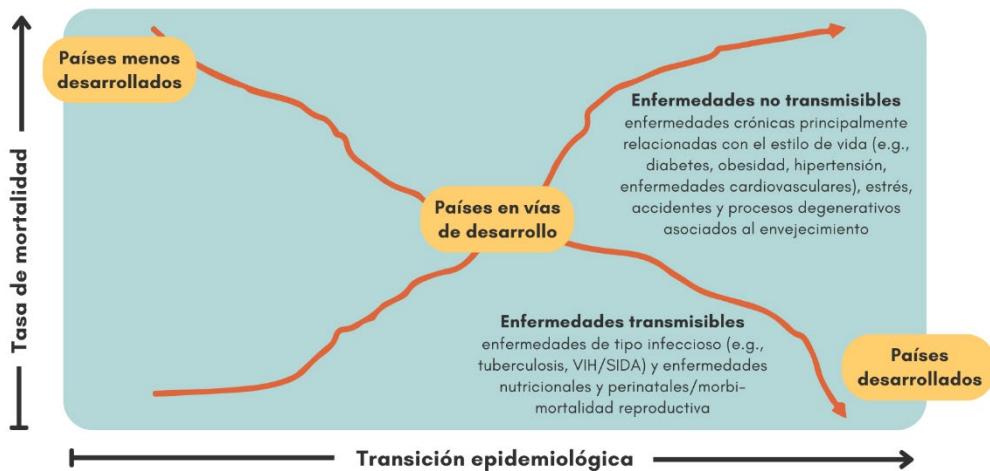
mayor calidad de vida de las personas que integran una sociedad (Fadnes et al., 2022; Martín Cervantes et al., 2019; Wirayuda & Chan, 2021).



**Figura 1.** Evolución y proyección de la esperanza de vida en España segregada por sexo para los años 1990, 2020 y 2035 (elaboración propia a partir de INE, 2022a).

Una de las principales razones de este crecimiento, más allá de las notables mejoras en condiciones vitales, puede encontrarse en el cambio de aproximación en lo que respecta al entendimiento de la salud y enfermedad. El significativo descenso de la mortalidad y aumento en esperanza de vida en Europa no podía explicarse realizando únicamente un análisis a nivel demográfico, hecho que empezó a ser señalado por autores como Omran (1971). Por el contrario, como se venía observando desde la década de los años 40, era necesario un análisis epidemiológico que contemplase un cambio en las causas de mortalidad, entendiéndose con ellas los cambios en los factores de riesgo. Con este análisis se ha podido advertir una evolución que ha ido desde una mayor prevalencia de enfermedades infecciosas (como pueden ser la peste o el lupus) a un aumento *in crescendo* de muertes por enfermedades degenerativas o crónicas (como el cáncer, las

afecciones cardiovasculares, los accidentes cerebrovasculares, la diabetes mellitus, demencias, depresión, estrés, etc.), es decir, no transmisibles (Organización Mundial de la Salud [OMS], 2022). Este cambio de los patrones de morbi-mortalidad se conoce como **transición epidemiológica** (Figura 2).



**Figura 2.** Transición epidemiológica en función del nivel de desarrollo de los países  
(adaptación de Academia Nacional de Ciencias de Uganda, 2018; a partir de Omran, 1971, 1998).

Este fenómeno teorizado por primera vez por Omran (1971, 1983, 1998) puso en jaque las concepciones previas de salud y enfermedad. Hasta los años 70, el modelo de salud imperante era el modelo biomédico, que nace a mediados del siglo XIX de la mano de Richard Bright (Garzón deLaverde & Rojas-Gil, 2016) y pone de manifiesto una visión anatómico-patológica individualista y reduccionista de la enfermedad. Esta perspectiva se fundamenta en la visión dualista cartesiana mente-cuerpo, por lo que las personas eran entendidas como organismos biológicos que son el resultado de la suma de sus componentes biológicos, físicos y químicos (Mehta, 2011; Wade & Halligan, 2017). Desde este prisma, se entiende por tanto la enfermedad como todas aquellas disfunciones concretas y exclusivas en esos componentes (biológico-físico-químico). Este modelo, que

podía ser útil para entender algunas de las condiciones de salud, y responder a enfermedades transmisibles o explicar el funcionamiento del cuerpo humano y sus partes, como reconocía el propio Engel, proporcionaba una visión reduccionista y materialista de la salud y la enfermedad, y fallaba a la hora de proporcionar una aproximación global de los problemas de salud que escapaban de esas características. La causa de la enfermedad era única y debía ser siempre localizada en una parte del cuerpo (Wade & Halligan, 2017).

En contraposición a este modelo de salud, uno de los hitos que han marcado el cambio de dirección en esta manera de entender los procesos de salud-enfermedad lo podemos observar en el año 1946, cuando la OMS propone como primer artículo de su constitución que la salud ya no se entendía como la ausencia de enfermedad tal y como se recoge con el modelo médico, sino que se iba un paso más allá, y se entendía como un estado de completo bienestar psicológico, físico y social (OMS, 1946). Esto supuso un gran cambio en el entendimiento de todos los procesos que rodean la salud-enfermedad, y se convirtió en un reto que demandó su abordaje desde una aproximación holística, atendiendo a la multifactorialidad de la patogénesis (Weiss, 1987).

### **Modelo biopsicosocial**

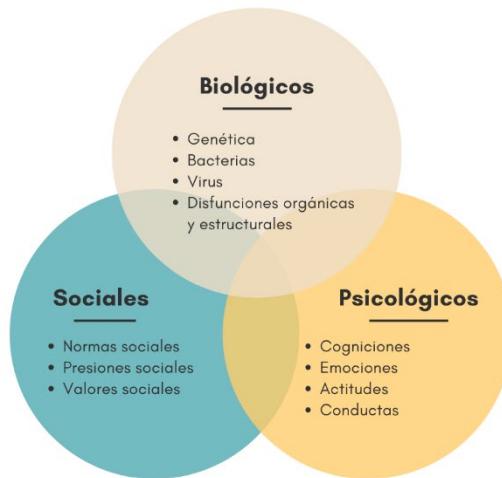
La transición epidemiológica, el cambio conceptual de la salud, así como el avance en investigación sobre esta, comienzan a presionar la necesidad de un marco teórico biopsicosocial en el cual se plantee la conducta como génesis y mantenimiento de la enfermedad, se modifique el rol de la persona en sus procesos de salud-enfermedad y se ponga el acento en la calidad de vida en enfermedades crónicas y degenerativas abogando por la promoción, prevención y mantenimiento de la salud. En esta dirección, es a partir de los años 60 cuando se produce un auge de las investigaciones que plantean el estilo de

vida como factor fundamental de la salud, en lo que se dio a conocer como la “era post-médica” en las décadas que siguieron (Kickbusch, 1986).

En el año 1977, George Engel, a través de la publicación *"The Need for a New Medical Model: A Challenge for Biomedicine"* en la prestigiosa revista científica *Science* recoge el testigo de la concepción de salud que planteaba la OMS y propone un modelo de salud que trata de resolver lo que él mismo considera como las tres características del modelo médico que causan la *deshumanización de la medicina* (Borrell-Carrió et al., 2004): 1) el ***dualismo mente-cuerpo***, entendiéndolo, por el contrario, como un continuo y una relación indispensable para entender los procesos salud-enfermedad, 2) la ***visión materialista y reduccionista***, considerando otros factores que no puedan ser medibles como procesos celulares o moleculares, y 3) la ***influencia del observador sobre el observado***, a través de la cual critica la relación jerárquica entre profesionales sanitarios y pacientes, dándole importancia a la dimensión humana desde la cual esa relación debe de ser construida.

La persona deja de ser vista como un “cuerpo enfermo” (Syed et al., 2020). De este modo, el modelo propuesto por Engel contempla no solo los aspectos biológicos-físico-químicos que pueden afectar y estar relacionados con la salud y la *-no salud-* de una persona, sino que añade y da valor a otros factores, los *psicológicos* y los *sociales*, hasta el momento ignorados, considerándolos de suma importancia (Figura 3). Además de la relevancia de dichos factores, es importante resaltar que este enfoque, basado en la teoría de sistemas, afirma la interrelación de unos factores con otros dentro de una relación jerárquica e interactiva, de manera que los cambios en uno de los factores o sistemas produce cambios en los demás (Engel, 1977; Suls & Rothman, 2004). Esta vinculación entre sistemas supone que no solo todos ellos afectan a la salud de una

persona, sino que, además, los factores psicológicos, sociales y biológicos se influyen mutuamente.



**Figura 3.** Factores relevantes en el modelo biopsicosocial (elaboración propia a partir de Engel, 1977, 1980, 1981).

Tener en cuenta variables de corte psicológico, así como las condiciones socioambientales que rodean la vida de las personas, suponía cambiar el punto de partida de lo que se consideraba hasta el momento los *determinantes de la salud*. Esto significa principalmente entender que el estudio -investigaciones, objetivos e hipótesis que se planteen- para intentar explicar una enfermedad, ya sea física o psicológica, tengan en consideración todos aquellos factores internos y externos que puedan estar afectando a su aparición, diagnóstico, pronóstico, tratamiento y comorbilidad. Por tanto, este modelo permite el abordaje de las problemáticas de salud de cualquier índole, desde condiciones históricamente entendidas como enfermedades médicas (e.g., diabetes, Amsah et al., 2022) hasta problemas de salud mental como la esquizofrenia (Hettige et al., 2018), que deberían ser todas ellas entendidas de manera holística siguiendo este enfoque. En este sentido, se asiste a un crecimiento exponencial de los estudios que introducen el término

biopsicosocial desde que fuese acuñado por Engel (Suls & Rothman, 2004; Wade & Halligan, 2017).

Pero además de un marco teórico, este modelo nace para liderar un cambio de paradigma en la práctica clínica, de manera que quienes se posicionan como profesionales de la salud, deben entender a sus pacientes y a sus malestares desde una perspectiva integral, más que como la mera composición de sus condiciones biológicas (e.g., órganos, hormonas, estructuras cerebrales), alejándose de la visión anatómico-patológica de la medicina y la psiquiatría del modelo biomédico. Schwartz (1982) predecía que la aplicación de este modelo integrativo como alternativa al modelo biomédico supondría una mejora en los procesos de diagnóstico y en los resultados hallados en el tratamiento y seguimiento de la evolución terapéutica.

Años más tarde, un cuerpo importante de investigaciones ha demostrado una mejora operativizable en numerosas condiciones y resultados de salud y asistencia sanitaria (e.g., Gong & Tao, 2021; Register-Mihalik et al., 2020; Staiger et al., 2020; van Erp et al., 2019), no solo en la cura de lesiones, sino en la recuperación de actividades diarias (Syed et al., 2020). Además, ha supuesto un impulso a la necesidad de nueva formación teórico-práctica en el campo de la salud (Suls & Rothman, 2004; Syed et al., 2020), y a una transformación de la relación profesional-paciente, minimizando la jerarquía médica dominante de pasadas épocas al focalizarse en la historia global de la persona y en un enfoque colaborativo con la misma (Bolton & Gillett, 2019; Wade & Halligan, 2017). Este cambio de paradigma clínico, que no solo tiene en consideración los sistemas psicológicos, sociales y biológicos de los y las pacientes, sino que altera la relación terapéutica, tendría como resultado mejoras en variables de alta importancia, como por ejemplo la adherencia al tratamiento, reducción del número de visitas médicas, mejor salud física y psicológica, así como una mejor comunicación profesional-paciente

y una mayor satisfacción por parte de las personas atendidas (Taukeni, 2020), demostrando su validez y utilidad.

Sin embargo, a pesar de las numerosas investigaciones que lo apoyan, este modelo no ha estado libre de críticas (Bolton & Gillett, 2019; Wade & Halligan, 2017). Varios estudios han documentado la dificultad de implementar estos enfoques clínicamente. Por ejemplo, hay quienes argumentan explícitamente que debido a las características inherentes al modelo biopsicosocial (por ejemplo, la subjetividad y la individualidad en el abordaje del paciente), su aplicabilidad en la práctica clínica es difícil y, por lo tanto, debe entenderse sólo como un modelo teórico (Álvarez et al., 2012). Otra de las críticas es la dificultad de establecer relaciones de causalidad entre los distintos determinantes psicológicos, biológicos y sociales (Taukeni, 2019); así como no saber delimitar sus limitaciones como puede ser no aplicarse de manera universal y para todas las condiciones de salud (Wade & Halligan, 2017).

Finalmente, las críticas a su aplicabilidad pasan por la falta de comunicación recíproca entre la investigación y las políticas públicas, que conlleva que importantes resultados no lleguen a implementarse en la práctica y, viceversa, no permitiendo a la comunidad científica conocer el alcance real de sus recomendaciones (Suls & Rothman, 2004). Aunque puede no constituir una crítica al modelo *per se*, la falta de conciencia y adopción por parte tanto de profesionales (Xiao et al., 2021), como de los organismos que financian y establecen los recursos de asistencia sanitaria (Wade & Halligan, 2017), es aun una preocupación constante. En cualquier caso, la incorporación de este y otros modelos alternativos al biomédico sacudió la manera de entender el continuo de salud-enfermedad y sirve para comprender la evolución en la concepción de estos procesos, dejando atrás el reduccionismo y el dualismo históricos (Bolton & Gillet, 2019).

## **La Psicología de la Salud**

Este concepto integrador de la salud tuvo como resultado el desarrollo de nuevas disciplinas que intentaban estudiar e interconectar los determinantes biopsicosociales de salud. Desde el campo de la medicina nace la Medicina Conductual -*Behavioral Medicine*- que ponía el foco en los factores no biológicos que afectaban a la salud y estudiaba la influencia del comportamiento en la salud y el bienestar. Esta disciplina por tanto comprende el conjunto del conocimiento y técnicas de ciencias biomédicas y del comportamiento desde un enfoque interdisciplinar para prevenir, diagnosticar, tratar y rehabilitar las enfermedades (Schwartz & Weiss, 1978).

Desde la Psicología, por su parte, aparece la Psicología de la Salud -*Health Psychology*. En el encuentro producido en la *Task Force on Health Research* de la Asociación Americana de Psicología (APA) establecido en 1973 se muestra en abierto el descontento por el enfoque precedente y la creciente adopción del enfoque biopsicosocial en la asistencia a la salud entre distintos perfiles de profesionales de la Psicología (APA Task Force on Health Research, 1976; Friedman & Adler, 2007). Pocos años después, en 1978, la *Division of Health Psychology* se convirtió en la trigésimo-octava división de la APA (Wallston, 1997) y esta organización definió la nueva disciplina como aquella cuyos principales objetivos eran *promover y mantener* la salud, *prevenir y tratar* la enfermedad, así como *analizar y mejorar los sistemas de atención sanitaria* y la elaboración de *políticas sanitarias* (Matarazzo, 1982). Al igual que la medicina conductual, es un campo que apuesta por la interdisciplinariedad y en concreto examina cómo pensamientos, emociones y conductas interaccionan con los factores biológicos y sociales para influir en los procesos de salud y enfermedad, poniendo el énfasis en variables de naturaleza psicológica-social (Friedman & Adler, 2007; Gurung, 2018; Marks, 2013).

Esta disciplina, derivando del modelo biopsicosocial, entiende la salud como un proceso multicausal en el que intervienen el sistema sanitario, el medio ambiente, la

biología humana, y los estilos de vida. La conducta fue uno de los pilares o focos fundamentales en el estudio del estilo de vida en la era post-médica tradicional (Kickbusch, 1986). Una premisa esencial desde la Psicología de la Salud es que las personas son **agentes activos y causales** y tienen, por tanto, poder para influir en su salud y en sus factores de riesgo y protección que fluyen dentro de un continuo. En este sentido, el cuerpo entero como activo está involucrado pero el sistema nervioso juega un papel central en la regulación de la conducta (Bolton & Gillet, 2019). Es precisamente esta idea, junto al interés en la prevención y promoción de la salud, lo que fomenta el estudio de los comportamientos saludables y cómo estos influyen y pueden ser influidos en los procesos de salud-enfermedad.

De todos aquellos factores que intervienen en estos procesos, la Psicología de la Salud ha puesto especial atención en aquellos factores de tipo comportamental que tienen consecuencias perjudiciales (consumo de tabaco, dieta pobre, alcohol, sedentarismo, etc.) (Marks, 2013). La naturaleza modificable de estos factores de riesgo los hacen especialmente interesantes ya que implican que se deja margen de actuación para la prevención, de manera que la Psicología de la Salud, nutriéndose de la Psicología clínica, social y comunitaria, estudia cuáles son los mecanismos psicológicos subyacentes en estas conductas de riesgo, para posteriormente proporcionar una atención sanitaria integral a la persona a través de la intervención directa con pacientes, así como intervenir a gran escala a partir de políticas públicas (APA, 2014). Se trata por tanto de una disciplina que pone el énfasis en la intersección de la salud y el comportamiento, aunque sin olvidar la influencia global de la actuación y factores sociosanitarios (Marks, 2013).

### *Modelos explicativos de la Psicología de la Salud*

Como se ha mencionado anteriormente, más allá de interesarse por la génesis de los problemas de salud, esta disciplina pone el foco en cuáles son los factores psicológicos

que favorecen o dificultan los comportamientos de salud y, por tanto, tiene como objetivo prioritario conocer qué motiva a las personas a realizar y llevar a cabo dichas conductas saludables (Medina Anzano & León Rubio, 2004). Esto conllevaría contestar, por ejemplo, a por qué si, a pesar de ser de conocimiento público que el consumo de tabaco se relaciona con altos índices de muerte y cáncer, las personas continúan fumando, comienzan a fumar y no abandonan el hábito o, por ejemplo, qué motiva a las personas a comenzar una dieta saludable o a iniciar una rutina de ejercicio físico.

Desde la Psicología de la Salud se han propuesto múltiples modelos explicativos que tratan de dar respuesta a cuestiones de este tipo. Estos modelos ponen el foco en variables psicológicas y en cómo estas pueden influir en las conductas de salud. Lo que las personas piensan sobre la salud influye sobre su actitud a las conductas de salud, su uso de los servicios de prevención y detección, así como sobre las respuestas a la enfermedad y cómo comunican la misma (Kickbusch, 1986). Dentro de los citados modelos se pueden diferenciar dos tipos de teorías que pueden ser aplicadas a cualquier condición de salud. Se trataría de los modelos y teorías expectativa-valor y los modelos y teorías de autorregulación del comportamiento.

#### Modelos y teorías expectativa-valor

Estos modelos plantean como ejes moduladores del comportamiento a las creencias y actitudes (Medina Anzano & León Rubio, 2004). Dentro de esta se encuentran el *Modelo de Creencias de Salud* (Hochbaum, 1958; Rosenstock, 1966, 1974; la *Teoría de la Acción Razonada* (Fishbein y Ajzen, 1975) y *Conducta Planificada* (Ajzen, 1985; Ajzen y Maden, 1986) y la *Teoría de la Motivación Protectora* (Rogers, 1975; 1983; Harris y Middleton, 1995).

Según estos modelos, para poder predecir el comportamiento saludable habría que focalizarse en la probabilidad subjetiva y la valoración de los resultados de la conducta

que tiene una persona. De esta manera, la persona comenzará o mantendrá una conducta saludable solo si considera probable que esas acciones tendrán unos resultados y considere que dichos resultados sean lo suficientemente positivos para que merezca la pena llevarla a cabo. Además de creencias y actitudes se añaden las normas subjetivas y la percepción de control como determinantes que pueden afianzar la predictibilidad de la conducta.

#### Modelos y teorías de autorregulación del comportamiento

Desde esta perspectiva el principal determinante del comportamiento relacionado con la salud sería la autoeficacia (Bandura, 1986a), entendida como la percepción personal de eficacia para realizar una determinada conducta y obtener unos determinados resultados derivados de esa conducta. Esta percepción de eficacia personal tiene como resultado unas expectativas que hacen de antesala a los resultados esperados. Es en base a dicho proceso de expectativas y resultados esperados a partir del cual la persona autorregula su propia conducta.

De este constructo psicológico se derivan el *Modelo de proceso de Adopción Precauciones* (Weinstein, 1988), el *Proceso Acción a Favor de Salud* (Schwarzer, 1992) y la *Teoría de Acción Social* (Ewart, 1991); todos ellos con la autoeficacia como referente del comportamiento de salud y con el establecimiento de diferentes etapas para la consecución de los objetivos saludables.

## Resumen

En este capítulo se ha hecho una revisión sobre los cambios en la concepción de la salud y la enfermedad a lo largo de la historia, poniendo especial énfasis en la transición epidemiológica y cómo se ha producido un cambio en los patrones de morbi-mortalidad en países occidentales desde el último siglo. Esto ha conllevado la crítica al modelo de salud tradicional o biomédico, que partía de la dualidad mente-cuerpo para explicar e intervenir en los procesos de salud-enfermedad. De esta crítica nacen nuevas aproximaciones, destacando especialmente el modelo biopsicosocial propuesto por Engel en el 1977, que plantea la necesidad de un abordaje holístico para entender la salud. Según este modelo los factores, o también llamados sistemas, biológicos, sociales y psicológicos interactúan entre sí afectando al estado de salud. Esta nueva perspectiva integradora dio lugar a nuevas disciplinas, entre las que se encuentran la medicina de la conducta o la Psicología de la Salud , que pone el acento en la agencia de las personas para influir en su salud a partir de comportamientos saludables. De esta disciplina surgen diferentes modelos que buscan explicar y predecir el comportamiento saludable para poder promover la salud, prevenir la enfermedad y mejorar los sistemas sanitarios.

## **Summary**

This chapter has reviewed the historical changes in the conception of health and disease, with special emphasis on the epidemiological transition and the evolution of morbidity and mortality patterns in Western countries since the last century. This conceptual change has led to criticism of the traditional or biomedical model of health that conceived of the mind-body duality to explain and intervene in health-disease processes. From this critique, new approaches and models were born, such as the one proposed by Engel in 1977, which exposes the need for a holistic approach to understanding health. According to this model, health is affected by a combination of factors (biological, psychological and social) that interact with each other. This integrative perspective resulted in new disciplines, such as behavioral medicine or Health Psychology, which emphasizes the agency of individuals to influence their health through healthy behaviors. This discipline has led to different explanatory models that seek to explain and predict healthy behavior in order to promote health, prevent disease and improve healthcare systems.

## Capítulo 2

### Enfermedades crónicas y modelo biopsicosocial

#### Introducción

El modelo biopsicosocial, los modelos explicativos de la Psicología de la Salud y todas las teorías que abordan aproximaciones holísticas para entender la salud adquieren una mayor relevancia en este momento histórico. La transición epidemiológica (Omran, 1971) puso de manifiesto que los países occidentales habían sufrido una evolución en las causas de enfermedad y muerte, pasándose de un mayor índice de enfermedades infecciosas a enfermedades crónicas no transmisibles, lo que llevó y lleva a occidente a nuevos desafíos en sus sistemas de salud. Por otro lado, si bien los países más desfavorecidos siguen padeciendo en mayor medida enfermedades infecciosas, se está observando cómo estas enfermedades crónicas aumentan en prevalencia, ocasionándose lo que se conoce como doble carga de enfermedad (Phaswana-Mafuya & Tassiopoulos, 2011). Lo que parece claro es que desde las últimas décadas se ha podido ver un incremento significativo de la prevalencia de enfermedades crónicas no transmisibles convirtiéndose estas en la principal causa de muerte y discapacidad a nivel mundial (OMS, 2022). Su impacto en la morbi-mortalidad poblacional global constituye, sin lugar a dudas, un problema de salud pública de alta relevancia. Por ello, se exige una agenda sanitaria que ponga en el centro su abordaje a todos los niveles.

#### Enfermedades no transmisibles

El concepto de enfermedades no transmisibles (ENT) hace referencia al conjunto de enfermedades cuya causa no es principalmente una infección aguda. Las ENT, también conocidas como enfermedades crónicas, suelen ser de largo recorrido suponiendo en la mayoría de los casos una necesidad de tratamiento y/o seguimiento a largo plazo

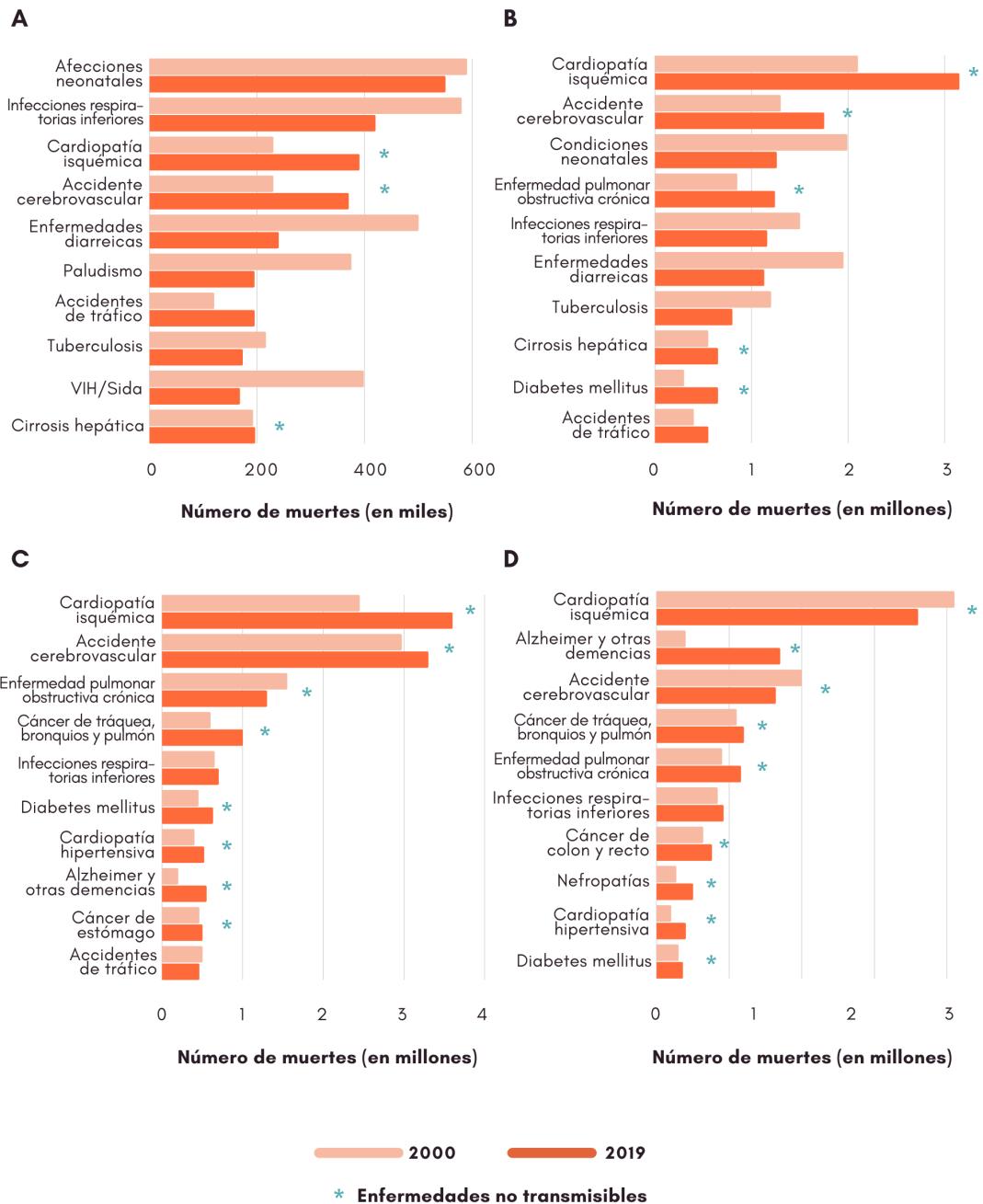
(Budreviciute et al., 2020; OMS, 2022). Son enfermedades que vienen determinadas por una combinación de factores genéticos, ambientales, fisiológicos y comportamentales (OMS, 2022). Resulta importante resaltar que la distinción entre ENT y enfermedad infecciosa a veces se torna difusa. Uno de los motivos es que enfermedades que se adquieren a través de una infección exigen posteriormente un abordaje prolongado o crónico, como es el caso del VIH (Finlay et al., 2020; Najafi et al., 2004), u otras más recientes como la COVID-19 en la que se han venido observando casos de COVID persistente (Fieiras et al., 2020). De hecho, a pesar de la examinada transición epidemiológica, las enfermedades infecciosas y transmisibles aun deben ser abordadas (Lewnard & Reingold, 2019), y es necesario apuntar que en ellas no influyen únicamente factores fisiológicos, por lo que un modelo biopsicosocial sigue pareciendo más apropiado para atender al rango de factores y consecuencias asociadas, aun en enfermedades trasmisibles como la COVID-19 (Laher et al., 2021; Sunder et al., 2021). Aun así, la diferenciación entre ENT y no transmisibles parece todavía útil para su estudio y abordaje clínico.

Dentro de las ENT, se encuentran las enfermedades respiratorias, como el asma o la enfermedad pulmonar obstructiva crónica, las problemáticas cardiovasculares, el cáncer, la obesidad, la diabetes y el Alzheimer, entre otras (Comisión Europea, 2022; OMS, 2022). Las ENT son, actualmente, el conjunto de enfermedades que provocan una mayor tasa de mortalidad a nivel mundial. Según los datos proporcionados por la OMS, cerca de un 75% de las muertes anuales son causadas por una ENT, lo que equivaldría a 41 millones de muertes al año, de las cuales 17 millones corresponden a muertes prematuras (menores de 70 años) (OMS, 2022). Estas enfermedades afectan a personas de todos los grupos de edad, pero son significativamente más frecuentes en edades avanzadas (Jakovljevic et al., 2019). También es importante destacar que existen

diferencias entre hombres y mujeres en la prevalencia de las diferentes ENT más frecuentes. Por ejemplo, según la *Encuesta Europea de Salud en España* del año 2020, el 49% de hombres y el 59% de las mujeres con más de 15 años tenían alguna enfermedad o problema de salud crónico percibido. Estos porcentajes crecían conforme avanzaba la edad siendo siempre superior en el grupo de las mujeres (INE, 2020).

Tal y como se expuso en el capítulo anterior, los avances y nivel de desarrollo socio-económicos, con todo lo que ello conlleva a nivel de salud y asistencia sanitaria, implican un perfil de morbi-mortalidad diverso en los diferentes países. Según la clasificación del Banco Mundial, se puede hablar de 4 clúster o perfiles de países en función del nivel de ingreso per cápita (Fantom & Serajuddin, 2016): 1) países de ingreso bajo, 2) medio-bajo, 3) medio-alto y 4) nivel de ingresos altos, entre los que se encuentra España, ocupando el puesto 27 de 173 (Banco Mundial, 2022). Partiendo de esta clasificación, la OMS ha analizado los datos de prevalencia de las principales causas de muerte en los 4 clúster mencionados. Los resultados, que pueden verse en la Figura 4, proporcionan una imagen clara de lo que Abdel R. Omran, ya en el 1971, planteaba. El patrón de mortalidad viene determinado por las condiciones socioeconómicas de los países, siendo las ENT actualmente la principal causa de muerte en occidente, pero, sin embargo, se puede observar como en países de bajos ingresos, las muertes por este tipo de enfermedades van en aumento (Hunter & Reddy, 2013). De hecho, el 75% de las muertes por ENT, y el 86% de aquellas prematuras, se producen en países con un nivel económico medio y bajo (OMS, 2022). Estos imponentes datos perfilan una transición similar a la que se vivió en los países occidentales (Omran, 1998), generando una doble carga a sus sistemas de salud y socioeconómicos entre las enfermedades de tipo infeccioso previamente presentes y las ENT (Phaswana-Mafuya & Tassiopoulos, 2011), que parecen instaurarse con fuerza (e.g., Gyasi & Phillips, 2020; Mohan et al., 2019).

Es precisamente este aumento de la tasa de mortalidad y prevalencia asociada a las ENT uno de los aspectos que más preocupa a los Estados y organizaciones mundiales (OMS, 2022; Organización de las Naciones Unidas [ONU], 2020). El envejecimiento progresivo de la población derivado de los cambios sociodemográficos, sumado a la creciente esperanza de vida, conlleva nuevos retos para la salud. Vivir más no significa vivir mejor. En los últimos 19 años se ha incrementado la esperanza de vida en 6 años a nivel mundial, sin embargo, solo 5 de esos años se disfrutaron con buena salud, encontrándose que las ENT fueron causantes de la pérdida de cerca de 100 millones de años de vida saludables colectivos comparando el año 2019 con el año 2000 (ONU, 2020). Sin embargo, este aumento de las ENT, a su vez parece haber frenado el ritmo de crecimiento esperado de expectativa de vida. En el caso de España, esta esperanza aumentó en 2,61 años en la década de los 2000-2010 y solo un 1,53 desde el 2010 hasta el 2019. Paralelamente, con respecto al número de muertes prematuras a causa de una ENT (ECV, diabetes, cáncer, enfermedades respiratorias), se observa una reducción en 2,6 puntos porcentuales del 2000 al 2010 y en 1,3 desde el 2010 al 2019 (INE, 2022a). Estos datos acerca de la esperanza y calidad de vida y su relación ENT, arrojan luz sobre la necesidad de abordar estas enfermedades desde la promoción, prevención e intervención eficaz. Por todo lo anterior, las ENT son un problema de desarrollo sostenible y desde la Agenda 2030 de Asamblea General sobre los Objetivos de Desarrollo Sostenible, dentro del “Objetivo 3. *Salud y Bienestar*” se tiene como meta (3.4) “reducir en un tercio la mortalidad prematura por enfermedades no transmisibles mediante su prevención y tratamiento, y promover la salud mental y el bienestar” a nivel mundial (Asamblea General de las Naciones Unidas, 2015).



**Figura 4.** Diez causas de muerte más frecuentes en los países de ingresos bajos (A), medios-bajos (B), medios-altos (C) y altos (D), según la clasificación del Banco Mundial en 2020, para los años 2000 y 2019 (adaptación de OMS, 2020b).

*ENT y Salud Mental: del enfoque “4x4” al “5x5”*

Históricamente, las ENT habían sido tratadas de manera globalizada dentro de un modelo “4x4” que correspondía a los 4 tipos de ENT más prevalentes a nivel mundial, las ECV, el cáncer, las enfermedades respiratorias, y la diabetes y 4 sus factores de riesgo más importantes, a saber, el consumo de tabaco, dietas no saludables, sedentarismo y consumo nocivo de alcohol (Budreviciute et al., 2020; Hunter & Reddy, 2013; OMS, 2020a). Sin embargo, eran numerosos los estudios que apuntaban a la infravaloración de la carga que suponían los problemas de salud mental en el mundo y que abogaban por su inclusión en este tradicional “4x4” (Hunter & Reddy, 2013; Ngo et al., 2013; O’Neil et al., 2015; Stein et al., 2019). De hecho, se estima que los problemas de salud mental supusieron una carga global medida por años de vida ajustados por discapacidad de 418 millones en el año 2019 (Arias et al., 2022). En la pasada década, varios fueron los informes oficiales en pro de responder a los principales problemas de las ENT que comenzaron a plantearse la necesaria idea de ampliar la agenda de salud incluyendo la salud mental como parte de sus objetivos (Global Ministerial Mental Health Summit, 2018; OMS, 2016, 2018a; OMS y Fundación Calouste Gulbenkian, 2014). De esta manera, en la cumbre de Alto Nivel organizada por la Organización de Naciones Unidas en el año 2018, se publica la declaración política en la que se pasa de un modelo 4x4 a un modelo 5x5 (Asamblea General de las Naciones Unidas, 2018). En este nuevo enfoque, se incluyen las enfermedades relacionadas con la salud mental al mismo nivel que las antes mencionadas ENT, y se añaden además los problemas de polución y contaminación medio ambiental como factor de riesgo común (OMS, 2019a). Esta inclusión de la salud mental en el modelo, equiparando su importancia a las ENT, constituía una declaración de intenciones, un compromiso en dirección a un abordaje integral y a una atención colaborativa,

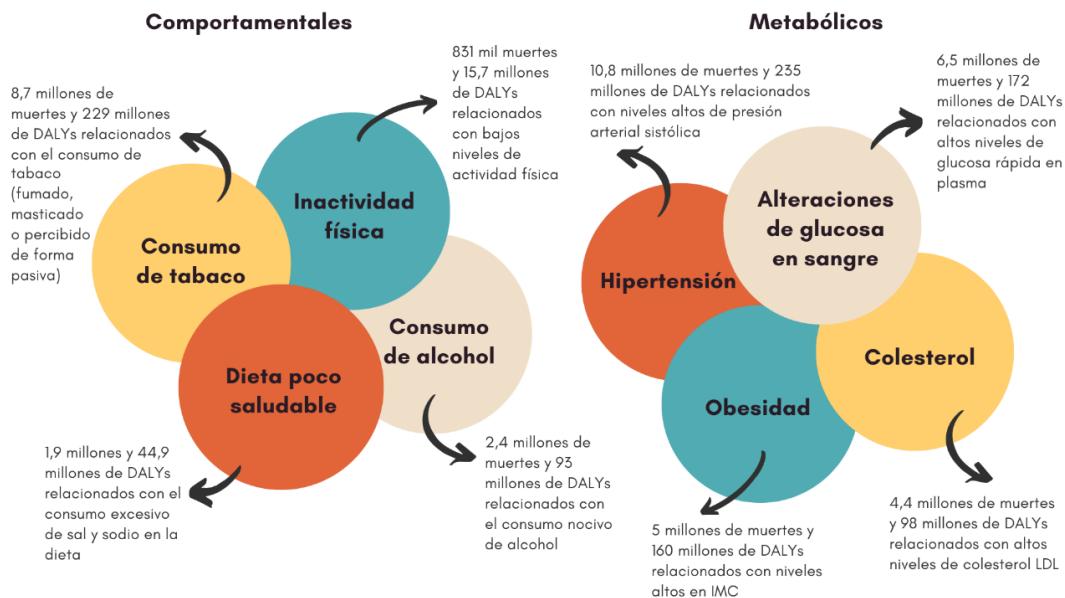
centrándose en la subjetividad e individualidad de los y las pacientes con ENT, que se trasladaría a la promoción y prevención de las mismas.

