TESIS DE LA UNIVERSIDAD DE ZARAGOZA
2024
489

Alejandra Aguilar Latorre

# Efectividad de un Programa de Psicoeducación y Modificación del Estilo de Vida en la prevención y tratamiento de la depresión en atención primaria. Ensayo clínico aleatorizado

http://zaguan.unizar.es/collection/Tesis

Director/es
Oliván Blázquez, Bárbara

ISSN 2254-7606

Prensas de la Universidad
Universidad Zaragoza

Universidad de Zaragoza
Servicio de Publicaciones

ISSN 2254-7606

Universidad Zaragoza
1542

Tesis Doctoral

# EFECTIVIDAD DE UN PROGRAMA DE PSICOEDUCACIÓN Y MODIFICACIÓN DEL ESTILO DE VIDA EN LA PREVENCIÓN Y TRATAMIENTO DE LA DEPRESIÓN EN ATENCIÓN PRIMARIA. ENSAYO CLÍNICO ALEATORIZADO

Autor

Alejandra Aguilar Latorre

Director/es

Oliván Blázquez, Bárbara

**UNIVERSIDAD DE ZARAGOZA**
**Escuela de Doctorado**

Programa de Doctorado en Psicología

2022

Repositorio de la Universidad de Zaragoza – Zaguan http://zaguan.unizar.es

**TESIS DOCTORAL**

**2022**

**Programa de Doctorado en Psicología**

# Efectividad de un Programa de Psicoeducación y Modificación del Estilo de Vida en la prevención y tratamiento de la depresión en atención primaria. Ensayo clínico aleatorizado.

**ALEJANDRA AGUILAR LATORRE**

**Directora y tutora: Bárbara Oliván Blázquez**

*Sometimes, science is more art than science*

(Rick de *Rick and Morty*. Temporada 1, Episodio 6)

A mi hermana Carlota,
que me enseña cada día lo que es la bondad, el cariño y el esfuerzo

**AGRADECIMIENTOS**

A mi tutora y directora, la doctora Bárbara Oliván, por su gran trabajo, paciencia, dedicación, motivación y confianza.

A la investigadora principal del Grupo Aragonés de Investigación en Atención Primaria, la doctora Rosa Magallón, por su trabajo y tesón.

Ambas han sido un modelo a seguir durante estos cuatro años y lo seguirán siendo.

A mis compañeras y compañeros del Centro de Salud Arrabal, de la Universidad de Zaragoza, de Lancaster, de las Islas Baleares, de Galicia y a todos/as los/as que estuvieron trabajando a mi lado en algún momento durante estos años. Vuestro trabajo, compresión, apoyo, resolución de problemas y creatividad ha sido indispensable.

A Gema y Gabriela, por su mentoría inicial en la psicología clínica y en la investigación.

A mis profesoras y profesores del grado de psicología de Teruel y del máster en neurociencias de Barcelona, y a mis compañeras y compañeros de clase y de laboratorio de ambos sitios.

A toda mi familia, en especial, a mis padres, mi hermana, mi tía y mi pareja.

A mis amigas, amigos y a todas las personas presentes y no presentes en mi vida que formaron parte de este proceso en algún momento.

A todas y todos mi mayor reconocimiento y gratitud.

También me gustaría agradecer al Gobierno de Aragón, al Instituto de Investigación Sanitaria Aragón, al Instituto de Salud Carlos III, al Campus de Excelencia Internacional del Valle del Ebro, a la Universidad de Zaragoza, a la Fundación Bancaria Ibercaja, a la Fundación CAI y a la Unión Europea, por la financiación económica que me ha permitido desarrollar mi carrera investigadora.

## LISTADO DE PUBLICACIONES DE LA TESIS

La presente tesis doctoral, de acuerdo con el informe correspondiente, autorizado por la Directora de Tesis y el Órgano Responsable del Programa de Doctorado, se presenta como un compendio de cuatro trabajos previamente publicados. Las referencias completas de los artículos que constituyen el cuerpo de la tesis son los siguientes:

### Manuscrito I

Aguilar-Latorre, A., Navarro, C., Oliván-Blázquez, B., Gervilla, E., Magallón Botaya, R., Calafat-Villalonga, C., García-Toro, M., Boira, S., & Serrano-Ripoll, M. J. (2020). Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol. *BMJ Open*, *10*(12). https://doi.org/10.1136/bmjopen-2020-038457

Factor de Impacto (JCR 2020): 2,692 (Q2)

### Manuscrito II

Aguilar-Latorre, A., Pérez Algorta, G., Navarro-Guzmán, C., Serrano-Ripoll, M. J., & Oliván-Blázquez, B. (2022). Effectiveness of a lifestyle modification programme in the treatment of depression symptoms in primary care. *Frontiers in Medicine*, *9*(954644), 1–10. https://doi.org/10.3389/fmed.2022.954644

Factor de Impacto (JCR 2021): 5,058 (Q2)

### Manuscrito III

Aguilar-Latorre, A., Serrano-Ripoll, M. J., Oliván-Blázquez, B., Gervilla, E., & Navarro, C. (2022). Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial. *Frontiers in Psychology*, *13*(856139). https://doi.org/10.3389/fpsyg.2022.856139

Factor de Impacto (JCR 2021): 4,232 (Q1)

### Manuscrito IV

Aguilar-Latorre, A., Oliván-Blázquez, B., Porroche-Escudero, A., Méndez-López, F., García-Gallego, V., Benedé-Azagra, B., & Magallón-Botaya, R. (2022). The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain. *BMC Public Health*, *22*(780), 1–13. https://doi.org/10.1186/s12889-022-13083-2

Factor de Impacto (JCR 2021): 4,135 (Q2)

# Índice general

*Resumen* ..... *8*

*Abstract* ..... *13*

*1. INTRODUCCIÓN* ..... *17*

**1.1 Depresión** ..... **17**

**1.2 La depresión en atención primaria de salud** ..... **19**

**1.3 Factores de estilo de vida** ..... **20**

1.3.1 Ejercicio físico y sedentarismo ..... 21

1.3.2 Calidad del sueño ..... 22

1.3.3 Exposición cuidadosa a la luz del sol ..... 24

1.3.4 Adherencia a la dieta mediterránea ..... 25

1.3.5 Facilitadores de la adherencia a los Programas de Modificación de Estilos de Vida ..... 26

**1.4 Los factores personales relacionados con la salud mental** ..... **28**

**1.5 Los determinantes sociales de la salud relacionados con la salud mental** ..... **29**

1.5.1 Los determinantes sociales de la salud y su relación con la salud mental en tiempos de COVID-19 ..... 31

*2. OBJETIVOS* ..... *34*

*3. COPIA DE LOS TRABAJOS PUBLICADOS* ..... *36*

**Manuscrito I. Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol** ..... **37**

**Manuscrito II. Effectiveness of a lifestyle modification programme in the treatment of depression symptoms in primary care.** ..... **58**

**Manuscrito III. Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial** ..... **70**

**Manuscrito IV. The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain** ..... **79**

*4. DISCUSIÓN* ..... *92*

**4.1 Efectividad de los Programas de Modificación de Estilos de Vida para la disminución de la sintomatología depresiva** ..... **92**

**4.2 Efectividad de los Programas de Modificación de Estilos de Vida para la mejora de los estilos de vida** ..... **94**

4.2.1 Ejercicio físico ..... 95

4.2.2 Sedentarismo ..... 96

4.2.3 Calidad del sueño ..... 97

4.2.4 Adherencia a la dieta mediterránea ..... 98

**4.3 Facilitadores de la adherencia a los Programas de Modificación de Estilos de Vida** ..... **100**

4.3.1 Uso de TICs ..... 100

4.3.2 Apoyo social ..... 102

**4.4 Los factores personales relacionados con los estilos de vida y la salud mental ..... 103**

**4.5 Los determinantes sociales de la salud y su relación con la salud mental en tiempos de COVID-19 ..... 107**

**4.6 Fortalezas ..... 111**

**4.7 Limitaciones ..... 112**

**4.8 Futuros estudios ..... 114**

***5. CONCLUSIONES GENERALES ..... 115***

***GENERAL CONCLUSIONS ..... 117***

***6. BIBLIOGRAFÍA ..... 119***

***Anexo I. Effectiveness of a lifestyle modification programme in the treatment of depression in primary care: randomised clinical trial pre-post results ..... 160***

***Anexo II. One-year follow-up of the effectiveness of a lifestyle modification programme as an adjuvant treatment of depression in primary care: a randomised clinical trial ..... 197***

***Anexo III. Información adicional sobre los manuscritos que se recogen en la tesis 225***

# Resumen

Introducción:

La depresión mayor es una patología de alta prevalencia que, actualmente, es una de las principales causas de discapacidad y contribuye de forma muy importante a la carga mundial de morbilidad. El inicio y continuación de la depresión están relacionados con factores biológicos y psicosociales, muchos de los cuales están relacionados con aspectos del estilo de vida. Los programas de promoción de la salud y modificación del estilo de vida (LMPs, por sus siglas en inglés) pueden ser efectivos para reducir la sintomatología depresiva. Por otro lado, algunos determinantes psicosociales tienen un impacto en el cambio de comportamiento relacionado con la salud de las personas. Estos determinantes incluyen diversos factores personales como el sentido de coherencia, la activación respecto a la salud, la alfabetización en salud, la autoeficacia y la procrastinación.

El objetivo principal de esta tesis fue analizar la efectividad de un LMP (TAU+LMP) y un LMP junto con el uso de Tecnologías de la Información y la Comunicación (TAU+LMP+ICTs, por sus siglas en inglés), en comparación con el tratamiento habitual (TAU, por sus siglas en inglés) para la disminución de la sintomatología depresiva. Las intervenciones se ofrecieron como un tratamiento adyuvante administrado en Centros de Atención Primaria de Salud (APS) para personas con síntomas de depresión. El objetivo secundario fue el de analizar la relación entre los factores personales, estilos de vida y síntomas depresivos. Por último, debido a la situación excepcional provocada por la pandemia, se hizo necesario estudiar el posible impacto del confinamiento por la COVID-19 en las personas participantes y, por ende, la posible influencia que éste pudiera tener en los resultados de la presente tesis, en función de los determinantes sociales de la salud (DSS).

Métodos:

Se realizó un ensayo clínico aleatorizado (ECA), pragmático, multicéntrico y de etiqueta abierta. Las personas participantes fueron reclutadas de varios centros de APS. Se invitó a participar en el estudio a personas que visitaron a su médico o a su médica de familia por cualquier motivo y que cumplieron con los criterios de inclusión [obtener una puntuación de 10 a 30 puntos en el Inventario de depresión autoaplicado de Beck II (BDI-II)]. El TAU+LMP consistió en seis sesiones grupales semanales de 90 minutos cada una enfocadas en mejorar el estilo de vida. El TAU+LMP+ICTs replicó el formato del TAU+LMP, más la adición de un reloj inteligente portátil que registraba los minutos diarios caminados y los patrones de sueño. La sintomatología depresiva medida con el BDI-II fue la variable principal. Las variables de estilo de vida (ejercicio físico y sedentarismo, adherencia a la dieta mediterránea y calidad del sueño), el apoyo social y los factores personales (autoeficacia, activación del paciente en su propia salud, sentido de coherencia, alfabetización en salud y procrastinación) se consideraron variables secundarias. Las variables de midieron antes y después de la intervención, y en seguimientos a los 6 y 12 meses.

Un total de 188 personas participantes aceptaron formar parte del estudio y fueron aleatorizadas. En primer lugar, se realizaron análisis descriptivos, univariados y análisis de covarianza (ANCOVAs) con los resultados de los cuestionarios administrados al inicio del estudio (antes de la intervención -pre-) e inmediatamente después de la intervención (posterior a la intervención -post-) para comprobar la existencia de diferencias estadísticamente significativas entre los programas de intervención y el TAU.

En segundo lugar, se utilizaron modelos mixtos lineales, con una intersección aleatoria y una covarianza no estructurada para evaluar la efectividad de las intervenciones en comparación con el TAU para la reducir la sintomatología depresiva y mejorar los estilos de vida, tanto en el seguimiento de los 6 meses como en el de los 12.

En tercer lugar, se realizó un análisis de datos secundarios (SDA, por sus siglas en inglés) con los datos recopilados al comienzo del ECA. Para ello, se utilizó una muestra de 226 personas y se realizaron análisis descriptivos, bivariados, multivariados y de moderación.

Por último, se realizaron 52 entrevistas telefónicas estructuradas sobre el impacto del confinamiento en la salud mental de las personas participantes y se analizó el discurso de manera cualitativa. Primero, el audio de las entrevistas se grabó digitalmente y se realizó una transcripción literal de las mismas. Posteriormente, se llevó a cabo un análisis de contenido inductivo para identificar y analizar los temas que surgían de las entrevistas.

Resultados:

En cuanto al análisis de los datos pre-intevención y post-intervención, hubo una reducción significativa de la puntuación del BDI-II en los grupos TAU+LMP y TAU+LMP+ICTs en comparación con el TAU ($B$ = -9,703, $p$ < 0,001 y $B$ = -8,742, $p$ < 0,001, respectivamente). También hubo una mejora significativa de los estilos de vida y los factores personales en ambos grupos de intervención. Sin embargo, solo el grupo TAU+LMP mostró una mejora significativa de la calidad de vida, y solo el grupo TAU+LMP+ICTs mostró una reducción significativa de la procrastinación. Además, no hubo una mejora significativa del sedentarismo ni de la alfabetización en salud en ningún grupo.

Con respecto al seguimiento a los 6 meses, ambas intervenciones (TAU+LMP y TAU+LMP+ICTs) mostraron una reducción estadísticamente significativa de los síntomas depresivos en comparación con el TAU ($b$ = -3,38, $p$ < 0,001 y $b$ = -4,05, $p$ < 0,001, respectivamente). Estas reducciones tenían un tamaño del efecto moderado. En el TAU+LMP+ICTs hubo un aumento significativo en cuanto a minutos de caminata a la semana ($b$ = 99,77, $p$ = 0,005) y adherencia a la dieta mediterránea ($b$ = 0,702, $p$ < 0,001).

En el TAU+LMP hubo una disminución significativa en cuanto a la mala calidad del sueño ($b$ = -1,24, $p$ = 0,006).

Acerca del seguimiento a los 12 meses, el grupo TAU+LMP+ICTs mostró una reducción estadísticamente significativa en los síntomas depresivos ($b$ = -2,68, $p$ = 0,001) y sedentarismo ($b$ = -37,38, $p$ = 0,004) en comparación con TAU.

En cuanto al análisis basal de los datos, se obtuvo que el bajo sentido de coherencia ($b$ = -0,172; $p$ < 0,001), mala calidad del sueño ($b$ = 0,179; $p$ = 0,008), baja activación respecto a la salud ($b$ = -0,119; $p$ = 0,019) y sedentarismo (más minutos sentados al día) ($b$ = 0,003; $p$ = 0,025) son predictores de tener más síntomas depresivos. Los análisis de moderación no fueron significativos.

En lo que concierne al estudio cualitativo, se observó cómo la salud mental de las personas participantes durante el confinamiento se vio afectada por las condiciones de vivienda, los espacios públicos para socializar, el apoyo social, las responsabilidades de cuidado, las tecnologías digitales y el acceso a servicios de atención médica.

Discusión:

El estilo de vida y los factores personales están relacionados con la sintomatología depresiva. Los análisis de datos basales revelaron que el sentido de coherencia, el nivel de activación del paciente, el sedentarismo y la calidad del sueño explicaban el nivel de sintomatología depresiva. A corto plazo, los LMPs realizados en centros de APS fueron efectivos para reducir la sintomatología depresiva y mejorar el estilo de vida y los factores personales en comparación con el TAU. A los 6 meses, los LMPs siguen siendo efectivos para reducir los síntomas depresivos y tienen un impacto positivo en el cambio de varios factores de estilo de vida. A los 12 meses, solo el LMP junto con el uso de TICs fue efectivo para reducir la sintomatología depresiva y el sedentarismo en comparación con

el TAU. Por otro lado, los DSS tuvieron un impacto considerable en la salud mental de las personas durante la pandemia de COVID-19.

Estos hallazgos indican que estas intervenciones pueden ser estrategias prometedoras para los centros de APS. Se necesita más investigación para mejorar la adherencia a las recomendaciones de estilo de vida y la interrelación entre los estilos de vida, los factores personales y la depresión.

# Abstract

Introduction:

Major depression is a highly prevalent pathology that is currently one of the main causes of disease-induced disability and contributes significantly to the global burden of disease. The onset and continuation of depression are related to biological and psychosocial factors, many of which are related to different lifestyle aspects. Health promotion and Lifestyle Modification Programs (LMPs) can be effective in reducing depression symptoms. On the other hand, some psychosocial determinants have an impact on the change of behavior related to people's health. These determinants include various personal factors such as sense of coherence, health activation, health literacy, self-efficacy, and procrastination.

The main objective of this thesis was to analyze the efficacy of an LMP (TAU+LMP) and an LMP together with the use of Information and Communication Technologies (TAU+LMP+ICTs), compared to Treatment as Usual (TAU) for the reduction of depressive symptomatology. The interventions were offered as an adjunctive treatment administered in Primary Healthcare Centers (PHCs) for people with symptoms of depression. The secondary objective was to analyze the relationship between personal factors, lifestyles and depressive symptoms. Finally, due to the exceptional situation caused by the pandemic, it became necessary to study the possible impact of the lockdown due to COVID-19 on the participants and, therefore, the possible influence that it could have on the results of this thesis, based on the social determinants of health (SDH) framework.

Methods:

A pragmatic, multicentred, open-label, randomized clinical trial (RCT) was conducted. Participants were recruited from various PHCs. People who visited a general practitioner

for any reason and met the inclusion criteria [score between 10 and 30 points on the Beck Self-Applied Depression Inventory II (BDI-II) were invited to participate in the study]. The TAU+LMP consisted of six weekly group sessions of 90 minutes, each focused on improving participants' lifestyle. The TAU+LMP+ICTs replicated the format of the TAU+LMP, plus the addition of a wearable smartwatch that tracked daily minutes walked and sleep patterns. Depressive symptomatology measured with the BDI-II was the main variable. Lifestyle variables (physical exercise and sedentary lifestyle, adherence to the Mediterranean diet and sleep quality), social support and personal factors (self-efficacy, health activation, sense of coherence, health literacy and procrastination) were considered as secondary variables. The variables were measured before and after the intervention, and in follow-up session at 6 and 12 months.