El cambio de enfoque y la incorporación de la salud mental vinieron determinados por el apoyo empírico que numerosas investigaciones habían aportado relacionando las más prevalentes ENT y las enfermedades relacionadas con la salud mental más frecuentes, como son la ansiedad y la depresión (O’Neil et al., 2015). Por ejemplo, la relación bidireccional entre la diabetes y la depresión (Alzoubi et al., 2018; Renn et al., 2011), la más alta prevalencia y el factor predictivo de la ansiedad y depresión en problemas cardiovasculares (Cohen et al., 2015; Hare et al., 2014; Tully et al., 2016), la alta sintomatología e impacto de la depresión y ansiedad también en pacientes con enfermedad respiratoria (Goodwin et al., 2014; Jang et al., 2019) o la alta proporción de pacientes con cáncer y ansiedad o depresión concomitante (Pitman et al., 2018; Yi & Syrjala, 2017). Además de esta relación, se podía observar la interdependencia entre las ENT y la salud mental ya que compartían factores de riesgos (e.g., consumo nocivo de alcohol), causas, consecuencias y características que hacía necesario su abordaje holístico (Ngo et al., 2013; Patel & Chatterji, 2015). A su vez, las enfermedades que afectan a la salud mental son causas y consecuencias de las ENT, y la literatura explicaba el riesgo de esta comorbilidad en el pronóstico de las mismas, así como la repercusión negativa en la calidad de vida de las personas que la sufren (Ngo et al., 2013; Stein et al., 2019) y los enormes costes personales y económicos asociados a su coocurrencia (Armbrecht et al., 2020).

#### *Factores de riesgo*

Una de las características de las ENT es que, a pesar de tratarse de enfermedades de diversa etiología, comparten factores de riesgo que además son prevenibles los cuales las hacen especialmente adecuadas para abordarse desde el modelo biopsicosocial de salud.

Estos factores de riesgo se pueden dividir en factores de riesgo metabólicos y, por otro lado, aquellos que son de naturaleza comportamental y, por tanto, de gran interés para la Psicología de la Salud (Figura 5).



**Figura 5.** Número de muertes y años de vida ajustados por discapacidad (DALYs) relacionadas con distintos factores de riesgo en el año 2019 (elaboración propia a partir de Global Burden of Disease Collaborative Network, 2020). IMC: Índice de masa corporal. LDL: lipoproteínas de baja densidad.

Aunque se presenten de manera independiente, ambos tipos de factores de riesgo están relacionados entre sí. Los factores de riesgo comportamentales provocan o influyen en los factores de riesgo metabólico, de manera que, por ejemplo, se ha relacionado el consumo excesivo de sal y tabaco con la hipertensión arterial y la ECV (He et al., 2020; Kondo et al., 2019) o la inactividad física y la dieta poco saludable con la obesidad y la diabetes (Eaton & Eaton, 2017; Kopp, 2019). La evidencia muestra cómo los cambios en el estilo de vida pueden mejorar los índices metabólicos y reducir el riesgo de

complicaciones de salud, y es precisamente esta relación entre factores lo que motiva y fundamenta la Psicología de la Salud. Las personas se entienden como agentes activos de sus procesos de salud-enfermedad, siendo responsables de cara a influir en su salud. A través de cambios de hábitos, factores que son modificables, se puede disminuir, directamente e indirectamente el riesgo, al mejorar marcadores biológicos, reduciendo aún más las probabilidades de padecer, en este caso, una ENT.

### **Enfermedades cardiovasculares**

Dentro de las ENT, cabe destacar las enfermedades cardiovasculares (ECV), ya que son el conjunto de afecciones médicas más prevalentes dentro de esta categoría. Es, además, la población diana en la que se han centrado los estudios empíricos de la presente Tesis Doctoral.

Con ECV se hace referencia al conjunto de problemas de salud que se relacionan con el corazón y los vasos sanguíneos. Dentro de ellas, se pueden encontrar la cardiopatía isquémica, la insuficiencia cardíaca, las arritmias, arteriopatía periférica, presión arterial alta (hipertensión), accidente cerebrovascular y la cardiopatía congénita, entre otras, siendo la cardiopatía isquémica la más frecuente (Roth et al., 2017).

#### *Datos epidemiológicos de las ECV*

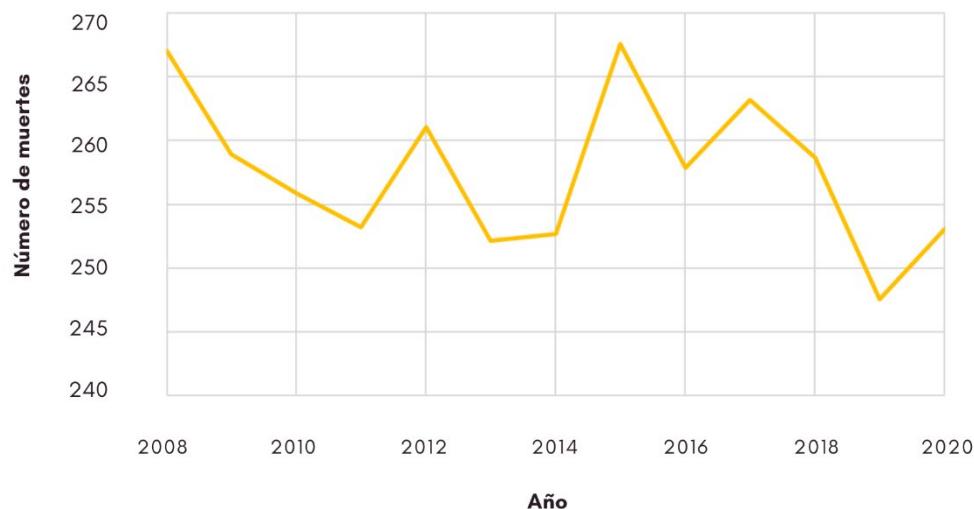
Las ECV son la principal causa de muerte relacionada con enfermedades que no son trasmisibles a nivel mundial (Hunter & Reddy, 2013). Según la OMS, en el año 2019, 17,9 millones de personas fallecieron a causa de una ECV, correspondiendo al 32% del porcentaje global de muertes y erigiéndose como las ENT que acumulan el mayor número de muertes (OMS, 2022). Dentro de las ECV, la cardiopatía isquémica es la afección cardiovascular con una mayor tasa de mortalidad, causando el 16% de las muertes a nivel mundial. Este alto porcentaje, ha ido en aumento en las últimas décadas, habiéndose

incrementado en cerca de 7 millones de fallecimientos desde el año 2000 (OMS, 2020b). Al igual que ocurría en las estadísticas de las ENT, en las ECV, el número de muertes se relaciona con el nivel económico del país, siendo tres cuartas partes de los fallecimientos localizados en países con bajo o medio desarrollo económico (OMS, 2017). Otro aspecto importante, que destaca en las ECV, es que se les asigna cerca del 40% de las muertes prematuras causadas por ENT (OMS, 2017).

En Europa, los datos reflejan estadísticas similares. Una revisión actual sobre la carga de estas enfermedades en la región europea las señala como la primera causa de muerte (Townsend et al., 2022). Cerca de 4 millones de personas fallecen al año a causa de alguna ECV, siendo la cardiopatía isquémica de nuevo, la mayor causante (44%), seguida del infarto (25%) (Panico & Mattiello, 2010). También se encuentra en los datos europeos que, si bien la incidencia y la prevalencia de las ECV es mayor en hombres, el número de muertes es mayor en mujeres, correspondiendo a un 46% de las muertes totales de mujeres (Townsend et al., 2022). En general, se puede observar un aumento progresivo de la incidencia de las ECV en Europa, si comparamos los datos entre 1990 – 2015 (Timmis et al., 2018).

En lo que respecta a España, en el año 2016 la cardiopatía isquémica fue la principal causa de muerte específica (Soriano et al., 2018). Según el INE (2021), durante el año 2020, las ECV se han cobrado la vida de cerca de 30.000 personas (61% hombres), convirtiéndose en la segunda causa de muerte después de la COVID-19. En relación a los Objetivos de Desarrollo sostenible y su indicador “3.4.1. Tasa de mortalidad atribuida a las ECV”, en España se ha podido observar una disminución de la mortalidad a causa de las enfermedades cardiovasculares, el cáncer, la diabetes o las enfermedades respiratorias crónicas” desde los años 1990 hasta la actualidad con un índice en el año 2020 de 253,09 cada 100.000 habitantes en contraposición con 336 en el año 1980 (INE, 2021) (Figura

6). Sin embargo, parece haberse producido un enlentecimiento de este descenso en los últimos años, pasando del -3,7% en hombres y -4,0% en mujeres para el periodo de 1999 a 2013, a un decremento del -1,7% en hombres y -2,2% en mujeres desde 2013 hasta 2018 (Cayuela et al., 2021).



**Figura 6.** Número de muertes por enfermedad cardiovascular en España entre los años 2008-2020 (elaboración propia a partir de INE, 2021).

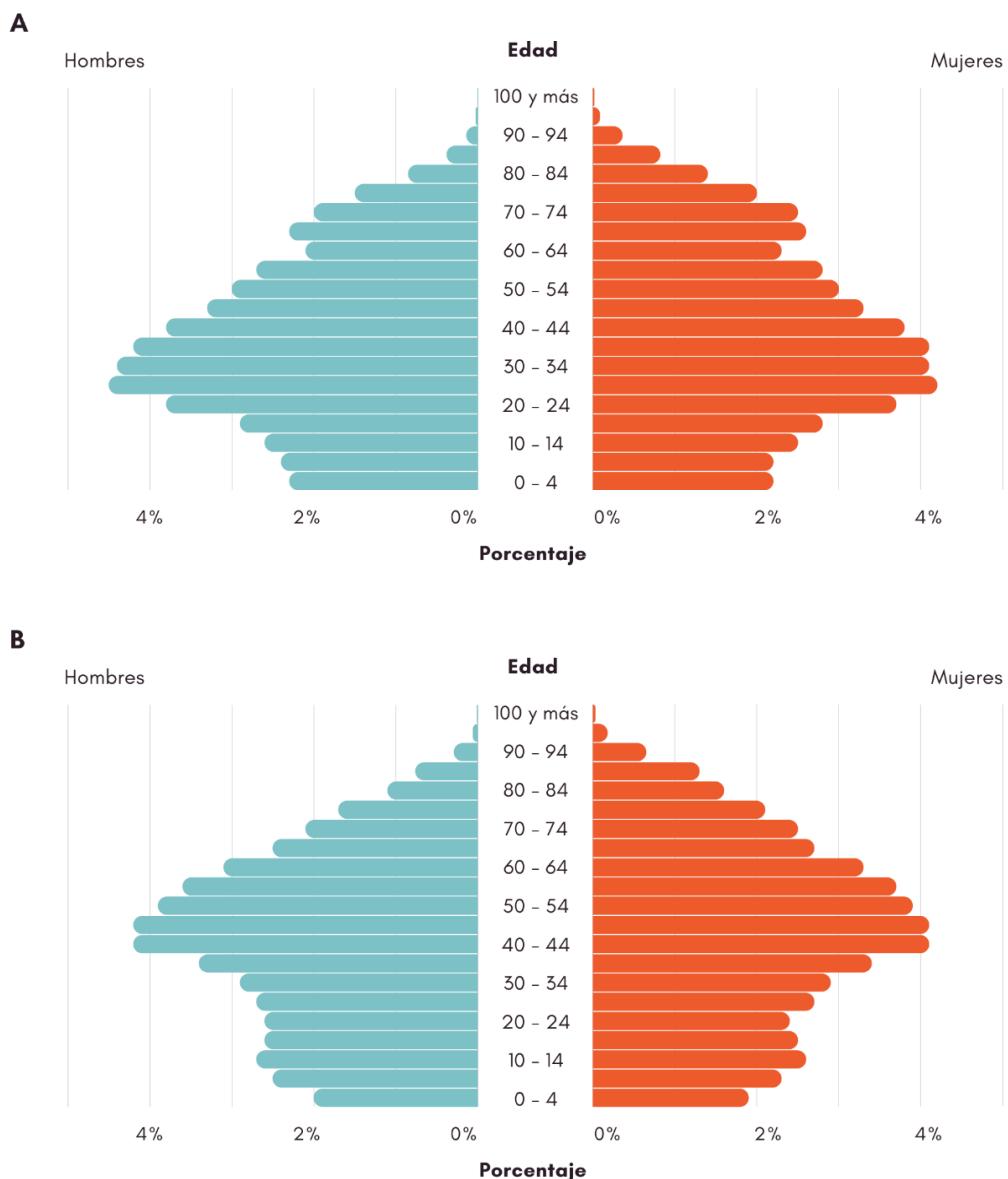
#### *Factores determinantes de salud cardiovascular*

La etiología de las ECV, al igual que el resto de las ENT más prevalentes, puede atribuirse a una combinación de factores biológicos, fisiológicos, ambientales y comportamentales. Pese a la importancia de todos estos factores, pues como se ha mencionado son interdependientes, existen dos motivos importantes que pueden ayudar a explicar el aumento en la incidencia, prevalencia y mortalidad de este tipo enfermedades. Por un lado, el envejecimiento de la población y, por otro lado, la mayor prevalencia de hábitos o estilos de vida no saludables.

**Envejecimiento de la población.** Actualmente, en 2022, la población mundial de 65 años o más alcanza el 10%, un punto más que en 2019, estimándose que esta población con

edad avanzada alcance el 16% en el año 2050 (Departamento de Asuntos Económicos y Sociales de las Naciones Unidas, 2018). De estas proyecciones se desprende que este grupo de edad doblará a los grupos de menores 5 años y se equiparará a los menores de 12 años. En España, estos datos se recrudecen y se ha podido observar una tendencia

similar, donde la población de 65 años o más ha pasado de representar del 15,5% en el año 2003 al 19,6% en 2021 (INE, 2022b) (Figura 7).



**Figura 7.** Pirámides poblacionales de España segregadas por sexo para los años 2003 (A) y 2021 (B) (adaptación de INE, 2022b).

La longevidad puede ser un reto para la calidad de vida, especialmente para las personas con enfermedades crónicas, ya que implica convivir durante más tiempo con su enfermedad, y la multimorbilidad frecuentemente asociada, con las consiguientes

consecuencias y desgaste que a todos los niveles (físico, psicológico, social) pueda suponer (Divo et al., 2014; Prince et al., 2015). En comparación a las enfermedades comunicables o de tipo infeccioso, las ENT se concentran más en la población mayor (Gong et al., 2018). Esto hace que el envejecimiento de la población, principalmente en la mayoría de países occidentales, suponga para los Estados nuevos retos a la hora de abordar la salud, entre los que se encuentran la elevada carga económica que este tipo de enfermedad supone para los sistemas de salud (Bernal-Delgado et al., 2018; Jakovljevic et al., 2019).

**Estilo de vida.** La longevidad también se ha visto íntimamente relacionada con el estilo de vida. La evidencia apunta a que las personas con menos factores de riesgo modificables relacionados con hábitos nocivos para la salud tienen más probabilidades de superar la edad de 90 años con vida (Wilhelmsen et al., 2011; Yates et al., 2008). Ciertamente, los datos muestran que el 80% de las enfermedades cardíacas y los accidentes cerebrovasculares prematuros se pueden prevenir (Departamento de Salud y Servicios Humanos de Estados Unidos, 2018). La evolución socioeconómica de un país parece venir asociada a una serie de estilos de vida no saludable, como por ejemplo la obesidad y el nivel de ingresos (Broyles et al., 2015). Esto se constata también en los cambios producidos en los países en desarrollo, no solo en su transformación demográfica y económica, sino en el cambio epidemiológico al tiempo que se acercaban hacia estilos de vida similares a los países de occidente (Phaswana-Mafuya & Tassiopoulos, 2011). De hecho, las ECV se encuentran entre las que se han dado a conocer desde hace tiempo en la literatura como “enfermedades de la civilización”, haciendo referencia a su claro vínculo entre el estilo de vida “occidentalizado” y las ENT (Burkitt, 1973; Carrera-Bastos et al., 2011). Por tanto, está ampliamente documentado que, más allá de los factores genéticos, los factores socioeconómicos y el estilo de vida tienen un papel esencial en el

riesgo de sufrimiento y muerte por ECV, ictus o infarto de miocardio (Livingstone et al., 2021; Zhang et al., 2021). Por su parte, la adopción de hábitos saludables parece esencial en el tratamiento y prevención de dichas enfermedades, por ejemplo, se ha visto que una dieta equilibrada reducía, también a pesar de los factores genéticos, el riesgo de ECV (Livingstone et al., 2021). Lo que parece tener más apoyo empírico, es que, para poder hablar de factor protector de este riesgo cardiovascular, se deben incluir un conjunto de conductas saludables. De hecho, numerosas investigaciones han aportado evidencia de cómo la adherencia a varios hábitos saludables se asociaba con una reducción riesgo cardiovascular de hasta un 66% (Barbaresko et al., 2018), o como el no fumar y no beber reducía el riesgo de mortalidad (Hu et al., 2022; Tsai et al., 2020). En su conjunto, esta evidencia permite observar cómo los principales factores de riesgo de las ENT y ECV son factores tipo comportamental asociados a los cambios de hábitos dominantes en las últimas décadas. Las muertes por ECV se han reducido drásticamente en muchos países desarrollados que han implementado políticas de promoción de estilos de vida saludable, si bien es necesario seguir aunando esfuerzos para seguir esta línea en países con ingresos medios y bajos, así como mejorar la calidad de vida de quienes conviven con estas enfermedades (OMS, 2014). La lectura positiva de estos datos es que los factores de riesgo, así como la probabilidad de que estos deriven en consecuencias negativas a nivel cardiovascular, serían modificables.

#### *Factores de riesgo cardiovascular prevenibles*

Anteriormente se expusieron los principales factores de riesgo comunes de las ENT; a continuación, se van a describir aquellos específicos de las ECV, poniendo el foco en los dos tipos de factores que se relacionan directamente con el ámbito de trabajo de la Psicología de la Salud, esto es, los factores de riesgo comportamentales y los psicosociales.

### Factores de riesgo comportamentales

#### ***Consumo de tabaco***

El consumo de tabaco es un importantísimo factor de riesgo, relacionándose directamente con un cuarto de las muertes por ECV (Departamento de Salud y Servicios Humanos de Estados Unidos, 2014). Fumar tabaco aumenta la grasa en sangre (triglicéridos), reduce el colesterol HDL, favorece la aparición de trombos, aumenta la acumulación de placa en los vasos sanguíneos y daña las células de los vasos sanguíneos y ensancha y reduce estos vasos (Departamento de Salud y Servicios Humanos de Estados Unidos, 2014). También se ha establecido como factor asociado a los accidentes cerebrovasculares (Piloto Cruz et al., 2020). Al mismo tiempo, el tabaquismo es un factor de riesgo para las personas fumadoras, pero también lo es para quienes reciben sus efectos de forma pasiva, aumentando en un 25% la probabilidad de desarrollar una ECV en estas personas no fumadoras directas, y causando al año 8.000 muertes por enfermedad cerebrovascular (Departamento de Salud y Servicios Humanos de Estados Unidos, 2014).

#### ***Consumo nocivo de alcohol***

El consumo de alcohol se ha relacionado con un incremento del riesgo de más de 50 enfermedades (OMS, 2018b). La relación entre el elevado consumo de alcohol y riesgo cardiovascular ha sido ampliamente estudiada. El consumo nocivo de alcohol se relaciona con una mayor probabilidad de desarrollar eventos cardiovasculares como miocardiopatía, hipertensión, fibrilación arterial, enfermedades isquémicas del corazón, así como accidentes cerebrovasculares (Federación Mundial del Corazón, 2022; OMS, 2018b; Piloto Cruz et al., 2020). Este riesgo aumenta conforme aumenta el nivel de consumo de alcohol (Goel et al., 2018). A pesar de ello, la literatura reporta controversia en relación al consumo de alcohol y la ECV. Numerosos estudios defienden que un consumo de alcohol leve - moderado (hasta 20 g/día) reduce el riesgo cardiovascular

(Piano, 2017), sin embargo, otros advierten sus limitaciones metodológicas y concluyen que no hay diferencias con la abstención o el consumo ocasional (Federación Mundial del Corazón, 2022; Stockwell et al., 2016). En España, se establece el consumo de alcohol intensivo o excesivo en 60 g/día en hombres y 40g/día en mujeres, aunque se mencionan riesgos cardiovasculares a menores dosis y se afirma que el posible beneficio de un bajo consumo no compensa las consecuencias negativas de la ingesta de esta sustancia (Ministerio de Sanidad, 2020). En todo caso, se pide sopesar el riesgo-beneficio en función de los casos, y el inicio de consumo, aunque moderado, no se recomienda en aquellas personas que no consumen (Federación Mundial del Corazón, 2022; Fernández-Solà, 2015; Goel et al., 2018). Se observan beneficios claros al reducir el consumo, incluso en quienes lo hacen de forma leve o moderada (Holmes et al., 2014). Reducir el consumo perjudicial de alcohol es uno de los prerrequisitos del control de ENT como las ECV reconocidos de forma global (OMS, 2018b).

### ***Dieta***

Numerosos estudios han avalado la relación entre la dieta y el riesgo cardiovascular. Tal y como se ha mencionado anteriormente, el excesivo consumo de sal y sodio constituye el principal factor de riesgo en relación a la dieta. Se calcula que cerca de 1,65 millones de muerte anuales causadas por una ECV, es decir el 9,5 % de las muertes correspondían al elevado consumo de sal (Mozaffarian et al., 2014). Aunque no libre de controversias, se puede concluir que el consumo de sal debería mantenerse por debajo de 5 g/día para reducir el riesgo (O'Donnell et al., 2020). Además de la sal, el azúcar es otro componente a tener en cuenta, sin embargo, la literatura presenta resultados no unánimes en relación al consumo de azúcar y la reducción del riesgo (Bergwall et al., 2022; Gómez Morales et al., 2013). Lo que sí parece indicado es seguir una dieta equilibrada y variada (Shan

et al., 2020), como puede ser la mediterránea (Delgado-Lista et al., 2022; Widmer et al., 2015), de cara a la reducción del riesgo cardiovascular.

### ***Inactividad física***

La inactividad física y el comportamiento sedentario se han relacionado con un mayor riesgo cardiovascular. Permanecer en posición sentada durante tiempo prolongado ( $\geq 10$  h/día en comparación a  $\leq 4-5$  h/día) se ha asociado con un aumento del riesgo cardiovascular en mujeres y hombres (Chomistek et al., 2013; Warren et al., 2010). De igual modo, los estudios muestran cómo la actividad física mejora los lípidos sanguíneos, la presión arterial, la sensibilidad a la insulina, los factores inflamatorios y hemostáticos y reduce los factores de riesgo cardiovasculares (Curtis et al., 2017; Myers et al., 2021). De hecho, se ha encontrado que incluso un pequeño aumento en la actividad física (1.25 h/semana) en personas previamente inactivas puede suponer una reducción del riesgo de diabetes del 26% y del 23% sobre la probabilidad de mortalidad por causa cardiovascular (Wahid et al., 2016). Así mismo, el aumento de la actividad física mejora la calidad de vida relacionada con la salud (Arija et al., 2018). Las personas que ya tienen una ECV pueden beneficiarse de igual modo de las ventajas de la actividad física, encontrándose una importante reducción del riesgo de mortalidad (Jeong et al., 2019).

### **Factores de riesgo psicosociales para la ECV**

La evidencia empírica ha demostrado que el riesgo de desarrollar ECV no solo proviene de factores biológicos, sino también de factores conductuales, psicológicos y sociales, que, según un modelo biopsicosocial de la salud, interactúan entre sí (Mozaffarian et al., 2014). Por ello, además de los factores metabólicos y comportamentales, se deben de tener en cuenta los siguientes factores psicosociales.

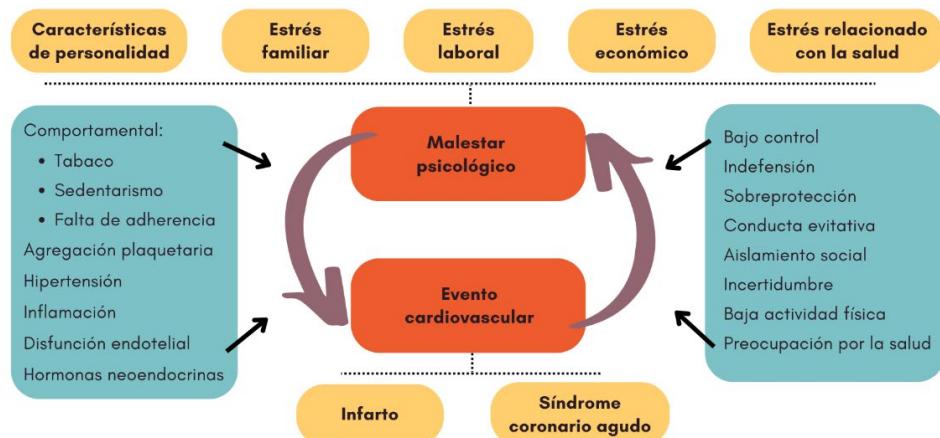
### **Malestar psicológico y ECV**

La evidencia muestra que el malestar psicológico es un factor de riesgo para todas las causas de muerte, especialmente en enfermedades crónicas como las ECV (Hockey et al., 2022). Son numerosas las investigaciones que han encontrado una relación entre las ECV y el malestar psicológico, especialmente con la sintomatología ansiosa-depresiva y el estrés (Cohen et al., 2015), factores que afectan tanto a cambios a nivel fisiológico como conductual (McGuire et al., 2015) (Figura 8). En primer lugar, la aparición y diagnóstico de una ECV supone para quienes la padecen un gran impacto a nivel psicológico desde los inicios. Por ejemplo, muchos pacientes informan de gran malestar psicológico tras haber sufrido paro cardíaco, presentando síntomas de depresión y ansiedad, incluso estrés postraumático (Agarwal et al., 2022). Al mismo tiempo, el diagnóstico de ECV suele requerir un ajuste de vida importante ya que supone hacer frente a una condición médica de carácter crónico que afecta directamente con cambios en el estilo de vida (APA, 2010). Estos cambios irían de la mano de los determinantes comportamentales y, por tanto, puede significar la adopción de nuevas medidas y conductas de salud, como cuidar la dieta, hacer más ejercicio físico o abandonar hábitos nocivos como el tabaco o el alcohol. Pero, además, en muchas ocasiones este diagnóstico supone dejar atrás algunas actividades laborales o de ocio y *hobbies*, que por la condición médica deben ser reajustadas a las posibilidades reales que el cuerpo pueda permitir (APA, 2010). En cualquier caso, esos cambios en el estilo de vida, sacuden la vida de las personas con ECV y en muchas ocasiones no disponen de los recursos psicológicos necesarios para poder afrontar y gestionar la enfermedad y lo que conlleva. Todo lo anterior justifica, por tanto, el alto porcentaje de comorbilidad de las ECV con malestar psicológico (Matsumura et al., 2022).

Estas afecciones y malestar psicológico influyen sobre el compromiso terapéutico, afectando al desarrollo de la enfermedad y su pronóstico, y pudiendo complicar la recuperación. Además, influyen en la experiencia que se tiene de la ECV y se vinculan con una peor calidad de vida (Jankowska-Polańska et al., 2018) lo que puede relacionarse con una dificultad para aceptar el diagnóstico (Jankowska-Polańska et al., 2018; Kocjan, 2015). Todo ello se relaciona con una peor adaptación a la enfermedad y la elevada tasa de no adherencia al tratamiento en estos pacientes y baja participación en programas de rehabilitación cardíaca, afectando negativamente en su salud física y mental (Gostoli et al., 2016; Silverman et al., 2019; Welsh et al., 2019). Se ha observado también que el seguimiento de hábitos de vida saludables, como la actividad física, la dieta sana o dejar de fumar es mejor en pacientes que muestran mayor malestar psicológico (Silverman et al., 2019).

Sin embargo, se ha demostrado que la relación entre la ECV y esta sintomatología psicológica es bidireccional, es decir, que no solo el diagnóstico de ECV parece favorecer la sintomatología ansioso-depresiva, sino que además parece haber una conexión entre personas con altos niveles de ansiedad, depresión y estrés y un mayor riesgo de ECV (Emdin et al., 2016; OMS, 2019a). De hecho, el malestar psicológico constituye un predictor independiente de la ECV, hay estudios que hablan incluso de una relación causal entre la ansiedad y la depresión y algunos eventos como el infarto de miocardio y la muerte súbita relacionada con ECV (Silverman et al., 2019). En un metaanálisis realizado por Batelaan et al. (2016) se encontró que la ansiedad se asociaba a un mayor riesgo del 52% para la incidencia de la ECV. Por otra parte, en las ECV, al igual que se comentó con los factores de riesgo de las ENT, estos determinantes de la salud se relacionan e interaccionan unos con otros. De esta manera, la depresión y la ansiedad se ha visto vinculadas a menor ejercicio físico, mayor consumo de tabaco o menor atención a la

alimentación (OMS y Fundación Calouste Gulbenkian, 2014) produciendo un efecto acumulativo en lo que respecta al riesgo ECV. Además, identificar los aspectos modificables que ponen en riesgo a las personas con problemáticas severas de salud mental (como el consumo de tabaco o alcohol, pero también la discriminación) es señalado por las organizaciones internacionales como imprescindible para reducir los mayores riesgos de las ECV en estas poblaciones (OMS, 2019a).



**Figura 8.** Vínculo entre el malestar psicológico y la enfermedad cardiovascular con relación a distintas variables biopsicosociales (adaptación de McGuire et al., 2015).

Además de la ansiedad, depresión y el estrés, diversos estudios han aportado evidencia sobre cómo determinados rasgos de personalidad pueden relacionarse con un mayor riesgo ECV. La personalidad tipo D, cuya “D” hace referencia al término inglés “*Distressed*”, que se traduce como angustiado o afligido, se refiere a la tendencia a la afectividad negativa, entendida como una predisposición a la preocupación, irritabilidad, abatimiento, así como a una inhibición social caracterizada, entre otras, por una falta de confianza en uno mismo (Denollet et al., 2010). Se ha visto asociada una mayor

prevalencia de este tipo de personalidad en ECV como el síndrome coronario agudo, siendo un fuerte predictor de la misma (Khoshamouz et al., 2022). Por otro lado, también se ha relacionado el patrón de conducta tipo A, que se corresponde con personas altamente competitivas, ambiciosas, muy orientadas al éxito laboral, preocupadas por el tiempo y agresivas, con un mayor riesgo ECV (Petticrew et al., 2012).

Finalmente, como determinante de salud ECV, se encuentra el nivel socioeconómico, entendido como el conjunto del nivel educativo, de ingresos, status de la ocupación, así como factores ambientales asociados (Schultz, et al., 2018). Ampliamente estudiada es la relación entre este nivel socioeconómico y el riesgo de ECV quedando demostrada con los datos epidemiológicos mencionados en apartados anteriores donde se reportaba que la mayoría de las muertes por ENT y por ECV concretamente, eran significativamente mayores en países de bajos y medio nivel económico (OMS, 2017, 2022). El gasto sanitario per cápita traducido en la falta de recursos médicos, la peor asistencia, mayor tiempo de espera, la falta de políticas de salud públicas dirigidas a la promoción y prevención ECV, la dificultad en el acceso a las adaptaciones tecnológicas de diagnóstico y tratamiento, son algunos de los factores que intervienen en un alto porcentaje de mortalidad en estos países (Rosengren et al., 2019). Así mismo, en los países de mayores ingresos, la incidencia de ECV y su enorme impacto a todos los niveles continua. Puede verse un mayor riesgo en personas con estatus socioeconómico bajo dentro de estos países, observándose en la literatura que esta carga puede atribuirse a un conjunto de factores, entre los que los psicosociales ostentan gran peso para estas personas (Schultz, et al., 2018). Junto a las desventajas materiales, se estima que el 70% de los casos y muertes por ECV en la población general se deben a factores modificables (Yusuf et al., 2020). De igual modo, parece que la educación para la salud y la implementación de intervenciones hacia conductas saludables puede reducir

la brecha de salud por causa socioeconómica en el riesgo cardiovascular (Petrovic et al., 2018). La doble relación entre los comportamientos de riesgo y el malestar psicológico, incrementada en la población con menor nivel socioeconómico, también debe tenerse en cuenta a la hora de entender estos hallazgos (Lazzarino et al., 2013).

El malestar psicológico parece tener, por tanto, un papel fundamental en la aparición, curso, pronóstico y manejo de la ECV, de forma independiente y con una importante relación con los factores de riesgo comportamentales mencionados en el apartado anterior. Sin embargo, la evidencia muestra que este conocimiento es raramente tenido en cuenta en la asistencia sanitaria (McGuire et al., 2015). Considerando la interrelación entre factores psicosociales modificables y el riesgo cardiovascular, se pone en aviso a la comunidad sanitaria para adoptar un enfoque positivo al intervenir con pacientes cardíacos, en que una mejor salud psicológica y condiciones de vida pueden promover la salud cardiovascular y prevenir o disminuir los riesgos conocidos (Levine et al., 2021; Silverman et al., 2019). En este sentido, tener en cuenta las variables que mejoren el bienestar psicológico (es decir, satisfacción vital, felicidad, equilibrio afectivo; (Diener, 2009) y favorezcan la aceptación diagnóstica, podría fomentar el compromiso terapéutico y facilitar la adaptación a la enfermedad, minimizando así el malestar psicológico relacionado con el diagnóstico de la ECV.

## Resumen

En este capítulo se han abordado las ENT, que son enfermedades de curso crónico que demandan atención y abordaje sanitario a largo plazo. Entre ellas destacan las ECV, diabetes, enfermedades respiratorias y el cáncer. Causadas por una combinación de factores biopsicosociales, las ENT están en el foco de atención de las agendas de políticas sanitarias por su progresivo ascenso en prevalencia y mortalidad a nivel mundial que comienza a afectar especialmente a países vulnerables. Dentro de las ENT, destacan las ECV por su mayor prevalencia y tasa de mortalidad a nivel mundial. Resulta especialmente relevante que en la aparición, diagnóstico, pronóstico y recuperación de las ECV se encuentran factores determinantes comportamentales (dieta, tabaco, alcohol, sedentarismo) y sobre todo psicosociales, entre los que destacan la ansiedad, la depresión y el estrés. El malestar psicológico se relaciona, además, con un menor compromiso terapéutico y un peor pronóstico de la enfermedad, afectando a la calidad de vida los pacientes, lo que justifica y reivindica un abordaje psicológico dentro de los programas de rehabilitación cardíaca.

## **Summary**

This chapter has discussed non-communicable diseases (NCDs), which are chronic diseases that require attention and a long-term health care approach. These include cardiovascular diseases (CVD), diabetes, respiratory diseases and cancer. Caused by a combination of biopsychosocial factors, NCDs are the focus of attention in health policy agendas due to their progressive increase in prevalence and mortality worldwide, which is especially affecting vulnerable countries nowadays. Among NCDs, CVD are particularly noteworthy due to their high prevalence and mortality rate at the worldwide. It is particularly relevant that behavioral determinants (diet, smoking, alcohol, sedentary lifestyle) and, above all, psychosocial factors, including anxiety, depression and stress, are involved in the onset, diagnosis, prognosis and recovery of CVD. Psychological distress is also related to a lower therapeutic commitment and a worse prognosis of the disease, affecting the quality of life of patients, which justifies and demands a psychological approach within cardiac rehabilitation programs.

## Capítulo 3

# Bienestar psicológico, bienestar subjetivo y enfermedad cardiovascular

### Introducción

El malestar psicológico asociado a personas con ECV pone en valor la necesidad de intervenir con estos pacientes la esfera psicológica-emocional, ya que fomentar el bienestar psicológico por otra parte, podría tener efectos positivos y de protección (Boehm & Kubzansky, 2012; Sin, 2016).

Según Carol Ryff (1989), el bienestar psicológico es un constructo amplio y complejo de definir que se relaciona con la resiliencia y la personalidad resistente o *hardiness*, que hace referencia a la capacidad o resistencia para hacer frente a situaciones estresantes (Kobasa, 1979). El bienestar psicológico engloba, según la autora, seis dimensiones: la autoaceptación, las relaciones positivas y de calidad, tener un propósito, crecimiento personal, autonomía y dominio del entorno. Hace referencia, por tanto, a un funcionamiento psicológico óptimo lo cual incluye el conjunto de aspectos emocionales, donde se encuentran: las sensaciones de felicidad, disfrute, placer, la presencia de emociones positivas, así como funciones de más alto nivel como sentirse realizado/a, la resiliencia, el afrontamiento, la regulación emocional y la resolución de problemas (Ryff, 1989). Se podría definir como la manera en la cual las personas se sienten al realizar sus actividades de la vida diaria (Warr, 1978).