A total of 188 participants agreed to be part of the study and were randomized. Firstly, descriptive and univariate analyses, and analyses of covariance (ANCOVAs) were performed with the results of the questionnaires administered at the beginning of the study (before the intervention -pre-) and immediately after the intervention (after the intervention -post) to verify the existence of statistically significant differences between the intervention programs and the TAU.

Secondly, linear mixed models, with random intercept and unstructured covariance, were used to assess the efficacy of interventions compared to TAU in reducing depressive symptomatology and improving lifestyles, both at 6- and 12-month follow-up sessions.

Thirdly, a secondary data analysis (SDA) was performed on the data collected at the baseline of the RCT. For this, a sample of 226 people was used and descriptive, bivariate, multivariate and moderation analyses were performed.

Finally, 52 structured telephone interviews were conducted on the impact of confinement on the mental health of the participants and the discourse was analyzed qualitatively. First,

the audio of the interviews was digitally recorded and a verbatim transcript was made. Subsequently, an inductive content analysis was carried out to identify and analyze the themes that emerged from the interviews.

Results:

Regarding the analysis of the pre-intervention and post-intervention data, there was a significant reduction in the BDI-II score in the TAU+LMP and TAU+LMP+ICTs groups compared to the TAU ($B$ = -9.703, $p < 0.001$ and $B$ = -8.742, $p < 0.001$, respectively). There was also a significant improvement in lifestyle and personal factors in both intervention groups. However, only the TAU+LMP group showed a significant improvement in quality of life, and only the TAU+LMP+ICTs group showed a significant reduction in procrastination. Furthermore, there was no significant improvement in sedentary lifestyle or health literacy in any group.

Concerning the 6-month follow-up, both interventions (TAU+LMP and TAU+LMP+ICTs) showed a statistically significant reduction in depressive symptoms compared to TAU ($b$ = -3.38, $p < 0.001$ and $b$ = - 4.05, $p < 0.001$, respectively). These reductions had a moderate effect size. In the TAU+LMP+ICTs there was a significant increase in walking minutes per week ($b$ = 99.77, $p$ = 0.005) and adherence to the Mediterranean diet ($b$ = 0.702, $p < 0.001$). In TAU+LMP there was a significant decrease in poor sleep quality ($b$ = -1.24, $p$ = 0.006).

With regard to the 12-month follow-up, the TAU+LMP+ICTs group showed a statistically significant reduction in depressive symptoms ($b$ = -2.68, $p$ = 0.001) and sedentarism ($b$ = -37.38, $p$ = 0.004) compared to TAU.

Regarding the baseline analysis of the data, it was found that the low sense of coherence ($b$ = -0.172; $p < 0.001$), poor quality of sleep ($b$ = 0.179; $p$ = 0.008), low health activation ($b$ = -0.119; $p$ = 0.019) and a sedentarism (more minutes sitting per day) ($b$ = 0.003; $p$ =

0.025) are predictors of having more depressive symptoms. Moderation analyses were not significant.

Addressing the qualitative study, it was observed how the mental health of the participants during confinement was affected by housing conditions, public spaces to socialize, social support, care responsibilities, digital technologies and access to health care services.

Discussion:

Lifestyle and personal factors are related to depressive symptomatology. Baseline data analyses revealed that the patient's sense of coherence, health activation, sedentary lifestyle, and sleep quality explained the level of depressive symptomatology. In the short term, LMPs performed in PHCs were effective in reducing depressive symptomatology and improving lifestyle and personal factors compared with TAU. At 6 months, LMPs remain effective in reducing depressive symptoms and have a positive impact on changing several lifestyle factors. At 12 months, only the LMP together with the use of ICTs was effective in reducing depressive symptomatology and sedentary lifestyle compared to TAU. Besides, SDH had a considerable impact on people's mental health during the COVID-19 pandemic.

These findings indicate that these interventions may be promising strategies for PHCs. More research is needed to improve adherence to lifestyle recommendations and the interrelationship between lifestyles, personal factors, and depression.

# 1. INTRODUCCIÓN

## 1.1 Depresión

La depresión es un trastorno mental con el cual una persona experimenta un estado de ánimo deprimido o una pérdida de placer o interés en las actividades de su vida cotidiana. Simultáneamente, también pueden aparecer una variedad de otros síntomas, que incluyen dificultad para concentrarse o tomar decisiones, culpa excesiva o baja autoestima, falta de esperanza para el futuro, pensamientos de muerte o suicidio, insomnio o hipersomnia, cambios en el apetito o en el peso, agitación o retraso psicomotor, sensación de cansancio significativo o falta de energía (Organización Mundial de la Salud (WHO, por sus siglas en inglés), 2021). Según el *Manual diagnóstico y estadístico de los trastornos mentales 5ª edición* (DSM-V, por sus siglas en inglés), para que se diagnostique a una persona con depresión, al menos uno de los dos primeros síntomas mencionados, más cuatro síntomas más, tienen que estar presentes la mayor parte del día casi todos los días, durante al menos dos semanas (American Psychiatric Association, 2013). Estos síntomas afectan considerablemente al funcionamiento personal, familiar, social, académico y profesional de la persona. Según el grado de esta afectación y el número y la magnitud de los síntomas, los episodios depresivos se pueden clasificar como leves, moderados o graves (Goldberg et al., 2011).

Hoy en día, la depresión afecta a unos 280 millones de personas en todo el mundo, es decir, a un 3,8% de la población, lo que la convierte en una de las principales causas de discapacidad inducida por enfermedad y contribuye de forma muy importante a la carga mundial de morbilidad (WHO, 2021a). Para 2030, se espera que sea el principal contribuyente a la carga de morbilidad (Ferrari et al., 2013; Gabilondo et al., 2010; WHO, 2017b), y por ello se considera un problema de salud pública (WHO, 2017b). Además de generar una gran discapacidad, también genera altos costes económicos y sociales

(Andlin-Sobocki et al., 2005) y tiene un impacto significativo en el funcionamiento psicosocial y la calidad de vida de la persona que la padece (Malhi & Mann, 2018).

Las mujeres son más propensas que los hombres a experimentar estrés y depresión y, en general, la prevalencia de la depresión es mayor en la población adulta que en la joven (Acciai & Hardy, 2017; Demura & Sato, 2003; Song et al., 2014; WHO, 2021a).

La prevalencia de la depresión a lo largo de la vida en España es del 13% y la prevalencia de 12 meses es del 4% (Alonso et al., 2004b). Según el Instituto Nacional de Estadística (INE), el 5,4% de la población española (2,1 millones de personas) experimenta algún cuadro depresivo, de los cuales, 230.000 son depresiones graves. En consonancia con los datos mundiales, la prevalencia de la depresión en mujeres también duplica a la de hombres (7,1% frente a 3,5%), y en depresiones graves esta prevalencia se triplica (por cada caso grave en hombres hay 3,5 en mujeres). Del mismo modo, la prevalencia de la depresión aumenta en edades más avanzadas, alcanzando esta cifra el 16% entre las personas de 85 años o más. Por otro lado, la incidencia también es más alta entre las personas incapacitadas para trabajar (24,4% en hombres y 23,4% en mujeres) (INE, 2021).

La comorbilidad con otras condiciones crónicas (diabetes, hipertensión, enfermedades cardiovasculares y cáncer, entre otras) también es alta (del 64,9% al 71%) (Cassano & Fava, 2002; Katon, 2003; O'Neil et al., 2015), así como con otras enfermedades psiquiátricas como los trastornos de ansiedad (del 40% al 66%) (Aragonès et al., 2004).

Respecto a los tratamientos psicológicos más comunes, se encuentran la activación conductual, la terapia cognitiva conductual y la psicoterapia interpersonal, y/o medicamentos antidepresivos, como los inhibidores selectivos de la recaptación de serotonina (ISRS) y los antidepresivos tricíclicos (WHO, 2021a). Desafortunadamente,

el recibir un tratamiento adecuado para la depresión es algo bastante limitado (Wittchen et al., 2011). Incluso en los países desarrollados, la mayoría de las personas que sufren trastornos mentales comunes no reciben tratamiento, y las personas con ansiedad reciben menos tratamiento que las personas con depresión (20% y 28%, respectivamente) (Chisholm et al., 2016).

## 1.2 La depresión en atención primaria de salud

Los servicios de atención primaria de salud (APS) juegan un papel fundamental en la identificación y el tratamiento de la depresión. Alrededor del 60% de toda la distribución de tratamientos de salud mental tiene lugar en entornos de APS (Frank et al., 2003). Aproximadamente el 25-35% de todas las personas usuarias de APS sufren trastornos psiquiátricos, y más del 80% de estas personas sufren depresión o ansiedad (Alonso et al., 2004a; Kessler & Bromet, 2013). En general, una de cada diez personas usuarias de APS presenta síntomas depresivos (Malhi & Mann, 2018). En los centros de APS españoles la prevalencia de depresión oscila entre el 9,6% y el 20,2% (Codony et al., 2007; Vindel et al., 2012).