Entre las variables que afectan al bienestar psicológico y que tienen especial relevancia en pacientes con enfermedad crónica, se encuentra el bienestar subjetivo (Diener, 2009). Este constructo, al igual que el bienestar psicológico, está muy relacionado con el funcionamiento positivo de las personas. Surgió como medida de la

felicidad en base a tres factores, dos de ellos dentro de la esfera emocional, el afecto positivo y el afecto negativo, y un último factor de corte cognitivo, la satisfacción vital. El afecto positivo se refiere al grado en que una persona se siente alegre, activa, inspirada, alerta y el afecto negativo, en cambio, refleja el malestar subjetivo que incluye una serie de emociones desagradables (e.g., ira, asco, culpa, miedo y nerviosismo) (Watson et al., 1988). La satisfacción vital por otro lado corresponde a las evaluaciones que las personas realizan acerca de su experiencia vital, a nivel global (Diener, 2009; Garcia et al., 2017). Existe mucha literatura que aporta evidencia sobre la contribución de ambas variables a la salud cardiovascular (Boehm & Kubzansky, 2012; DuBois et al., 2015). El bienestar psicológico, por un lado, se ha encontrado relacionado con una menor probabilidad de ocurrencia y recurrencia de sufrir un infarto (Kim et al., 2013; Lambiase et al., 2015; Sin, 2016). El bienestar subjetivo, más concretamente el afecto positivo, también se relaciona con menor riesgo de sufrir un evento cardíaco, así como con otros indicadores fisiológicos (menores niveles de cortisol, inflamación, mejor funcionamiento inmunológico, mayor calidad del sueño, menor actividad fisiológica) (Brummett et al., 2009; Dockray & Steptoe, 2010). Además, estas variables parecen tener influencia en el establecimiento y mantenimiento de hábitos saludables (Huffman et al., 2016; Kim et al., 2017; Kubzansky et al., 2018), lo cual, a su vez, podría repercutir en una mejor calidad de vida en las personas con ECV. Por todo lo anterior, focalizar las intervenciones en aras de mejorar el bienestar psicológico en estos pacientes podría repercutir positivamente en su manejo de la ECV, pues puede favorecer la adquisición de conductas saludables que se relacionan con un mejor pronóstico de la misma (Kubzansky et al., 2018).

Teniendo en cuenta la literatura previa, para la realización de la tesis, se ha centrado en dos de las variables que se han encontrado muy relacionadas con el bienestar

psicológico y por tanto con las conductas saludables y calidad de vida, la autoeficacia y la regulación emocional.

### **Variables psicológicas como determinantes del bienestar psicológico y comportamiento saludable**

#### *Autoeficacia*

La autoeficacia, como ya se mencionó en el Capítulo 1, es una de las variables más relevantes dentro de la Psicología de la Salud . Este factor tiene un gran efecto en la autorregulación del comportamiento, motivando la aparición de diversos modelos explicativos del comportamiento saludable.

Definida por primera vez por Albert Bandura en el año 1986 dentro del marco de la Teoría Social Cognitiva como la percepción de capacidad que tiene una persona para influir en los acontecimientos que afectan a su vida, la convicción de que uno puede realizar con éxito una actividad determinada (Bandura, 1986b). Sería la autoeficacia el mecanismo central en la que se apoya entre otros la motivación y el bienestar emocional y ejerce, por tanto, su impacto a través de procesos cognitivos, motivacionales, afectivos y de toma de decisiones (Bandura & Wood, 1989).

La autoeficacia vendría determinada por 4 factores o fuentes, las cuales pueden ser utilizadas para aumentar esa percepción de eficacia personal y conseguir así el inicio y mantenimiento de conductas saludables. Estas fuentes son la experiencia previa, la experiencia vicaria, la persuasión verbal y los estados somáticos y emocionales (Bandura, 1997).

- ***Experiencias previas de éxito:*** las experiencias de éxito pasadas proporcionan una fuerte creencia de eficacia personal. Es la fuente con una mayor influencia sobre la autoeficacia.

- **Experiencia vicaria:** otra fuente importante para mejorar la autoeficacia es a través de la observación y aprendizaje a partir de otros modelos. Observar a personas que sean similares conseguir sus objetivos a través de un esfuerzo mantenido, aumenta la creencia personal de que se también poseen las capacidades necesarias para conseguir dichos objetivos en actividades que sean comparables.
- **Persuasión verbal:** recibir mensajes verbales alentadores que intenten convencer de que se poseen las capacidades necesarias para realizar una determinada tarea o conseguir un objetivo concreto, fomenta una movilización y mantenimiento de los esfuerzos en la dirección de los objetivos, mejorando la autoeficacia y aumentando las probabilidades de éxito.
- **Estados somáticos y emocionales:** la última fuente que influye sobre la percepción de capacidad personal viene determinada por la interpretación de las sensaciones fisiológicas. Una manera de modificar la autoeficacia reside en reducir los estados de estrés y en aprender a reinterpretar las reacciones fisiológicas. Los indicadores fisiológicos pueden ejercer un rol positivo en la salud si se entienden como motivadores para la acción más que como una debilidad.

### Autoeficacia y ECV

Teniendo en cuenta la naturaleza de la autoeficacia y cómo se relaciona con la motivación y el comportamiento, este constructo psicológico cobra una mayor relevancia en la promoción del comportamiento saludable en las enfermedades crónicas (Chan, 2021; Kırca & Kutlutürkan, 2021). Este tipo de enfermedades, como ya se ha comentado, implican un cambio en el estilo de vida de las personas a largo plazo y en la mayoría de los casos de manera permanente. Por tanto, la motivación para llevar a cabo los cambios propuestos y necesarios para un mejor pronóstico de la enfermedad y una reducción de

los factores de riesgo asociados (dieta, medicación, cambio de hábitos, etc.) puede venir influenciada por la percepción de capacidad para llevarlos a cabo y mantenerlos sostenidamente en el tiempo. Por ello, la autoeficacia ha sido ampliamente estudiada en este ámbito y la literatura previa ha demostrado su influencia en el manejo de la enfermedad crónica (Chan, 2021; Kırca & Kutlutürkan, 2021) y concretamente en la rehabilitación cardíaca y calidad de vida percibida en pacientes con ECV (Banik et al., 2018; Nguyen et al., 2022; Pakaya et al., 2021). En esta dirección, se ha visto una relación entre la autoeficacia y los factores determinantes de salud cardiovascular de tipo comportamental como la adherencia a una dieta saludable (Cuadrado et al., 2018), ejercicio físico y la realización de actividades de autocuidado (Banik et al., 2018; Tan et al., 2021). Por otro lado, se ha visto además una relación con el bienestar psicológico y subjetivo, más concretamente en la satisfacción vital, el afecto positivo y la calidad de vida relacionada con la salud de pacientes con ECV (Krok & Gerymski, 2019; Krok & Zarzycka, 2020). Estos resultados apoyan y sustentan el rol central que la autoeficacia tiene en los pacientes ECV, tanto a nivel emocional como a nivel comportamental, ya que ayuda a modular la conducta y mejorar así su salud.

### *Regulación emocional*

Las emociones son respuestas automáticas con base biológica hacia situaciones que los sujetos consideran personalmente relevantes (McRae & Gross, 2020). Estas pueden clasificarse en emociones positivas o agradables (alegría, felicidad, tranquilidad, etc.) y en negativas o desagradables (enfado, ansiedad, estrés, ira, tristeza, decepción, etc.) (Solomon & Stone, 2002). Ambas juegan un papel fundamental en la salud mental, así como en la salud en general. Son el punto de referencia del bienestar psicológico y se convierten en factores de riesgo cuando no son bien gestionadas, relacionándose entre otras con las ECV. La regulación emocional se convierte por tanto en un recurso

primordial que permite una gestión saludable de las dificultades del día a día como puede suponer una enfermedad crónica o un evento cardíaco (Gross, 2013).

La regulación emocional ha sido definida por numerosos autores desde hace décadas, Gross (1998) considerado uno de los primeros psicólogos en intentar dar respuesta a este proceso, lo define como el “*procedimiento mediante el cual las personas influyen en las emociones que tienen, cuándo las tienen, cómo las viven y cómo las expresan*” (p.275). Según este autor, este proceso puede englobar todas las estrategias automáticas o controladas y conscientes o inconscientes que las personas utilizan para aumentar, mantener o disminuir los componentes de una respuesta emocional (Gross, 2001). Por otro lado, Thompson (1994) la describía como los procesos intrínsecos o extrínsecos que las personas realizan para monitorizar, evaluar y modificar las reacciones emocionales, sobre todo cuando se presentan en alta intensidad, para conseguir los propios objetivos. Esta definición de Thompson añade la motivación por la cual las personas regulan las emociones orientada siempre a la consecución de objetivos, lo cual, siguiendo la idea de Bandura, podría también verse influenciada por la autoeficacia. En cualquier caso, es un proceso que incluye diferentes etapas las cuales varían en función del modelo explicativo que intente dar respuesta al procesamiento emocional.

Hervás (2011), por su parte, plantea un modelo integrativo en el cual incluye 6 etapas o tareas para entender el proceso de regulación emocional. Según este modelo, la regulación adaptativa de las emociones pasa por tener la capacidad para:

- Tener acceso consciente a las emociones (apertura emocional)
- Focalizar la atención hacia la información emocional (atención emocional)
- Aceptar sin enjuiciar la propia experiencia emocional (aceptación emocional)
- Identificar, reconocer y nombrar correctamente las emociones sin confundirlas (etiquetado emocional)

- Interpretar, reflexionar y entender la experiencia emocional (análisis emocional)
- Modular o regular las emociones a través del uso de una serie de estrategias, cognitivas, conductuales, o emocionales que ayuden a gestionar adecuadamente la emoción y la situación que la provoca.

La adecuada regulación emocional, por tanto, implica el uso de unas estrategias adaptativas que ayudarán a afrontar las situaciones que generen una alta intensidad emocional negativa o desagradable (Pascual et al., 2016). Estas estrategias han sido definidas y clasificadas por diversos autores como Parkinson y Tottedell (Parkinson & Totterdell, 1999), que diferenciaban entre las *estrategias cognitivas* (desconectar, distracción del pensamiento, reevaluación de la situación) y las *estrategias conductuales* (abandonar la situación, hacer algún tipo de actividad física, relajación, buscar apoyo). Otras autoras las clasifican en función del nivel de actividad demandada en la estrategia (Castillo-Mayén et al., 2021), y se encuentran, de menor a mayor demanda, *las estrategias pasivas*, aquellas que se basan en la “desconexión” como tumbarse, darse un baño o ver la tele, las *estrategias intelectuales*, que serían, entre otras, leer, escribir o escuchar música, y las *estrategias físicas*, como ir al gimnasio, caminar, salir a la calle, etc. Estas estrategias de afrontamiento tienen por objetivo reducir el afecto negativo y aumentar el afecto positivo, resultando en una mejora del bienestar subjetivo y favoreciendo la regulación emocional. Lo contrario a este procesamiento emocional sería la **desregulación emocional** (Gross & Levenson, 1997), que se puede entender como la supresión, inhibición, no expresión emocional, así como el uso de estrategias de regulación desadaptativas, como, por ejemplo, el consumo de alcohol, tabaco y otras drogas, comportamientos nocivos que empeoran la salud ECV y además aumentan las

probabilidades de aparición de patologías comórbidas (e.g., abuso de sustancias) (Woodhead et al., 2014).

### Regulación emocional y ECV

Por la relación entre las emociones y los comportamientos saludables, la Psicología de la Salud ha estado motivada a estudiar la vinculación entre la regulación emocional y factores de riesgo relacionados con la salud y concretamente con la ECV.

Por un lado, partiendo de investigaciones que informan de que la depresión, la ansiedad y el estrés predicen el desarrollo de las ECV y empeoran su pronóstico, se ha visto que la regulación emocional desadaptativa es un factor de riesgo para estas enfermedades (Van Beek et al., 2016). La desregulación emocional se relaciona con la hipertensión y la enfermedad coronaria y el estilo de afrontamiento represivo correlaciona con un mayor riesgo de desarrollo de ECV (Howard et al., 2017). Además, el uso de estrategias de regulación emocional desadaptativas se relacionan con otros factores de riesgo cardiovasculares como un mayor índice de masa corporal, el consumo de alcohol, tabaco, una dieta poco saludable y la falta de actividad física, entre otras (Parkinson & Totterdell, 1999). Esta relación entre la supresión emocional y la salud física parece venir determinada por la elevada activación simpática del sistema nervioso central, así como por una reacción fisiológica mantenida que excede las demandas metabólicas (Gross & Levenson, 1997). Por otro lado, el uso de estrategias de afrontamiento adaptativas se relaciona con la salud cardiovascular y un menor riesgo de eventos cardíacos adversos (Messerli-Bürgy et al., 2015).

Por otro lado, las personas con ECV parecen mostrar una peor regulación emocional (Appleton et al., 2014; Spitznagel et al., 2013), siendo esto a su vez un riesgo para el desarrollo de algún trastorno o alteración emocional comórbida sumado al peor al peor pronóstico de la ECV, ya que se relaciona inversamente con el ajuste, aceptación y

adaptación a la misma. La regulación emocional es por tanto decisiva no solo para el bienestar psicológico, sino que de manera indirecta se traduciría en un factor protector de la salud cardiovascular e incluso podría favorecer y fomentar la autoeficacia (Appleton et al., 2014).

Por todo lo anterior, por la relación entre la desregulación y el riesgo cardiovascular, así como la relación entre el bienestar emocional y psicológico con una la reducción de esos riesgos, las intervenciones psicológicas dirigidas a mejorar y entrenar un adecuado manejo de las emociones parecen claves para disminuir las probabilidades de desarrollar problemas comórbidos y para mejorar la calidad de vida de los pacientes con ECV.

### **Sexo, género y salud**

Otras variables a tener en cuenta cuando hablamos de salud y que son de vital importancia para su análisis y abordaje son el sexo y el género. Ambas variables, y sobre todo en el ámbito de la salud, necesitan ser diferenciadas. El sexo se entiende comúnmente como una variable biológica, una condición inherente inmutable que clasifica a los individuos como mujeres y hombres de acuerdo con factores biológicos como son los cromosomas, las hormonas, etc. (National Institutes of Health, 2015). El género, por otro lado, hace referencia a la construcción sociocultural que tiene lugar a través de un proceso de socialización de género constante en el que la persona se ve influida por las normas, reglas, roles, estereotipos y expectativas de su cultura en función de su sexo biológico (Leaper & Farkas, 2015; OMS, 2019b).

Tanto sexo como género son variables con un gran efecto en la salud de las personas ya sea mental o física. Sin embargo, la identificación de esta influencia quizá ha sido más asequible en el caso del sexo por motivos de objetividad y accesibilidad de los datos, como puede ser la significativa diferencia entre la prevalencia del cáncer de mama

entre hombres y mujeres, fibromialgia, depresión o ansiedad, así como otras afecciones (Valls Llobet, 2011). Estos análisis de prevalencia diferencial por sexo resultan de la, *a priori*, sencilla tarea de analizar las estadísticas atendiendo al sexo. Sin embargo, realizar un análisis sobre cómo la sociedad y la cultura pueden afectar diferencialmente a la salud y la enfermedad, a su percepción y experiencias a mujeres y hombres parece una tarea más difícil de resolver. Es justo este punto uno de las principales críticas que el modelo biopsicosocial ha recibido por parte de muchas autoras, las cuales consideran insuficiente el abordaje de la salud desde este prisma integrativo, siendo necesario una perspectiva de género-feminista para poder dar respuesta con precisión a las causas de las considerables diferencias entre mujeres y hombres en las condiciones de salud (Day et al., 2016; Fine, 2018).

En cualquier caso, el análisis de la morbi-mortalidad por sexo es esencial y ha servido para delimitar las evidentes diferencias entre hombres y mujeres en los principales y más prevalentes problemas de salud, ya sea psicológica como física. Son varias las investigaciones que informan de cómo las mujeres duplican en porcentaje en problemas de ansiedad y de depresión (Kessler et al., 2012; Van Droogenbroeck et al., 2018), siendo estos las principales causas de incapacidad laboral a nivel mundial.

El género, por otro lado, como variable sociocultural permea todo y por tanto tiene un gran impacto en factores psicosociales que se relacionan con la salud. Afectando entre otras a las variables que se han explicado anteriormente, la autoeficacia y la regulación emocional. Esta relación o influencia puede ser explicada por el proceso de socialización de género, a través del cual niñas y niños crecen, aprenden, viven, experimentan y exploran de manera diferencial el mundo que les rodea. Desde esta socialización tradicional, se realiza una clara diferenciación entre el género masculino, aquel designado a los niños, y el femenino, aquel designado a las niñas. Estos géneros llevan roles, expectativas,

deseos y permisos diferentes que modulan la conducta y las experiencias. De este modo, el género masculino, caracterizado por la instrumentalidad y el foco en el self, orienta a los menores a la acción, a la resolución de problemas, favoreciendo la adquisición y desarrollo de comportamientos, patrones de pensamiento y emociones que facilita el afrontamiento de posibles dificultades o retos (Richmond et al., 2015; Shields, 2013; Stake & Eisele, 2010). En este sentido, se ha demostrado que tanto niños como hombres poseen una mayor percepción de eficacia personal, lo que como ya se ha visto, ejerce como factor de protección, se relaciona con el bienestar psicológico y con la motivación orientada a comportamientos saludables, así como en diferentes ámbitos (Berke et al., 2018; Mayor, 2015; Stake & Eisele, 2010). Por otro lado, la socialización de género que reciben niñas y mujeres se relaciona más con la esfera emocional. la socialización de género femenina, caracterizada por la expresividad y un foco en los demás y en las relaciones, orienta a las niñas a roles de dependencia, pasividad, miedos y obediencia. De este modo, permite y fomenta en ellas la expresión de miedos y preocupaciones, favoreciendo la búsqueda de ayuda y las relaciones interpersonales de apoyo. En este sentido, la literatura aporta evidencia de una mayor supresión y contención emocional en los hombres y adolescentes y unos mayores niveles de ansiedad y depresión en las mujeres (Fisher et al., 2021; Van Droogenbroeck et al., 2018).

Por todos los motivos mencionados, es necesario un análisis de cómo afecta el género al desarrollo de distintas enfermedades y malestares para complementar aquellos resultados basados únicamente en el análisis de la variable sexo (Fine, 2018). De esta manera, se podrá realizar, en primer lugar, una adecuada lectura de los problemas y determinantes de la salud para poder, en segundo lugar, proporcionar una respuesta integrativa más eficaz a los problemas de salud (Day et al., 2016). Esto, sin embargo, parece ser más complejo.

### *Género y ECV*

Las ECV son un claro ejemplo de la importancia de analizar las variables sexo y género. Históricamente, se han considerado a las ECV como enfermedades característicamente masculinas por la alta y significativamente prevalencia diferente entre hombres y mujeres (Gao et al., 2019). En este sentido, la tarea de desagregar las estadísticas por sexo proporcionaba una panorámica sesgada si se atendía únicamente al índice de mortalidad. Los hombres padecían más problemas cardiovasculares, pero las mujeres morían más (Gao et al., 2019; Stehli et al., 2019). De hecho, para las mujeres la ECV constituye la primera causa de muerte a nivel mundial y una de las causas más comunes de pérdida de años de vida saludables (Woodward, 2019). Esto, en principio, era explicado además desde el punto de vista médico por una serie de características biológicas que hacían a los hombres más propensos a este tipo de afecciones médicas (Desai et al., 2021). Sin embargo, desde el punto de vista psicosocial, también podía ser explicado a partir de hábitos comportamentales, tradicionalmente asociados a los varones como el consumo de tabaco, alcohol y el estrés laboral, relacionados también con el rol masculino (Etienne, 2019). Además, esta mayor prevalencia podía relacionarse con lo que se ha mencionado anteriormente, los hombres, al menos hasta ahora, han sido educados en una cultura del bloqueo emocional (Fisher et al., 2021), lo cual ya se ha visto relacionado con otros factores de riesgo cardiovasculares fisiológicos (Gross & Levenson, 1997).

Sin embargo, la diferencia en la tasa de mortalidad en detrimento de las mujeres no parecía haber acaparado la misma atención hasta hace relativamente poco. Es justamente la búsqueda de la respuesta a esta casuística lo que resaltan autoras feministas, cuando se critica que, a pesar de la extensión de un concepto biopsicosocial de salud, no se ponía el foco en explicar la brecha género-sexo que hay en las ciencias de la salud (Fine, 2018; Valls Llobet, 2011). Una de las posibles explicaciones a este fenómeno es el

*sesgo de género* a la hora del diagnóstico, tratamiento y el entendimiento de los síntomas. En relación a lo último, las investigaciones han demostrado que los síntomas del infarto difieren en hombres y mujeres (Albaran et al., 2007; Berg et al., 2009), sin embargo, comúnmente a través de los medios de comunicación y las campañas de prevención las señales de alarma predominantes correspondían únicamente a aquellos síntomas de infarto más comunes en los hombres (Caldwell & Miaskowski, 2002). El androcentrismo médico en todas sus vertientes, investigación, análisis y divulgación provocaba una desinformación en las mujeres que, según indican Kim et al. (2022), estas tendían a confundir síntomas y a no buscar ayuda médica o bien cuando lo hacían era demasiado tarde, teniendo consecuencias fatales. Este sesgo de género en la salud ha primado y extrapolado los problemas de salud que ocurren en los cuerpos masculinos y realizando durante décadas una simple extrapolación a los cuerpos de las mujeres, obviando negligentemente las diferencias que a nivel biológico separan a hombres y mujeres y su repercusión en la salud.

Este mismo sesgo de género parece estar detrás del diagnóstico precoz. Existe evidencia de que, a igualdad de sintomatología, la toma de decisiones por parte de profesionales médicos varía en función del sexo (Daugherty et al., 2017). De hecho, según un estudio Clerc Liaudat et al., (2018), los hombres eran 2,5 veces más probables de ser enviados a un especialista de cardiología cuando acudían a su médico de cabecera por dolor de pecho que las mujeres bajo las mismas circunstancias. En la misma línea, diferentes estudios muestran cómo la probabilidad de que los pacientes recibieran educación cardíaca durante las visitas médicas era menor en las mujeres (Hilleary et al., 2019). En relación al tratamiento también se han encontrados sesgos, pues parece más frecuente la prescripción de tratamientos más agresivos en hombres que en mujeres, a las

cuales se les suele recomendar cambios de tipo comportamental como bajar de peso, hacer deporte o cuidar la dieta (Desai et al., 2021).

Sin embargo, y a pesar de lo anterior, todavía en comparación con los hombres, las mujeres, reciben menos exámenes de detección de ECV, pruebas diagnósticas, atención oportuna y terapias invasivas o de reperfusión, todos ellos factores que contribuyen a su posible diagnóstico erróneo y a la mala gestión, experiencia y resultados (Ski et al., 2020).

En relación a los hábitos y estilo de vida, las estadísticas reportan que actualmente las mujeres se igualan a los hombres en relación a los comportamientos y hábitos nocivos aumentando en sí su prevalencia cardiovascular (Gao et al., 2019). A todo lo anterior se debe tener en cuenta que hombres y mujeres con ECV parecen establecer diferentes estrategias de regulación emocional. Las mujeres parecen utilizar más frecuentemente *estrategias pasivas* que los hombres, lo cual como se ha visto anteriormente se relaciona con una menor percepción de salud (Castillo-Mayén et al., 2021). Esta elección de estrategias de afrontamiento de la ansiedad y el estrés que se relacionan directamente con la salud.

En resumen, las variables sexo y género actúan como determinantes relevantes en la salud cardiovascular, con consecuencias perjudiciales para hombres y mujeres, pero especialmente para ellas, quien además sufren el sesgo de género androcéntrico que dificulta su diagnóstico y correcto tratamiento. Las principales causas subyacentes a la mayor mortalidad de las mujeres son las siguientes (Kim et al., 2022):

- Presión social y responsabilidades, como los roles de género femeninos que implican tareas de cuidado a los demás, dando lugar a una triple jornada, peores condiciones laborales y el estrés y consecuencias que eso conlleva.

- Una mayor probabilidad de minimización del riesgo. Esto tiene un doble efecto, la *no-búsqueda* de ayuda por parte de las mujeres y el error diagnóstico por parte de los profesionales médicos.
- Relacionado con lo anterior, un mayor retraso en el diagnóstico.
- En relación a la intervención, la menor probabilidad de recibir tratamientos agresivos, así como educación cardíaca.
- Con respecto a la adaptación a la enfermedad, el uso de estrategias de afrontamiento pasivas para gestionar el estrés y la ansiedad asociada a la enfermedad.
- A nivel de investigación, la infrarrepresentación de mujeres en los ensayos clínicos, lo que sesga los resultados y puede tener grandes implicaciones.

Ski et al. (2020) sintetizan la mayor exposición de las mujeres al riesgo de ECV haciendo alusión a la confusión de los términos sexo y género, y la falta de atención a ambos en el acercamiento a estas enfermedades, lo que resultaría en la infrarrepresentación de las mujeres (sexo) y el estereotipo que haría tratarlas como “enfermedades de los hombres” (género). Por todo lo expuesto, investigaciones dirigidas a explicar los mecanismos subyacentes de las diferencias entre hombres y mujeres en las principales variables y problemáticas de la salud, teniendo en cuenta ambos conceptos, son más que necesarias para poder determinar y realizar un correcto abordaje de las mismas.

## Resumen

Este capítulo enfatiza en la relación entre el bienestar psicológico y la salud cardiovascular. Específicamente, se hace un repaso por tres variables que tienen un papel relevante en esa relación. En primer lugar, se describe la autoeficacia como un constructo clave para la motivación conductual. Numerosos son los estudios que han relacionado la autoeficacia con aspectos relevantes para la ECV, como es el manejo de la enfermedad, la adherencia al tratamiento o la actividad física entre otros comportamientos saludables. Relacionada con la autoeficacia, en segundo lugar, se enfatiza en la regulación emocional como proceso esencial para la gestión de situaciones difíciles tal y como puede ser una ECV. Una mala gestión emocional se ha relacionado con un mayor riesgo cardiovascular. Finalmente, se hace necesario destacar el efecto de las variables sexo y género en la salud y las ECV. A pesar de ser un conjunto de enfermedades más prevalentes en hombres, las estadísticas reflejan una mayor tasa de mortalidad en mujeres. Investigaciones apuntan como responsable a un sesgo de género que afecta tanto a la investigación como a la práctica clínica, dificultando un diagnóstico precoz y afectando al tipo de tratamiento que reciben estas pacientes.

## **Summary**

This chapter emphasizes on the relationship between psychological well-being and cardiovascular health. Specifically, it reviews three variables that play a relevant role in this association. First, self-efficacy is described as a key construct for behavioral motivation. Numerous studies have related self-efficacy to aspects relevant to CVD, such as disease management, adherence to treatment, and physical activity, among other healthy behaviors. Secondly, related to self-efficacy, emotional regulation is reported as an essential process for the management of difficult situations such as CVD. Inadequate emotional regulation has been associated with greater cardiovascular risk. Finally, it is necessary to highlight the effect of sex and gender variables on health and CVD. Despite these diseases are generally more prevalent in men, the statistics show a higher mortality rate in women. Research has pointed to a gender bias as being responsible, which affects both research and clinical practice, hindering early diagnosis and affecting the type of treatment received by these patients.

## Capítulo 4

# Nuevas estrategias terapéuticas – Intervenciones *mHealth*

### Introducción

Teniendo en cuenta la complejidad de la naturaleza de las ECV, así como el importante peso que para su buen pronóstico tienen los cambios comportamentales, las intervenciones que se realicen con las personas afectadas desde el modelo biopsicosocial o la Psicología de la Salud deben ir dirigidas a entrenar en recursos y habilidades que promuevan o favorezcan el bienestar psicológico y las variables relacionadas, destacando entre las que se han comentado, la autoeficacia y la regulación emocional. Para unos mejores resultados, se deben de tener en cuenta las características específicas de la población con ECV y adaptar a sus necesidades estas intervenciones.

### Intervenciones *mHealth*

En las últimas décadas se ha podido observar un aumento exponencial del uso de las nuevas tecnologías en nuestra vida diaria (Paglialonga et al., 2019). Estas innovaciones han llegado al ámbito de la asistencia sanitaria con la progresiva inclusión de la telemedicina y la salud electrónica o la también denominada *e-salud*. De estas aproximaciones y maneras de entender la práctica clínica nacen las llamadas intervenciones *mHealth*, concepto que deriva de la combinación las palabras en inglés “mobile” y “health”, en español conocido como salud móvil. Este término hace referencia al uso de dispositivos móviles como teléfonos inteligentes – *smartphones* –, tabletas electrónicas – *tablets* –, relojes y pulseras inteligentes – *smartwatches, smartbands* –, así como otros dispositivos tecnológicos inalámbricos con fines terapéuticos en el ámbito de la salud (Cruz-Ramos et al., 2022).

Este tipo de intervenciones tienen como objetivo la promoción de la salud (Baretta et al., 2019), prevención de enfermedades asociadas a determinantes comportamentales (Palmer et al., 2018) y la intervención con dicha población. Como principal meta estaría facilitar la comunicación directa con los y las pacientes, mejorar la adherencia al tratamiento, facilitar la prescripción médica y atender a resultados concretos de salud (Cruz-Ramos et al., 2022)

### **Ventajas de las intervenciones *mHealth***

El uso de estrategias *mHealth* parte de la premisa de que las personas son agentes activos y supone, por tanto, trasladar y hacerles consciente de su responsabilidad para con su salud (Qudah & Luetsch, 2019). De este modo, busca el empoderamiento de las y los pacientes, favoreciendo la percepción de control sobre su propio comportamiento (Morley & Floridi, 2020). En este sentido, son intervenciones de especial utilidad para abordar patologías crónicas (ECV, diabetes, obesidad, etc., Hamine et al., 2015; Kebapci et al., 2020) debido a la compleja naturaleza de estas enfermedades y el gran impacto que tienen en su pronóstico determinantes de tipo comportamental (e.g., adherencia al tratamiento, Kebapci et al., 2020).

Una de sus grandes ventajas es la facilidad de aplicación en todos los niveles de actuación buscados desde la Psicología de la Salud, esto es, la promoción, prevención e intervención. Además, destaca su bajo coste y gran alcance, pues la naturaleza *online* favorece la accesibilidad de la atención sanitaria (Roncoroni et al., 2019), aspecto que en muchas ocasiones viene derivado de desigualdades sociales y ocasiona grandes desventajas con graves consecuencias sanitarias (Farley, 2019). Esta accesibilidad es especialmente relevante en pacientes con ECV, cuya población, con una media de edad avanzada, frecuentemente puede presentar problemas de movilidad y falta de autonomía para asistir a sus visitas regulares en los centros médicos (Henson et al., 2019). Este tipo

de intervenciones supone, por tanto, un acercamiento con los pacientes, una atención directa a través de su propio dispositivo, su propia casa, con numerosas ventajas. Asimismo, el uso de herramientas *mHealth* permite un enfoque de investigación ecológico, al poder permearse en la vida diaria de las personas sin necesidad de un cambio del contexto habitual, favoreciendo la incorporación de la intervención en su rutina diaria y promoviendo, entre otras, la adherencia al tratamiento y en algunos casos la alianza terapéutica (Henson et al., 2019; Nilsen, 2015). Relacionado con esto, las intervenciones basadas en la *mHealth* pueden permitir la recolección de información en tiempo real, con fines terapéuticos y de investigación, con la ventaja de reducir el sesgo de la respuesta y memoria de participantes y pacientes de gran importancia para un correcto tratamiento y optimización de los resultados (Brys et al., 2020).

Por todo lo anterior, las herramientas *mHealth* están siendo ampliamente utilizadas en intervenciones terapéuticas para abordar especialmente aquellas condiciones médicas en las que puede suponer una dificultad el acceso tradicional a las visitas médicas, o en aquellos casos en los que los tratamientos impliquen una alta demanda de tiempo, como son en este caso las enfermedades crónicas cuyo seguimiento e intervenciones se plantean a largo plazo (Scherrenberg et al., 2021).

### **Eficacia de las intervenciones mHealth - Resultados relacionados con la salud y ECV**

Más que centrarse en condiciones médicas concretas, las intervenciones que se valen de herramientas *mHealth* han sido principalmente diseñadas para evaluar, entrenar y mejorar una serie de variables relacionadas con la salud que tienen gran impacto en el pronóstico de la misma. En este sentido, los determinantes de la salud ECV de tipo comportamental son el principal objetivo a trabajar en este tipo de intervenciones, como son la adherencia al tratamiento y medicación, la inclusión de hábitos saludables, el abandono de conductas nocivas para la salud, la promoción de la actividad física, etc. (Adler et al., 2015; Kebapci

et al., 2020; Palmer et al., 2017). Esto indica que esta modalidad de abordaje pone el foco especialmente en aspectos relacionados con la salud en los cuales la motivación, y por tanto la autoeficacia, juegan un papel esencial. Por ello, no es de extrañar que las enfermedades en las cuales esas variables son fundamentales para un mejor pronóstico de la enfermedad sean aquellas a las que hayan ido dirigidas principalmente estas intervenciones. Estas enfermedades, de corte crónico serían la obesidad (Wang et al., 2020), el asma (Kosse et al., 2019; Xiao et al., 2018), la diabetes (Cajita et al., 2021; Hamidi et al., 2022) y, por supuesto, las ECV (Klimis et al., 2018; Wongvibulsin et al., 2021).

En esta dirección, la literatura aporta resultados positivos de las intervenciones *mHealth* en el mejor manejo de la enfermedad, una mejor adherencia a la prescripción médica, en características físicas relacionadas con la salud, como una reducción o mantenimiento del peso o reducción de glucemia, mejoras significativas en el bienestar físico y mental de los pacientes favoreciendo el manejo de sintomatología ansiosa-depresiva (Rathbone & Prescott, 2017; Wongvibulsin et al., 2021). En programas de rehabilitación cardíaca se ha encontrado que las *mHealth* favorecen a diferentes determinantes de salud cardiovascular (Klimis et al., 2018). Por un lado, en relación a **factores fisiológicos y metabólicos**, intervenciones dirigidas a pacientes con ECV que incorporaban herramientas *mHealth* han mostrado una mejora en indicadores clave para la ECV como es una reducción del índice de masa corporal, la presión arterial y una reducción o control de la diabetes (Ni et al., 2022; Hamine et al., 2015; Wongvibulsin et al., 2021). Con respecto a **determinantes comportamentales**, estas intervenciones parecen favorecer en pacientes ECV la adherencia al tratamiento , la actividad física, así como la asunción de hábitos de vida saludable, entendida como la mejora de la dieta (Cajita et al., 2021; Kebapci et al., 2020; Maddison et al., 2019; Wongvibulsin et al.,

2021) y el abandono de hábitos no saludables relacionados con la enfermedad como el consumo de tabaco (Adler et al., 2015; Cajita et al., 2021; Kebapci et al., 2020; Palmer et al., 2017). Finalmente, y en relación a **factores psicosociales** también se ha encontrado que este tipo de intervenciones en pacientes con ECV ha producido una mejora en su calidad de vida percibida y mejores resultados en el estado de ánimo (Rathbone & Prescott, 2017), entendido como reducción de síntomas ansioso-depresivos (Firth et al., 2017) y un aumento de la autoeficacia (Changizi & Kaveh, 2017; Wongvibulsin et al., 2021)

Por otro lado, a pesar de los resultados prometedores de este tipo de intervenciones para pacientes con enfermedades crónicas y, concretamente, para las ECV, no se pueden obviar que existen numerosas investigaciones que informan de resultados ambiguos en cuanto a su eficacia y efectividad, en los cuales, por ejemplo, no se muestran mejoras con respecto a la intervención tradicional en los resultados de salud mencionados anteriormente (Kebapci et al., 2020; Marcolino et al., 2018; McCarroll et al., 2017). Por ello, son necesarias más intervenciones para esclarecer las ventajas de esta metodología terapéutica a la hora de abordar las ECV y sus determinantes de salud.

### **Futuras líneas y principales desafíos de las intervenciones mHealth**

Los prometedores resultados de las intervenciones móviles posicionan a este tipo de estrategias como una interesante elección a la hora de buscar cambios en los comportamientos saludables. Maximizar los beneficios de estas herramientas sería, por tanto, un objetivo a cumplir (Nilsen, 2015). La naturaleza *online* y accesible de este tipo de intervenciones, y de la telemedicina en general, puede permitir la personalización de la práctica clínica (Saxena & Saxena, 2020). La intervención centrada en la persona o personalización de la atención sanitaria sería el principal reto a asumir por este tipo de metodología terapéutica con pacientes ECV y otras afecciones crónicas. Esto supondría

dar un paso más allá en el acercamiento a las necesidades de este tipo de pacientes, atendiendo a uno de los principios básicos del modelo biopsicosocial en que se tiene en cuenta la esfera subjetiva y la idiosincrasia de cada persona en su salud. Adaptar las estrategias *mHealth* considerando las individualidades de las y los pacientes con respecto al objetivo de la intervención podría traducirse en resultados muy positivos en la consecución de dichas metas de salud (Cioe et al., 2021; Xu et al., 2020).

Por otro lado, estas intervenciones advierten una serie de dificultades que deben preverse para un adecuado desarrollo y maximización de su eficacia y efectividad. Como se ha mencionado, el perfil de la población con problemas cardiovaseulares, con una media de edad avanzada, supone un reto a la hora de planificar y diseñar intervenciones *mHealth* (Alleman & Poli, 2020). Esto implica tener en cuenta casuísticas como puede ser la falta de habilidades digitales que constituiría una barrera de cara al seguimiento de las intervenciones (Alleman & Poli, 2020; König et al., 2018). Posibles soluciones a este respecto serían, por ejemplo, utilizar aplicaciones de las que ya tienen conocimiento previo para minimizar el impacto de esta posible dificultad tecnológica, así como incorporar sesiones informativas y formativas en las cuales se entrene en el manejo de los dispositivos a quienes participen de las intervenciones.

En línea con lo anterior, pese al avance tecnológico y su aplicación en la práctica clínica no se debe perder de vista la necesidad y relevancia del contacto humano (Mohr et al., 2011). Uno de los desafíos y futuras líneas de investigación en este sentido sería, por tanto, aprender cómo combinar ese contacto humano con las y los pacientes a la vez que se aprovechan las ventajas de la salud móvil. Por ello, intervenciones que conjuguen este tipo de metodología son necesarias ya que las actuaciones cara a cara con profesionales pueden facilitar y favorecer los resultados buscados (Hamidi et al., 2022).