A pesar del impacto negativo de la depresión en la vida de las personas y de la existencia de numerosos tratamientos (Davidson, 2010), las tasas de detección y tratamiento en APS son bajas (Craven & Bland, 2013; Smithson & Pignone, 2017). Solo el 9% de todas las personas usuarias de APS con depresión reciben un tratamiento adecuado y solo el 6% logra la remisión, por lo que la gestión de la depresión en APS debe mejorarse (Pence et al., 2012). En una revisión reciente sobre el sistema de salud español, se destaca la alta especificidad y la baja sensibilidad en la detección de casos de depresión mayor por parte de los médicos y las médicas de APS, concluyendo que la detección de la depresión es superior en Atención Especializada que en APS (Gili et al., 2022). Este hecho se debe principalmente a limitaciones de tiempo o recursos del médico

y de la médica (Codony et al., 2007). Es por ello que normalmente se recomienda el tratamiento farmacológico (Cuijpers et al., 2009), aunque la investigación ha demostrado que en la depresión subclínica, leve o moderada, se recomiendan intervenciones no farmacológicas (Cuijpers et al., 2009; NICE, 2022).

Debido a la alta prevalencia de la depresión en APS, se recomienda su tratamiento en este nivel de atención (Aguilera-Martín et al., 2022). Además de por la prevalencia, la organización de terapias grupales en los centros de APS también genera una variedad de beneficios organizacionales. Estos beneficios están relacionados con el uso eficiente de las instalaciones, las altas proporciones de terapeutas por pacientes y las posibles reducciones en los tiempos de espera para obtener un tratamiento (Piper, 2008). Un tratamiento eficaz para la depresión que se puede implementar en los centros de APS es la psicoterapia breve (programas de 6 a 8 sesiones), que tiene la ventaja de ser efectiva y rentable, y de ser realizada tanto por profesionales de la salud mental como por otros profesionales de la salud capacitados (Cameron et al., 2014; Nieuwsma et al., 2012; Raya-Tena et al., 2021). Uno de los objetivos de estas intervenciones de APS es educar a las personas sobre hábitos de vida saludables (Malhi et al., 2018), ya que los Programas de Modificación del Estilo de Vida (LMP, por sus siglas en inglés) han demostrado su efectividad en varios estudios (Garcia-Toro et al., 2012; Null & Pennesi, 2017; Toobert et al., 2007).

## 1.3 Factores de estilo de vida

El comienzo y la continuación de la depresión se han relacionado con una variedad de factores biológicos y psicosociales, muchos de las cuales están asociados con el empobrecimiento del estilo de vida moderno (p. ej., mala calidad del sueño, tendencia al sedentarismo, dieta pobre e insuficiente exposición al sol) (Cabello et al., 2017; Hidaka, 2012; Kupfer et al., 2012; Lopresti et al., 2013; Maher et al., 2016). De ahí que muchos

de los tratamientos que promueven un estilo de vida más saludable podrían tener una utilidad antidepresiva (Ka-Yan Ip et al., 2021; Olivan-Blázquez et al., 2018; V. W. H. Wong et al., 2021). Además, respecto al estilo de vida poco saludable, añadimos que nuestro entorno social puede actuar como un entorno dañino debido al aumento de la competencia, la inequidad y el aislamiento social (Hidaka, 2012).

En su gran mayoría, los estudios sobre la modificación de los estilos de vida se han centrado en un aspecto concreto del estilo de vida. A continuación, se expone la evidencia para cada uno de los factores del estilo de vida estudiados: actividad física y sedentarismo, calidad de sueño y exposición cuidadosa a la luz del sol y adherencia a la dieta mediterránea.

### 1.3.1 Ejercicio físico y sedentarismo

Respecto al ejercicio físico, existe una relación negativa entre el ejercicio físico regular y los síntomas depresivos (Kim, 2022). Se ha demostrado que el ejercicio físico regular y de cualquier intensidad en el tiempo libre mejora la salud mental y previene la depresión (Harvey et al., 2018; Lin et al., 2019). En particular, el ejercicio físico moderado disminuye, incluso previene, los síntomas depresivos (Andrade-Gómez et al., 2018; Carek et al., 2011). Además, incluir el ejercicio físico en el tratamiento con fármacos antidepresivos puede ofrecer ventajas significativas sobre los síntomas afectivos de la depresión (Murri et al., 2018). Las intervenciones de ejercicio físico como tratamiento para la depresión parecen tener un tamaño del efecto de moderado a grande (Josefsson et al., 2014; Kvam et al., 2016). En esta línea, el sedentarismo y una duración del sueño corta se asocian con síntomas depresivos en adultos mayores (Luo et al., 2022).

Esta relación se puede deber a los fenómenos fisiológicos que el ejercicio físico mantenido en el tiempo desencadena. Por ejemplo, tiene efecto antiinflamatorio, aumenta la biodisponibilidad de la serotonina y del triptófano, aumenta la expresión de enzimas

antioxidantes, mejora la respuesta al estrés por actuar sobre el eje hipotálamo-hipofiso-adrenal, y posiblemente aumenta los niveles del factor neurotrófico cerebral (BDNF) (Lopresti et al., 2013). Por otro lado, el ejercicio físico también actúa psicológicamente, por ejemplo, promoviendo la autoestima, la autoeficacia y la activación conductual, y combatiendo patrones evitativos (García-Toro, 2014).

Desde hace unos años, la OMS aconseja la realización de ejercicio físico como suplemento a los antidepresivos y a la psicoterapia estructura breve a las personas con depresión moderada o grave (WHO, 2010). Igualmente, la Guía de Práctica Clínica sobre el Manejo de la Depresión Mayor en el Adulto más reciente (2014) recomienda los programas de ejercicio físico aeróbico supervisado como primer paso para el tratamiento de la depresión leve, sin la necesidad de recurrir a la toma de medicamentos para lograr resultados terapéuticos.

### 1.3.2 Calidad del sueño

La Guía Práctica Clínica más reciente para el Manejo de Pacientes con Insomnio en Atención Primaria (2009) determinó que entre el 30 y el 48% de los adultos españoles se quejan de una mala calidad del sueño (es decir, de tener dificultad para iniciar y/o mantener el sueño o tener un sueño no reparador). Además, del 9 al 15% se quejan de las consecuencias diurnas que tiene la falta de horas de sueño o su mala calidad.

La falta de una buena calidad del sueño se ha relacionado significativamente con la depresión (Becker et al., 2017). La alteración del sueño no es solo una manifestación de la depresión (Wakefield et al., 2019), sino que también puede considerarse un síntoma prodrómico, por lo que es necesario priorizar su identificación y tratamiento antes, durante y después del curso de la depresión (Asarnow et al., 2014; Fang et al., 2019). Un estudio de cohortes con personas usuarias de APS españolas concluyó que las alteraciones del sueño están íntimamente relacionadas con la aparición de un episodio depresivo y, del

mismo modo, la remisión de dichas alteraciones del sueño también está significativamente asociada con la remisión de la depresión (Olivan-Blázquez et al., 2016). Además, los trastornos del sueño aumentan el riesgo de aparición de conductas suicidas en personas deprimidas (Wang et al., 2019). Específicamente, en adultos mayores, existe un mayor riesgo de depresión entre los que tienen más problemas con el sueño (Hill Almeida et al., 2022; Zhang et al., 2022). Del mismo modo, también existen asociaciones entre la salud mental, tener una dieta saludable y una buena cantidad de sueño (Hepsomali & Groeger, 2021).

Esta relación entre mala calidad del sueño y depresión puede deberse a la disfunción del ritmo circadiano. En general, se recomienda dormir entre 7 y 9 horas diarias, pero durante el último siglo, las horas de sueño han disminuido y los horarios de acostarse y levantarse se han vuelto más irregulares, produciendo así las alteraciones en el ritmo circadiano (Hidaka, 2012).

Uno de los tratamientos para los problemas de sueño es el de instruir a las personas sobre hábitos saludables de conducta para ayudar a mejorar el sueño, lo que se conoce como higiene del sueño (Grupo de Trabajo de la Guía de Práctica Clínica para el Manejo de Pacientes con Insomnio en Atención Primaria, 2009). Ejemplos de estos hábitos saludables serían el evitar el consumo de tabaco, alcohol y cafeína; hacer ejercicio físico; reducir el ruido de la habitación, mantener horarios de sueño regulares y evitar siestas excesivas. Además de instruir esas pautas sobre higiene del sueño, también se recomienda tener en cuenta otros factores conductuales y ambientales que se sabe que afectan al sueño (p. ej., el uso de la televisión y los dispositivos electrónicos durante la noche, el entorno interpersonal y el uso de somníferos) (Irish et al., 2015).

### 1.3.3 Exposición cuidadosa a la luz del sol

En el último siglo, el tiempo total y las horas diarias en las que las personas están expuestas a la luz solar directa ha disminuido significativamente (Hidaka, 2012). Este hecho puede acarrear un detrimento de la salud, puesto que la luz solar es uno de los referentes temporales externos que diariamente sincronizan el núcleo supraquiasmático (NSQ) en los mamíferos. El NSQ es el centro principal de regulación de los ritmos circadianos (p. ej., el de sueño-vigilia, fisiológicos, conductuales, etc.), ya que controla la secreción de melatonina en la glándula pineal (García-Toro, 2014). La falta de exposición a la luz solar también está relacionada con niveles altos de cortisol y niveles más bajos de melatonina durante la noche (Harb et al., 2014).