Uno de los aspectos observados en la literatura previa es que los estudios clínicos que se han llevado a cabo utilizando la salud móvil con pacientes cardiovasculares tenían como principal objetivo (*primary outcome*) la mejora de alguno de los determinantes comportamentales (mejora de la actividad física, dieta equilibrada, etc.) y evaluaban, de manera secundaria (*secondary outcome*) cambios en las variables psicológicas como la autoeficacia o mejoras en aspectos emocionales como la sintomatología ansiosa-depresiva (Devi et al., 2014; Maddison et al., 2015, 2019). Sin embargo, investigaciones que evalúen como principal resultado de la intervención la mejora de estas variables psicológicas, así como estudios cuyas intervenciones estén dirigidas directamente a mejorarlas, son escasos. Se plantea, por tanto, como un objetivo interesante y necesario realizar intervenciones que busquen mejorar específicamente aquellas variables psicológicas que juegan un papel fundamental en la motivación, mecanismos de autorregulación del comportamiento, estados emocionales, etc., que estén relacionadas con estrategias, comportamientos y alcance de objetivos de salud de manera global. De este modo, no se buscaría únicamente la mejora de un único comportamiento saludable, sino más bien proporcionar los recursos psicológicos necesarios que sirvan como base para un cambio comportamental en pro de una mejora de la salud en todos los sentidos.

### Otras consideraciones

Estas innovadoras estrategias terapéuticas representan nuevos retos para la organización y conceptualización de la atención sanitaria. La incorporación de aplicaciones móviles y uso de dispositivos tecnológicos empuja la colaboración multidisciplinar de los diversos agentes de salud a todos los niveles (Molina Recio et al., 2016; Williams et al., 2020). Un correcto diseño de intervenciones que trabajen y evalúen variables psicológicas en pacientes con ECV obliga a la incorporación de profesionales de la psicología, de la nutrición, especialistas de cardiología, así como profesionales de ramas como la

informática o la ingeniería que ayuden a la elaboración de las aplicaciones. El auge de este tipo de intervenciones supone, por tanto, el desafío del enriquecimiento interdisciplinar en la investigación de la salud y la práctica clínica (Molina Recio et al., 2016; Nilsen, 2015; Williams et al., 2020).

Este tipo de intervenciones parecen estar mostrando resultados prometedores que podrían resultar en mejores pronósticos para pacientes con ECV, mejor índice de salud y mayor calidad de vida (Wongvibulsin et al., 2021). Además, tal y como se ha mencionado, las *mHealth* son estrategias también utilizadas para la promoción de la salud a partir de hábitos de vida saludable (Baretta et al., 2019). Sin embargo, la mayoría de los estudios realizados hasta la fecha con intervenciones *mHealth* se han llevado a cabo en países de un alto desarrollo económico, lo que plantea una brecha de desigualdad a tener en cuenta (Hall et al., 2014; Marcolino et al., 2018). Considerando, como se ha visto en el capítulo 2, que el mayor número de muertes de este tipo de enfermedades se produce en países de niveles socioeconómico medio-bajo (OMS, 2017), disminuir esta brecha en relación a la telemedicina se torna uno de los principales retos de salud pública global.

## Resumen

Las herramientas *mHealth* se están instaurando con fuerza como nuevas estrategias de intervención terapéutica. Derivadas de la telemedicina, consisten en el uso de dispositivos móviles de carácter inalámbrico con fines terapéuticos en el ámbito sanitario. Poseen numerosas ventajas, entre ellas la accesibilidad de la atención sanitaria, su gran alcance y el positivo balance de coste-beneficio. Por todo lo anterior, son muy convenientes para abordar integralmente los procesos de promoción, prevención e intervención sanitaria. Son especialmente útiles para intervenir en condiciones de carácter crónico que demanden un desplazamiento y seguimiento continuado a largo plazo. Numerosos estudios avalan su efectividad en programas de rehabilitación cardíaca, mejorando resultados en determinantes de la salud cardiovascular metabólicos, conductuales y psicosociales. Este tipo de metodología plantea, sin embargo, nuevos desafíos que deben ser atendidos en pro de maximizar sus beneficios, la incorporación de la personalización terapéutica, la falta de habilidades digitales en poblaciones con edades avanzadas, así como la combinación de estas estrategias con el contacto humano, aspecto esencial para una buena alianza terapéutica. A nivel general se posan nuevos retos como es la interdisciplinariedad de la atención sanitaria, así como la reducción de las desigualdades sociales en el acceso a este tipo de intervenciones.

## **Summary**

mHealth tools are gaining popularity as new therapeutic intervention strategies. Derived from telemedicine, they are based on the use of wireless mobile devices for therapeutic purposes in healthcare. They have numerous advantages, among them the accessibility of health care, their wide reach and the positive cost-benefit balance. For all these reasons, they are highly suitable for a comprehensive approach to the processes of health promotion, prevention and intervention. They are especially useful for intervening in chronic conditions that require long-term monitoring. Numerous studies support their effectiveness in cardiac rehabilitation programs, improving results in metabolic, behavioral and psychosocial determinants of cardiovascular health. However, this type of methodology poses new challenges that must be addressed in order to maximize its benefits: the incorporation of therapeutic personalization, the lack of digital skills in elderly populations, as well as the combination of these strategies with human contact, an essential aspect for a good therapeutic alliance. At a general level, new challenges are posed, such as the interdisciplinary nature of health care, as well as the reduction of social inequalities in access to this type of intervention.

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# **MÉTODO Y RESULTADOS**

## **-ESTUDIOS INCLUIDOS-**

*METHODS AND RESULTS*

*-STUDIES INCLUDED-*

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## Capítulo 5

### Methods

Throughout this chapter, the studies included in this doctoral thesis will be presented, including their objectives, hypotheses and methodology.

#### General objectives of the thesis

The main objectives to be pursued in the thesis were the following:

1. To explore the psychosocial factors involved in the differential vulnerability of psychological well-being between women and men.
2. To evaluate the effectiveness of a psychological intervention in improving emotional well-being in patients with CVD disease.
3. To evaluate the effectiveness of a brief psychological intervention in improving emotional well-being and management self-efficacy in patients with chronic illness, in general, and specifically in women and men.

To achieve these objectives, three studies have been conducted (Table 1).

#### Specific objectives and hypotheses of each study

##### *Study 1*

##### Objectives

The aim of the first study was to explore the psychosocial factors involved in the differential vulnerability of psychological well-being between women and men. We focused on the study of anxiety and its comorbidity given its relationship with other relevant psychological variables in chronic diseases and cardiac patients. It is also one of the most prevalent conditions in mental health, and, following the biopsychosocial model of health, it could lead to the worsening of different physical health conditions as well as CVD. Furthermore, the aim of this review was, first, to identify which specific factors,

both psychosocial and biological, have so far been considered to explain the difference in anxiety between women and men and, secondly, to explore whether these factors are able to explain any differences in anxiety comorbidity. The results will be analyzed following a holistic integrative approach including, inexorably, the gender-feminist perspective.

### Hypothesis

There will be studies that assess differences in anxiety prevalence and comorbidity between women and men on the basis of biological factors and others that attempt to explain them on the basis of psychosocial factors, but the biopsychosocial and gender perspectives will not be the main approaches of the studies.

### *Studies 2 and 3*

In the second and third studies, we already focused on addressing the psychological variables discussed in the introduction of this thesis (Chapter 3) that are related to the psychological well-being of CVD patients using the innovative therapeutic approach of the telemedicine (Chapter 4). Following the biopsychosocial model framework, we aimed to test the effectiveness of mHealth psychological interventions to improve subjective well-being and self-efficacy in CVD patients. It was expected to have an impact on the behavioral daily basis of this patients.

### Objectives of the Study 2

The study 2 is focused on emotion regulation and positive subjective well-being. The main objective was to evaluate the effectiveness of an mHealth brief psychological intervention in emotional regulation to improve positive subjective well-being in patients with CVD compared to regular follow-up medication and treatment.

### Objectives of the Study 3

The study 3 was focused on self-efficacy. In this later study, we aimed at designing, developing and pilot testing the effectiveness of a multicomponent and personalized

mHealth intervention in self-efficacy to improve cardiac patients' subjective well-being and self-efficacy for managing the disease. In this study, taking into account the sex and gender differences and bias reported in the introduction, we analyzed this effectiveness considering the sex of the participants, in order to discuss the results from the gender perspective.

#### Hypotheses of the Study 2

**Hypothesis 1:** The mHealth intervention in emotion regulation would be effective to improve positive subjective well-being in CVD patients.

**Hypothesis 2:** The mHealth intervention in emotion regulation would be effective to improve self-efficacy (chronic-cardiac) for managing the disease in CVD patients.

**Hypothesis 3:** The improvements on subjective well-being and self-efficacy would be maintained over time.

#### Hypotheses of the Study 3

**Hypothesis 1:** The multicomponent mHealth intervention would be effective to improve subjective well-being (i.e., increasing the positive affect and decreasing the negative affect) in CVD patients.

**Hypothesis 2:** The multicomponent mHealth intervention would be effective to improve self-efficacy (chronic-cardiac) for managing the disease in CVD patients.

**Hypothesis 3:** The improvements on subjective well-being and self-efficacy would be maintained over time.

**Hypothesis 4:** The effectiveness of the multicomponent mHealth intervention would be different in men and women.

**Hypothesis 5:** The differences between men and women (if any) would be consistent with gender socialization, that is, with better self-efficacy outcomes for men and greater improvement in subjective well-being for women.

**Table 1.** Summary of the main characteristics of the studies included in the thesis.

<b>Study</b>	<b>Study design</b>	<b>Search strategy</b>	<b>Results (studies included)</b>	<b>Factors analyzed</b>	<b>Data analysis</b>
<b>S1. Factors Associated with Gender and Sex Differences in Anxiety Prevalence and Comorbidity: A Systematic Review</b>	Systematic review following the PRISMA guidelines	Empirical studies and reviews analyzing psychosocial and biological factors published from 2008 to 2021 were searched in PsycInfo and PubMed databases	44 studies included from which the majority were empirical/quantitative studies (n = 31) and the rest were reviews (n = 13)	Psychosocial factors (n = 21) or biological factors (n = 16), comorbidity (n = 7)	Qualitative-narrative analysis of the results.
<b>Study</b>	<b>Study design</b>	<b>Participants</b>	<b>Main variables</b>	<b>Measurements*</b>	<b>Data analysis</b>
<b>S2. A Brief mHealth-Based Psychological Intervention in Emotion Regulation to Promote Positive Subjective Well-Being in Cardiovascular Disease Patients: A Non-Randomized Controlled Trial</b>	Two-arm Non-randomized controlled trial	The study sample was composed by 69 CVD patients (78% men, M = 63.7 ± 11.5 y/o). The two arms englobe an experimental group (n = 34, 85% men, M = 61.24 ± 11.1 y/o) and a control group (n = 35, 75% men, M = 66.1 ± 11.6 y/o)	Sociodemographic Characteristics (SDCs), specific cardiovascular characteristics, positivity (P -scale), anxiety and depressive symptoms (HADS), positive subjective well-being (positive affect, PA from PANAS), self-efficacy (cardiac and chronic self-efficacy, CMSES and SEMCD, respectively)	1) Baseline 2) Post-psychoeducational session (only the experimental group) 3) Post-mhealth 4) Follow-up 1 5) Follow up 2	SDCs analyses (means and standard deviations) Student's t-test, Chi-square test Fisher's exact test. Effectiveness of the intervention (between and within groups) Repeated Measures ANOVA
<b>Study</b>	<b>Study design</b>	<b>Participants</b>	<b>Main variables</b>	<b>Measurements*</b>	<b>Data analysis</b>
<b>S3. Effectiveness of an eHealth intervention to improve subjective well-being and self-efficacy in cardiovascular disease patients: A pilot non-randomized controlled trial</b>	Two-arm Non-randomized controlled trial	The study sample was composed by 42 CVD patients (69% men, M = 63.6 ± 10.61 y/o). The two arms englobe an experimental group (n = 21, 66% men, M = 61.8 ± 6.61 y/o) and a control group (n = 21, 71% men, M = 65.43 ± 13.42 y/o)	SDCs, specific cardiovascular characteristics, subjective well-being (positive and negative affect; PANAS), self-efficacy (cardiac and chronic self-efficacy, CMSES and SEMCD)	1) Baseline 2) Post-personalized session (only the experimental group) 3) Post-mhealth 4) Follow-up 1 5) Follow up 2	SDCs analyses (means and standard deviations) U Mann-Whitney test. Chi-squared test. Fisher's exact test. Effectiveness of the intervention Non-parametric analysis (Mann-Whitney U, Wilcoxon signed-rank test)

\*The latency between measurements 1, 3, 4 and 5 is 2 weeks, but from the measurements 1 to 2 is 1h, the time that the intervention lasted. CVD = Cardiovascular disease; PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analyses (Moher et al., 2009); y/o = years old; M = mean.

The following three chapters report the studies that comprise this doctoral thesis. As it is a thesis by compendium of articles, the structure, the headings, as well as the way of citing and referencing follow the particularities of the journal in which each one has been published or accepted for publication. For this reason, the structure and sections of each chapter may vary according to the aforementioned.

*En los tres siguientes capítulos se reportan los estudios componen la presente tesis doctoral. Al tratarse de una tesis por compendio de artículos, la estructura, los epígrafes, así como la forma de citar y referenciar siguen las particularidades de la revista en la que cada uno ha sido publicado o aceptado para publicación. Por este motivo, la estructura y apartados de cada capítulo puede variar en función de lo mencionado anteriormente.*

## Capítulo 6

### Study 1

#### Factors Associated with Gender and Sex Differences in Anxiety Prevalence and Comorbidity: A Systematic Review\*

##### Abstract

**Background:** The prevalence and comorbidity of anxiety disorders are significantly different between women and men, with research showing a greater impact on women. The aim of this review was to identify the psychosocial and biological factors that have been considered to explain this gender and sex difference in prevalence and determine whether these factors are related to any anxiety comorbidity differences between men and women. **Methods:** Following the PRISMA guidelines, we carried out a systematic review of studies published between 2008 and 2021 in PsycINFO and PubMed databases. Empirical and review studies evaluating psychosocial and biological factors that could influence the difference in prevalence and comorbidity between men and women were included. A qualitative narrative synthesis was performed to describe the results. **Results:** From 1012 studies, 44 studies were included. Retrieved articles were categorized depending on their object of study: psychosocial factors ( $n = 21$ ), biological factors ( $n = 16$ ), or comorbidity ( $n = 7$ ). Results showed that differences in anxiety

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\*Farhane-Medina, N. Z., Luque, B., Tabernero, C. & Castillo-Mayén, R. (2022). Factors Associated with Gender and Sex Differences in Anxiety Prevalence and Comorbidity: A Systematic Review. *Science Progress*. 105. <https://doi.org/10.1177/00368504221135469>

between women and men have been analyzed by psychosocial and biological factors but rarely together. Among the psychosocial factors analyzed, masculinity may be a protective factor for anxiety development, whilst femininity can be a risk factor. In the studies that took biological factors into account, the potential influence of brain structures, genetic factors, and fluctuations in sexual hormones are pointed out as causes of greater anxiety in women. Concerning comorbidity, the results noted that women tend to develop other internalizing disorders (e.g., depression), while men tend to develop externalizing disorders (e.g., substance abuse). **Conclusions:** For an accurate understanding of differences between women and men in anxiety, both biological and psychosocial factors should be considered. This review highlights the need to apply the biopsychosocial model of health and the gender perspective to address differences in anxiety between sexes.

**Keywords:** anxiety; sex differences; gender differences; women's mental health; systematic review.

## Introduction

The prevalence of anxiety disorders is significantly higher in women than in men.<sup>1</sup> This difference occurs not only in adults but also in children and teenagers.<sup>2,3</sup> To better understand this issue, it is necessary to identify the protective and risk factors that may influence the vulnerability of each sex to present anxiety and related comorbidities. The biopsychosocial model of health<sup>4</sup> already raised the need to adopt a holistic perspective. From this model, biological, psychological, and social factors must be accounted for to respond to health-related issues. However, some authors have pointed out that despite the great relevance of this approach, the sex-gender gap is not yet fully explained in the health sciences.<sup>5</sup> According to them, a gender-feminist perspective is required to accurately

address the reasons for the considerable differences between women and men in health conditions such as anxiety disorders.<sup>6,7</sup>

A gender perspective allows the identification of the influence of sociocultural factors in women's mental health so that these factors are also considered when establishing a treatment. The incorporation of this perspective into the study of sex-gender differences in anxiety implies much more than the simple task of "adding" women to the data as a simple item of statistical information. It requires to delve deeper into what it means to be a woman or a man in health research, especially when sex-gender differences are a central analytical category.<sup>8-10</sup> In other words, it is necessary to include a gender/feminist-specific vision in the vulnerability of each sex to present an anxiety disorder. This relies on the requirement of differentiating two concepts, sex and gender, both of which need to be clarified to understand the further analysis of this article. Sex is commonly understood as a biological variable, an immutable inherent condition that classifies individuals as women and men according to biological factors (i.e., hormones, chromosomes, etc.).<sup>11</sup> Gender, on the other hand, refers to the sociocultural construction that takes place through a process of constant gender socialization in which the person is influenced by the norms, rules, roles, stereotypes, and expectations of their culture based on their biological sex.<sup>12,13</sup> Adopting the gender perspective involves the analysis of how this different gender socialization might affect this mental health condition in terms of diagnosis, prognosis, treatment, and comorbidity. In fact, gender socialization has a great impact on the psychosocial factors involved in mental health.<sup>14</sup> In this way, this socialization might influence the acquisition and development of certain behaviors, as well as the patterns of thought and feelings related to anxiety. For example, throughout their socialization process, girls are more likely to ask for help; they are allowed and encouraged to express their fears and worries and are more frequently oriented towards

dependence, fearfulness, passivity, and obedience, which leads to an education according to the feminine role or the expressivity dimension.<sup>15,16</sup> In contrast, boys are more likely to be taught to contain feelings of fear and insecurity and are more frequently prepared for action, problem solving, goal achievement, and success, that is, attitudes and behavior typically associated with a masculine role or instrumental dimension.<sup>17,18</sup>

As a consequence of this gender socialization, anxiety levels could differ between sexes.<sup>14</sup> In fact, experiencing certain feelings, such as anxiety and fear, is normalized for women, and it is expected that they express them. In the case of men, the reinforcement of the suppression of certain emotions and the social expectation that they should be strong and brave might facilitate their development of useful resources to cope with those feelings.<sup>18</sup> However, despite this clear connection between gender socialization and anxiety, this gender perspective is seldom taken into account to explain the differences observed between women and men in its diagnosis and prognosis and, even less, to establish its treatment.<sup>19,20</sup> Therefore, data on the prevalence of anxiety disorders may reflect a patriarchally biased explanation that places women in a situation of greater mental health vulnerability.

In any case, the literature consistently indicates that anxiety disorders are more prevalent in women than in men. However, research on the origin of these differences between women and men in the expression of anxiety is rather inconsistent. Evidence addressing this issue is generally focused on biological factors.<sup>21</sup> Many of them are even centralized on animal studies,<sup>22</sup> which precludes the analysis of gender and other psychosocial factors. Other studies do not distinguish between gender and sex differences,<sup>23</sup> which may lead to ambiguity in the analysis. These studies, while offering valuable information on the mechanisms underlying this difference, still fail to provide a panoramic insight into the specific roles of the sex and gender variables (i.e., they refer

to gender or sex but rarely together). In addition, despite the existence of recommendations and guidelines in this field,<sup>24</sup> the frequent confusion between these two terms makes it difficult to identify and understand previous research findings on anxiety in both sexes.<sup>5</sup>

Furthermore, another relevant aspect for mental health and, specifically, for anxiety disorders is that comorbidity is the rule rather than the exception.<sup>25,26</sup> However, little is known about how these gender and sex differences have been studied regarding anxiety and related mental health comorbidities. This makes it necessary to examine whether, along with biological influences, psychosocial factors also have an impact on any differences in anxiety comorbidity between women and men. Thus, an integrative overview of this issue seems to be required.

Given this context, the present study was designed to systematically identify and synthesize the contributions made by empirical and review studies concerning anxiety and sex/gender differences in the last decades. To this end, the framework of the biopsychosocial model of health and the feminist perspective were considered. In particular, the aim was to, firstly, identify what specific factors, both psychosocial and biological, have been considered so far to explain the difference in anxiety between women and men and, secondly, explore whether these factors are able to explain any differences in anxiety comorbidity. To the best of our knowledge, an updated systematic review of the differences observed in the manifestation of anxiety between women and men and its comorbidity has not been provided to date.

## **Methods**

### *Eligibility criteria*

The inclusion criteria were documents that analyzed a) the prevalence of anxiety disorders in men and women and b) the psychological, social, and/or biological factors

that explained the difference in the prevalence of various anxiety disorders or in the anxious symptomatology between the sexes or c) the difference in the comorbidity of anxiety disorders in men and women. Eligible articles could include d) empirical or review studies, e) published between 2008 and 2021, f) in either Spanish or English. Exclusion criteria were a) research studying anxiety in clinical populations of other mental disorders, b) studies that addressed the gender or sexual difference of anxiety from a single anxiety disorder, and c) articles whose object of study did not answer the research question (those that match the search terms but are out of our scope).

#### *Search strategies, data sources, and selection process*

A systematic database search was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) methodological framework (see Supplementary file 1).<sup>27</sup> Suggestions from Siddaway et al. (2019)<sup>28</sup> were also considered for reporting this research. The search was carried out between December 2021 and February 2022 in the PsycINFO and PubMed databases. The search terms were "gender differences" AND anxiety AND prevalence; "sex differences" AND anxiety AND prevalence; "gender differences" AND anxiety AND comorbidity; and "sex differences" AND anxiety AND comorbidity. The selection process, including the search, screening, and evaluation of the studies, was conducted by two independent researchers. In case of disagreement between reviewers, the article was preselected and fully analyzed by a third researcher.

#### *Data collection*

Regarding data collection, selected studies were examined and classified by two independent researchers following a template that was developed to compile the information related to factors analyzed, method and/or study design, sex sample

representation, instruments, etc., in order to facilitate the synthesis of the results. Then, we performed a narrative synthesis of the findings of the included articles, classifying the documents according to their object of study.

#### *Quality assessment of the studies included*

An adaptation of the QualSyst<sup>29</sup> was used to analyze the quality of the studies included in this review considering seven categories (see Supplementary file 2). Specifically, this assessment addressed information related to the objectives, inclusion/exclusion criteria, sample size and participants' sex representation, instruments, and results of the studies analyzed. Most of the studies showed a high quality according to these standards. Quality assessment was also performed by two independent reviewers.

## **Results**

#### *Study selection*

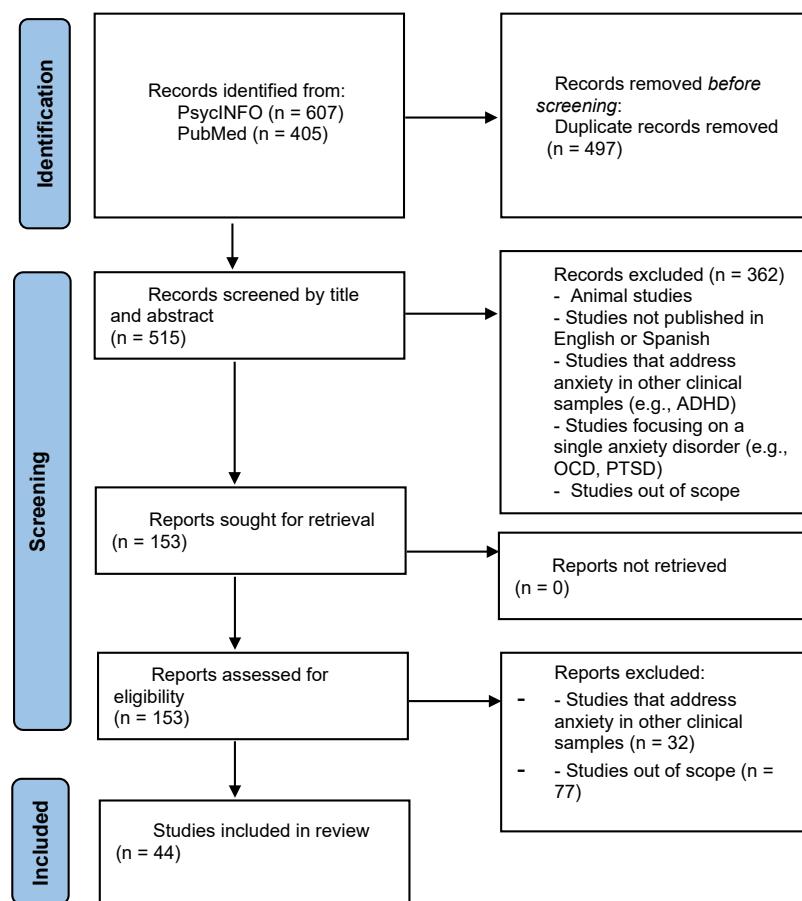
The initial search generated 1012 results, 607 in psycINFO and 405 in PubMED. Eliminating duplicated documents between both databases, 515 articles were obtained and screened. After screening, 362 articles were excluded and 153 were analyzed in depth. After reading the full text, 109 were discarded using the aforementioned criteria, leaving 44 articles for final inclusion in this systematic review (Figure 1).

#### *Characteristics of the studies included*

Of the 44 documents, 31 were empirical/quantitative studies<sup>30-60</sup> and 13 were reviews<sup>61-73</sup>. With respect to their objectives, most articles analyzed the difference in the prevalence of anxiety in men and women considering psychosocial (n = 21) or biological (n = 16) factors, and seven articles analyzed the difference in the comorbidity of anxiety with other disorders based on psychosocial factors. Out of the 31 empirical studies, 25 were

conducted in western countries; 11 were performed in North America (10 in the United States of America and 1 in Canada), 10 in Europe, and 4 in Australia. Five were conducted in Asia: Pakistan ( $n = 1$ ), Mongolia ( $n = 1$ ), Hong Kong ( $n = 1$ ), and China ( $n = 2$ ). The remaining study was conducted with a cross-national sample that included different continents.

Tables 1 and 2 present the data and characteristics of the studies analyzed, including their objectives, key findings, and conclusions, classified according to their object of study.



**Figure 1.** PRISMA Flow Chart of the Selection Process. Note. ADHD = Attention Deficit Hyperactivity Disorder; OCD = Obsessive-Compulsive Disorder; PTSD = Post-traumatic Stress Disorder.

**Table 1**

*Characteristics, main aim(s), and key findings of the studies included in the systematic review (empirical studies)*

Authors (year)	Country	Factors analyzed	Sample (%W/M)	Instruments*	Study aim(s)	Key findings
Ask et al. (2014) <sup>30</sup>	Norway	Biological factors	2788 (54.9/45.1)	SCARED	To evaluate the influence of genetics and environment on the variability of anxiety symptoms in twin adolescents.	<ul style="list-style-type: none"> <li>- Higher levels of anxiety in girls were mainly due to genetic factors.</li> <li>- Heritability explained 74% of the variance in anxiety in girls and 65% in boys. Environmental factors explained the rest of the variance in anxiety between sexes.</li> <li>- Environment might decrease boys' but not girls' anxious tendencies.</li> </ul>
Burton et al. (2015) <sup>31</sup>	Australia	Biological factors	1500**	DASS- 42	To estimate if sex differences in self-reported depression and anxiety are caused by genetic and/or environmental factors.	<ul style="list-style-type: none"> <li>- Genetic factors played a different role in anxiety, depression, and their comorbidity between the sexes. Men only had genetic risk factors for anxiety-depression co-occurrence, and women for both depression, anxiety, and their comorbidity.</li> <li>- The higher prevalence of internalizing symptoms in women could be due to sex-related biological vulnerability and the type of environmental exposure.</li> </ul>
Cerasa et al. (2014) <sup>32</sup>	Italy	Biological factors	138 (55.1/44.9)	SCID-I, SCID-II, HAM-A	To identify interactions between gender, anxiety, and 5-HTTLPR genotype and to determine whether these connections would be reflected in the neuroanatomy of anxiety-related brain structures (e.g., amygdala).	<ul style="list-style-type: none"> <li>- An interaction effect was found between the 5-HTTLPR, anxiety, and the right amygdala in females.</li> <li>- An association between subclinical anxiety and higher right amygdala volume was found in short allele homozygous female.</li> <li>- Sex influences the relationship between the 5-HTTLPR and anxiety given its effect on the amygdala.</li> </ul>
Chan et al. (2015) <sup>33</sup>	Hong Kong	Psychosocial factors	2802 (55.1/44.9)	SCARED, CERQ, CNCEQ	To describe the prevalence of anxiety symptoms in adolescents and to explore their relationship with rumination, catastrophizing, or daily hassles.	<ul style="list-style-type: none"> <li>- There was a direct effect of catastrophizing on anxiety in girls and boys.</li> <li>- Rumination was found to have an impact only on girls' anxiety.</li> <li>- Girls' tendency to ruminate and catastrophize increases their vulnerability to anxiety disorders.</li> </ul>

Chen et al. (2019) <sup>34</sup>	Mongolia	Comorbidity	4528 (53.9/46.1)	WMH-CIDI (CIDI 3.0)	To explore gender differences in the prevalence and patterns of anxiety-depression comorbidity and related risk factors.	<ul style="list-style-type: none"> <li>The comorbidity pattern of anxiety and depression is different between sexes, being more prevalent in women.</li> <li>There is a need to address comorbidity from a symptom-based approach.</li> </ul>
Curran et al. (2020) <sup>35</sup>	Ireland	Psychosocial factors	8504 (55.6/44.4)	HADS-A	To study gender differences in anxiety and depression prevalence among older adults considering the social and health characteristics and conditions.	<ul style="list-style-type: none"> <li>Women presented more anxiety-depressive symptoms.</li> <li>The comorbidity pattern of anxiety in women is related to psychosocial variables (e.g., partner support, relationship stress) and to alcohol concern in men.</li> <li>When considering only anxiety, men reported supportive marital relationships and women reported quality social networks, which could act as a bulwark to combat loneliness.</li> </ul>
Derdikman-Eiron et al. (2011) <sup>36</sup>	Norway	Psychosocial factors	8704 (49.1/50.1)	SCL 5	To explore gender differences in psychosocial functioning (e.g., subjective well-being - SWB) of adolescents with and without anxiety-depressive symptoms (ADS).	<ul style="list-style-type: none"> <li>Sex moderated the associations between SWB and functioning with ADS. Girls presented more ADS, but boys with ADS showed lower psychosocial functioning, poorer SWB and self-esteem than girls.</li> <li>Gender socialization favors girls' emotional expression when experiencing ADS, reinforcing their social network, while emotionally blocking boys, which explains these differences.</li> </ul>
Eaton et al. (2012) <sup>37</sup>	USA	Comorbidity	43093 (57.1/42.9)	DIS, WMH-CIDI	To examine sex differences in the prevalence of common mental health disorders. To explore the pattern of comorbidity through sex differences in the prevalence of internalizing and externalizing disorders.	<ul style="list-style-type: none"> <li>Women exhibited higher prevalence of internalizing disorders (e.g., depression), while men exhibited externalizing ones (e.g., antisocial personality).</li> <li>The comorbidity pattern in women (anxiety-depression) may be explained by the connection between internalizing dimensions (e.g., rumination).</li> <li>Genetics could explain this association, but environmental factors (e.g., stressful events in women) need to be explored.</li> </ul>
Gao et al. (2020) <sup>38</sup>	China	Psychosocial factors	1892 (47.5/52.5)	DASS-21	To study gender differences among university students in the prevalence of depression, anxiety, and stress, considering the influence of socio-demographic variables.	<ul style="list-style-type: none"> <li>Women showed higher anxiety than men.</li> <li>Higher levels of anxiety were related to drinking habits, poorer academic progress, and an unhealthy body mass index only in females.</li> <li>Social pressures (e.g., body image stereotypes) are risk factors for women's mental health.</li> </ul>
Gardener et al. (2013) <sup>39</sup>	Australia	Biological factors	43 (53.5/46.5)	DASS-42	To examine sex differences in emotional reactivity and emotional regulation measuring	<ul style="list-style-type: none"> <li>Women showed higher emotional reactivity to negative stimuli. Sex differences in emotion regulation were found too.</li> </ul>

					the brain response to negative stimuli.	- The greater activity in brain structures (limbic, amygdala) in response to negative stimuli in women supports the hypothesis of a negativity bias in them. - This bias could contribute to sex differences in the prevalence of affective disorders.
Gili et al. (2016) <sup>40</sup>	Spain	Psychosocial factors	13816 (59.7/40.3)	PRIME-MD	To evaluate gender differences in the prevalence of mental disorders during the Spain economic crisis (2006–2010).	- The prevalence of affective disorders during the economic crisis increased in men. - Men who assume traditional masculine gender roles are more likely to suffer, in economic recessions, higher rates of anxiety and depression, among other somatic symptoms.
Gitay et al. (2019) <sup>41</sup>	Pakistan	Psychosocial factors	300 (61.7/38.3)	GAD-7	To assess gender differences in the prevalence of mental health conditions in health science students.	- Women were more prevalent in anxiety, depression, and phobia. - Cognitive variables (e.g., metaworry) and sex hormonal fluctuations (estrogen) play an important role in this vulnerability of women in anxiety.
Höglund et al. (2020) <sup>42</sup>	Sweden	Biological factors	3406 (55.7/44.3)	HADS-A	To compare different types of mental health disorders and its prevalence considering groups of age and sex.	- The prevalence of anxiety and other internalizing disorders and symptoms (i.e., somatization, burnout, insomnia) were higher in women, especially for the youngest cohort. - In men, the middle-aged cohort was the one with higher vulnerability and with higher depression levels compared to other age groups.
Kramer et al. (2008) <sup>43</sup>	USA	Comorbidity	2992 (62.8/37.2)	PDSQ, MPQ	To explore if comorbidity between the most common psychopathological disorders is explained by gender differences in the presence of internalizing and externalizing factors.	- Sex differences were found in the prevalence and comorbidity of internalizing and externalizing syndromes. - Women have more internalizing risk factors (e.g., neuroticism) associated with internalizing spectrum disorders, while men have more externalizing risk factors (e.g., aggressive personality trait) associated with externalizing syndromes.
Leach et al. (2008) <sup>44</sup>	Australia	Psychosocial factors	7485 (50.9/49.1)	SF-12, EPQ, BIS-BAS, RSQ, GADS	To examine if gender differences in anxiety and depression are mediated by psychosocial factors.	- Women had more anxiety and depression than men at all ages. - Some health-psychosocial variables explained the effect between gender and anxiety (e.g., physical activity, mastery, interpersonal relationship), all of them lower in women.