Por otro lado, la piel, a través de la radiación solar, proporciona el 90% de la vitamina D que necesitamos (Aguilar-Shea et al., 2020). A la vitamina D se le han atribuido efectos beneficiosos como la prevención de diversos cánceres, de la esclerosis múltiple, de la hipertensión y de la diabetes (van der Rhee et al., 2016). También, la hipovitaminosis D (es decir, la baja concentración de vitamina D) se ha asociado con la depresión (Anglin et al., 2013). Recientemente, se hizo evidente que no solo la vitamina D tiene esos efectos preventivos, sino que también están involucrados la inmunomodulación, la formación de óxido nítrico, la melatonina, la serotonina y el efecto de la luz del sol en los relojes circadianos (van der Rhee et al., 2016).

En un estudio de casos y controles, las personas con depresión (casos) tenían dosis significativamente más bajas de vitamina D proveniente de la luz solar ultravioleta B, en comparación con las personas sanas (controles) de la misma edad y sexo (Jahrami et al., 2020). En mujeres de edad avanzada, también se relacionó significativamente una mayor duración de la exposición a la luz solar con una menor prevalencia de síntomas depresivos (Cui et al., 2021). Por otro lado, en personas con depresión se encontró una asociación

entre la disminución de la exposición a la luz solar y una mayor probabilidad de deterioro cognitivo (Kent et al., 2009).

En conclusión, se ha demostrado que la exposición cuidadosa a la luz solar alivia los síntomas depresivos (Penckofer et al., 2010; Thomas & Al-Anouti, 2017; Veleva et al., 2018). En personas a las que les resulta difícil pasar horas al sol de manera regular se les puede recomendar la terapia lumínica, ya que un metaanálisis reciente concluyó que ésta puede reducir significativamente los síntomas depresivos, con tamaños de efecto que van de leve a moderados (Tao et al., 2020).

### 1.3.4 Adherencia a la dieta mediterránea

El tipo de alimentos que consumimos, y a la forma en que los cocinamos es lo que se denomina “dieta”. Una dieta equilibrada es aquella que nos aporta todos los nutrientes que necesitamos para el funcionamiento óptimo de nuestro organismo. Por el contrario, una dieta desequilibrada o poco saludable sería aquella con abundantes grasas saturadas, dulces, comida ultra procesada y escasos vegetales y pescados (Sarasa-Bosque et al., 2017).

Una ingesta dietética poco saludable está asociada con múltiples enfermedades, entre ellas con un mayor riesgo de demencia (Li et al., 2022) y con una mayor incidencia de la depresión (Gómez-Donoso et al., 2020). En contraposición, si intervenimos para mejorar la ingesta dietética, se pueden mejorar los síntomas depresivos (Farzi et al., 2019; Lambrinakou et al., 2017; Opie et al., 2021; Segal et al., 2020; van Dammen et al., 2018). Por ejemplo, una revisión sistemática de estudios observacionales que analizaban la asociación entre la ingesta de frutas y verduras y la salud mental en adultos demostró que la recomendación general de consumir al menos 5 raciones de frutas y verduras al día es beneficiosa para la salud mental (Głąbska et al., 2020).

Tradicionalmente, España se ha asociado con la dieta mediterránea, la cual ha sido considerada como uno de los patrones dietéticos más saludables del mundo (González-García et al., 2020). Sin embargo, hay estudios que demuestran que la población española está disminuyendo su adherencia a la dieta mediterránea, al reducir su consumo de aceite de oliva, verduras, frutas, frutos secos y pescado (Conde-Pipó et al., 2022; León-Muñoz et al., 2012). Este hecho puede resultar problemático ya que la dieta mediterránea se ha asociado con la salud reproductiva, la disminución del riesgo de enfermedades neurodegenerativas (Gantenbein & Kanaka-Gantenbein, 2021) y la mejora de los síntomas de la depresión (Pano et al., 2021). Más allá de esto, hay evidencia de que el estilo de vida mediterráneo puede ser una estrategia de prevención efectiva para la depresión (Hershey et al., 2022). Por lo que recomendar la adherencia a este patrón dietético puede ser una medida segura y de bajo costo para la prevención de la depresión (Pano et al., 2021).

Esta eficacia de la adherencia a la dieta mediterránea se debe a que los nutrientes vinculados a la prevención de la depresión están incluidos en ella, ya que proporciona una ingesta adecuada de frutas, frutos secos, verduras, cereales, legumbres y pescado (Roca et al., 2016; Sánchez-Villegas et al., 2006). Estos nutrientes con efectos protectores son los ácidos grasos poliinsaturados omega 3 (Liao et al., 2019), la vitamina D (Xie et al., 2022), vitaminas del grupo B (Hanna et al., 2022; Mikkelsen et al., 2016), el ácido fólico (o B9) (Abdelmaksoud et al., 2019; Bender et al., 2017), el zinc y el selenio (J. Wang et al., 2018).

### 1.3.5 Facilitadores de la adherencia a los Programas de Modificación de Estilos de Vida

En los LMPs se recomienda utilizar facilitadores que promuevan la adherencia de las personas participantes. La adherencia se puede facilitar siguiendo pautas sencillas en

las intervenciones, realizando entrevistas motivacionales, ofreciendo seguimiento prolongado e intenso durante las diferentes etapas del trastorno y recibiendo la retroalimentación adecuada (Olivan-Blázquez et al., 2018).

Un facilitador sería el uso de las Tecnologías de la Información y la Comunicación (TICs) (NICE, 2014). Más específicamente, se ha demostrado que los dispositivos portátiles (como los relojes inteligentes de pulsera) son útiles, y su uso es aceptado entre las personas con sobrepeso y con enfermedades mentales graves (Naslund et al., 2015). Estos dispositivos permiten registrar comportamientos en tiempo real de manera discreta, lo que permite a las personas ser conscientes de las actividades realizadas. Al recordar la actividad física realizada y los patrones de sueño (Nadal et al., 2021), se puede mejorar el autocontrol y producir un cambio en el comportamiento (Lee et al., 2021). En este sentido y más específicamente, investigaciones previas sugieren que el monitoreo de los comportamientos cotidianos promueve modificaciones en el estilo de vida en personas con depresión usuarias de APS (Olivan-Blázquez et al., 2018; Serrano Ripoll et al., 2015).

Otro facilitador sería el formato de intervención grupal, ya que promueve el apoyo social (NICE, 2014). Está bien establecido que el apoyo social proporciona importantes recursos sociales, emocionales y materiales que ayudan en la mejora de la depresión y ansiedad (WHO, 2003). En general, es igual de probable que las personas participantes se involucren en el tratamiento grupal como en el tratamiento individual y los beneficios se mantienen a lo largo del tiempo en ambos tipos de intervenciones (Simmonds-Buckley et al., 2019).

Los factores personales, detallados en el apartado 1.4, también pueden dificultar la aceptación o el cumplimiento del tratamiento. Por ejemplo, una baja necesidad de tratamiento percibida por uno mismo, conocimientos de salud mental deficientes y temor

a la estigmatización dificultan la adherencia al tratamiento (Gulliver et al., 2010; Mojtabai et al., 2011).

## 1.4 Los factores personales relacionados con la salud mental

La presente tesis se enmarca en la teoría de la salutogénesis (Antonovsky, 1996), la cual establece que la capacidad de un individuo para modificar su estilo de vida está influenciada por los Recursos de Resistencia Psicosocial Generalizados, los cuales consisten en recursos personales, interpersonales o contextuales (dinero, conocimiento, experiencia, autoestima, hábitos saludables, compromiso, apoyo social, capital cultural, inteligencia, tradiciones y visión de la vida). El enfoque salutogénico tiene como objetivo mejorar la salud mental y el bienestar de las personas participantes al aumentar su conciencia, confianza y capacidad para utilizar sus factores personales relacionados con el comportamiento de salud (Langeland & Vinje, 2016).

Los factores personales estudiados en la presente tesis son el sentido de coherencia (Antonovsky, 1993), la autoeficacia (Sherer et al., 1982), la activación de uno/a mismo/a en su propia salud (Hibbard et al., 2004), la alfabetización en salud (Sørensen et al., 2015) y la procrastinación (Guilera et al., 2018).

En primer lugar, Antonovsky postuló que la manera que tienen las personas de dar sentido al mundo podría afectar a su salud, ya que determina qué tan bien un individuo maneja el estrés (Antonovsky, 1993). A este concepto lo denominó sentido de coherencia, y su relación con la depresión ha sido reportada en la literatura (Boelen & O'Connor, 2022; Giglio et al., 2015; Konttinen et al., 2008; Silventoinen et al., 2022).

En segundo lugar, la autoeficacia representa la confianza de una persona en su capacidad para autorregular comportamientos específicos cuando se enfrenta a diversos obstáculos/barreras (Bandura, 1977; Sherer et al., 1982). La autoeficacia facilita la

intención de adoptar conductas de salud preventivas (Dominick et al., 2013) y está relacionada con la depresión (Milanovic et al., 2018). La autoeficacia también es uno de los mecanismos psicológicos que median la relación entre ejercicio físico y el estado de ánimo (Guszkowska, 2004).

En tercer lugar, la activación de uno/a mismo/a en su propia salud es un factor presente en personas con mejor salud física y mental, que realizan ejercicio individual con mayor frecuencia (Hibbard et al., 2004). La activación en salud se asocia negativamente con la depresión (Magnezi et al., 2014).

En cuarto lugar, la alfabetización en salud refleja la capacidad de un individuo para llevar a cabo de forma autónoma y efectiva comunicaciones sobre su salud, además de saber utilizar recursos relacionados con la salud (Nutbeam, 2000). Las personas con un adecuado nivel de alfabetización en salud tienen más probabilidades de participar en comportamientos preventivos, tienen más conocimientos específicos sobre las enfermedades y tienen buenas habilidades de gestión de la salud (Dominick et al., 2013). La alfabetización en salud y la depresión se correlacionan negativamente (Hsu et al., 2020).

En quinto lugar, la procrastinación es el retraso irracional y voluntario de las tareas importantes y necesarias (Guilera et al., 2018). La procrastinación se asocia con el estrés percibido, la depresión, la ansiedad y la fatiga (Beutel et al., 2016).

## 1.5 Los determinantes sociales de la salud relacionados con la salud mental

Como se ha desarrollado durante la introducción y más exhaustivamente en el punto 1.3, los estilos de vida tienen una notable influencia en el estado de ánimo. Para comprender mejor qué determina que los individuos sigan determinados estilos de vida,

tenemos que tener en cuenta que éstos están integrados en redes sociales y comunitarias relacionadas con las condiciones de vida y de trabajo que, de manera más amplia, están a la vez relacionadas con el entorno cultural y socioeconómico (Evans et al., 2001) (Figura 1).


**Figura 1.** Modelo de Dahlgren y Whitehead de producción de inequidades en salud. Imagen extraída del libro *Determinantes sociales de la salud en Chile: En la perspectiva de la equidad* (Jadue et al., 2005).

El estatus socioeconómico, la educación, el vecindario y el entorno físico, el trabajo/empleo y las redes de apoyo social, así como el acceso a la atención médica, son todos Determinantes Sociales de la Salud (DSS) (Artiga & Hinton, 2018; WHO, 2017a). Los DSS son cruciales para nuestra salud mental (Evans et al., 2001; Santamaría-García et al., 2020), por lo que abordarlos es esencial para mejorar la salud y reducir las inequidades (Promotion Office of Disease Prevention and Health, 2020). El análisis social

de los problemas de salud se evidenció en el Informe Lalonde de Canadá en 1974 (Lalonde, 1974). Este informe propuso que entendiéramos la salud como un derecho humano fundamental, aceptando como condiciones fundamentales para la salud: la paz, la educación, la vivienda, la alimentación, los ingresos económicos, un ecosistema estable, la justicia social y la equidad (Solar & Irwin, 2010; WHO, 2007).

### 1.5.1 Los determinantes sociales de la salud y su relación con la salud mental en tiempos de COVID-19

La enfermedad por coronavirus 2019 (COVID-19) causada por el Síndrome Respiratorio Agudo Severo SARS-CoV-2 ha provocado una crisis sanitaria, social y económica a nivel mundial devastadora (WHO, 2021b; Zhou et al., 2020).

España ha sido uno de los países más afectados por la enfermedad (Spain Ministry of Health, 2020), e implementó uno de los confinamientos más estrictos de Europa durante siete semanas. Durante el primer "Estado de Alarma" impuesto por el Gobierno (provisionalmente del 15 al 29 de marzo de 2020), la circulación de personas se restringió a desplazamientos a puntos de venta específicos (por ejemplo, para adquirir alimentos y medicamentos), asistir a citas médicas, acudir al trabajo y asuntos de fuerza mayor (las fronteras interiores se cerraron una semana después). Durante la primera imposición del confinamiento (del 30 de marzo al 12 de abril de 2020), España ascendió al tercer y segundo puesto mundial en diagnósticos confirmados y fallecimientos por la COVID-19, respectivamente. Tras seis prórrogas del confinamiento (la última el 7 de junio de 2020) y cuatro etapas de transición en las que se contemplaban medidas algo más relajadas similares a otros países de la Unión Europea, España finalmente entró en la "nueva normalidad" el 21 de junio de 2020 (Pérez-Laurrabaquio, 2021).

Los gobiernos de todo el mundo implementaron medidas de emergencia de salud pública de gran alcance para hacer frente a los brotes que se propagaban rápidamente.

Estas medidas incluyeron el autoaislamiento, toques de queda y órdenes de quedarse en casa, distanciamiento físico, restricciones de viaje, cierre de fronteras, de escuelas, de tiendas, de restaurantes y de lugares de trabajo, así como la cancelación de eventos públicos (Arendt et al., 2020; Doron Amsalem et al., 2021).

El impacto de la COVID-19 y sus medidas de control en el bienestar mental no pueden subestimarse. La evidencia sugiere que la pandemia ha exacerbado las condiciones de salud mental existentes y ha desencadenado otras nuevas (Brooks et al., 2020; Gao et al., 2020; Huang & Zhao, 2020; Stuart et al., 2020). Las medidas de distanciamiento social se han relacionado con síntomas psicológicos comunes como aburrimiento, estrés, ansiedad, depresión, sueño interrumpido y sentimientos de impotencia (Bozdağ, 2021; H. H. Kim & Jung, 2021; Kshirsagar et al., 2021). Los largos períodos de incertidumbre e inseguridad, combinados con la soledad y el aislamiento, se han asociado significativamente con trastornos mentales y un detrimento del bienestar mental (Campion et al., 2020). Así mismo, las personas con problemas de salud mental pueden verse afectadas de manera desproporcionada debido al cierre de los centros de día o la suspensión de actividades sociales que eran necesarias para su bienestar (Spain Ministry of Health, 2020).

En lo que respecta al impacto de los DSS, éste se ha intensificado durante la pandemia. Las condiciones de trabajo y de vida han tenido una influencia considerable en la salud mental. Los DSS han interactuado con el género (Amendola et al., 2021), etnicidad, estatus social y otros factores, aumentando las desigualdades relacionadas con la COVID-19 (Burstrom & Tao, 2020; Paremoer et al., 2021). Por otro lado, los bajos ingresos económicos pueden afectar a la capacidad de las personas para acceder a Internet y a las TICs (p. ej., tabletas, teléfonos inteligentes y ordenadores portátiles), ya que algunas familias no pueden pagar dichos dispositivos.

La gran cantidad de estudios que se han llevado a cabo estos últimos años sobre la COVID-19 tienden a tener un enfoque biomédico o epidemiológico (Rodriguez-Morales et al., 2020; Zhu et al., 2020). Sin embargo, los métodos cualitativos pueden proporcionar información valiosa sobre las experiencias de las personas y sobre las condiciones sociales y ambientales más amplias que influyen en el impacto diferencial que tiene la COVID-19, además de permitir una perspectiva temporal (Bavel et al., 2020; Teti et al., 2020). Hay pocos estudios cualitativos que exploren los vínculos entre la salud mental, la depresión y la COVID-19 (Chen, K.-L., Hung, W.-C., Lee, M.-B., Chen, I.-M., & Wu, 2020; Hamm et al., 2020) y obtener conocimientos sobre esos vínculos es esencial para desarrollar estrategias de prevención más efectivas.

# 2. OBJETIVOS

El eje conductor de esta tesis doctoral es el desarrollo de una intervención terapéutica adyuvante para los síntomas depresivos en APS.

Después de ver todos los elementos presentados en la introducción, tales como la alta prevalencia de depresión existente, su impacto económico y social, el abandono progresivo de los estilos de vida saludables que influyen en la vulnerabilidad de la depresión, y los factores personales que influye en las conductas de salud, entre otros, surgió la necesidad de probar la efectividad de un Programa de Modificación de Estilos de Vida (LMP, por sus siglas en inglés) como tratamiento adyuvante a los tratamientos de primera elección.

Es por ello por lo que planteamos los siguientes objetivos:

El objetivo principal fue analizar la efectividad clínica de un programa novedoso que combinara y promoviera conjuntamente varios estilos de vida saludables (centrado, en concreto, en la actividad física, los patrones de sueño y la alimentación) en un formato presencial y grupal en APS, y del mismo programa añadiendo el uso de TICs (en concreto, de un reloj inteligente de pulsera), ambos comparados con la efectividad del grupo control (grupo que sigue el tratamiento habitual, TAU). Para ello se diseñó un ensayo clínico multicéntrico, aleatorizado, controlado, de tres brazos de intervención (TAU, TAU+LMP, TAU+LMP+ICTs) y de 6 semanas de duración, dirigido principalmente a sujetos con depresión subclínica, leve y moderada provenientes de APS. Su diseño metodológico y el protocolo están publicados en el Manuscrito I (Aguilar-Latorre et al., 2020) (Registro de ensayos clínicos: NCT03951350). El ensayo clínico completo se llevó a cabo con un total de 188 sujetos. Los resultados pre-intervención y post-intervención y su interpretación se encuentran en el Anexo I. Este artículo ha sido aceptado provisionalmente en la revista *BMJ Open* y se encuentra en la fase de revisión previa a la

fase de producción, edición y composición tipográfica. Los resultados longitudinales de la intervención a los 6 meses y su interpretación se encuentran en el Manuscrito II (Aguilar-Latorre, Pérez Algorta, et al., 2022). Los resultados longitudinales de la intervención a los 12 meses y su interpretación se encuentran en el Anexo II. Este artículo se ha enviado a la revista *Journal of Affective Disorders* y se encuentra en la primera ronda de revisión por pares.