						- Higher anxiety in women may be due to different lifestyles, types of stressors, and their coping strategies for them.
Liu et al. (2021) <sup>45</sup>	China	Psychosocial factors	1563 (82.7/17.3)	GAD-7, IES-R	To assess gender differences in the prevalence of mental health conditions among healthcare workers (HCW) in China during the Covid-19 pandemic.	<ul style="list-style-type: none"> <li>- The prevalence of anxiety symptoms, depression, stress, and insomnia was higher in women than in men.</li> <li>- This greater psychological impact in female HCW can be explained by biological (e.g., hormonal fluctuation), psychological (e.g., unhealthy stress coping strategies: avoidance, self-blame), and social (e.g., social roles, economic and social support) factors.</li> </ul>
Lungu et al. (2015) <sup>46</sup>	Canada	Biological factors	46 (54.3/45.7)	M/FGRS	To examine if there are sex differences in fronto-limbic connections when processing negative emotions. To explore the effect of sex hormones and other gender connected factors on these connections.	<ul style="list-style-type: none"> <li>- Sex differences in the prevalence of anxiety and depression may be explained by different fronto-limbic connections when processing negative emotions.</li> <li>- Men showed more activation in the dorso-medial prefrontal cortex, area related to action planning, associated with testosterone and negatively correlated with femininity.</li> <li>- Gender roles may contribute to sex differences in brain connectivity in emotion processing.</li> </ul>
McLaughlin et al. (2014) <sup>47</sup>	USA	Comorbidity	1065 (48.8/51.2)	MASC	To examine sex differences in the bidirectional association between rumination, externalizing symptoms and anxiety, and depression in adolescents.	<ul style="list-style-type: none"> <li>- Girls presented more anxiety symptoms and rumination.</li> <li>- Rumination played an important role in the transition between anxiety symptoms (internalizing) and aggressive behavior (externalizing) and vice versa only for boys.</li> <li>- Gender roles make boys exhibit more aggressive behavior as a coping mechanism for distress, especially when adjusting to traditional masculinity.</li> </ul>
McLean & Hope (2010) <sup>48</sup>	USA	Psychosocial factors	109 (54.1/45.9)	BAT, PAQ	To examine if gender and gender roles influenced subjective anxiety (SA) and behavioral avoidance (BA) during a fear task.	<ul style="list-style-type: none"> <li>- Women scored higher on expressivity (feminine gender role) and men on instrumentality (masculine role).</li> <li>- Women had greater SA and BA.</li> <li>- Sex but not gender roles predict SA and BA. However, higher expressivity was related to higher BA in men and instrumentality to less BA in both sexes.</li> </ul>
McLean et al. (2011) <sup>49</sup>	USA	Comorbidity	20013 (57.3/42.7)	WMH-CIDI	To describe the prevalence of anxiety disorders and to analyze differences in onset, prognosis, comorbidity, and rates of impaired functioning between men and women.	<ul style="list-style-type: none"> <li>- The prevalence and chronicity of anxiety disorders were higher in women.</li> <li>- The presence of internalizing risk factors (negative affect, neuroticism) in women facilitate their comorbidity with other internalizing disorders.</li> </ul>

						- Gender socialization moderates these factors, supporting the expression of certain symptoms, favoring these sex differences in anxiety and its comorbidity.
Mwinyi et al. (2017) <sup>50</sup>	Switzerland	Psychosocial factors	3695 (52.9/47.1)	SADS-LA	To examine whether there are gender differences in the prevalence of anxiety disorders and how these differences are related to negative economic changes.	<ul style="list-style-type: none"> <li>- Women were more likely to have lower socio-economic status, alcohol consumption and substance abuse disorder, and higher depression than men.</li> <li>- Compared to anxious men, anxious women reported a greater income reduction.</li> <li>- Anxiety has a more negative impact in women, worsening their already poorer economic situation.</li> </ul>
Norr et al. (2015) <sup>51</sup>	USA	Psychosocial factors	106 (53.8/46.2)	ASI-3, BAI	To assess if anxiety sensitivity (AS) mediates between gender and anxiety-depression symptomatology.	<ul style="list-style-type: none"> <li>- AS was found to be a mediating factor between gender and symptoms of anxiety and depression.</li> <li>- The influence of biological and environmental factors contributes to a higher AS in women.</li> <li>- AS is a relevant risk factor for women and a possible explanation for its higher anxiety and other internalizing disorders prevalence.</li> </ul>
Palma-Gudiel et al. (2019) <sup>52</sup>	Spain	Biological factors	148 (60.8/39.2)	SCID-I/BSI	To study the potential influence of SLC6A4 methylation on anxiety and depression disorders and other psychopathological dimensions (e.g., somatization, hostility).	<ul style="list-style-type: none"> <li>- Sex was significantly associated with SLC6A4 methylation.</li> <li>- Higher SLC6A4 methylation correlated with higher somatization scores.</li> <li>- This hypermethylation of SLC6A4 in women could explain sex differences in SERT expression, with women having a higher vulnerability to certain psychopathological conditions.</li> </ul>
Rees et al. (2011) <sup>53</sup>	Australia	Comorbidity	4451 (100/0)	WMH-CIDI	To analyze how gender-based violence (GBV) influences women's mental health.	<ul style="list-style-type: none"> <li>- GBV increases the prevalence of suffering any mental health disorder, especially anxiety.</li> <li>- GBV was related to higher physical problems, disability, and suicide attempts and poorer prognosis, comorbidity, and quality of life.</li> <li>- These findings highlight the importance of addressing GBV as a public health problem due to its consequences for women's mental health.</li> </ul>
Seedat et al. (2009) <sup>54</sup>	Colombia, Lebanon, Mexico, South Africa,	Psychosocial factors	72933**	WMH-CIDI	To study gender differences in the mental health of men and women in four cohorts of 15 countries and explore if they are	<ul style="list-style-type: none"> <li>- Females had a higher risk of developing an affective disorder; for males, it was externalizing disorders (e.g., substance abuse).</li> <li>- The gender role of traditionality predicted this sex difference. Higher traditionality, higher prevalence of</li> </ul>

		Ukraine, Belgium, France, Germany, Israel, Italy, Japan, Netherlands, New Zealand, Spain, USA		determined by psychosocial factors (e.g., gender roles).	internalizing disorders in women. Lower traditionality, lower sex differences in substance abuse.	
Stassart et al. (2014) <sup>55</sup>	Belgium	Psychosocial factors	200 (52.5/47.5)	CASI, CPAQ	To explore the identification of gender roles among adolescents and to assess whether these gender roles explain the association between sex and anxiety sensitivity (AS).	<ul style="list-style-type: none"> <li>- AS correlated with femininity and negatively correlated with masculinity.</li> <li>- Biological sex mediated between gender roles and anxiety. Boys (higher masculinity) were associated with lower AS, whereas girls (higher femininity) were associated with greater AS.</li> <li>- Gender roles explain sex differences in anxiety. Masculinity (related to problem-solving, action-oriented strategies), may help to cope with anxiety.</li> </ul>
Stoyanova & Hope (2012) <sup>56</sup>	USA	Psychosocial factors	144 (46.5/53.5)	FSQ, PAQ, BAT	To examine the effect of gender on self-reported fear, subjective anxiety, and other anxiety-related variables (e.g., heart rate, avoidance behavior) during an anxiety-inducing task.	<ul style="list-style-type: none"> <li>- Women had higher anxiety, fear, and phobic avoidance during a spider behavioral avoidance task than men.</li> <li>- Masculinity (i.e., instrumentality) was negatively associated with anticipatory anxiety in women but not in men.</li> <li>- In women, instrumentality would encourage fear coping, while tending and befriending might inhibit an active coping style.</li> </ul>
Van Dam et al. (2009) <sup>57</sup>	USA	Psychosocial factors	818 (49.9/50.1)	ASI	To explore differences in anxiety sensitivity (AS) between men and women and to analyze if these differences are determined by their response pattern to the ASI.	<ul style="list-style-type: none"> <li>- Women scored higher on the ASI. However, when items 2 and 4 were removed, sex differences disappeared.</li> <li>- The ASI-scale different pattern response between sexes may be biased by gender roles.</li> <li>- A review of instruments measuring AS and anxiety is needed before assuming sex-gender differences.</li> </ul>
Van de Velde et al. (2019) <sup>58</sup>	Belgium; Bulgaria; France; Germany; Italy;	Psychosocial factors	37289 (54.4/45.6)	CIDI 3.0	To assess and study the connection between different European welfare regimes and	<ul style="list-style-type: none"> <li>- Sex differences in the prevalence of AMD depended on the country's welfare regime,</li> <li>- Social factors (e.g., marital status) mediated the effect of sex on the AMD prevalence.</li> <li>- This sex differences could be explained by social factors</li> </ul>

	Netherlands; Northern Ireland; Portugal; Romania; Spain			gender differences in any mental health disorder (AMD).  (e.g., political actions, gender norms in the economic structure of the country).		
Zalta & Chambliss (2012) <sup>59</sup>	USA	Psychosocial factors	398 (60.1/39.9)	SMS, PAQ, PSWQ, DASS-21	To investigate the mediating influence of gender roles on the relationship between anxiety and gender.	<ul style="list-style-type: none"> <li>- Women reported higher levels of anxiety, discomfort, and lower instrumentality and mastery. These latter traits predicted the association between anxiety and gender.</li> <li>- Gender roles related to mastery and instrumentality may place women at greater vulnerability to anxiety.</li> <li>- How biological factors influenced these traits need to be explored.</li> </ul>
Zlomke & Hahn (2010) <sup>60</sup>	USA	Psychosocial factors	1080 (73.1/26.9)	DASS-42, PSWQ	To explore the different emotional regulation (ER) coping strategies used by men and women and to investigate whether these strategies are related to their different levels of anxiety and worry.	<ul style="list-style-type: none"> <li>- ER strategies to cope with worry, anxiety, and stress differed between sexes.</li> <li>- In stressful situations, men blamed others, while women ruminated and relativized. Women's lower worry was associated with acceptance and positive reappraisal, whilst men's lower anxiety, worry, and stress were associated with reorientation towards planning.</li> <li>- Gender socialization may contribute to sex differences in ER and its subsequent consequences.</li> </ul>

Note. \* Only instruments that assess anxiety or related constructs are included. \*\* Percentage of women and men non available in the paper. W = Women; M = Men; USA = United States of America; ASI = The 16-item Anxiety Sensitivity Index; ASI-3 = Anxiety Sensitivity Index – 3 ; BAI = Beck Anxiety Inventory; BAT = Self-report measures and a Behavioral Avoidance Task; BIS-BAS = The 24-item Behavioral Inhibition and Activation Scales; BSI = Brief Symptom Inventory; CASI = Childhood Anxiety Sensitivity Index; CIDI 3.0 = Composite International Diagnostic Interview; CPAQ = Children's Personality Attributes Questionnaire; DASS-21 = Depression, Anxiety and Stress Scales-21; DASS-42 = Depression, Anxiety and Stress Scale-42; DIS= Diagnostic Interview Schedule; EPQ = Eysenck Personality Questionnaire; FSQ = The Fear of Spiders Questionnaire; GADS = Goldberg Anxiety and Depression Scales; GAD-7 = Generalized Anxiety Disorder, GAD-7 ; HADS-A = Hospital Anxiety and Depression Scale ; HAM-A = Hamilton Rating Scale for Anxiety; IES-R = Impact of Event Scale Revised; MASC= The Multidimensional Anxiety Scale for Children ; M/FGRS = The Masculine and Feminine Gender Role Stress; MPQ = Multidimensional Personality Questionnaire, PAQ = Personal Attributes Questionnaire; PCL-C = Post Traumatic Stress Disorder; PDSQ = Psychiatric Diagnostic Screening Questionnaire; PRIME-MD = Primary Care Evaluation of Mental Disorder; PSWQ = Penn State Worry Questionnaire; RSQ = Response Styles Questionnaire; SADS-LA = Lifetime and Anxiety disorder version; SCARED = Screen for Child Anxiety-Related Disorders; SCL 5 = Short version of the Symptom Checklist for anxiety and depression; SF-12 = The 12-item Short Form Health Survey; SCID-I, SCID-II = Structured Clinical Interviews for DSM-IV-TR; SMS = Self Mastery Scale; WMH-CIDI = The World Mental Health Survey Initiative Version of the World Health Organization Composite International Interview.

**Table 2**

*Characteristics, main aim(s), and conclusions of the studies included in the systematic review (reviews)*

Study Authors (year)	Country	Factors analyzed	Study aim(s)	Conclusions
Brivio et al. (2020) <sup>61</sup>	Germany	Biological factors	To review how sex influences stress-specific transcriptomic changes and explore how literature discusses how stress affects men and women.	Evidence proves sex as a variable that modulates the process involving response to stress. Differences in the transcriptional signatures of genes related to stress between sexes were found.
Cummings et al. (2014) <sup>62</sup>	USA	Comorbidity	To review the existing models that explained the anxiety-depression comorbidity and propose new pathways considering several psychosocial variables (e.g., gender differences).	Anxiety-depression comorbidity may be due to the presence of vulnerability factors for both disorders (rumination, exposure to stressors, etc.), with those factors being more present in women.
Day & Stevenson (2020) <sup>63</sup>	UK	Biological factors	To review the factors involved in sex differences in anxiety disorders.	Sex differences in anxiety disorders could be explained by differences in fear learning, extinction, and inhibition, and how it relates to sex-related hormones and the activation of brain regions involved in learned fear and emotional regulation.
Donner & Lowry (2013) <sup>64</sup>	Netherlands	Biological factors	To review gender differences in anxiety disorders and to analyze the influence of biological factors involved in this difference.	Sex differences in emotional behavior may be the result of anatomical and functional differences in serotonergic circuits involved in the modulation of anxiety and panic.
Hantsoo & Epperson (2017) <sup>65</sup>	USA	Psychosocial factors	To provide an overview of anxiety disorders in women defining the biopsychosocial factors that may underlie them. To propose guidelines that consider these differences and the factors involved for better assessment, differential diagnosis, and treatment.	The prevalence of anxiety disorders in women is due to a combination of biological (hormonal fluctuations) and psychosocial (stressors and coping cognitive strategies) factors. The different evolutive phase of women should be considered when establishing a treatment for anxiety.
Hodes & Epperson (2019) <sup>66</sup>	USA	Biological factors	To review how sex and epigenetic regulation of hormones affect the impact of stress exposure at different periods of life (perinatal, puberty, menopause, andropause) in men and women.	The impact of stress varies according to sex. In men, it affects on a cognitive level; in women, the impact is emotional and sensitive to hormonal changes. The type of stressor, the evolutive period, and sex should be considered when studying the mechanisms that underlie the stress.

Holingue et al. (2020) <sup>67</sup>	USA	Biological factors	To explore the role of the gut-brain axis to explain sex differences in the prevalence of neurodevelopmental, psychiatric, and neurodegenerative disorders.	Gut-brain axis has an important role in behavior and brain function. Its plasticity and sensitivity to environmental exposures could explain sex differences in mental health. This should be considered to better understand these disorders and to establish accurate treatments.
Kaczkurkin et al. (2019) <sup>68</sup>	USA	Biological factors	To review sex differences in the development of brain structures, cerebral blood flow, and white matter. To describe if these differences are connected to sex differences in psychopathology.	Related to anxiety, there are sex differences in cerebral blood flow in adults under the same stress conditions. This is also observed in adolescents, where anxiety-depressive symptoms are related to a higher level of perfusion of the amygdala in girls.
Li & Graham (2017) <sup>69</sup>	Australia	Biological factors	To give an overview of the literature exploring the role of sex hormones in biopsychological factors influencing sex differences in anxiety disorders.	The natural sex hormone fluctuations in women (e.g., menstrual cycle, menopause, pregnancy) could lead to intermittent periods of increased vulnerability to anxiety.
McLean & Anderson (2009) <sup>70</sup>	USA	Psychosocial factors	To review the relationship between gender, fear, and anxiety considering biological (e.g., genes) psychological (e.g., rumination), and environmental (e.g., gender roles) factors.	Gender socialization seems to have an important role in sex differences in fear and anxiety. This socialization process may facilitate the development of different traits and cognitive factors that are related to a greater anxiety vulnerability, especially on girls and women.
Merikangas & Almasy (2020) <sup>71</sup>	USA	Biological factors	To review the mechanisms proposed in the literature to explain sex differences in neuropsychiatric disorders.	The studies analyzed proposed sex hormones, genes, and environmental factors as the explanation of differences in prevalence, course, and severity of anxiety disorders in women.
Murphy et al. (2019) <sup>72</sup>	UK	Biological factors	To deepen the hypothesis of the interoception (focus on the internal state of the body) as the mechanism that underlies sex differences in some mental health disorders.	Atypical interoception (perceptive bias) found in women caused by biological changes (puberty, menstrual cycle) and life experiences (related to socialization) could explain the sex differences in certain mental illnesses, such as anxiety.
Smith et al. (2016) <sup>73</sup>	USA	Psychosocial factors	To explore which variables have been studied to explain sex differences in the expression of mental health conditions.	Gender socialization, seeking help, coping styles, and socioeconomic status influenced the sex difference tendency to develop any mental health disorder.

Note. USA = United States of America, UK = United Kingdom.

*Qualitative narrative synthesis****Psychosocial Factors***

These documents focused their analysis on the difference in prevalence of anxiety disorders as well as in the morphology and severity of those symptoms. Their results concluded that women experience higher rates of anxious-depressive symptoms compared to men, with these symptoms also being more severe.<sup>41,42,45</sup> According to these studies, this difference must be understood as an important factor to take into account for treatments in the clinical population, as well as in other areas of life, such as in academia.<sup>38,41,42</sup>

The results from other studies also showed that women generally identified themselves with expressive or feminine traits such as kindness and sweetness, while men identified themselves with instrumental or masculine traits such as competitiveness, assertiveness, and self-confidence.<sup>59,64</sup> These studies found a relationship between gender roles and anxiety.<sup>54</sup> Instrumentality was positively correlated with protective traits for mental health, such as subjective well-being, perceived control, independence, and self-confidence. Masculinity, therefore, seems to act as a buffer between gender and anxiety.<sup>44,54,56,59,70</sup> Importantly, women who scored higher on instrumentality reported lower subjective anxiety and less fear.<sup>64</sup> Therefore, instrumentality mediates between anxiety and gender, not biological sex.

With respect to femininity, the results showed contradictory information. While there are studies that have not found a relationship between femininity and anxiety,<sup>64</sup> other studies revealed that femininity accompanied by low self-esteem favored the development of anxiety.<sup>49,70</sup> This latter finding relates to studies that examined the relationship between anxiety and gender based on psychological factors. Such studies showed that rumination, neuroticism, behavioral inhibition, worry, anxiety sensitivity,

trauma, and low self-esteem correlated positively with anxiety, with all variables being typical of the female stereotype.<sup>33,44,51,55,65,73</sup>

Derdikman-Eiron et al. (2011)<sup>36</sup> compared the psychosocial functioning, subjective well-being, and self-esteem of adolescents with and without anxiety and found that girls with anxiety had more adaptive psychosocial functioning than boys with anxiety. Other studies indicated that although instrumentality was a protective factor in the appearance of anxiety, expressiveness helped in coping strategies, as it was related to seeking help and support in interpersonal relationships.<sup>44,73</sup>

Finally, in relation to the nature of anxiety-related stimuli, gender differences were also found. The main cause of anxiety in men was of a work-related nature,<sup>44</sup> especially in those who identified with the stereotypical male role.<sup>40</sup> In women, anxiety stemmed from problems in interpersonal relationships.<sup>65</sup> However, women had different ways to express anxiety in relation to their social network compared to men. Anxious women tended to maintain contact with their social environment, which may protect them from loneliness and depression.<sup>35</sup> Therefore, women had more positive experiences in their environment and felt more supported by their social network. Thus, it seems that interpersonal relationships, which can be covered by partners, friends, family, acquaintances, etc., played a dual role in women's anxiety: on the one hand, they constituted the main source of anxiety, and on the other hand, they acted as a protective factor of it.<sup>35,44</sup>

The political, economic, and social situation, individually and globally, may also have a differential effect on women's and men's mental health, both in general terms and in anxiety specifically. Van de Velde et al. (2019)<sup>58</sup> analyzed the gender gap in common mental disorders according to the welfare regime of the country and social risk factors. The higher gender gap in the prevalence of any type of anxiety disorder (18.8% women vs 9.4% men) was found in the southern countries of Europe where the female

unemployment rates are pretty high. According to social risk factors, in countries with a southern regime, women who stay at home as a housekeeper reported less mental health problems than the employees. Other studies reported the importance of social gender roles in the result of anxiety under struggling economical situations. Men who identified themselves with the traditional male role were more likely to develop anxiety as a result of economic difficulties,<sup>40</sup> while in the presence of an anxiety disorder, women were more likely to have economic difficulties than men.<sup>50</sup> According to the social sphere, it is necessary to highlight the results found by Liu et al. (2021)<sup>45</sup> regarding how the Covid-19 pandemic has had a more severe effect on women's mental health than in men's mental health, with higher levels of anxiety and other anxiety-related variables such as insomnia, stress, and depression.

### ***Biological Factors***

These studies indicated that anxiety is determined by genetic, hormonal, and/or neuroanatomical factors. With respect to the latter, it has been pointed out that one of the possible explanations for differences in anxiety between the sexes resides in the brain regions relevant to emotions (i.e., fear) and their regulation, such as the hippocampus, amygdala, and prefrontal cortex.<sup>63,64</sup> The results of several studies have shown that they are dimorphic structures and that they react differently in men and women.<sup>32</sup> Specifically, the left central amygdala is activated by stimuli and negative emotions in women<sup>39</sup>, while in men, it is activated by positive emotions.<sup>64</sup> However, other studies, as exposed in Kaczkurkin et al. (2019),<sup>68</sup> have shown contradictory results regarding the influence of brain structures on sex differences in anxiety. In addition to brain regions, the conclusions of this review highlighted the role of the cerebral blood flow as an important brain phenotype for understanding sex differences. Not specifically related to cerebral regions but with the neurological communication, Holingue et al. (2020)<sup>67</sup> pointed out that a

possible explanation of sex differences in mental health is the gut-brain axis, which responds to the bidirectional canal communication between microbiota and the neurological system. This study indicated that there are sex differences in the microbiome associated with childhood temperament. The plasticity and susceptibility to environmental exposures of the microbiome at early ages could be one of the variables associated with these differences in anxiety, trauma, and stressor-related disorders.<sup>67</sup>

Regarding genetic factors, some studies indicated the influence of genes on anxiety. These studies explored the relationship between the alteration of the FMR1 gene on anxiety disorders,<sup>71</sup> as well as the influence of genes on anxiety vulnerability factors, such as anxiety sensitivity and neuroticism.<sup>64</sup> The implication of serotonergic pathways on mood regulation has also been analyzed, with results indicating that these pathways seem to be damaged in some mental health disorders. The research of Palma-Gudiel et al. (2019)<sup>52</sup> aimed to analyze if the serotonin transporter (SERT), encoded by the SLC6A4 gene, was responsible for sex differences in mental health. The results of this study pointed out that in women, the SLC6A4 methylation was higher compared to men, which could underlie the differential SERT expression in women, leading to a higher prevalence of somatic disorders in them. Other studies indicated that the variable sex may modulate the response to the stress process. According to them, the reason for the sex differences in anxiety is due to the transcriptional signatures of genes related to stress.<sup>31</sup> In any case, a biological explanation of anxiety contemplates the possibility of a mutual influence between factors. In this way, the influence of genetic factors, which depend on sex and moderate the risk for anxiety disorders, can affect anxiety-related brain regions such as the amygdala and the hippocampus function.<sup>63</sup> This vulnerability is bi-directionally related to the environment; therefore, environmental factors such as gender socialization could counteract the anxious tendency in men and enhance it in women.<sup>30,71</sup>

Finally, some studies suggest that women's hormonal fluctuations (progesterone, estrogens, and oxytocin) may be the cause of sexual differences in anxiety.<sup>30,49,64,69</sup> According to Murphy et al. (2019),<sup>72</sup> these biological changes could make women exhibit an interoceptive processing pattern characterized by an increased interoceptive attention and low objective accuracy of internal sensations. This pattern has been named atypical interoception. In their review, it is discussed that this "disrupted" pattern of perception may explain the difference in anxiety between women and men. This hypothesis leans on the studies that suggest that during the physical change periods, there is more vulnerability to experience this atypical interoception, making women more vulnerable due to their biological condition. Related to this, Hodes & Epperson (2019)<sup>66</sup> postulate that stress impacts men and women at different levels. According to these authors, the vulnerability in women resides in periods of hormonal changes and affects their emotional sphere, while stress on men impacts them at a cognitive level. Other studies have analyzed how hormonal periods can affect variables related to anxiety. For example, Day & Stevenson (2020)<sup>63</sup> in their review exposed a deep literature of fear learning, and even though there are some inconclusive results, the majority of the studies found differences between men and women, reflecting the important role of hormones in this process. Lungu et al. (2015)<sup>46</sup> provided another explanation, indicating that differences between men and women in anxiety could be explained by the relationship between sex hormones and the processing of negative information, given that testosterone seems to be related to less frontolimbic activity before negative stimuli and progesterone is related to greater activity. However, the authors did not rule out that this difference between the sexes in emotional regulation might be mediated by sociocultural factors such as gender roles.

### ***Comorbidity***

The results of the studies revealed differences in the comorbidity of anxiety. Women are more likely to experience a depressive disorder along with anxiety.<sup>34,48</sup> Studies indicated that the relationship between the two disorders is based on the common presence of internalizing factors (i.e., neuroticism, rumination).<sup>47,62</sup> Therefore, other internalizing disorders, such as bulimia nervosa or another anxiety disorder, may appear alongside anxiety.<sup>37</sup> In men, anxiety is often comorbid with disorders characterized by the presence of externalizing traits (i.e., hyperactivity, aggressiveness). Thus, according to the studies reviewed, the most common comorbid anxiety disorders and/or symptoms in men are substance abuse, attention deficit hyperactivity disorder (ADHD), and intermittent explosive disorder.<sup>35,43,47</sup>

### **Discussion**

The aim of this study was to provide a systematic updated review of the literature that have addressed differences in anxiety between women and men and its comorbidity. Importantly, it also aimed to reflect the necessity of applying the gender perspective in the conceptualization and analysis of the influence of sex and gender factors on health. Our purpose included the exploration of the hypothesis considered, the instruments used, and the principal conclusions of the studies reviewed. To cover every aspect about this issue, we tried to gather as many studies as possible involving both psychosocial and biological factors.

Our results complement and expand the findings of recent reviews that address this topic by focusing only on biological factors,<sup>21,74</sup> those that consider gender-sex differences but only in a specific anxiety disorder<sup>74,75</sup>, or those that do not clearly distinguish between gender and sex differences.<sup>23</sup> A novel contribution of this review is that it provides a broad overview of this subject, considering both studies that support the

biological hypothesis and those that address gender roles, social and economic situation, life experiences, discrimination, etc., as significant factors in explaining why men and women experience anxiety differently. This approach contributes to support a biopsychosocial model of health, which should be enhanced by a gender/feminist analysis of mental health.

### *Psychosocial factors*

The results seem to indicate that gender socialization is, at least in part, responsible for the development of the psychosocial characteristics that act as risk factors for women and protective factors for men in the onset and course of anxiety.<sup>44,54,56,59,64,70</sup>

The psychosocial factors highlighted in the studies reviewed are aligned with those explored in recent literature. For example, in the Spanish context, Aparicio-García et al. (2018)<sup>76</sup> found that greater adjustment to gender norms (i.e., femininity) in women was related to greater anxiety symptoms, especially in the cognitive domain. According to this statement, some of the most salient risk factors for women observed from our review were rumination<sup>33,44,49,65,73</sup> and anxiety sensitivity<sup>51,55,57,65</sup>.

The results also suggest that gender socialization mediates the type of stimuli that are anxiogenic in women and men.<sup>40</sup> Such stressors are congruent with the differential socialization received by each sex found in the literature, centred on the achievement, competitiveness, and attainment of economic resources for men and masculinity and on relationships with others, sociability, and care for women and femininity.<sup>77</sup>

These findings offer further evidence that traditional socialization appears to be more advantageous for men in terms of health, whereas with regard to the expected gender roles in society, women are more likely to suffer from mental health problems, particularly stress and anxiety.<sup>78</sup> Previous research even reinforces the idea that women's internalization of gender norms, highly connected to anxiety and depression, might be

understood as hidden social violence.<sup>79</sup> The studies reviewed also underline that women's poorer living conditions may contribute to anxiety problems. Indeed, other studies have pointed to social conditions such as the sexual division of labor, beauty standards, the market economy, and environmental degradation as major challenges to improve women's health.<sup>80</sup> These factors may worsen with socioeconomic crises, as occurred during the COVID-19 situation,<sup>81</sup> which is also in line with the greater impact of anxiety problems on women noted in this review.

In addition, although men appear to exhibit lower levels of anxiety, there are authors who warn of a bias in this interpretation. A recent systematic review focused on anxiety in men suggested that when following the masculine gender norms, men have a general preference for self-reliance over help-seeking when dealing with anxiety problems.<sup>82</sup> A lack of awareness of anxiety, limited resources available for help-seeking, as well as a distrust of being helped, are other possible risk variables found to be relevant when considering anxiety in men.<sup>83</sup> Even so, the different presentation of anxiety in men would still be linked to gender norms. In brief, awareness of such evidence provides further support for the need to integrate the gender-feminist perspective in health, not only in research but also in its translation into real practical implications.<sup>84</sup>

#### *Biological factors*

Conversely, other studies show that differences in anxiety disorders between sexes may be due to a) differences in the brain structures involved in emotional regulation, which explain the difference in the processing of negative information,<sup>32,39,68</sup> b) the fluctuations of sexual hormones that affect the anxious state of women,<sup>46,49,63,64,66,69</sup> and c) genetic factors.<sup>30,31,52,61,64,71</sup>

The biological factors reported in this review are consistent with factors analysed in recent research. Several studies exploring this direction include the impact of the

menstrual cycle on anxiety,<sup>85</sup> the sex differences in the activation of brain structures in fear conditioning,<sup>86</sup> and the gen-specific risk in women.<sup>87</sup> Nevertheless, when it comes to biological factors, the still predominant literature of animal studies and their influence on the interpretation of human studies to address this question can be noted. Despite their importance, animal models have obvious limitations for the study of this topic that should not be neglected.<sup>88</sup> Importantly, they hamper the inclusion of other important aspects such as the analysis of gender and other psychosocial factors mentioned above. Also, it has been argued that the results of preclinical or animal studies should be interpreted with caution when generalizing the findings to differences between female and male humans in health-related issues.<sup>89</sup> In addition, some neuroscientists warn of the role of gender socialization in neuroplasticity, so that differences between women and men that have been understood as purely sexual may not be so.<sup>90,91</sup> Therefore, if and how the psychosocial factors, such as life experiences, gender stereotypes, and cultural expectations, could directly influence the differences found in biological factors associated to anxiety in women and men still need to be clarified.

### *Comorbidity*

Finally, the results relating to comorbidity reveal that considering gender differences in anxiety, comorbidity is the key to understanding discrepancies in the prevalence of anxiety disorders between the sexes. Thus, comorbid disorders may favor the chronicity of anxiety and mediate throughout its prognosis.<sup>53</sup>

In summary, it can be concluded that psychosocial factors related to gender are not only responsible, at least partially, for the difference in the prevalence of anxiety in men and women but also influence its comorbidity.

However, comorbidity results should be carefully considered. Just as a diagnosis bias has been demonstrated in anxiety stemming from gender norms,<sup>92</sup> there is also a vast

literature supporting a similar bias in concomitant disorders. Depression, for instance, is known to be underdiagnosed in men. Several studies have explained this fact by the high presence of externalizing symptoms (e.g., avoidance, anger) as well as the lack of help-seeking followed by masculinity, which makes depression more difficult to be diagnosed in men.<sup>93</sup> Conversely, several authors defend that depression criteria are similar to femininity roles and stereotypes, facilitating this diagnosis in women.<sup>94</sup> Another example of this phenomenon can be seen in ADHD. It has been widely documented that it is underdiagnosed in women and girls due to a more prevalence of internalizing symptoms (i.e., low self-esteem, inattention) compared to men and boys.<sup>95</sup> This presentation of internalizing symptoms tends to be mistaken for other mental health conditions, such as depression.<sup>96</sup>

Moreover, it is important to highlight that regarding affective and anxiety disorder diagnosis, several studies have reported the need to conceptualize, examine, and treat them as a continuum rather than discrete categories.<sup>97,98</sup> From this perspective, it would be difficult to delimitate, for example, the diagnosis between anxiety and depression, as both disorders share risk and maintaining factors and symptoms.<sup>97</sup> This spectrum approach is scarcely acknowledged in the studies reviewed, which may lead to a misinterpretation of the anxiety expression, implying an inadequate diagnostic response affecting men and women differently. The continuum perspective would act as an artefact to the theoretical concept of comorbidity and could help to better address the differential clinical symptomatology in men and women, mitigating the sex-gender diagnostic bias.

#### *Practical implications and future lines of research*

This systematic review reflects the heterogeneity and complexity of the factors that have been analyzed to explain sex and gender differences in anxiety. This fact supports the need to apply the biopsychosocial model of health and the gender perspective

to conceptualize, research, and intervene on this issue. However, several studies have documented the difficulty of implementing these approaches clinically.<sup>99</sup> For instance, some authors explicitly argue that due to the inherent characteristics of the biopsychosocial model (e.g., subjectivity and individuality in the patient's approach), its applicability in clinical practice is difficult and should, therefore, be understood only as a theoretical model.<sup>99</sup> Other authors doubt the scientific view of the gender/feminist perspective and its implementation in health.<sup>6</sup> The belief that the consideration of gender in health sciences is far from neutrality, together with other prejudices such as sexism or androcentrism that still persist in science, could act as barriers to an effective application of this perspective in clinical research and practice.<sup>6</sup> The medicalization of women with anxiety is a good example of an inadequate, or at least insufficient, treatment, as it continues to focus on a predominant biomedical model despite the strong evidence of the contribution of psychosocial factors.<sup>100</sup>

Consequently, future studies should focus on how to effectively implement the combination of the biological, psychosocial, and social factors to address anxiety, overcoming the obstacles mentioned above. This main challenge could be approached by incorporating new treatment strategies such as person-centred care interventions. This perspective would allow consideration of not only the biological aspects but also the psychosocial context of patients, as it takes subjectivity and individuality as the heart of the intervention. It is clear that exploring the extent to which it would be beneficial for women's health to apply such health care strategies to intervene in anxiety and its comorbidities remains an interesting research question.<sup>101</sup> Furthermore, it is important to consider other essential factors that may have a great influence on health issues, such as the patient-professional relationship, the existence of implicit and explicit gender

stereotypes in health care providers, the training of health professionals on gender perspective, and so on.<sup>102</sup>

Overall, the results of this review indicate that it is necessary to reformulate the explanation about the occurrence, symptomatology, or treatment orientation for anxiety disorders. In doing so, therapeutic models that pathologize and medicate women's experiences should be left behind<sup>103,104</sup> because it is necessary to assume a new approach that considers any political, social, and developmental inequalities that contribute to and harm women's health.<sup>105,106</sup>

### *Limitations*

This study presents some limitations that need to be pointed out. First, the number of databases consulted was limited. In addition, databases were selected for their suitability to address our subject of study given their broad scope in the literature related to the topic. Second, even if both empirical studies and reviews were included, the absence of qualitative studies could pose another limitation, reducing the variety of results obtained. Therefore, studies examining the experience of men and women facing anxiety from a qualitative analysis could complement the findings of this review. Thirdly, some studies aimed at analyzing gender differences in anxiety did not use specific instruments to assess psychosocial factors involved (e.g., identification with gender roles, gender stereotypes). They reduced their evaluation to the measurement of anxiety in both men and women, which could limit their conclusions and can affect the quality of their findings. To overcome this issue, it should be clear for future studies addressing this topic that sex disaggregation alone is insufficient to make gender-based assumptions.<sup>10</sup> Another limitation is related to a potential language bias, given that the review was targeted at English and/or Spanish written studies only. Although both languages are widely used throughout the world and in the scientific community, it is likely that this linguistic

restriction has led to the sample of studies coming mainly from Western countries. Considering the potential influence of culture on psychosocial factors (e.g., gender), it would be interesting for future research to analyze whether such factors have the same influence on anxiety in different countries and backgrounds.<sup>14</sup> Finally, concerning the review process, our systematic review protocol was not registered publicly; however, our methods are fully and systematically described in the present article.

The results of this review are relevant because they highlight the importance of explaining the onset and course of anxiety from a gender perspective. Considering that health is framed within a biopsychosocial model, psychosocial factors, in addition to biological factors, must be considered during the evaluation and treatment process. These results indicate the need to implement new therapeutic models that consider how gender inequalities at different levels place women in a position of greater vulnerability to experience anxiety. In this way, women would be depathologized and the focus would be placed on how to pay attention to the patriarchal culture and how this affects their mental health.<sup>94,100,103,104</sup>

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## Capítulo 7

### Study 2

#### **A Brief mHealth-Based Psychological Intervention in Emotion Regulation to Promote Positive Subjective Well-Being in Cardiovascular Disease Patients: A Non-Randomized Controlled Trial\***

##### **Abstract**

The emotional impact that a cardiovascular disease may have on a person's life can affect the prognosis and comorbidity of the disease. Therefore, emotion regulation is most important for the management of the disease. The aim of this study was to analyze the effectiveness of a brief mHealth psychological intervention in emotion regulation to promote positive subjective well-being in cardiovascular disease patients. The study sample ( $N = 69$ ,  $63.7 \pm 11.5$  years) was allocated to either the experimental group ( $n = 34$ ) or control group ( $n = 35$ ). The intervention consisted of a psychoeducational session in emotion regulation and an mHealth-based intervention for 2 weeks. Positive subjective well-being as a primary outcome and self-efficacy to manage the disease as a secondary outcome were assessed at five time points evaluated over a period of 6 weeks. The experimental group showed higher improvement in positive subjective well-being and

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self-efficacy for managing the disease compared to the control group over time. The experimental group also improved after the intervention on all outcome measures. Brief mHealth interventions in emotion regulation might be effective for improving positive subjective well-being and self-efficacy to manage the disease in cardiovascular patients.

**Keywords:** cardiovascular disease; positive subjective well-being; emotion regulation; brief psychological intervention; mHealt

## 1. Introduction

The prevalence of cardiovascular disease (CVD) seems to be stable over time, being the first cause of death and a major loss of health worldwide [1,2]. Empiric evidence has proven that the risk of developing CVD comes not only from biological factors but also from behavioral, psychological, and social factors, which, according to a biopsychosocial model of health, interact with each other [3]. In the same way, the consequences or repercussions of CVD involve the daily life of the people who suffer it, their quality of life, and the emotional balance to cope with it [4]. Therefore, depression [5], anxiety, and stress [6] may appear after CVD. This could be a result of coping with the chronic disease in itself, as well as a consequence of the multi-level changes that these patients have to face after the diagnosis. Comorbid anxiety-depressive symptomatology may complicate their recovery [7] and can also affect their self-efficacy for managing the disease, resulting in the abandonment of medical recommendations, putting their health at risk. Consequently, psychological interventions are needed in order to help patients regulate these emotions in a healthy manner to prevent comorbidity and promote a healthy quality of life. Thus, the purpose of this study is to develop and test a brief mHealth-based psychological intervention in emotion regulation to promote positive subjective well-being and self-efficacy for managing the disease in CVD patients.

### 1.1. Brief Psychological Interventions

There are already studies that have incorporated brief psychological interventions into cardiac rehabilitation [8,9]. Their low cost and promising results that seem to have lasting benefits [10–12] place this type of intervention as an interesting supplement to be considered when treating patients with CVD [13]. The chronic nature of this disease implies the need to adopt healthy habits on a continuous basis. The difficulty of modifying lifestyle and adherence to treatment is added to the anxiety-depressive symptomatology as possible conditioning factors for the physical vulnerability of a cardiac pathology [14,15]. Brief psychological interventions improve the prognosis of cardiac rehabilitation, helping patients to adapt to the long-term challenges related to CVD [8]. This kind of intervention appears to have a positive effect in this sense, enhancing psychological well-being, reducing anxiety and depressive symptoms, encouraging the promotion of healthy habits, promoting awareness of the disease, and controlling risk factors [8,9].

### *1.2. Emotion Regulation and Positive Well-Being*

Healthy emotion regulation is crucial for psychological functioning and may be one variable that can also help to protect health and, indirectly, to promote self-efficacy [16]. Historically, emotional psychological interventions have been focused on regulating negative and unpleasant emotions such as depressive and anxious symptoms. However, health and positive psychology have promoted an alternative approach that places positive emotions as the axis of change in these interventions [17]. Related to that, some studies have pointed to an association between positive well-being (i.e., positive affect) and a lower risk of a CVD event [18,19]. In particular, positive well-being has been found to be associated with lower odds of stroke [20], myocardial infarction, and the reduced probability of the recurrence of CVD [21,22]. Positive affect is also related to other CVD characteristics, such as biological responses that may be health protective, lower blood pressure, a lower level of cortisol, and less physiological activation [23–25]. Other studies

indicate that the physiological reactivity to positive emotions acts as a counterbalance to the harmful reactivity of negative emotions, for example, helping patients to overcome the psychological consequences, including unpleasant emotions, after a CVD event [26,27]. From this positive perspective, a relationship is established between emotional well-being, focusing on positive emotions, and improving the emotional state of patients with CVD with better development and management of CVD [28].

Given the importance of experiencing positive emotions, having greater positive well-being, and the common anxiety-depression comorbidity [29], emotion regulation intervention oriented to CVD patients becomes highly recommended. Gross defined emotion regulation as “the processes by which individuals influence the emotions they have, when they have them and how they experience and express these emotions” [29], which includes the process of the identification, recognition, acceptance, and normalization of emotions. Healthy emotion regulation becomes critical to coping with challenging situations [30] such as a cardiac event. Even though there is not a lot of research that analyzes the relationship between emotion regulation and CVD, its influence on how patients with CVD deal with their disease seems clear. On the one hand, research has shown that patients with CVD had lower emotion regulation, which can, in some way, be negative to the prognosis of this chronic disease [16,31]. The use of unhealthy emotion regulation strategies may be responsible for the appearance of cardiovascular risk factors, such as body mass index, unhealthy diet, heavy alcohol consumption, sedentariness, etc. [16,32]. On the other hand, people diagnosed with CVD could be prone to deficits in emotion regulation [31]; hence, they would become more vulnerable to developing a mood disorder [33]. Then, for this bidirectional risk between emotional dysregulation and CVD risk factors, a psychological intervention to promote healthy emotional regulation

seems necessary to decrease the odds of developing comorbid problems and, consequently, improve the quality of life of CVD patients.

### *1.3. mHealth*

The term mHealth (mobile health) refers to the use of mobile devices, tablets, health-related applications, and other wireless technologies in health services, medical care, and clinical practice [34]. The incorporation of mHealth strategies aims to facilitate prescribing, adherence, patient communication, and health outcomes [34,35]. Currently, it has stimulated the use of mHealth tools, especially for risk groups such as CVD patients that may have some difficulties attending regular hospital follow-ups [36]. The unstoppable growth of the use of new technologies by the adult population favors the insertion of new techniques to promote, prevent, and intervene in health. The low adherence to treatment for CVD [37], which is probably due to its chronic nature, raises the need for interventions within the reach of these patients [38]. The evidence for this type of intervention is ambiguous so far. On the one hand, there is research that shows poor evidence of the effect of mHealth interventions to improve adherence to treatment (management and medication) in patients with CVD [39,40]. On the other hand, there are studies that point out the potential of mHealth to improve the adherence and management of chronic diseases [41] such as CVD [42]. This kind of intervention has also shown improvements in the physical and mental well-being of patients [43], favoring the management of depressive and anxiety symptoms [44].

### *1.4. The Present Study*

The evidence reviewed above supports the relevance of incorporating an emotional psychological perspective to intervene with CVD patients. It also highlights the cost-effectiveness of brief psychological interventions, together with the promising results of

the incorporation of mHealth strategies into healthcare. However, the literature addressing CVD interventions combining these components remains scarce. Therefore, the main aim of this study was to evaluate the effectiveness of a brief mHealth-based psychological intervention in emotion regulation to improve positive subjective well-being (enhancing positive affect) as well as self-efficacy for managing the disease in patients diagnosed with CVD. The first hypothesis was that participants included in the experimental group would have significantly greater positive subjective well-being and better self-efficacy for managing their chronic/cardiac disease compared to the control group. A secondary objective was to test if the expected differences between the groups would be maintained over time. Therefore, the second hypothesis was that better outcomes in positive subjective well-being and in self-efficacy for managing their chronic/cardiac disease in the experimental group would also appear in the follow-up evaluations.

## **2. Methods**

### *2.1. Study Design*

This was an interventional study, specifically, a two-arm non-randomized controlled prospective trial. The experimental group received a psychoeducational session in emotion regulation and a subsequent brief mHealth-based psychological intervention in emotion regulation, while the control group continued with their treatment as usual. The study was approved by the Andalusian Health Service's Research Ethics Committee and the Reina Sofía Hospital in June 2015 (Acta 242, Ref. 2886, 29 June 2015).

### *2.2. Participants*

Participants diagnosed with any type of CVD (angina pectoris, myocardial infarction, heart failure, arrhythmia, etc.) were recruited between March 2019 and April 2019 from

the Cardiology Unit of Reina Sofía University Hospital of Córdoba, Spain. The inclusion criteria were: (1) women and men with a diagnosis of a CVD aged > 18, (2) ability to be fluent in Spanish, (3) having a smartphone compatible with the app used for the mHealth intervention (*WhatsApp*) and daily access to the internet, (4) having the required digital skills to follow the mHealth intervention, (5) not currently participating in another clinical trial, and (6) not currently receiving other psychological treatment. The exclusion criteria were: (1) women and men with a diagnosis of a CVD < 18 years, (2) not fluent in Spanish, (3) not having a smartphone compatible with the app used for the mHealth intervention and daily access to the internet, (4) not having the required digital skills, (5) serious mental health condition, (6) currently participating in another clinical trial, and (7) currently receiving other psychological treatment.

Potential participants ( $N = 132$ ) were approached by telephone by an assistant researcher. Sixty-nine patients ( $M = 63.70$  years,  $SD = 11.50$ ) met the inclusion criteria and agreed to participate in the study, giving their informed consent. The participants were assigned to either the experimental group ( $n = 34$ ) or the control group ( $n = 35$ ) depending on their availability to attend the face-to-face session. There were seven dropouts and one death. Finally, 61 patients remained and completed all the study phases (Figure 1). The sociodemographic characteristics of the sample are described in Table 1.

### 2.3. Procedure

#### 2.3.1. Experimental Group

The experimental condition included a one-and-only face-to-face emotion regulation psychoeducational session and a subsequent mHealth-based emotion regulation psychological intervention.

*Psychoeducational session.* It was performed by a General Health psychologist in a private room at the Clinical Research Building of the Maimonides Biomedical Research

Institute of Cordoba in small groups of about two to four people and lasted 60 min. The aim of this face-to-face session was psychoeducation about emotions, including identification, recognition, acceptance, and regulation, in order to facilitate the following mHealth intervention. Therefore, the session was structured in accordance with the above-mentioned objectives following the next headings and content: (a) What are emotions? Description and explanation of emotions concept, (b) Differences between basic and complex emotions: Provision of information about the different types of emotions regarding its nature, (c) Function and structure of emotions: Analyzing the function of emotions on a daily basis and, (d) Emotion regulation: Psychoeducation about the emotion regulation strategies, more specifically related to the management of their CVD diagnosis and provision of resources to improve emotion regulation.

In this session, two evaluations were conducted: the pre-test evaluation (baseline measurements) and after the psychoeducational session (post-session). In order to promote the intervention adherence, the patients were given a description of the mHealth intervention procedure with some motivational messages reinforcing their participation at the end of the session.

*mHealth intervention.* It started the day after the face-to-face session. The patients received for the next 14 days a *WhatsApp* message every day at the same time with an emotion regulation activity they had to perform (Supplementary File S1). The program of activities was based on Leahy et al. [45]. The order and content of the messages followed the scheme explained in the face-to-face session: the identification, recognition, acceptance, and regulation of emotions. The messages were prepared to be as brief and understandable as possible to be in accordance with brief psychological interventions.

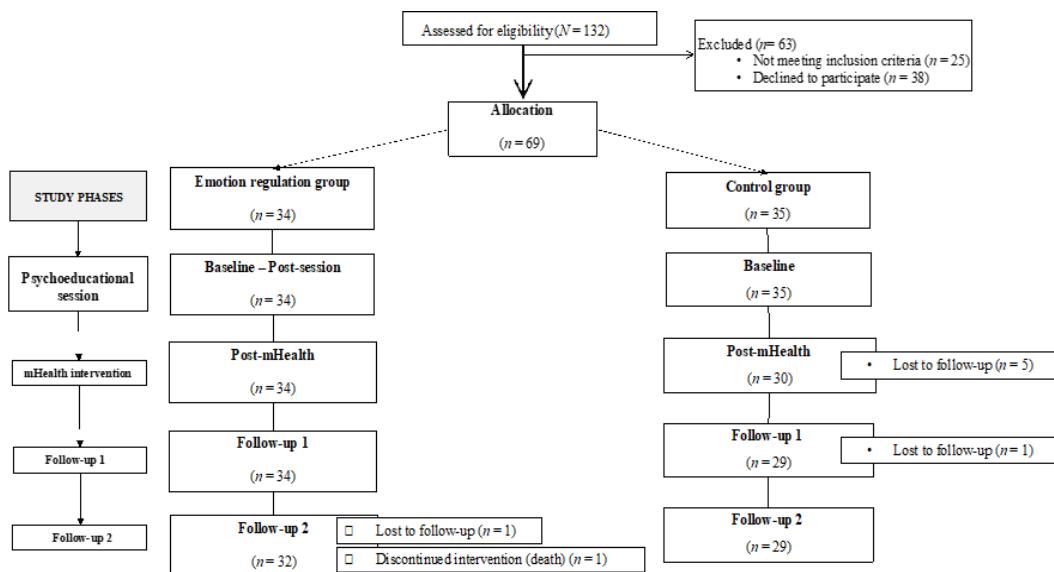
After this intervention, the effectiveness of the mHealth intervention was evaluated (post-mHealth). To assess the changes, if any were maintained over time, two follow-up

evaluations were included 2 weeks (follow-up 1) and 4 weeks (follow-up 2) after the mHealth intervention.

### 2.3.2. Control Group

The participants of this group continued their regular medical follow-up without attending the psychoeducational session or receiving the mHealth intervention.

Thus, each participant of the experimental group was assessed at five different time points (baseline, post-session, post-mHealth, follow-up 1, and follow-up 2), whilst the participants of the control group were evaluated four times (baseline, post-mHealth, follow-up 1, and follow-up 2, Figure 1). The baseline and post-session evaluations of the experimental group were measured in situ through an online questionnaire. The baseline measurements of the control group, as well as the three post-evaluations (post-mHealth, follow-up 1, and follow-up 2) of both groups were conducted by phone calls.



**Figure 1.** Flow chart of the sample and phases of the study.

## 2.4. Outcome Measures

### 2.4.1. Participant Characteristics

Sociodemographic characteristics including, age, sex, marital status, employment status, educational level, as well as the type of CVD and the level of limitation on activities of daily living (ADL) were asked of the participants. In addition, relevant psychological variables to the aim of the intervention, anxiety, and depression states and positivity, were also assessed to complete the description of the study sample. The scales used were the Spanish-validated version of the Hospital Anxiety and Depression Scale—HADS [46,47] (e.g., anxiety: Worrying thoughts go through my mind; depression: I still enjoy the things I used to enjoy)—and the Spanish-validated version of the Positivity Scale—P-scale [48] (e.g., I have great faith in the future).

#### 2.4.2. Primary Outcome

##### Positive Subjective Well-Being (PSWB)

It was assessed through the Positive Affect subscale (PA), from PANAS [49], the brief Spanish version [50]. The PA is a 10-item Likert-type scale that assesses to what extent participants experience pleasant emotions (e.g., To what extent do you feel interest [enthusiasm, inspiration]). The items are rated from 1 (not at all) to 5 (very much). The value for Cronbach's alpha in the original study was 0.88 for this subscale. In this sample, the reliability value was  $\alpha = 0.88$  too.

#### 2.4.3. Secondary Outcome

*Self-Efficacy for Managing the Disease.* To provide a more complete evaluation of this outcome, it was assessed by means of two instruments that measure different types of disease management self-efficacy:

*Self-Efficacy for Managing Chronic Disease* (SEMCD—Spanish validated version) [51]. This Likert-type scale assesses self-efficacy for managing a chronic disease. It is composed of six items (e.g., How confident do you feel that you can keep the emotional

distress caused by your disease from interfering with the things you want to do?) rated from 1 = (not at all confident) to 10 (totally confident). In the original study, Cronbach's alpha coefficient was 0.85, and in this study sample, it was  $\alpha = 0.86$ .

*Cardiovascular Management Self-Efficacy Scale* (CMSES—Spanish translated version) [52]. The CMSES was used to evaluate the perceived self-efficacy to manage the CVD. The CMSES is composed of nine items divided into three factors: cardiac risk (e.g., How well can you avoid problems or difficult situations and reduce sources of stress?), adherence to treatment (e.g., How well can you follow the prescriptions about food, even when you feel very nervous), and the recognition of cardiac symptomatology (e.g., How well can you recognize illness symptoms, such as palpitations, tachycardia, and short breath?). It uses a Likert-type scale of 5 points, from 1 (not at all confident) to 5 (totally confident). The reliability in the original study was  $\alpha = 0.68$ ; in this sample, it was 0.71. In addition to the instruments mentioned above, a specific scale was created to obtain a subjective evaluation of the intervention at each phase of the study from the participants of the experimental group. This was a Likert-type scale composed of three items regarding adherence to the intervention, satisfaction with the intervention, and a general evaluation. The adherence to the intervention was measured in terms of frequency in reading and following the instructions of the mHealth intervention, from 1 (never) to 5 (every day). The degree of satisfaction with the messages received was evaluated from 1 (not at all satisfied) to 5 (completely satisfied), and finally, the general evaluation of the study was assessed from 1 (not at all satisfied) to 5 (completely satisfied). Cronbach's alpha value for this scale was 0.75.

## 2.5. Data Analysis

The sample size was calculated using the G\*Power 3.1.9.6 program [53] based on a previous study [54]. This study required a minimum of 34 participants in total to maintain

a significance level of 0.05, an effect size of 0.25, and a power of 80.0%. The whole sample comprised 69 participants considering a dropout rate higher than 20% [55]. Student's *t*-test, the chi-square test, and Fisher's exact test were performed to compare the sociodemographic and clinical characteristics between groups. A dependent sample *t*-test was conducted to test if there were differences before and after the psychoeducational session for the experimental group. To test the effect of the intervention, a repeated-measures ANOVA was performed with each study variable with Time as a within-subject factor (baseline, post-mHealth, follow-up 1, and follow-up 2) and the experimental condition as a between-subject factor (experimental vs. control group). Bonferroni correction was used for pairwise comparisons. The data were analyzed using SPSS statistic software (v. 28).

### 3. Results

Table 1 shows the sociodemographic and clinical characteristics of the study sample. Statistically significant differences between groups were only found for employment status ( $p = 0.004$ ). The baseline scores for each group on all outcome measures are shown in Table 2. No differences were found between the groups.

**Table 1.** Participant sociodemographic and clinical characteristics of the study sample.

	Total (N = 69)	Experimental Group (n = 34)	Control Group (n = 35)	Statistical Significance
Age (M, SD)	63.7 (11.5)	61.24 (11.1)	66.1 (11.6)	$t(67) = 1.77, p = 0.081^a$
Sex, n (%)				$\chi^2(1) = 1.95, p = 0.163^b$
Male	54 (78.3%)	29	25	
Female	15 (21.7%)	5	10	
Marital status, n (%)				$p = 0.924^c$
Single	2 (2.9%)	1	1	
Single with partner	1 (1.4%)	1	0	
Married	57 (82.6%)	28	29	
Separated	2 (2.9%)	1	1	
Divorced	3 (4.3%)	2	1	

## Study 2

Widowed	4 (5.8%)	1	3	
Employment status, n (%)				<i>p</i> = 0.004 <sup>c</sup>
Retired	40 (58%)	13	27	
Full-time work	21 (30.4%)	15	6	
Unemployed	6 (8.7%)	5	1	
Home care	2 (2.9%)	1	1	
Educational level, n (%)				<i>p</i> = 0.119 <sup>c</sup>
Basic primary school	54 (78.3%)	24	30	
High school or higher	15 (21.7%)	10	5	
Type of CVD, n (%)				<i>p</i> = 0.677 <sup>c</sup>
Angina pectoris	8 (11.6%)	3	5	
Myocardial infarction	33 (47.8%)	17	16	
Heart failure	5 (7.3%)	1	4	
Arrhythmia	5 (7.3%)	2	3	
Other	11 (15.9%)	7	4	
More than one of the above	7 (10.1%)	4	3	
Level of limitation of ADLs, n (%)				
Level 1	29 (42%)	17	12	
Level 2	22 (31.9%)	10	12	
Level 3	14 (20.3%)	4	10	
Level 4	4 (5.8%)	3	1	
HADS ( <i>M</i> , <i>SD</i> )	1.84 (0.49)	1.95 (0.44)	1.73 (0.52)	<i>t</i> (65) = -1.88, <i>p</i> = 0.065 <sup>a</sup>
P-scale ( <i>M</i> , <i>SD</i> )	3.94 (0.82)	3.89 (0.69)	3.99 (0.93)	<i>t</i> (67) = 0.50, <i>p</i> = 0.614 <sup>a</sup>

Note. *M* = mean, *SD* = standard deviation, ADLs = activities of daily living, CVD = cardiovascular disease, HADS = Hospital Anxiety and Depression Scale, P-scale = Positivity scale. <sup>a</sup>Student's *t*-test, <sup>b</sup>Chi-square test, <sup>c</sup>Fisher's exact Test.

**Table 2.** Baseline scores in the experimental and the control group in all the outcome measures.

	Experimental Group (n = 34)		Control Group (n = 35)		
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>p</i>
PSWB	3.28	0.76	3.36	0.85	0.674
SEMCD	7.71	1.79	6.85	1.92	0.059
CMSES	4.11	0.66	4.31	0.47	0.144

Note. *M* = Note. *M* = mean, *SD* = standard deviation, PSWB = Positive Subjective Well-Being, SEMCD = Self-Efficacy for Managing Chronic Disease, CMSES = Cardiovascular Management Self-Efficacy Scale.

### 3.1. Psychoeducational Session

Table 3 shows the means, standard deviations, and *t*-test results of PSWB, SEMCD, and CMSES at the baseline and after the face-to-face session for the intervention group. The results from dependent *t*-test analysis showed differences between these two phases in positive subjective well-being and self-efficacy for managing the CVD, with higher scores in both scales in the post-session evaluation compared to the baseline.

**Table 3.** Baseline and post-session scores of PSWB, SEMCD, and CMSES in the experimental group.

	Baseline		Post-Session (Face-to-Face)		Baseline–Post-Session Emotion Regulation		
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>t(33)</i>	<i>p</i>	<i>d</i>
PSWB	3.28	0.76	3.93	0.68	-6.60	<0.001	0.57
SEMCD	7.71	1.79	8.02	2.00	-1.40	0.170	1.31
CMSES	4.11	0.66	4.26	0.67	-2.42	0.021	0.35

Note. *M* = mean, *SD* = standard deviation, PSWB = Positive Subjective Well-Being, SEMCD = Self-Efficacy for Managing Chronic Disease, CMSES = Cardiovascular Management Self-Efficacy Scale.

### 3.2. *mHealth Intervention*

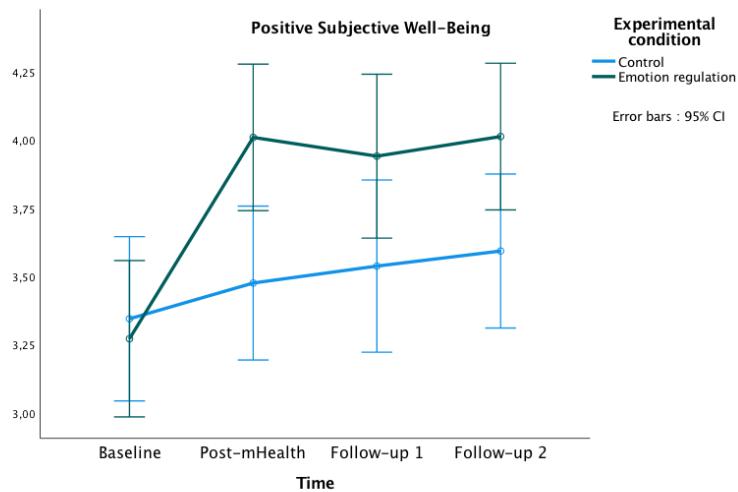
The graphics presented in Figures 2–4 show the marginal estimated means for both groups at the baseline and at the three post-test measures on PSWB, CMSES, and SEMCD.

#### 3.2.1. Primary Outcome

##### Positive Subjective Well-being (PSWB)

The repeated-measures ANOVA showed a significant main effect of time [ $F(3177) = 13.60, p < 0.001, \eta^2 = 0.19$ , observed power (OP) = 1.00], and a significant interaction effect of time x experimental condition [ $F(3177) = 4.70, p = 0.003, \eta^2 = 0.07$ , OP = 0.89]. Bonferroni pairwise comparisons showed significant differences between groups

at post-mHealth ( $M_{\text{Experimental}} = 4.01$ ,  $M_{\text{Control}} = 3.48$ ,  $p = 0.008$ ; 95% IC = [0.14, -0.92]), and follow-up 2 ( $M_{\text{Experimental}} = 4.01$ ,  $M_{\text{Control}} = 3.59$ ,  $p = 0.035$ ; 95% IC = [0.03, 0.81]). Additionally, within the experimental group, some differences were found in PSWB between the study phases, being the scores higher in all post-evaluations compared to the baseline (all  $p < 0.001$ ).



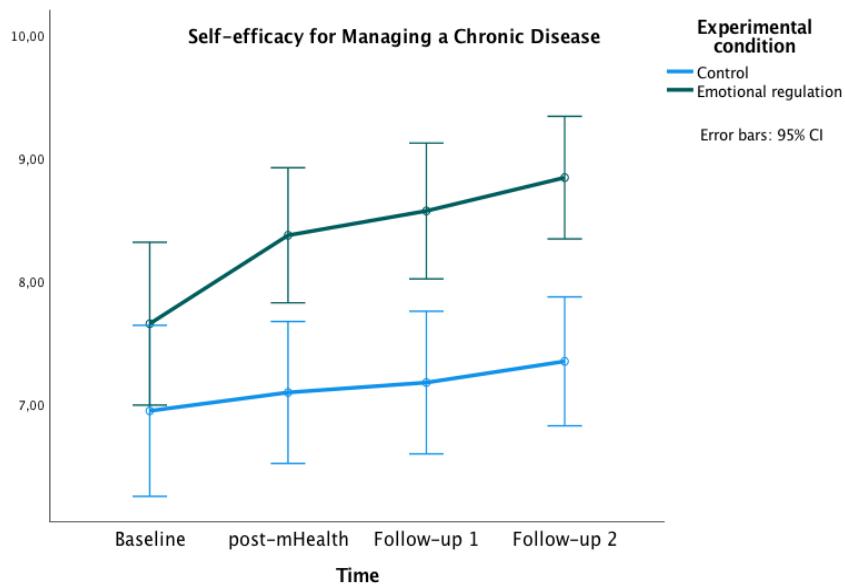
**Figure 2.** Changes in Positive Subjective Well-being in both groups over time.

### 3.2.2. Secondary Outcome

#### Self-Efficacy for Managing the Disease

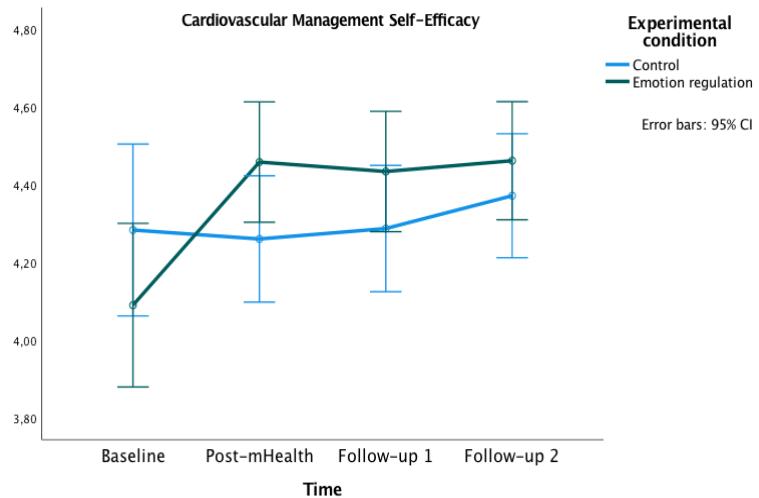
With regard to the SEMCD, a significant main effect of time was found [ $F(2,585,152.50) = 7.27$ ,  $p < 0.01$ ,  $\eta^2 = 0.11$ , potency = 0.97, Greenhouse-Geisser correction applied because Mauchly's  $W = 0.759$ ,  $p = 0.007$ ]. Additionally, a main effect of the experimental condition was found [ $F(1) = 12.04$ ,  $p = 0.001$ ,  $\eta^2 = 0.17$ , OP = 0.93]. Bonferroni pairwise comparisons showed significant differences between groups at post-mHealth ( $M_{\text{Experimental}} = 8.38$ ,  $M_{\text{Control}} = 7.10$ ,  $p = 0.002$ ; 95% IC = [0.48, 2.07]), follow-up 1 ( $M_{\text{Experimental}} = 8.57$ ,  $M_{\text{Control}} = 7.19$ ,  $p = 0.001$ ; 95% IC = [0.60, 2.20]), and follow-up 2 ( $M_{\text{Experimental}} = 8.84$ ,

$M_{control} = 7.35$ ,  $p < 0.001$ ; 95% IC = [0.77, 2.22]). Within the experimental group, differences were also found with higher scores on SEMCD at all post-evaluations compared to the baseline (all  $ps < 0.05$ ).



**Figure 3.** Changes in Self-efficacy for Managing Chronic Disease in both groups over time.

Related to the CMSES, a significant main effect of time [ $F(2,45,144.74) = 6.40$ ,  $p < 0.001$ ,  $\eta^2 = 0.10$ , OP = 0.94] and an interaction effect of time x experimental condition [ $F(2,45, 144.74) = 4.91$ ,  $p = 0.005$ ,  $\eta^2 = 0.08$ , OP = 0.86] were found. In both cases, the Greenhouse–Geisser correction was applied because Mauchly's W = 0.70,  $p = 0.001$ . Bonferroni pairwise comparisons were not significant. However, the experimental group showed higher values on CMSES at post-mHealth ( $M = 4.46$ ), follow-up 1 ( $M = 4.43$ ) and follow-up 2 ( $M = 4.46$ ) compared to the baseline ( $M = 4.09$ ), all  $ps = 0.001$ .



**Figure 4.** Changes in Cardiac Management Self-Efficacy in both groups over time.

### 3.3. Subjective Evaluation of the Intervention

The results indicated a great commitment and a positive evaluation of the intervention, showing differences over the three time point evaluations [ $F(2,62) = 15.5, p < 0.001, \eta^2 = 0.33$ , OP = 0.99]. Specifically, the results showed improvements in each phase, comparing post-mHealth ( $M = 4.27$ ), follow-up 1 ( $M = 4.44$ ), and follow-up 2 ( $M = 4.69$ ), all  $p < 0.05$ .

## 4. Discussion

The aim of this study was to evaluate the effectiveness of an mHealth-based brief psychological intervention in emotion regulation to enhance positive subjective well-

being and self-efficacy to manage the chronic cardiac disease in patients with CVD. The study sample of 69 CVD patients (54 men, 15 women) was assigned to either the experimental ( $n = 34$ ) or the control group ( $n = 35$ ). Both groups were composed mostly of men in line with the sex distribution in CVD patients [56]. A face-to-face psychoeducational session followed by an mHealth intervention was conducted. Regarding the effectiveness of the face-to-face session, the results showed remarkable differences. The 1 h psychological intervention in emotion regulation strongly improved the patients' positive subjective well-being. Moreover, this face-to-face session seemed to increase their perception of self-efficacy in managing the CVD. The mHealth emotion regulation intervention improved the positive subjective well-being of patients, as well as provided better management of the disease compared to the control group. According to the hypotheses of the study, the results showed a higher positive subjective well-being across the evaluations and a better cardiac and chronic management self-efficacy comparing both follow-ups with the baseline. Important differences over time were also found between the groups. The experimental group showed a greater positive subjective well-being in post-mHealth and follow-up 2, and a higher self-efficacy for managing chronic disease in post-mHealth, follow-up 1, and follow-up 2 compared to the control group.

These results corroborate those obtained by other studies, backing up the effectiveness of emotion regulation in improving psychological well-being [57–59]. The present results further suggest the effectiveness of psychological interventions in improving well-being in patients with CVD, according to previous research findings [28], as well as in enhancing self-efficacy in patients with CVD. These results are in line with several studies that analyzed the connection between positive affect, psychological well-being, and the management of CVD. Some of them found that patients with higher

subjective well-being were prone to have healthier habits, such as taking care of diet, better sleep quality, reduced alcohol consumption, and better adherence to treatment [22,60–62], resulting in lower CVD risk [20,22].

Results from this study are consistent with research findings that highlight the importance of implementing emotion regulation techniques with patients who manifest cardiovascular problems [16,57,63] in order to favor healthy physical and psychological functioning, as well as reduce cardiovascular risk. Moreover, according to this study, an mHealth-based brief psychological intervention seems to be at least a good start to achieve these benefits in this population. This would not only be because of the increased subjective positive well-being, which would have already led to an improvement in quality of life and other health-related variables [64] but also because it has an effect, at least at the middle term, on the management of cardiac and chronic disease. Therefore, these findings contribute to the growing evidence that regards psychological well-being as a “bulwark” of health [19,20,59]. The significance and maintenance of the intervention effect in both self-efficacy measures and subjective well-being support the existing evidence of the lasting benefits of this brief type of educational intervention [10–12], giving strength to the idea of incorporating this kind of psychological intervention in cardiac rehabilitation programs [8,9].

In addition, as other studies have suggested, the use of new technologies allowed us to reach directly to the *patient's hand*, which may have been one of the reasons for the high adherence to the intervention as shown in the results about the subjective evaluation in the study [41,42]. The effectiveness of a positive brief mHealth psychological intervention could imply a better adaptation to the disease, adherence to treatment, and the adoption of a new healthy lifestyle [8,60,61]. This may suppose an improvement in well-being and quality of life [28], reducing long-term risk factors such as comorbidities

[5,6]. The results of this study seem to indicate that the combination of brief psychological interventions, due to their low cost and promptness, together with the adaptation of the treatments to the rising technological reality, are an attractive and effective alternative which can be considered from different approaches of health care when treating these patients [65].

#### *4.1. Limitations*

Although the results indicated the effectiveness of the intervention, this study has some limitations. The non-random allocation of the participants on the experimental conditions may bias the results. However, no differences between groups were found in clinical characteristics such as anxiety and depression states, positivity, or any outcome measure at baseline. Regarding the study sample size, though limited, it was similar to previous intervention studies with CVD patients [66,67]. Similar results are expected in wider samples, but this needs to be tested in future research. A potential bias in the data collection also needs to be mentioned. Baseline measurements were conducted differently for the experimental and the control groups (*in situ* vs. phone call, respectively), which could have affected the study results. However, as mentioned before, no differences between the groups were found at baseline, indicating that the different procedure would have not affected the participants' responses. Finally, the low presence of women in the study sample is consistent with the pattern of a higher prevalence of most CVD in men. However, several studies argue that this sex prevalence ratio is based on a gender bias in the diagnosis of CVD [56]. Relating to that, in our study, the underrepresentation of women is higher in the experimental group (29 men/5 women) compared to the control group (25 men/10 women). This lower enrolment of women in CVD programs has been observed in other studies [68]. This could be explained, among other things, by the underestimation of CVD risk in women, a lower importance of self-care, as well as some

gender barriers (e.g., lower social and family support, transport-economic problems, lack of time due to the caregiving role) [69]. Although this issue might bias the results, it is important to note that in our study there were no statistical differences in the sex representation between groups.

#### *4.2. Future Research*

Regarding future lines of research, it would be interesting to evaluate and compare the effectiveness of the intervention proposed with other types of intervention modalities (i.e., only face-to-face, only mHealth, and no treatment). This would shed light on the effect of interventions mediated by the incorporation of mHealth strategies. It is also proposed to go one step further and take advantage of the fact that mHealth interventions are projected as a patient-centered strategy to encourage a personalized intervention, a tailored communication, considering the individualities of the patients with regard to the objective of the intervention. In this line, the gender bias mentioned above should be taken into account when designing future interventions in CVD. The personalization of these interventions would allow to address the specific characteristics of women, facilitating their enrolment and hopefully improving their CVD-related outcomes. In addition, other variables could also be evaluated at baseline, considering the gender perspective and the profiles of patients with CVD. Furthermore, the possibility of adding biomarkers in future research should be contemplated in order to obtain richer and likely less-biased information on the intervention.

### **5. Conclusions**

This study shows the effectiveness of an mHealth-based brief psychological intervention in emotion regulation to enhance positive subjective well-being (showing an increase in positive affect) and to improve self-efficacy in the management of chronic and cardiac

disease in CVD patients. The adaptation of psychological interventions with new technologies and new forms of understanding life and healthcare treatments was a good option to reach different patient profiles and to promote adherence to the psychological intervention. The results of this study are significant as they provide evidence on how brief psychological interventions together with mHealth are a good combination treatment for CVD patients. It has been proved that with a low cost and promising benefits, together they can contribute to an improvement in psychological well-being and the management of the disease that may translate in the long term to a better quality of life of CVD patients.

**Supplementary Materials:** The following supporting information can be downloaded at: [www.mdpi.com/xxx/s1](http://www.mdpi.com/xxx/s1), Supplementary File S1: WhatsApp Messages from the mHealth Intervention.

**Author Contributions:** Conceptualization, R.C.-M., B.L., and C.T.; Data curation, N.Z.F.-M. and T.G.-D.; Formal analysis, N.Z.F.-M., R.C.-M., and B.L.; Funding acquisition, B.L. and C.T.; Investigation, N.Z.F.-M., R.C.-M., B.L., S.J.R., T.G.-D., E.C., A.A., and C.T.; Methodology, R.C.-M., B.L., and C.T.; Project administration, B.L. and C.T.; Resources, B.L. and C.T.; Software, S.J.R.; Supervision, R.C.-M., B.L., and C.T.; Validation, N.Z.F.-M., R.C.-M., B.L., S.J.R., T.G.-D., E.C., A.A., and C.T.; Visualization, N.Z.F.-M., R.C.-M., B.L., S.J.R., T.G.-D., E.C., A.A., and C.T.; Writing—original draft, N.Z.F.-M.; Writing—review and editing, N.Z.F.-M., R.C.-M., B.L., and C.T. All authors have read and agreed to the published version of the manuscript.

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**Informed Consent Statement:** Informed consent was obtained from all subjects involved in the study.

**Data Availability Statement:** The data presented in this study are available on request from the corresponding author.

**Conflicts of Interest:** The authors declare no conflicts of interest.

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## Capítulo 8

### Study 3

#### **Effectiveness of an eHealth intervention to improve subjective well-being and self-efficacy in cardiovascular disease patients: A Pilot Non-Randomized Controlled Trial\***

#### **ABSTRACT**

**AIM:** To evaluate the effectiveness of a multicomponent, eHealth-based self-efficacy intervention to promote subjective well-being and self-efficacy in patients with cardiovascular disease, exploring sex differences.

**DESIGN:** A pilot study of a two-arm non-randomized controlled trial.

**METHODS:** Forty-two cardiovascular patients (31% women) participated in the study. The experimental group received a personalized psychoeducational session and a 14-days eHealth intervention. Subjective well-being (positive and negative affect) and self-efficacy (chronic and cardiac) were assessed at baseline, post psychoeducational session, post eHealth intervention and at two follow-ups.

**RESULTS:** The levels of the experimental group in positive affect, at post-eHealth and follow-up 1, and self-efficacy, at post-eHealth, and both follow-ups, were significantly

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higher compared to the control group (all  $ps < .05$ ). When considering sex, the intervention was effective only for men. The results highlight the potential of eHealth interventions for cardiac patients and underline the importance of considering a gender perspective in their treatment.

**Keywords:** Cardiovascular disease; eHealth; Self-efficacy; Subjective well-being; Sex differences; Nursing

## 1. INTRODUCTION

Population ageing and increased life expectancy are signs of an improvement in healthcare and quality of life (QOL) but this also means having to manage chronic disease for longer (Atella et al., 2019). This supposes a challenge to public health systems as well as to the patients who have to live and struggle with their health condition.

Cardiovascular disease (CVD) is the most prevalent of the chronic diseases and the leading cause of death worldwide (World Health Organization, 2019), forming most of the burden on healthcare systems (Roth et al., 2017). Nonadherence to treatment (Al-Ganmi et al., 2020; Leslie et al., 2018), low acceptance and adjustment to the disease and poor self-efficacy for coping with the new requirements of the diagnosis, are some of the variables that may affect to the morbidity of CVD. Therefore, to support these patients in this process focusing on variables related to the engagement with medical treatment and healthcare behaviors (i.e., healthy diet, exercising, etc.) should be a priority.

## 2. BACKGROUND

From a biopsychosocial model of health, several studies have proved a well-established relationship between cardiovascular disease and psychological distress such as anxiety/depressive symptoms, poor emotion regulation and low self-efficacy to manage the disease (Appleton et al., 2014; Hare et al., 2013; Wierenga et al., 2017). Variables

closely related to the prognosis of the disease and QOL. Considering the interaction between biomedical conditions and psychosocial functioning, and vice versa (O'Leary, 1985), to include a psychological approach when intervening with cardiac patients is vital. In this sense, to take into account variables that affect subjective well-being (i.e., life satisfaction, happiness, affective balance) (Diener, 2009) as well as self-management and self-efficacy, could facilitate the adjustment to the disease as also minimize the psychological distress related to CVD diagnosis.