El objetivo secundario fue el de analizar la asociación entre la gravedad de la depresión, algunos patrones de estilo de vida (ejercicio físico, sueño y dieta) y algunos factores personales relacionados con el comportamiento de salud (autoeficacia, activación en salud, sentido de coherencia, alfabetización en salud y procrastinación). También se pretendía analizar si los factores personales moderaban la relación entre estilos de vida y depresión. Para ello se realizó un análisis de datos secundario con datos basales recogidos al inicio del ensayo clínico. Para este estudio se pudieron obtener datos de 226 participantes. Los resultados y su interpretación se encuentran en el Manuscrito III (Aguilar-Latorre, Serrano-Ripoll, et al., 2022).

Adicionalmente y debido a la llegada y coincidencia del ensayo clínico con la COVID-19, se decidió llevar a cabo un estudio cualitativo que evaluara el impacto del confinamiento en las personas participantes. Para ello se trabajó con una submuestra de 52 personas de las 188 que estaban participando en el ensayo clínico. Este estudio se llevó a cabo en el mes de junio de 2020, tras siete semanas de estricto confinamiento. Los resultados y su interpretación se encuentran en el Manuscrito IV (Aguilar-Latorre, Oliván-Blázquez, et al., 2022).

# 3. COPIA DE LOS TRABAJOS PUBLICADOS

**Manuscrito I**

Aguilar-Latorre, A., Navarro, C., Oliván-Blázquez, B., Gervilla, E., Magallón Botaya, R., Calafat-Villalonga, C., García-Toro, M., Boira, S., & Serrano-Ripoll, M. J. (2020). Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol. *BMJ Open, 10*(12). https://doi.org/10.1136/bmjopen-2020-038457

**Manuscrito II**

Aguilar-Latorre, A., Pérez Algorta, G., Navarro-Guzmán, C., Serrano-Ripoll, M. J., & Oliván-Blázquez, B. (2022). Effectiveness of a lifestyle modification programme in the treatment of depression symptoms in primary care. *Frontiers in Medicine, 9*(954644), 1–10. https://doi.org/10.3389/fmed.2022.954644

**Manuscrito III**

Aguilar-Latorre, A., Serrano-Ripoll, M. J., Oliván-Blázquez, B., Gervilla, E., & Navarro, C. (2022). Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial. *Frontiers in Psychology, 13*(856139). https://doi.org/10.3389/fpsyg.2022.856139

**Manuscrito IV**

Aguilar-Latorre, A., Oliván-Blázquez, B., Porroche-Escudero, A., Méndez-López, F., García-Gallego, V., Benedé-Azagra, B., & Magallón-Botaya, R. (2022). The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain. *BMC Public Health, 22*(780), 1–13. https://doi.org/10.1186/s12889-022-13083-2

# Manuscrito I. Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol

Open access Protocol

BMJ Open

## Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: a randomised clinical trial protocol

Alejandra Aguilar-Latorre ,[1] Capilla Navarro,[2] Bárbara Oliván-Blázquez,[1,3] Elena Gervilla,[2,4] Rosa Magallón Botaya,[1,5] Catalina Calafat-Villalonga,[2] Mauro García-Toro,[6,7] Santiago Boira,[3] María Jesús Serrano-Ripoll[2,8]

**To cite:** Aguilar-Latorre A, Navarro C, Oliván-Blázquez B, *et al*. Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: a randomised clinical trial protocol. *BMJ Open* 2020;**10**:e038457. doi:10.1136/bmjopen-2020-038457

► Prepublication history and additional materials for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-038457).

Received 11 March 2020
Revised 19 October 2020
Accepted 19 November 2020

Check for updates

© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

**Correspondence to**
Dr Bárbara Oliván-Blázquez; barbaraolivan@gmail.com

## ABSTRACT

**Introduction** Major depression is a highly prevalent pathology that is currently the second most common cause of disease-induced disability in our society. The onset and continuation of depression may be related to a wide variety of biological and psychosocial factors, many of which are linked to different lifestyle aspects. Therefore, health systems must design and implement health promotion and lifestyle modification programmes (LMPs), taking into account personal factors and facilitators. The main objective of this protocol is to analyse the clinical effectiveness, cost-effectiveness and cost utility of an LMP and an LMP with information and communication technologies (ICTs) as adjunctive treatment for depression in primary care patients. The secondary objectives are to analyse the clinical effectiveness in the subgroup that presents comorbidity and to analyse the correlation between personal factors on health behaviour and lifestyle patterns.

**Methods and analysis** A randomised, multicenter pragmatic clinical trial with three parallel groups consisting of primary healthcare patients suffering from subclinical, mild or moderate depression. The following interventions will be used: (1) Usual antidepressant treatment with psychological advice and/or psychotropic drugs prescribed by the general practitioner (treatment as usual (TAU)). (2) TAU+LMP. A programme to be imparted in six weekly 90-minute group sessions, intended to improve the following aspects: behavioural activation+daily physical activity+adherence to the Mediterranean diet pattern+sleep hygiene+careful exposure to sunlight. (3) TAU+LMP+ICTs: healthy lifestyle recommendations (TAU+LMP)+monitoring using ICTs (a wearable smartwatch). The primary outcome will be the depressive symptomatology and the secondary outcomes will be the quality of life, the use of health and social resources, personal factors on health behaviour, social support, lifestyle patterns and chronic comorbid pathology. Data will be collected before and after the intervention, with 6-month and 12-month follow-ups.

### Strengths and limitations of this study

- ► The intervention has the potential to be highly scalable and sustainable for the Spanish National Health Service.
- ► Increased motivation, on introducing self-registers for everyone and a group that will be monitored using wearable smartwatches.
- ► Most healthcare professionals can implement the intervention groups.
- ► Some individuals may refuse to participate in group intervention or may withdraw from the study during the 12-month trial period.
- ► Difficulty of entire group's attendance to a session held on one specific date and time.

**Ethics and dissemination** This study has been approved by the Clinical Research Ethics Committee of Aragón (approval number: C.P.-C.I. PI18/286) and the Research Ethics Committee of the Balearic Islands (IB3950/19 PI). Data distribution will be anonymous. Results will be disseminated via conferences and papers published in peer-reviewed, open-access journals.

**Trial registration number** ClinicalTrials.gov Registry (NCT03951350).

## INTRODUCTION

Depression is considered to be the principle cause of disability worldwide, and it contributes to the overall global burden of morbidity and mortality. By 2030, it is expected to be the main contributor to the burden of morbidity.[1–3] Approximately 25%–35% of all primary care patients suffer from psychiatric disorders, and over 80% of these patients suffer from depression or anxiety disorders.[4 5] In Spanish primary healthcare centres



BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

(PHCs), the prevalence of depression ranges from 9.6% to 20.2%.[6 7] Furthermore, depression generates great disability and high economic and social costs.[8]

The prevalence of depression in Spain is 13% over one's lifetime and 4% per year.[9] Indeed, comorbidity with other chronic conditions is high (64.9%–71.0%) (diabetes, hypertension, cardiovascular diseases and cancer, among others)[10–12] as well as comorbidity with other psychiatric diseases such as anxiety disorders is also high (40%–66%).[13]

Despite the negative impact of depression on people's lives and the existence of numerous treatment interventions,[14] these interventions are often not appropriately used in PHC services,[6] mainly due to physician time or resource limitations.[7] Thus, pharmacological[15] treatment is usually recommended, even though research has shown that in subclinical, mild or moderate depression, non-pharmacological interventions are recommended.[15 16]

Since options and outcomes for the care of individuals suffering from depression and their access to treatment remains limited,[17] it is important to promote cost-effective treatment options. The onset and continuation of depression has been linked to numerous biological and psychosocial factors, many of which are related to distinct lifestyle aspects.[18–21] Therefore, many of the strategies promoting a healthier lifestyle could have antidepressant utility.[20 22–24] In addition to multimodal studies, others have focused on one of the following aspects of lifestyle modification: daily physical activity,[25] adherence to the Mediterranean diet,[26 27] sleep hygiene practices[28 29] and careful exposure to sunlight.[30 31]

The present study will be framed around the theory of salutogenesis,[32] which establishes that an individual's ability to modify our lifestyle is influenced by psychosocial generalised resistance resources, which consist of personal, interpersonal or contextual resources (money, knowledge, experience, self-esteem, healthy habits, commitment, social support, cultural capital, intelligence, traditions and vision of life) and the sense of coherence (way of making sense of the world, which is a major factor in determining how well an individual manages stress and stays healthy).

Moreover, previous studies show that the use of facilitators is quite important (simplicity of guidelines, tailoring through motivational interviewing, prolonged and intense monitoring throughout the different stages of the disorder and the provision of adequate feedback and social support)[23] to facilitate adherence to lifestyle modification programmes (LMPs). For example, enhanced motivation can be achieved through the use of information and communication technologies (ICTs) and with the social support resulting from intervention group participation.[33] Personal factors and facilitators must be taken into account in lifestyle modification interventions, since they may determine the success of health promotion programmes.