Self-efficacy is a psychological factor known to have an influence on management of the chronic disease (Survonen et al., 2019), cardiac rehabilitation and perceived health-related QOL (Cuadrado et al., 2018). Defined by Bandura within the framework of the social learning theory of causation, self-efficacy explains the influence of people's perception of their capabilities on their behavior, motivation and emotional and cognitive patterns (O'Leary, 1985). Research has found a relationship between stronger self-efficacy and better psychological well-being (Krok & Zarzycka 2020) and life satisfaction (Castillo-Mayén et al., 2020) in patients with CVD. Other studies have shown, also for cardiac patients, positive influence of self-efficacy on adherence to healthy diet (Castillo-Mayén et al., 2020), exercising (Bergström et al., 2015), health-related QOL (Tabernero et al., 2020) and self-care activities (Banik et al., 2018). These results highlight the important role that self-efficacy has on CVD patients' well-being, reinforcing their perception of their ability to cope with the different situations that may occur throughout their disease (Banik et al., 2018).

Recently, there is a growing body of research assessing the effectiveness of cardiovascular programs. Some studies have shown that multicomponent programs that include different kinds of intervention (psychotherapy, psychoeducation, symptom recognition, weight control, etc.) are more efficient than single-component programs for

improving adherence (Jafar et al., 2017). Tailored or person-centered interventions are now the focus and have become the strongest challenge for intervening in CVD, with promising results (Cioe et al., 2021). Such interventions would allow to be more accurate in terms of attending patient's needs and circumstances, resulting in better outcomes of the interventions and greater impact on the quality of life of these patients.

Recently, eHealth-based interventions are gaining support, given their online nature and especially after the recent COVID-19 pandemic (Rauschenberg et al., 2021). The low cost and positive results shown for improving management of chronic diseases, adherence to prescribed medication and the physical and mental well-being of patients place them as a good option for CVD (Baretta et al., 2019; Palmer et al., 2018). However, self-efficacy programs based on tailored, eHealth or multicomponent interventions in CVD patients remain scarce.

Equally limited is research evaluating gender and/or sex differences in the efficacy of interventions with CVD patients. Attending to previous literature, men and women differ in how they experience this type of health condition, showing differences in prevalence, symptoms and prognosis (Gao et al., 2019; Peters et al., 2019). According to several studies, this is due not only to purely biological factors, but also to psychosocial factors that are undoubtedly related to gender, such as the burden derived from the dual work/domestic role, socioeconomic status or emotional distress caused by exposure to stressful life conditions (Luque et al., 2020; Medina-Inojosa et al., 2019).

In this pilot study, we propose a multicomponent intervention based on a personalized psychoeducation and an eHealth psychological intervention on self-efficacy. Thus, this paper presents a two-arm non-randomized controlled trial study aimed at designing, developing and pilot testing the effectiveness of the intervention to improve cardiac patients' subjective well-being and self-efficacy for managing the disease.

Furthermore, in order to apply a gender perspective on cardiovascular health and be more sensitive and accurate in our study results, sex differences in the effectiveness of the intervention were also assessed.

We hypothesized better subjective well-being and better self-efficacy for managing CVD in the experimental group compared to the control group. In particular, we expected these differences to be maintained over time. Furthermore, differences in both variables between men and women were expected consistent with gender socialization, with better self-efficacy outcomes for men and greater improvement in subjective well-being for women.

### **3. THE STUDY**

#### *3.1. Design*

This pilot study employed a two-arm non-randomized controlled trial design. The experimental group received a combined psychological intervention in self-efficacy, including a personalized psychoeducational face-to-face session with a subsequent eHealth intervention, while the control group continued with their treatment as usual.

#### *3.2. Method*

##### *3.2.1. Study Setting and Participants*

The study setting was the Clinical Research Building of the Maimonides Biomedical Research Institute of Cordoba, Spain. Patients were enrolled from The Cardiology Unit of the University Reina Sofia Hospital in Córdoba and the Association of Cardiac Patients of Córdoba and Province. Inclusion criteria were, 1) women and men with a diagnosis of a CVD (angina pectoris, myocardial infarction, heart failure, arrhythmia, etc.) aged > 18, 2) fluent in Spanish, 3) having a smartphone compatible with the APP used for the eHealth intervention (WhatsApp) and daily access to internet, and 4) having the required

digital skills to follow the eHealth intervention. Exclusion criteria were, 1) women and men with a diagnosis of a CVD < 18 years, 2) not having a smartphone compatible with WhatsApp, 3) not having the required digital skills, 4) currently participating in another clinical trial and 5) currently receiving other psychological treatment. According to the rules of thumb (Whitehead et al., 2016), sample sizes between 24 and 50 are recommended for pilot studies (Browne, 1995; Julious, 2005; Sim & Lewis, 2012). Eligible participants were recruited between September and November 2019. Of those initially approached ( $N = 64$ ), 42 patients agreed to participate and provided their written informed consent at the beginning of the first study phase. Participants were assigned to either the self-efficacy group ( $n = 21$ ) or the control group ( $n = 21$ ) based on their availability to participate in the face-to-face psychoeducational intervention. The program G-power 3.1 (Faul et al., 2009) was implemented to confirm that the statistical power was at least 0.8 for PANAS, SECMD and CMSES analyses with the actual sample size.

### 3.2.2 Intervention

#### **Experimental group – Self-efficacy intervention**

The experimental group received a multicomponent intervention including a personalized psychoeducational session in self-efficacy and a subsequent 14-days eHealth-based psychological intervention in self-efficacy. Both components of the intervention were designed and developed following the Bandura's theory of self-efficacy (1997).

***Personalized psychoeducational intervention in self-efficacy.*** It was performed by a General Health Psychologist in a private room at the Clinical Research Building of the Maimonides Biomedical Research Institute of Cordoba. The aims of the psychoeducational session were to: (1) familiarize patients with the self-efficacy concept and its influence in the course of CVD; (2) identify patients' health needs and provide the

resources to improve their self-efficacy and achieve their health-related goals; and (3) explain the eHealth intervention procedure.

The sessions were carried out individually, allowing the intervention to be personalized to the patient's needs. Once the patients were familiar with the concept of self-efficacy, the rest of the contents were adapted based on the participant's own objectives and experiences. At the end of this session, patients were given a brochure containing key information of the psychoeducation received and a scheme of the eHealth intervention procedure.

***eHealth-based psychological intervention in self-efficacy.*** It started the day after the psychoeducational session and lasted 14 days. We opted for a brief intervention because of its cost effectiveness and promising results shown in cardiac rehabilitation programs (Armitage, 2015; Fernandes et al., 2017). The main objective of this intervention was to train patients in self-efficacy in order to improve their management of CVD. This practice focused on the principal sources of self-efficacy (Bandura, 1997) – mastery experiences, vicarious experiences, verbal persuasion and emotional-physiological states – all of which were adapted to health issues, such as, following a healthy diet, stop smoking, increasing physical activity etc. The patients received a daily message (14 messages in total) at the same time (10 am) through *WhatsApp*. Each message contained a brief explanation with an activity they had to perform, a suggestion and/or advice linked to self-efficacy and health (Table 1). Patients were asked to do the activities considering their own cardiovascular health-related goals identified in the psychoeducational session.

### **Control group – Treatment as usual**

Patients of the control group continued with their usual treatment: medication and their ordinary medical follow-up. They did not attend to the psychoeducational session and did not receive the eHealth *WhatsApp* intervention.

**TABLE 1.** Examples of the eHealth Self-efficacy intervention online messages.

<b>Sources of self-efficacy</b>	<b>Message content type</b>
Mastery experiences	Remember a situation in your life that has been particularly difficult and that you had overcome successfully. Try to visualize it and reflect on how you felt (worried, tense, nervous) and how you felt when you overcame it (relieved, calm, etc.). Remembering moments of success can generate a pleasant feeling of security and confidence. If you did it then, why not now?
Vicarious experiences	Choose a situation that you find difficult to cope with, or stressful in your life in any domain. Think of a person close and important to you who copes effectively with that situation. Observe and record the behaviors and strategies that person uses to cope with this situation. Practice the behaviors you have observed and assessed as effective.
Verbal persuasion	Giving ourselves positive messages is important for self-esteem and self-efficacy. Repeat to yourself phrases such as "I am able to cope and overcome difficult situations" or "even though sometimes things don't go my way, I am able to find solutions, bounce back and thrive in the face of difficulties". Believing and trusting in yourself will make it easier for you to cope with difficult life situations.
Emotional-physiological states	It is time to become aware of our body and the sensations we experience on a regular basis to be able to recognize when things are not going as they should. How does your body feel right now? Take a few minutes and calmly review your body sensations, how do they relate to your current mood? Becoming aware of how we feel can help us improve our self-efficacy.

This study included five points of evaluation for the experimental group: at baseline; after the psychoeducational session (post-session); after the 2-weeks eHealth-based psychological intervention (post-eHealth); and at 2-week and 4-week follow-up evaluations (Follow-ups 1 and 2, respectively). The participants of the control group were

assessed at the same points except for the ‘post-session’, maintaining the same time elapse between each point than in the experimental group. Study evaluations were carried out via phone calls, except for the baseline and post-session evaluation which were collected in situ for the experimental group. Data collection of the experimental condition was conducted by the psychologist that performed the psychoeducational session and the control group by an independent researcher who was blind to the group assignment. Data analysis was also blinded and performed by a third independent researcher.

### 3.2.3. Study Instruments

#### **Sociodemographic and CVD characteristics**

Sociodemographic information, such as sex, age, employment status and educational level, as well as CVD-specific characteristics, such as type of CVD and level of limitation in the activities of daily life (ADL), were provided by the participants.

#### **Subjective well-being**

Subjective well-being was measured with the Positive and Negative Affect Scale (PANAS) (Tabernero et al., 2009; Watson et al., 1988). This is a self-report questionnaire with 20 items assessing positive and negative affect on two subscales of 10 items each. Positive affect is the dimension of subjective well-being referring to the degree to which a person feels excited, active, inspired and alert. Negative affect, on the other hand, reflects the subjective discomfort that include a range of unpleasant emotions (i.e., anger, disgust, guilt, fear, and nervousness) (Watson et al., 1988). Response statements were from 1 (nothing) to 5 (totally) with a total score from 10 to 50 points on each scale. Higher values in positive affect scale and lower values in negative affect scale indicate a better subjective well-being, a state of high energy, concentration, serenity and calmness (Watson et al., 1988). The Cronbach’s alpha in the original study for the positive and

negative scales were .0.88 and .89, respectively. In this study, Cronbach's alpha coefficient was .89 for positive affect and .93 for negative affect.

### **Self-efficacy**

For self-efficacy, we decided to use two different scales in order to enrich the information about this construct considering the study sample clinical population. The Self-Efficacy for Managing Chronic Disease (SEMCD) scale (Lorig et al., 2001; Lorig et al., 2003) and the Cardiovascular Management Self-Efficacy Scale (CMSES) (Steca et al., 2015). The SEMCD is a six-item Likert-type scale that measures self-efficacy for managing a chronic disease, from 1 (not at all confident) to 10 (completely confident) with a total range score from 6 to 60. The results of this scale would provide information related to the confidence perception to cope with the chronic condition with items encompassing this construct from an overall perspective (i.e., How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?). The CMSES, on the other side, assesses self-efficacy for managing CVD specifically and is a nine-item Likert-type scale measuring three different factors: cardiac risk (four items), adherence to therapy (two items) and recognition of cardiac symptomatology (three items). The range goes from 1 (not at all confident) to 5 (completely confident) with a total score from 9 to 45. The results of this scale would offer more concrete information about subjective self-efficacy to cope with cardiovascular disease, with items that englobe the principal characteristics and symptoms of this condition (i.e., How well can you recognize illness symptoms, such as palpitations, tachycardia, and short breath? How well can you Always recognize the symptoms of your illness, such as a chest pain?). Both scales, which complement each other, would provide well-rounded approach to the self-efficacy construct. Higher values in SEMCD and CMSES indicate a better self-efficacy to manage the chronic and cardiac disease. SEMCD Cronbach's  $\alpha$  coefficient in the original study

was .88, and .89 in this study. CMSES Cronbach's alpha were from .68 to .79 in the original study and .60 in this study.

### 3.2.4. Data analysis

Descriptive analyses were performed to identify the characteristics of the sample and of each group. Number, percentage, mean and standard deviations were calculated for patients' baseline data involving sociodemographic and CVD characteristics. The normal distribution of each variable at each evaluation moment was tested. The Shapiro-Wilk test indicated that normality was violated in 14 out of 16 assessments (4 scales x 4 time point evaluation). Following the recommendations when assumptions of normality is violated (Rana et al., 2016; Nahm, 2016), especially in small samples (Derrick et al., 2020; Happ et al., 2018), non-parametric tests were performed. Mann-Whitney U test was used to compare age, chi-square tests and Fisher's exact Test were used to compare dichotomized and categorical variables. To examine the effect of the psychoeducational session in the experimental group, a paired sample Wilcoxon test was utilized. To test differences between groups and phases of the study, a Mann-Whitney U test was used. Finally, a Wilcoxon signed-rank test was used to analyze the time effect of the intervention in the experimental group. A *p* value of <.05 was considered statistically significant. All analyses were conducted using IBM SPSS v25.0.

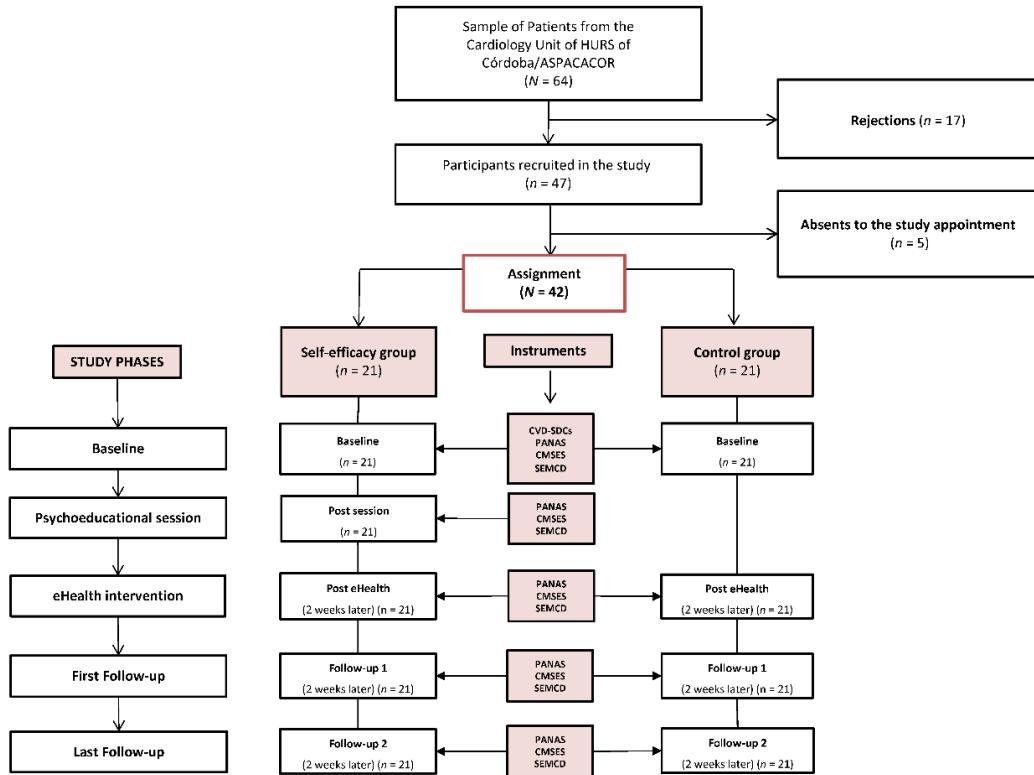
### 3.2.5. Ethics

This study was approved by the Andalusian Health Service's Research Ethics Committee and the Reina Sofía Hospital in June 2015 (Acta 242, Ref. 2886, 29/06/2015).

## 4. RESULTS

Figure 1 shows the flow chart of the participants and instruments utilized over the different phases of the study. According to the sociodemographic and CVD

characteristics, the results showed differences in age and marital status between groups (Table 2).



**FIGURE 1.** Flow chart of the sample phases and instruments of the study. Note.

ASPACACOR = Association of Cardiac Patients of Córdoba and Province; CMSES = Cardiovascular Management Self-Efficacy Scale; CVD-SDCs = cardiovascular disease and sociodemographic characteristics; HURS = University Hospital Reina Sofia; PANAS = positive and negative affect; SEMCD = Self-Efficacy for Managing Chronic Disease Scale.

**TABLE 2.** Sociodemographic and cardiovascular disease (CVD) characteristics of the sample, showing statistical differences between experimental and control groups.

Total (N = 42)	Self-efficacy group (n = 21)	Control group (n = 21)	Group comparison
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### Study 3

<b>Age (M.SD)</b>	63.6 (10.61)	61.8 (6.61)	65.43 (13.42)	$U = 124.00. z = -2.43.$ $p = .015^{*a}$
<b>Sex. n (%)</b>				$X^2 = .111. df = 1. p = .739^b$
Male	29 (69%)	14	15	
Female	13 (31%)	7	6	
<b>Marital status.</b>				$p = .016^{*c}$
<b>n (%)</b>				
Single	2 (4.8%)	1	1	
Married	32 (76.2%)	14	18	
Divorced	6 (14.3%)	6	0	
Widowed	2 (4.8%)	0	2	
<b>*Employment status. n (%)</b>				$p = .594^c$
Retired	27 (64.3%)	12	15	
Full-time work	10 (23.8%)	6	4	
Unemployed	3 (7.1%)	2	1	
Home care	1 (2.4%)	0	1	
Part time job	1 (2.4%)	1	0	
<b>*Educational level. n (%)</b>				$p = 1^c$
Basic primary school	35 (83.3%)	17	18	
High school or higher	7 (16.7%)	4	3	
<b>*Type of CVD.</b>				$p = .659^c$
<b>n (%)</b>				
Angina pectoris	5 (11.9%)	3	2	
Myocardial infarction	25 (59.5%)	14	11	
Heart failure	3 (7.1%)	1	2	
Arrhythmia	4 (9.5%)	2	2	
Other	6 (14.3%)	3	3	
<b>*Level of limitation of ADL. N (%)</b>				$p = .664^c$
Level 1	15 (37.5%)	8	7	
Level 2	13 (32.5%)	7	6	
Level 3	10 (25%)	4	6	
Level 4	2 (5%)	2	0	

Note. The type of CVD percentage was more than 100% because it was a multiple-answer question. Two participants of the control group did not answer the questions type of CVD and level of limitation of activities of daily living (ADL; N = 40). <sup>a</sup> U Mann-Whitney test, <sup>b</sup> Chi-squared test, <sup>c</sup> Fisher's exact test. \* Significant differences.

#### 4.1. Effects of intervention in the general sample

#### Personalized psychoeducational session

Regarding the 1-hour self-efficacy psychoeducational session, results from the Wilcoxon test showed significant differences between baseline and post-session phases in subjective well-being (PANAS) and in self-efficacy on the SEMCD, with higher scores in the post-session evaluation for positive affect and self-efficacy and lower scores for negative affect (Table 3).

**TABLE 3.** Comparison of subjective well-being and of self-efficacy on the SEMCD and CMSES at baseline and post-session in the experimental group.

	Baseline			Post-session (psychoeducation)			<i>z</i>	<i>p</i>
	<i>M</i>	SD	<i>Mdn</i>	<i>M</i>	SD	<i>Mdn</i>		
Positive affect	3.43	0.89	3.50	4.04	0.73	4.10	-2.91	.004*
Negative affect	2.33	1.09	2.20	1.36	0.59	1.10	-3.83	<.001*
SEMCD	7.52	2.07	7.83	8.13	1.44	8.00	-2.14	.003*
CMSES	4.14	0.58	4.30	4.23	0.58	4.22	-1.65	.098

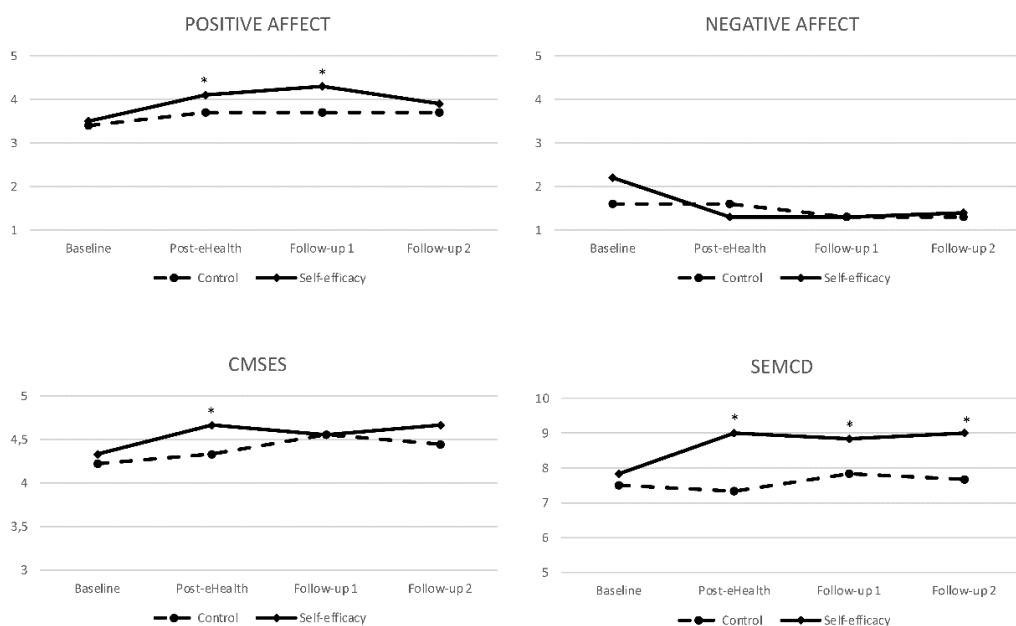
*Note.* *M* = mean; SD = standard deviation; *Mdn* = Median; CMSES = Cardiovascular Management Self-Efficacy Scale; SEMCD = Self-Efficacy for Managing Chronic Disease. \*Significant differences.

### **Effects of eHealth intervention: Between-group differences**

Regarding subjective well-being, for positive affect the Mann-Whitney U test showed differences between groups at post-eHealth, where the experimental group (*Mdn* = 4.10) showed higher scores compared to the control group (*Mdn* = 3.70), and at Follow-up 1, where the experimental group also showed higher scores (*Mdn* = 4.30) compared to the control group (*Mdn* = 3.70). For negative affect, no differences were found between the groups in any evaluation phase.

According to self-efficacy variables, both scales evaluated showed differences between groups. For the SEMCD, the Mann-Whitney U test showed differences at post-

eHealth, with higher scores in the experimental group ( $Mdn = 9$ ) compared to the control group ( $Mdn = 7.33$ ), at Follow-up 1, where the self-efficacy group showed higher scores ( $Mdn = 8.83$ ) compared to the control group ( $Mdn = 7.83$ ), and finally at Follow-up 2, with greater scores ( $Mdn = 9$ ) in the experimental group compared to the control group ( $Mdn = 7.66$ ). For the CMSES, results indicated differences between groups at post-eHealth, where the experimental group showed higher scores ( $Mdn = 4.66$ ) than the control group ( $Mdn = 4.33$ ). The results are shown in Figure 2 and Table 4. No differences were found at baseline between groups on the self-efficacy variable.



**FIGURE 2.** Graphical representation of differences between groups for subjective well-being and for self-efficacy. *Note.* CMSES: Cardiovascular Management Self-Efficacy Scale; SEMCD: Self-Efficacy for Managing Chronic Disease scale.

\*Significant differences.

**TABLE 4.** Results showing significant differences between groups in all phases of the study for SWB and of self-efficacy on the SEMCD and CMSES.

	<b>Control group (n = 21)</b>	<b>Self-efficacy group (n =21)</b>				
<b>Subjective well-being</b>						
<i>Positive affect</i>						
Post eHealth	Mean Rank	Mean Rank	U	<i>z</i>	<i>p</i>	
Post eHealth	17.60	27.40	138.50	-2.07	.039*	
Follow-up 1	17.24	25.76	131.00	-2.26	.024*	
<b>Self-efficacy</b>						
<i>SEMCD</i>						
Post eHealth	16.79	26.21	121.50	-2.49	.013*	
Follow-up 1	16.52	26.48	116.00	-2.64	.008*	
Follow-up 2	16.26	26.74	110.50	-2.77	.006*	
<i>CMSES</i>						
Post eHealth	17.17	19.07	129.50	-2.30	.021*	

*Note.* CMSES = Cardiovascular Management Self-Efficacy Scale; SEMCD = Self-Efficacy for Managing Chronic Disease; SWB = Subjective well-being. \*Significant differences.

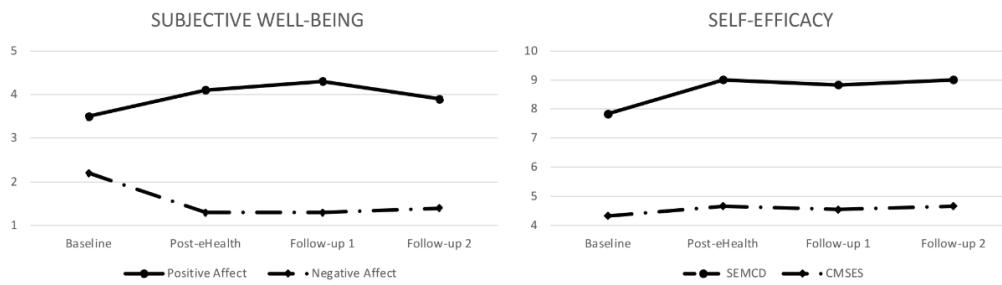
### **Effects of eHealth intervention: Within-group differences in the experimental group**

Regarding subjective well-being, for positive affect a Wilcoxon signed-rank test indicated that the post-eHealth and Follow-up 1 scores were significantly higher than baseline scores. For negative affect, a Wilcoxon signed-rank test indicated significant differences when comparing post-eHealth, Follow-up 1 and Follow-up 2 with baseline, the negative affect scores being lower at all three post-evaluation assessments.

For self-efficacy variables, the SEMCD results showed significant higher scores at follow-up 1 compared to baseline. Finally, the CMSES results indicated significant differences when comparing post-eHealth, Follow-up 1 and Follow-up 2 with baseline, the scores being higher at all the evaluations compared to baseline. No differences were

found between post-eHealth, Follow-up 1 and Follow-up 2 in any variable evaluated. The results are shown in Figure 3 and Table 5.

**FIGURE 3.** Graphical representation of within-group differences in the experimental



group for subjective well-being and for self-efficacy. *Note.* CMSES: Cardiovascular Management Self-Efficacy Scale; SEMCD: Self-Efficacy for Managing Chronic Disease scale.

**TABLE 5.** Results showing significant differences within the experimental group in all phases of the study for SWB and of self-efficacy on the SEMCD and CMSES.

	T	z	p
<b>Subjective well-being</b>			
<i>Positive affect</i>			
Post eHealth- Baseline	184	-2.96	.003*
Follow up 1- Baseline	172.5	-3.12	.002*
<i>Negative affect</i>			
Post eHealth- Baseline	27	-2.74	.006*
Follow up 1- Baseline	18.5	-3.08	.002*
Follow up 2- Baseline	42	-2.56	.011*
<b>Self-efficacy</b>			
<i>SEMCD</i>			
Follow up 1- Baseline	142	-2.46	.014*
<i>CMSES</i>			

Post eHealth- Baseline	173	-3.15	.002*
Follow up 1- Baseline	153.5	-2.97	.003*
Follow up 2- Baseline	152.5	-2.91	.004*

Note. CMSES = Cardiovascular Management Self-Efficacy Scale; SEMCD = Self-Efficacy for Managing Chronic Disease; SWB = Subjective well-being. \*Significant differences.

#### 4.2. Effect of the intervention according to sex

##### Personalized psychoeducational session

The psychoeducational session had a different effect for men and women. Women showed an improvement of their subjective well-being, with significant differences in both positive and negative affect, whereas men showed not only an increased subjective well-being but also higher scores in both self-efficacy measures (Table 6).

**TABLE 6.** Comparison of SWB and of self-efficacy on the SEMCD and CMSES at baseline and post-session for women and men.

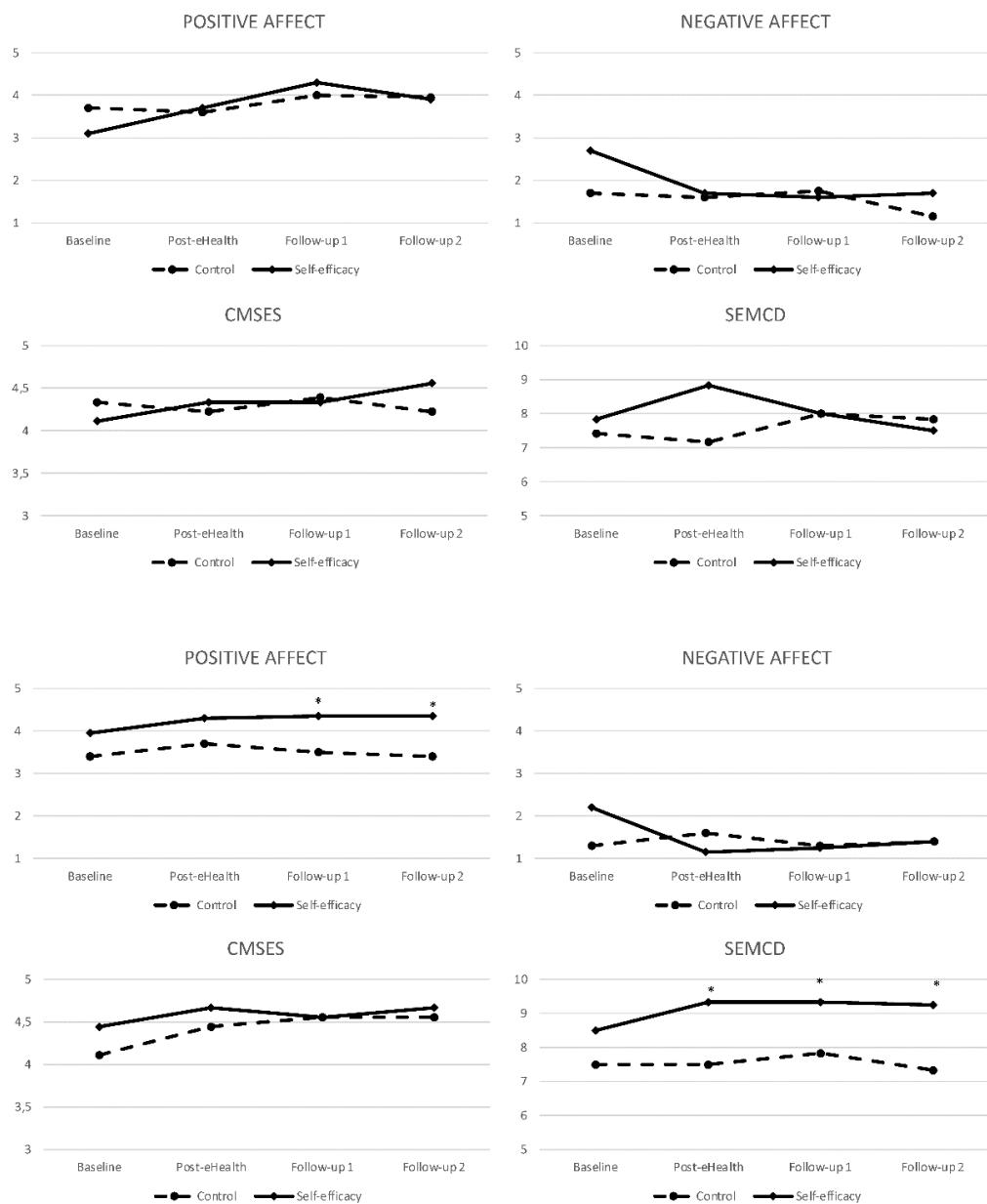
		Baseline			Post-session			<i>z</i>	<i>p</i>
		<i>M</i>	SD	<i>Mdn</i>	<i>M</i>	SD	<i>Mdn</i>		
<b>Positive Affect</b>	Women	3.35	0.72	3.10	4.01	0.35	4.40	-2.37	.018*
	Men	3.49	0.97	3.95	4.06	0.87	4.25	-1.89	.059
<b>Negative Affect</b>	Women	2.28	1.06	2.70	1.33	0.49	1.40	-2.21	.027*
	Men	1.90	0.93	2.20	1.37	0.65	1.05	-3.19	.001*
<b>SEMCD</b>	Women	7.08	1.77	7.83	7.90	0.88	9.00	-1.05	.293
	Men	7.25	2.23	8.50	8.24	1.68	9.08	-1.78	.075
<b>CMSES</b>	Women	4.21	0.24	4.11	4.06	0.22	4.22	-0.55	.581
	Men	4.12	0.63	4.44	4.31	0.69	4.56	-2.67	.008*

Note. *M* = mean; SD = standard deviation; *Mdn* = Median. CMSES = Cardiovascular Management Self-Efficacy Scale; SEMCD = Self-Efficacy for Managing Chronic Disease; SWB = Subjective well-being. \*Significant differences.

##### Effects of eHealth intervention: Between-group differences

Considering subjective well-being, men in the experimental group showed greater scores at post-eHealth and both follow-ups for positive affect ( $p = .051$ ,  $p = .006$ ,  $p = .018$ ) compared to men in the control group. No differences between any variable of subjective well-being were found when comparing women of both groups.

Regarding self-efficacy variables, differences between groups in men were shown on the SEMCD ( $p = .046$ ,  $p = .005$ ,  $p = .001$ ). No differences between groups were found in women. The results are shown in the Figure 4.



**FIGURE 4.** Between-group differences in men (a) and women (b) for subjective well-being scales and for self-efficacy scales. *Note.* CMSES: Cardiovascular Management Self-Efficacy Scale; SEMCD: Self-Efficacy for Managing Chronic Disease scale. \*Significant differences.

### **Effects of eHealth intervention: Within-group differences in the experimental group**

According to the effect of the intervention when comparing each phase evaluation with baseline, it was observed that men improved at some of the time points in all variables. Women, on the other hand, only showed significant improvements in self-efficacy on the CMSES at post-evaluation that are maintained until the end of the study at Follow-up 2 (Table 7).

**TABLE 7.** Differences within the experimental group in all phases of the study for SWB and for self-efficacy on the SEMCD and CMSES in men and women.

		<i>z</i>	<i>p</i>
<b>Subjective well-being</b>			
<i>Positive affect</i>			
Post eHealth- Baseline	Men	-1.824	.068
	Women	-2.371	.018*
Follow up 1- Baseline	Men	-2.625	.009*
	Women	-1.892	.058
Follow up 2- Baseline	Men	-1.090	.276
	Women	-1.355	.176
<i>Negative affect</i>			
Post eHealth- Baseline	Men	-2.308	.021*
	Women	-1.572	.116
Follow up 1- Baseline	Men	-2.864	.004*
	Women	-1.352	.176
Follow up 2- Baseline	Men	-1.916	.055
	Women	-1.521	.128
<b>Self-efficacy</b>			
<i>SECMD</i>			
Post eHealth - Baseline	Men	-1.295	.195
	Women	-1.051	.293
Follow up 1- Baseline	Men	-2.405	.016*
	Women	-1.051	.293
Follow up 2- Baseline	Men	-1.822	.068
	Women	-.847	.397
<i>CMSES</i>			
Post eHealth - Baseline	Men	-2.422	.015*
	Women	-2.003	.045*
Follow up 1- Baseline	Men	-2.501	.012*
	Women	-1.693	.090
Follow up 2- Baseline	Men	-1.998	.046*
	Women	-2.379	.017*

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*Note.* CMSES = Cardiovascular Management Self-Efficacy Scale; SEMCD = Self-Efficacy for Managing Chronic Disease; SWB = Subjective well-being. \*Significant differences.

## 5. DISCUSSION

The aim of this pilot study was to design, develop and evaluate the effectiveness of a multicomponent self-efficacy intervention to improve the subjective well-being and self-efficacy for patients to manage their CVD. The preliminary results showed that the 1-hour personalized psychoeducational session had a positive effect on the experimental group, showing increased subjective well-being and improved self-efficacy variables, especially on the SEMCD. These improvements were maintained over time with the eHealth intervention so that the experimental group showed better subjective well-being and self-efficacy across all the evaluations. When comparing the experimental and control groups, the eHealth intervention was effective for enhancing positive affect. Furthermore, focusing on self-efficacy variables, the experimental group showed greater self-efficacy on the SEMCD in all phases of the evaluation. For self-efficacy on the CMSES, the results followed the same direction, except for the last follow-up where no difference between groups was found.

The different results in both self-efficacy variables could be explained by the fact that the changes that patients need to make in order to achieve self-efficacy in CVD involve high investment in time, personal effort and commitment. In fact, the constructs that define the CMSES variable are related to structural changes in people's lives, such as changing habits, either by acquiring new healthy behaviors (e.g., having a healthy balanced diet and exercising) or by avoiding harmful or risky behaviors (e.g., giving up smoking) (Steca et al., 2015). On the other hand, the positive results found on the SEMCD variable raise the possibility of adapting this type of intervention and promote self-efficacy in other long-term diseases, such as diabetes, cancer, obesity, etc. (Jackson et al., 2014; Young et al., 2020).

When considering the within-subject effects of the eHealth intervention in the experimental group, improvements can be observed also in subjective emotional well-being and in both self-efficacy variables. Nevertheless, it should be noted that the positive effect of self-efficacy was higher on the CMSES than on the SEMCD. Given that this intervention was specifically focused on and developed for patients with cardiovascular problems and that the personalized intervention was targeted at achieving goals related to CVD, this difference appears to be coherent.

Although we carried out a pilot study, the results obtained support evidence from previous research that relates the improvement of self-efficacy with better psychological well-being in CVD patients (Krok & Zarzycka 2020). This research also contributes to support the influence of self-efficacy on the adherence of important healthy behaviors in order to cope with CVD (Bergström et al., 2015; Castillo-Mayén et al., 2020; Tabernero et al., 2020). Moreover, the results of this study add evidence to the growing body of research that supports the approach of personalized intervention to improve adherence to treatment and a better prognosis of the disease (Cioe et al., 2021; Xu et al., 2020). Finally, the current study provides additional evidence in this area of research that defends the combination of different types of intervention (Jafar et al., 2017) and specifically those that highlight the benefits of incorporating eHealth tools, which involve an update of the therapeutic process in chronic diseases (Baretta et al., 2019; Palmer et al., 2018; Rauschenberg et al., 2021) while economizing on resources. Compared to traditional approaches, eHealth interventions might be better tailored to characteristics of CVD patients, where the average age is frequently high and autonomy and mobility are often impaired, which can complicate health attendance. In addition, this type of intervention may facilitate direct contact with patients even when geographical limitations exist, such as that they live in rural areas far from the hospital complex, easing the access to health

care and cost saving (Farley, 2019). Moreover, the fact of receiving messages on a daily basis may be perceived by patients as an additional support, which is sometimes missing with traditional interventions, and this may have an effect on therapeutic adherence (Farley, 2019). However, human direct contact is always important, and eHealth interventions are known to be more effective when they are combined with in situ interventions. Therefore, health providers can reinforce this type of intervention to obtain better results given that the positive effect on therapeutic alliance that face-to-face sessions already produces (Mohr et al., 2011). The benefits of eHealth have been reflected in previous research where its efficacy in improving adherence in chronic patients has been demonstrated (Baretta et al, 2019; Palmer et al., 2018; Peng et al., 2020). Nevertheless, it is important to emphasize that the effectiveness of eHealth may also depend on other factors that should be considered when interpreting the results. For instance, effectiveness could depend on how familiar patients are with the use of new technologies (Lancaster et al., 2018; Peng et al., 2020).

### **Sex differences**

Regarding the effectiveness of the multicomponent program, we have developed for CVD patients, as expected, the findings revealed certain differences when analyzing the data by sex. The results obtained indicate that the program seems more effective for men than for women in this study. Even in the first phase of the intervention – the personalized psychoeducation – the results showed that women's improvement appeared in the area of emotional subjectivity whereas men improved in both subjective well-being and self-efficacy. This is consistent with gender socialization, which frequently implies the assumption of the socially accepted gender roles and stereotypes, according to which women are more related to the emotional sphere and men to action, the achievement of goals and other agency attributes (Castillo-Mayén & Montes-Berges, 2011), being these

last constructs closely connected to self-efficacy. Comparing both groups, the results of the eHealth intervention showed that men improved on positive affect and self-efficacy measures but no enhancement was found in these measures for women. Previous literature shows differences in prevalence between men and women regarding CVD (Gao et al., 2019; Peters et al., 2019); also, over and above prevalence, many studies have evaluated sex and gender differences concerning the symptoms, course and consequences of this health condition (Luque et al., 2020; Medina-Inojosa et al., 2019 Peters et al., 2019; Zhao et al., 2020). This fact should be carefully noted for practitioners as they might influence the accuracy of the response to symptoms and even clinical gender biases in establishing treatments, thus affecting the prognosis and QOL of female patients (Peters et al., 2019; Zhao et al., 2020).

### *5.1. Limitations and future research*

As a principal limitation, we acknowledge that without a random allocation of the study participants, there is a risk of bias in the results. Additionally, the fact that we excluded patients who did not have the digital skills to follow the eHealth intervention, could represent a sampling bias. A limitation regarding a potential bias in the data collection also needs to be mentioned given that the assessment of the experimental group was conducted by the psychologist/researcher who performed the psychoeducational session. Certainly, future studies should implement a double-blind procedure to avoid this risk of bias. Also, due to the small sample size, results should be interpreted with caution. However, the findings of this pilot study seem favorable for the improvement of the well-being and self-efficacy of patients with CVD. Previous pilot studies testing mHealth interventions in patients with chronic diseases, including CVD (Jonker et al., 2020; Licskai et al., 2013) also used a similar simple size. Notwithstanding, it is necessary to test the replicability and robustness of the results in future experimental studies with a

wider sample size, which would allow to improve the statistic power of the results. Finally, we did not consider previous mental health issues of participants, which could have interfered with the effectiveness of the intervention. Therefore, future research would benefit from including psychological well-being-related variables as a control.

Future research aiming to work from a multicomponent and personalized approach may need to include personalization in all phases of the intervention to guarantee a stronger therapeutic alliance and to obtain more solid results. For future research it would be very enriching to add other kinds of variables related to CVD, QOL and mental health to observe if this multicomponent personalized intervention positively influences other important aspects such as anxious-depressive symptomatology. The pandemic situation due to the COVID-19 has highlighted the need to bring interventions closer to patients. eHealth tools have been proved to be a powerful ally for reducing costs and efforts, as well as facilitating patient recovery during these times of pandemic. Due to the massive use of new technologies during the confinement and the safety measures implemented, it would be very useful to determine if the effects found in this study could be enhanced after the pandemic to replicate this intervention. Finally, further studies in this direction should analyze sex and gender variables in order to personalize the intervention and close the gap regarding the gender breach on health.

## *5.2. Conclusions*

In accordance with the limited evidence in this new area of research, this study provided preliminary evidence of the effectiveness of a multicomponent intervention that combined a personalized intervention with an eHealth tool. These results present a relevant advancement for intervention programs with CVD patients, with the advantage of being cost-effective due to the implementation of eHealth. This pilot study emphasizes the value of facilitating patients to become active agents of their own therapeutic process

by personalizing the objectives in order to achieve greater adherence and health benefits. This research also highlights the benefits of making psychological interventions more attractive and adapted to new realities, such as the growing use of new technologies in older populations or the need to adjust interventions to the current pandemic situation. Given the characteristics and limitations of this pilot study, the results should be interpreted with caution, being the purpose to continue testing the efficacy and effectiveness of this type of interventions. In summary, this study underlines the need to develop cardiac rehabilitation programs from a biopsychosocial perspective due to the high rates of comorbidity that surround this disease, both in causes and consequences, and with a gender perspective to take into account the psychosocial factors involved in the differences between men and women. This approach is fundamental when developing personalized interventions. Finally, in line with previous research on health-related behavior, this study focuses on self-efficacy as a therapeutic goal for better adaptation to the disease and thus better prognosis and QOL in CVD patients.

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# **DISCUSIÓN Y CONCLUSIONES GENERALES**

*DISCUSSION AND  
GENERAL CONCLUSIONS*

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## Capítulo 9

### Discussion

This doctoral thesis was aimed to accomplish several objectives that have been addressed in the three studies proposed. Specifically, the first purpose of this thesis was to explore the psychosocial factors involved in the differential vulnerability of psychological well-being between women and men from a biopsychosocial model of health and considering the gender perspective approach, focusing on anxiety and its comorbidity. The base of this aim is linked to what is known about the relationship between the mental and physical states and social conditions. Anxiety, besides of being the most prevalent mental health disorder worldwide, is a major psychosocial determinant of the CVD. Relating to that, the second objective of the thesis was to evaluate the efficacy of a psychological intervention in improving emotional well-being in patients with this kind of diseases. Finally, the third objective was aimed to assess the adequacy of a multicomponent psychological personalized intervention to improve self-efficacy in CVD patients, exploring, additionally, any sex differences. To achieve these objectives, three studies have been conducted.

Concerning the first aim, a systematic review (Study 1) was performed in order to identify and synthesize the contributions made by empirical and review studies addressing differences in anxiety between men and women in the last decades. To provide an updated and wide overview and to gather as many studies as possible regarding the subject, we considered all the factors involved in this differentiation (psychosocial and biological factors). A qualitative narrative analysis was conducted to explore the hypothesis posed and to synthesize the instruments used and the principal conclusions of the studies reviewed. Results of the studies included in the systematic review confirmed

the hypothesis that differences between men and women on anxiety and its comorbidity had been studied considering both biological (genes, hormonal fluctuations, brain structures, etc.) and also psychosocial factors such as economic situations, socialization and gender roles, as well as psychological variables (differences on personality traits such as neuroticism, anxiety sensitivity, etc.), but scarcely together. These results shed light of how studies in relation to a relevant determinant and health consequence as it is anxiety, with a significant sex difference prevalence, have failed in addressing this subject from a biopsychosocial approach and even less from a gender perspective view (Valls Llobet, 2011). Therefore, an integrative implementation on this issue seems to be required. This main challenge could be attended by incorporating new treatment strategies such as person-centered care interventions. This perspective would allow the consideration not only of biological aspects but also the psychosocial context of patients, as it takes individuality as the heart of the intervention (Minvielle et al., 2021). The results of this systematic review triggered the design of the following studies (2 and 3 of this thesis), focusing on the importance of psychological interventions on variables directly related to anxiety and consequently to other behavioral determinants of CVD.

From the second aim, the Study 2 was conducted. In this study, we aimed to evaluate the effectiveness of a brief-psychological intervention in emotion regulation to improve positive subjective well-being in CVD patients. For this goal we compared an experimental group receiving the emotion regulation training and intervention with a control group that continued with their regular treatment and medical follow-up. The experimental group was trained in emotion regulation in a face-to-face session of one hour where the participants received psychoeducation about the identification, recognition, acceptance, normalization and adaptative emotion regulation strategies (Leahy et al., 2011). This phase was followed by a 14-days mHealth intervention where

they had to perform a daily activity related to the emotion regulation information taught in the psychoeducational session. The results showed that emotion regulation intervention had a significant effect on positive subjective well-being and also on the self-efficacy for managing their chronic disease in those CVD patients. It was also found that the face-to-face session had already an effect on the positive subjective well-being and in their cardiac self-efficacy. These findings corroborate the hypothesis proposed and are in line with previous studies that support the idea of intervening on emotion regulation in order to improve psychological well-being (Appleton et al., 2014; Gross & John, 2003). The results from this study also suggest that psychological interventions on emotion regulation may be a good option to increase psychological relevant variables to CVD patients, given its relationship with cardiovascular health and therapeutic commitment (adherence to treatment, life style, etc.) (Appleton et al., 2014; Haedtke et al., 2017; Messerli-Bürgy et al., 2015).

As regard to the third aim, the Study 3 was carried out. In this study we evaluated the effectiveness of a multicomponent psychological intervention to improve subjective well-being and self-efficacy to manage the CVD in those patients. This study and its intervention were designed considering self-efficacy (Bandura, 1986a) as the central axis and therefore, as the primary outcome. The methodology of this study included two phases where patients of the experimental group had a *personalized* face-to-face training session on self-efficacy and a subsequent 14-days mHealth intervention. In the face-to-face session which lasted 1 hour, patients were familiarized with the concept of self-efficacy and their four different sources (Bandura, 1986a, 1997). During this session, participants set their own health related goal to achieve during the second phase of the study, the mHealth intervention, where they received a daily message related to training their own self-efficacy. The experimental group was compared with a control group.

From this study, and considering what it was reported on the systematic review results and the previous literature about gender bias in CVD (e.g., Kim et al., 2022; O’Neil et al., 2018; Woodward, 2019), sex differences were analyzed in order to explore whether the intervention proposed was equally effective for men and women.

The results indicated that the one-hour personalized training session on self-efficacy showed significant positive results on subjective well-being (increased the positive affect, decreased the negative affect) and on self-efficacy for managing the chronic disease. The positive outcomes were maintained over the mHealth intervention on positive subjective well-being and both cardiac and chronic self-efficacy when comparing both groups. These results corroborate the hypothesis proposed, that is, interventions aimed at improving self-efficacy in people with CVD are effective in increasing their perception of personal efficacy in managing the disease, as well as their positive affect, both key variables for CVD and the acquisition and maintenance of healthy behaviors. Furthermore, the effects found in relation to the personalized face-to-face session reinforce the idea of the therapeutic benefits that human contact can produce, providing evidence to support hybrid and multicomponent interventions in cardiac rehabilitation. Nevertheless, when analyzing the data by sex, positive results of the intervention were only found in men, which implies the need of considering sex and gender differences when designing and developing healthcare interventions for these patients.

It has to be noted that even though Studies 2 and 3 share a similar methodology, they posed some differences that need to be highlighted. The Study 3 added important determinants to the Study 2, for example, the fact that the psychoeducational session was tailored to the patients’ own health-related goal is an improvement that goes in line with recent literature that supports the benefits of the personalized medicine or tailored

communications and their incorporation into new mHealth strategies (Kimberly & Minvielle, 2017; Saxena & Saxena, 2020; Tong et al., 2021). Moreover, the analysis of the data by sex gave a very important information related to the necessity to consider the gender perspective into health sciences research.

Moreover, and according to what it was concluded from the results of the systematic review, the results of the third study support the idea that have been claimed that sex and gender matters in health, in chronic disease and in CVD (e.g., Kang et al., 2022; Ski et al., 2020). The fact that even after tailoring their own goal did not have any significant results in women may lead to the conclusion that sex differences are not just the result of the content of the intervention, but are more about the format, the design, and likely the variables analyzed. In this direction, it would be useful to replicate this research tailoring all the phases of the study. This would give light about this issue, and would help to respond if a fully person-centered intervention could act as a bulwark to the effectiveness gender breach. In any case, sex and gender are relevant variables that should be considered when designing future studies with CVD patients. This means to take into account the difference in the daily life experiences, symptoms and difficulties that men and women may have in order to follow an intervention and to get a clinical benefit from it. But also, when analyzing the results. Otherwise, we would be misreporting that interventions are effective when they actually contribute to the gender-sex gap in CVD, as it has been the case in clinical trials for decades (Feldman et al., 2019; Kim et al., 2022).

Even if there is a growing body of research addressing mHealth interventions to intervene with chronic and CVD patients, it is important to highlight that, to the best of our knowledge, the vast majority of these interventions are focused on a specific health outcome, physical activity, smoking cessation, adherence to treatment, etc. (Cajita et al.,

2021; Kebapci et al., 2020; Ni et al., 2022). Evidence suggests that new approaches and formats of delivering interventions, such as those offered by mHealth should be used in addressing psychological well-being in patients with CVD (Johansson et al., 2021). Therefore, in the studies of this thesis, we focused on psychological variables related to psychological well-being that have been found to be a great predictor of behavioral changes as primary outcomes. This means that we based the design of the studies in order to provide these patients with useful resources that would help them to cope with a wide range of health-related outcomes. In this regard, we trained patients in emotion regulation and self-efficacy to improve their subjective well-being and their management of the CVD, considering that the healthy management of emotions, and a high personal efficacy could favor health-related lifestyle changes (e.g., Castillo-Mayén et al., 2020; Cuadrado et al., 2018; Siow et al., 2018). This could be considered as a novelty perspective to mHealth interventions, that is, to focus on the psychological variables that influence those changes, and not only a specific one.

### **Practical implications and future lines of research**

The three studies included in this thesis have been developed under the theoretical framework of the biopsychosocial model. Some authors through the years have made some critics regarding the applicability of this approach in the clinical practice (Álvarez et al., 2012). From those critical perspectives, the biopsychosocial model should be considered just a theoretical model given the difficulty of considering the subjectivity and individuality of patients when designing and implementing treatments in medicine. The rising body of research going to the direction of person-centered interventions (Baker et al., 2015; Minvielle et al., 2021), as well as the unstoppable growth of mHealth strategies in healthcare (Cruz-Ramos et al., 2022), is providing more and more evidence that a holistic model of health and illness is needed to the conceptualization of health

conditions but also in how these conditions should be addressed. Results from the studies of this thesis provide empirical evidence supporting this latter perspective on clinical practice and healthcare in general, at least when considering CVD patients and, potentially, other chronic health conditions.

Compared to traditional therapeutic approaches, mHealth interventions might be better tailored to the characteristics of CVD patients, whose average age is frequently high and whose autonomy and mobility are often impaired, which can make it difficult for them to attend their regular medical follow-up. Likewise, this type of intervention may facilitate direct contact with patients even when geographical limitations exist, reducing inequalities conditions for those patients who live, for example, in rural areas, favoring their access to health care (Farley, 2019). In terms of the design of our two empirical studies, it is important to highlight that we did not perform just an mHealth intervention, but combined it with psychoeducation. According to previous literature the combination of these two methodologies have been found to be more effective than the single-component approaches (Jafar et al., 2017), which can be seen as a value.

In addition, direct human contact is always important, and mHealth interventions are known to be more effective when they are combined with in situ interventions. Consequently, healthcare providers (psychologists, nurses, physicians, etc.) can reinforce this type of online interventions with face-to-face sessions to obtain better results, given the positive effect on therapeutic alliance that these sessions already produce (Mohr et al., 2011). However, in the Study 2 and 3, the fact that the psychoeducational session was face-to-face may have already limited the sampling and participation of CVD patients, due to the above-mentioned limitations on autonomy and other relevant characteristics of this population. For this reason, and in order to pursue a complete mobile-based intervention without losing human contact, future studies should design multicomponent

mHealth interventions with synchronous online sessions that allow patients and health-care providers to interact in real time, facilitating their participation and thus achieving the accessibility that the digital health is trying to reach.

Additionally, with regard to mHealth, receiving messages on a daily basis may be perceived by patients as an additional support, which traditional interventions lack, and this may have an effect on therapeutic adherence (Farley, 2019), which has been showed to be high in both empirical studies. Nevertheless, it is important to emphasize that the real applicability of these interventions and their effectiveness may also depend on how familiar patients are with the use of new technologies (Lancaster et al., 2018; Peng et al., 2020). In this direction, for those patients that do not have the basic digital skills to follow the mobile interventions, digital training sessions might be needed in order to not to lose these patients on the therapeutic process.

Given the heterogeneous results that previous literature has shown regarding mHealth interventions, in order to clarify the effect of this technological therapeutic approach, more clinical studies are needed. In this sense, it may be very interesting to compare different type of interventions (mHealth vs traditional healthcare, vs psychoeducational) to improve psychological relevant variables or health-related behaviors (i.e., increase the physical activity). This would help to determine the extent of benefits of this methodology.

In a similar way, for future studies it would be very noteworthy to profit the online nature of this therapeutic approach and design these interventions following an ecological momentary assessment (EMA) methodology. EMA is completely suitable for this object of study as it evaluates people's thoughts, behavior, emotions, and physiological responses in their daily lives by repeatedly collecting data in the regular context of the participants (Junghaenel & Stone, 2020; McKay et al., 2016). This research technique

would allow to obtain and analyse the data reducing bias and would report more accurate information about the efficacy of future interventions, improving the validity of the research. One of the future goals is to deepen in the possibilities of what new technology (mobile devices, software, applications, etc.) together with EMA could contribute to the enrichment of data collection, as well as, to facilitate the CVD study sample, given its characteristics, the participation on future studies. In this sense, this combination of techniques could permit, for example, the record of physiological data, such as biomarkers (e.g., blood pressure, heart rate monitoring), using wearable devices. This objective information would extensively enhance the research reducing the known potential bias of self-reported data (Junghaenel & Stone, 2020).

Finally, the recent pandemic crisis caused by the COVID-19 has raised up the urgent need of digital transition in the healthcare agenda. Future studies should be in line with the challenges of the 2030 Agenda for Sustainable Development (Asamblea General de Naciones Unidas, 2015) to decrease the prevalence of NCDs by 33%, and to reduce the inequalities in the accessibility of interventions. This digitalization of clinical practice should be placed at the forefront of public health policies.

### **Strengths and Limitations**

Throughout the discussion, the strengths points of this thesis have been highlighted. In summary, according to the Study 1, the robust methodology of the systematic review, comprising explicit eligibility criteria and a comprehensive search strategy, ensured that both factors (psychological and biological) related to the aims of the review were included. A novel contribution of this review, therefore, is that it provides a wide overview of the variables that influence psychological distress in men and women, considering studies that support the biological hypothesis and those that address gender

roles, social and economic situation, life experiences, discrimination, etc., as significant factors to explain the issue.

Regarding to the studies 2 and 3, the following strengths can be pointed out. Firstly, the use of psychological variables (e.g., self-efficacy) as a primary outcome, places them at the core axis of the intervention, allowing potential improvements in a wide range of health-related outcomes that are commonly required in these chronic health conditions. Secondly, the longitudinal approach permitted to obtain data from different time points evaluations, allowing comparative analysis. The follow-up measurements also provide insight into the effectiveness of psychological interventions over time. Finally, the multicomponent design, including different types of methodology, enriched the model of the studies and favored the increase of the intervention effect. Also, the face-to-face session can be considered as a bonus value to maintain human contact and encourage adherence to the intervention.

Nevertheless, this doctoral thesis also presents some limitations that need to be acknowledged. Regarding the first study, although the electronic databases were strategically chosen according to the object of study, the limited number of databases consulted can be considered as a weakness. In addition, the eligibility criteria excluded qualitative studies, which could lead to missing relevant information regarding the psychological well-being of men and women. A further limitation may be the language and cultural bias of the studies included, only in Spanish and/or in English, and most of them performed in western countries. Concerning the second and third studies, the principal limitation is the study design. The non-random allocation of patients into the control and experimental arms may have biased the results. Related to the study sample, the limited sample size forces to be cautious with the generalization of the results. In this sense, the underrepresentation of women in both studies might also represent a limitation.

However, as discussed in the introduction section of this thesis, CVD are still considered a male health condition. Gender bias in the diagnosis of CVD in women (Gao et al., 2019), together with the known lower enrollment of women in cardiac programs (Samayoa et al., 2014), logistical barriers or lower self-care activities and lack of time and support (Resurrección et al., 2017) may be the reason of this lower presence of women in both samples. Future studies should guarantee the equal representation of both sexes, in order to provide an accurate interpretation of the exposed results. Finally, another limitation could be related to the follow-up duration. Future studies with longer follow-ups are needed to explore whether the effectiveness of mHealth intervention is maintained throughout time. Verifying the long-term effect of this interventions would confirm that the cost-benefit of these tools worthwhile the effort of the digital adaptation of healthcare.

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## **Capítulo 10**

### **Conclusiones generales**

Las ENT se han convertido en uno de los mayores retos para la salud pública a nivel mundial. El envejecimiento progresivo de la población y la mayor prevalencia de hábitos nocivos de riesgo en relación a estas enfermedades, posicionan su abordaje como uno de los mayores desafíos de los sistemas sanitarios. Las ECV son, dentro de estas, el conjunto de enfermedades crónicas más frecuentes y con un mayor impacto. Se consideran enfermedades multicausales en las que los factores modificables son especialmente relevantes. A su vez, el diagnóstico de una ECV, supone para quienes la padecen importantes cambios en el estilo de vida y puede conllevar un gran malestar psicológico. Fomentar en estos pacientes un bienestar psicológico sería doblemente beneficioso porque puede ayudar a manejar las consecuencias emocionales asociadas, así como favorecer el compromiso terapéutico. La autoeficacia, la regulación emocional y el género son variables determinantes en este bienestar psicológico por lo que tenerlas en cuenta se torna esencial. Por otra parte, recientemente se ha podido observar un incremento exponencial de las nuevas tecnologías en el ámbito sanitario, fomentando el desarrollo de las herramientas *mHealth*. Este tipo de estrategias terapéuticas parecen una buena alternativa para intervenir con pacientes con enfermedades crónicas para promover conductas saludables.

Esta tesis doctoral presenta un conjunto de investigaciones centradas en profundizar en la importancia de los factores psicosociales que influyen en la salud y especialmente en las tan prevalentes ECV dentro del marco teórico del modelo biopsicosocial. A continuación, se presentan las principales conclusiones de los tres estudios llevados a cabo:

- Existe una vulnerabilidad diferencial en el bienestar psicológico, concretamente en la prevalencia de la ansiedad y su comorbilidad, entre mujeres y hombres (Estudio 1)
- Los resultados reportaron diferencias en los patrones de comorbilidad de la ansiedad en hombres y mujeres, siendo más frecuente el desarrollo concomitante de trastornos externalizantes en los hombres (e.g., abuso de sustancias) e internalizantes en las mujeres (e.g., depresión) (Estudio 1)
- Esta diferencia ha sido explicada desde aproximaciones biológicas, que ponen de relevancia los factores genéticos, anatómicos y hormonales, y considerando factores psicosociales como la socialización de género, características psicológicas y condiciones vitales (Estudio 1)
- Se observa, sin embargo, una ausencia de estudios que evalúen de manera conjunta ambos factores, dificultando una lectura biopsicosocial y con enfoque de género (Estudio 1)
- Intervenciones psicológicas que utilicen herramientas *mHealth* en regulación emocional (Estudio 2) y autoeficacia (Estudio 3) son efectivas para promover el afecto positivo y autoeficacia para el manejo de la enfermedad en pacientes con ECV.
- Los análisis segregados por sexo revelaron que las mejoras en autoeficacia y afecto positivo encontradas solo se vieron en la muestra masculina (Estudio 3)
- El abordaje del bienestar psicológico y de las ECV debe realizarse desde una aproximación integral que utilice el modelo biopsicosocial y la perspectiva de género en todas sus fases, desde la conceptualización e investigación de las problemáticas de salud hasta la práctica clínica (Estudios 1-3)

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La presente tesis doctoral aporta evidencia sobre la importancia de incluir la perspectiva de género en la investigación en psicología para comprender con mayor exactitud las diferencias de sexo y/o género encontradas en variables relacionadas con el bienestar psicológico, concretamente en la ansiedad, factor de reconocida relevancia en el inicio, curso, adaptación y pronóstico de condiciones de salud física como la ECV. Además, los estudios empíricos realizados en esta tesis destacan los beneficios de incorporar intervenciones psicológicas con herramientas *mHealth* en pacientes cardiovasculares en aras de promover su bienestar y el manejo de la enfermedad, así como la necesidad de valorar las posibles diferencias entre mujeres y hombres en la efectividad de las intervenciones psicológicas. La personalización completa y la incorporación de la perspectiva de género en el diseño de estas intervenciones podrían resolver algunas limitaciones de los resultados encontrados. Futuras investigaciones deberían dilucidar las claves para una transición digital de la salud individualizada, sostenible y accesible.

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## General conclusions

NCDs have become one of the greatest challenges for public health worldwide. The progressive ageing of the population and the increased prevalence of harmful risk behaviours in relation to these diseases make tackling them one of the greatest healthcare system challenges. CVD is one of the most frequent chronic diseases with the greatest impact. They are considered multi-causal diseases in which modifiable factors are particularly relevant. In turn, the diagnosis of CVD entails major lifestyle changes for those who suffer from it and can lead to great psychological distress. Promoting psychological well-being in these patients would be extremely beneficial because it can help them to manage the associated emotional consequences, as well as favouring therapeutic commitment. Self-efficacy, emotion regulation and gender are determinant variables in this psychological well-being, so taking them into account is essential. On the other hand, recently there has been an exponential increase in the use of new technologies in the healthcare field, encouraging the development of mHealth tools. This type of therapeutic strategies seem to be a good alternative to intervene with patients with chronic diseases to promote healthy behaviours.

This doctoral thesis presents a set of research studies focused on the importance of psychosocial factors that influence health and especially the highly prevalent CVD within the theoretical framework of the biopsychosocial model. The main conclusions of the three studies carried out are presented below:

- There is differential vulnerability between women and men in psychological well-being, specifically in the prevalence of anxiety and its comorbidity (Study 1).
- The results reported differences in the comorbidity patterns of anxiety in men and women, with the concomitant development of externalising disorders being

more frequent in men (e.g., substance abuse) and internalising disorders more frequent in women (e.g., depression) (Study 1).

- This difference has been explained by biological approaches, which emphasise genetic, anatomical and hormonal factors, and also considering psychosocial factors such as gender socialisation, psychological characteristics and life conditions (Study 1).
- However, there is a lack of studies assessing both factors together, which makes a biopsychosocial and a gender perspective interpretation of this issue challenging (Study 1).
- Psychological interventions using mHealth tools in emotion regulation (Study 2) and self-efficacy (Study 3) are effective in promoting positive affect and self-efficacy for disease management in patients with CVD.
- Sex differences analyses revealed that the improvements found in self-efficacy and positive affect were only seen in the male sample (Study 3).
- Psychological well-being and CVD should be tackled from a holistic approach using the biopsychosocial model and the gender perspective in all its phases, from the conceptualisation and research of health problems to clinical practice (Studies 1-3).

This doctoral thesis provides evidence on the importance of including a gender perspective in psychology research to understand more accurately the sex and/or gender differences in psychological well-being, particularly in anxiety, a factor of recognised relevance in the onset, course, adaptation and prognosis of physical health conditions such as CVD. Furthermore, the empirical studies conducted in this thesis highlight the benefits of incorporating psychological interventions with mHealth tools in CVD patients in order to promote their well-being and disease management, as well as the need to assess the

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possible differences between women and men in the effectiveness of psychological interventions. Comprehensive personalisation and the incorporation of a gender perspective in the design of these interventions could overcome some of the limitations of the findings. Future research should elucidate the keys to an individualised, sustainable and accessible digital health transition.

**PUBLICACIONES DERIVADAS  
DE LA TESIS DOCTORAL**

*PUBLICATIONS DERIVED FROM  
THE DOCTORAL THESIS*

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## Informe de factor de impacto / Impact factor report

Estudio / Study	Indización / Indexation	Factor de impacto / Impact Factor
<p>1. Farhane-Medina, N. Z., Luque, B., Tabernero, C. &amp; Castillo-Mayén, R. (2022). Factors associated with gender and sex differences in anxiety prevalence and comorbidity: a systematic review. <i>Science Progress</i>, 105(4), 1-30.</p> <p><a href="https://doi.org/10.1177/0036850422135469">https://doi.org/10.1177/0036850422135469</a></p>	<p>Science Citation Index Expanded, Scopus, Academic Search Premier, Aerospace Database, Agricultural &amp; Environmental Science Database, Aquatic Science &amp; Fisheries Abstracts (ASFA), Civil Engineering Abstracts, EMBASE, Food Science &amp; Technology Abstracts, INSPEC, MEDLINE, Metadex, Communication Abstracts</p>	<p>Journal Citation Report (JCR), 2021 Impact factor: 1.512 Multidisciplinary science (50/74) (Q3)</p>
<p>2. Farhane-Medina, N. Z., Castillo-Mayén, R., Luque, B., Rubio, S. J., Gutiérrez-Domingo, T., Cuadrado, E., Arenas, A. &amp; Tabernero, C. (2022). A Brief mHealth-Based Psychological Intervention in Emotion Regulation to Promote Positive Subjective Well-Being in Cardiovascular Disease Patients: A Non-Randomized Controlled Trial. <i>Healthcare</i>, 10(9), 1640.</p> <p><a href="https://doi.org/10.3390/healthcare10091640">https://doi.org/10.3390/healthcare10091640</a></p>	<p>Science Citation Index Expanded, Scopus, Social Sciences Citation Index, DOAJ</p>	<p>JCR, 2021 Impact factor: 3.160 Health Care Sciences &amp; Services (50/109) (Q2)</p>
<p>3. Farhane-Medina, N. Z., Castillo-Mayén, R., Tabernero, C., Rubio, S. J., Gutiérrez-Domingo, T., Cuadrado, E., Arenas, A. &amp; Luque, B. (2022). Effectiveness of an eHealth intervention to improve subjective well-being and self-efficacy in cardiovascular disease patients: A pilot non-randomized controlled trial. <i>Nursing Open</i>, 00, 1-14.</p> <p><a href="https://doi.org/10.1002/nop2.1400">https://doi.org/10.1002/nop2.1400</a></p>	<p>Science Citation Index Expanded, Scopus, Social Sciences Citation Index, DOAJ, CINAHL, EM BASE, MEDLINE</p>	<p>JCR, 2021 Impact factor: 1.942 Nursing (69/125) (Q3)</p>



Review

SCIENCE PROGRESS

## Factors associated with gender and sex differences in anxiety prevalence and comorbidity: A systematic review

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### Abstract

**Background:** The prevalence and comorbidity of anxiety disorders are significantly different between women and men, with research showing a greater impact on women. The aim of this review was to identify the psychosocial and biological factors that have been considered to explain this gender and sex difference in prevalence and determine whether these factors are related to any anxiety comorbidity differences between men and women. **Methods:** Following the PRISMA guidelines, we carried out a systematic review of studies published between 2008 and 2021 in PsycINFO and PubMed databases. Empirical and review studies evaluating psychosocial and biological factors that could influence the difference in prevalence and comorbidity between men and women were included. A qualitative narrative synthesis was performed to describe the results. **Results:** From 1012 studies, 44 studies were included. Retrieved articles were categorized depending on their object of study: psychosocial factors ( $n=21$ ), biological factors ( $n=16$ ), or comorbidity ( $n=7$ ). Results showed that differences in anxiety between women and men have been analyzed by psychosocial and biological factors but rarely together. Among the psychosocial factors analyzed, masculinity may be a protective factor for anxiety development, while femininity can be a risk factor. In the studies that took biological factors into account, the potential influence of brain structures, genetic factors, and fluctuations in sexual hormones are pointed out as causes of greater anxiety in women. Concerning comorbidity, the results noted that women tend to develop other internalizing disorders (e.g. depression), while men tend to develop externalizing

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Article

# A Brief mHealth-Based Psychological Intervention in Emotion Regulation to Promote Positive Subjective Well-Being in Cardiovascular Disease Patients: A Non-Randomized Controlled Trial

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**Abstract:** The emotional impact that a cardiovascular disease may have on a person's life can affect the prognosis and comorbidity of the disease. Therefore, emotion regulation is most important for the management of the disease. The aim of this study was to analyze the effectiveness of a brief mHealth psychological intervention in emotion regulation to promote positive subjective well-being in cardiovascular disease patients. The study sample ( $N = 69$ ,  $63.7 \pm 11.5$  years) was allocated to either the experimental group ( $n = 34$ ) or control group ( $n = 35$ ). The intervention consisted of a psychoeducational session in emotion regulation and an mHealth-based intervention for 2 weeks. Positive subjective well-being as a primary outcome and self-efficacy to manage the disease as a secondary outcome were assessed at five time points evaluated over a period of 6 weeks. The experimental group showed higher improvement in positive subjective well-being and self-efficacy for managing the disease compared to the control group over time. The experimental group also improved after the intervention on all outcome measures. Brief mHealth interventions in emotion regulation might be effective for improving positive subjective well-being and self-efficacy to manage the disease in cardiovascular patients.

**Keywords:** cardiovascular disease; positive subjective well-being; emotion regulation; brief psychological intervention; mHealth



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## 1. Introduction

The prevalence of cardiovascular disease (CVD) seems to be stable over time, being the first cause of death and a major loss of health worldwide [1,2]. Empiric evidence has proven that the risk of developing CVD comes not only from biological factors but also from behavioral, psychological, and social factors, which, according to a biopsychosocial model of health, interact with each other [3]. In the same way, the consequences or repercussions of CVD involve the daily life of the people who suffer it, their quality of life, and the emotional balance to cope with it [4]. Therefore, depression [5], anxiety, and stress [6] may appear after CVD. This could be a result of coping with the chronic disease in itself, as well as a consequence of the multi-level changes that these patients have to face after the diagnosis. Comorbid anxiety-depressive symptomatology may complicate their recovery [7] and can also affect their self-efficacy for managing the disease, resulting in the abandonment of medical recommendations, putting their health at risk. Consequently, psychological interventions are needed in order to help patients regulate these emotions in a healthy manner to prevent comorbidity and promote a healthy quality of life. Thus, the purpose

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## Effectiveness of an eHealth intervention to improve subjective well-being and self-efficacy in cardiovascular disease patients: A pilot non-randomized controlled trial

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### Abstract

**Aim:** To evaluate the effectiveness of a multicomponent, eHealth-based self-efficacy intervention to promote subjective well-being and self-efficacy in patients with cardiovascular disease, exploring sex differences.

**Design:** A pilot study of a two-arm non-randomized controlled trial.

**Methods:** Forty-two cardiovascular patients (31% women) participated in the study. The experimental group received a personalized psychoeducational session and a 14-days eHealth intervention. Subjective well-being (positive and negative affect) and self-efficacy (chronic and cardiac) were assessed at baseline, post-psychological session, post-eHealth intervention and at two follow-ups.

**Results:** The levels of the experimental group in positive affect, at post-eHealth and follow-up 1, and self-efficacy, at post-eHealth, and both follow-ups, were statistically significantly higher compared to the control group (all  $p < .05$ ). When considering sex, the intervention was effective only for men. The results highlight the potential of eHealth interventions for cardiac patients and underline the importance of considering a gender perspective in their treatment.

**KEY WORDS**  
cardiovascular disease, eHealth, nursing, self-efficacy, sex differences, subjective well-being

### 1 | INTRODUCTION

Population ageing and increased life expectancy are signs of an improvement in health care and quality of life (QOL) but this also means having to manage chronic disease for longer (Atella et al., 2019). This supposes a challenge to public health systems and to the patients who have to live and struggle with their health condition.

Cardiovascular disease (CVD) is the most prevalent of the chronic diseases and the leading cause of death worldwide (World Health Organization, 2019), forming most of the burden on healthcare systems (Roth et al., 2017). Non-adherence to treatment (Al-Ganmi et al., 2020; Leslie et al., 2018), low acceptance and adjustment to the disease and poor self-efficacy for coping with the new requirements of the diagnosis, are some of the variables that may affect to

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