The main objective of this protocol is to analyse the clinical effectiveness, cost-effectiveness and cost utility of an LMP and an LMP with ICTs as adjunctive treatment for depression in primary care patients. The secondary objectives are to analyse the clinical effectiveness in the subgroup that presents comorbidity and to analyse the correlation between personal factors on health behaviour and lifestyle patterns.

## METHODS AND ANALYSIS

### Study design

Multicenter pragmatic randomised controlled trial in three parallel groups.

### Setting and study sample

We will recruit patients having subclinical, mild or moderate depression (scoring ≥10 and ≤30 points on the Beck II Self-Applied Depression Inventory (BDI-II))[34] from PHCs of two Spanish areas (Zaragoza and Mallorca). Inclusion criteria: individuals over the age of 18, both sexes, having a duration of depression symptoms of at least 2 months, who understand written and spoken Spanish and who have provided their informed consent (online supplemental file 1). Exclusion criteria will be: suffering from another disease that affects the brain (organic brain pathology or having suffered a traumatic brain injury of any severity, dementia); having another psychiatric diagnosis or serious psychiatric illness (substance dependence or abuse, a history of schizophrenia or other psychotic disorders, eating disorders) with the exception of anxious pathology or personality disorders (collected through a medical history and from the Mini-International Neuropsychiatric Interview (MINI))[35]; presence of a serious or uncontrolled medical, infectious or degenerative illness that may interfere with the affective symptoms; the presence of delirium or hallucinations, risk of suicide, pregnancy or lactation; patients who have participated in another clinical trial over the past 6 months, who are currently in psychotherapy or those who have been practicing mindfulness, yoga, meditation or similar practices over the past 6 months, engaging in formal practice at least once a week and the presence of any medical, psychological or social problem that could seriously interfere with the patient's participation in the study.

### Sample size

Scientific evidence suggests that a 17% reduction in the BDI-II[34] is considered clinically relevant.[36] In a previous study conducted by our team with psychiatric outpatients, we found that the average BDI score at the beginning of the study was 24.5 points (SD 9.8),[22] so we consider that a reduction of at least 4.8 points would have clinical significance and would benefit the patient. Accepting an $\alpha$ risk of 0.05 and a $\beta$ risk of 0.20 in a bilateral contrast, 44 subjects will be required for each group. With an estimated withdrawal rate of 20%, the sample size will require approximately 53 patients in each group. The total sample required is 159 subjects. A formula based on the Snedecor's $F$ distribution[37] has been used (see



BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

online supplemental file 2). It is estimated that approximately 50% of these patients will present some physical or mental comorbidity.[12]

### Recruitment

General practitioners (GPs) from the PHCs of Zaragoza and Mallorca will be invited to refer patients who are suspected of suffering from depression. Most representative PHCs in the area will be invited, based on size, urban or rural area, and PHCs with a different sociodemographic profile will be selected. GPs will explain the characteristics of the study to their patients and if they agree to participate, they will be asked to provide a phone number to be contacted by a trained research assistant (RA) during the next week. The RA will call patients and establish an appointment in their PHC, in which he will explain them the study, provide them the patient information sheet and get the informed consent signed. To ensure that they fulfil the inclusion criteria, the RA will administrate the BDI-II[34] and the MINI.[35] If participants meet the criteria, the RA will administer the baseline questionnaires at the same appointment. Recruitment and baseline assessments will be carried out until the final sample size has been achieved.

### Randomisation, allocation and masking of study groups

Once baseline data are collected, the participants will be randomised. An independent statistician will perform the individual randomisation using a computer-generated random number sequence. The randomisation will be carried out using a list of patients from Zaragoza and Mallorca (figure 1). Given the nature of the interventions, participants will not be blinded to their allocation. An RA will call them to explain their assigned intervention and where they should go and when. The RA will request that participants not to inform other researchers of their allocation.

### Data collection and monitoring

One RA will collect the data and another will perform entry and coding of the identified data. All RA managing the data will be blinded to participant allocation, as well as the RA conducting the outcome assessments and data analysis. All information collected will be treated in accordance with the provisions of current legislation on personal data protection.

The study will not have a formal data monitoring committee since adverse intervention events have not been reported. Any serious unexpected adverse events or outcomes will be discussed by the trial management committee (identical to the authors of this protocol). There are no plans to discontinue or modify interventions, or to improve adherence or promote participant retention. The trial management committee will monitor recruitment, treatment and attrition rates and any concerns related to the study. Reasons for dropping out will be also registered. Concomitant care is permitted and registered as long as it is not one of the exclusion criteria.

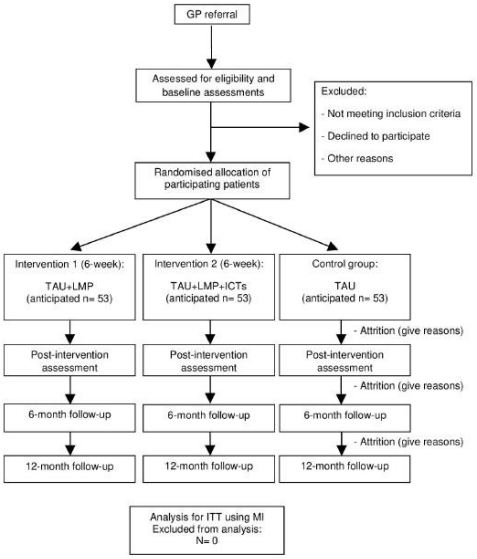



**Figure 1** Flowchart of the study: randomisation, sampling and monitoring of patients. GP, general practitioner; ICTs, information and communication technologies; ITT, intention to treat; LMP, lifestyle modification programme; MI, multiple imputation; TAU, treatment as usual.

Group-specific processes will be taken into account and will be evaluated and informed, in accordance with recommendations of the 'mechanisms of action in group-based interventions' (MAGI) framework.[38]

### Intervention development and evaluation

Patients allocated in the first arm (control group) will follow the usual treatment provided by their GP (treatment as usual (TAU)).

Patients allocated in the second arm (first intervention group) will follow the TAU and the LMP. This programme will consist of six weekly group sessions (lasting 90 min each) led by an experienced psychologist and complemented by PowerPoint presentations.

Patients allocated in the third arm (second intervention group) will follow TAU and LMP and will be monitored using a wearable smart wristwatch that will track their daily sleep patterns and physical activity (LMP+ICTs).

The group sessions will consist of the following content:

1. Presentation of the project and psychoeducation on depression: presentation of the project and a review of the study objectives. Definition, symptoms, causes, consequences of depression and, also, how lifestyles and social environment changes influence the symptomatology of depression.
2. Behaviour activation: a psychologist will provide information on the importance of establishing, maintaining



BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

and monitoring activities. For the LMP+ICTs group, they will also learn how to use the smart wristwatch, ensuring all participants are able to use it.

3. Sleep hygiene habits and careful exposure to sunlight: recommendations on healthy sleep habits, factors influencing sleep quality and possible solutions. The benefits of careful exposure to sunlight and recommendations of when to do so and for how long. Responding to questions regarding the previous session.
4. Physical activity: the benefits of engaging in regular physical activity. Personalised recommendations about what physical exercise may be practiced, how and when to do so. Responding to questions regarding the previous session.
5. Adherence to the Mediterranean diet: explanations about the Mediterranean diet, food groups and their characteristics, as well as the most beneficial foods for physical and mental health, how to cook it and food-related habits. Responding to questions regarding the previous session.
6. Summary of previous sessions with practical final suggestions: personalised experiences and doubts of the participants throughout the course. Recommendations for daily healthy lifestyle practices for the future and farewell.

At the end of each session, the participants will receive a paper with self-registration tables (online supplemental file 3). They will complete the tables with the information on their daily routines regarding the modification of lifestyles on which they have been instructed. They will be asked about when they wake up and when they go to bed, the duration of their sleep, the time spent exposed to sunlight, the diet pattern, the physical activity and sports practiced, the social support and the subjective perception of satisfaction after these activities. A qualitative study associated with this study will be included to analyse the participants' difficulties in following the intervention.

## Outcomes and measures

We will collect patient data using the questionnaires administered in baseline, immediately after the intervention (in a period of 2–7 days after the last intervention session) and at 6-month and 12-month follow-up after the last intervention session (with a margin of ±2 weeks) (see table 1). A blinded RA will call each patient of the three arms and set up an appointment in their PHC for questionnaire administration. Study outcomes and measures are summarised in table 1.

### Sociodemographic data

We will collect information on gender, age, marital status, education, occupation and economical level. These data will be collected through an ad hoc questionnaire.

**Table 1** Study variables

| Instrument | Assessment area | Measures |
|---|---|---|
| BDI-II[34 39] | Severity of depression | Baseline and follow-up sessions* |
| MINI[35] | Psychiatric diagnosis | Baseline |
| Gender, age, marital status, education, occupation, economical level | Sociodemographic | Baseline and follow-up sessions* |
| Glucose concentration (mg/dL), glycated haemoglobin (%), creatinine, arterial pressure (mm Hg) and cholesterol (mg/dL) | Comorbidity with chronic diseases | Baseline and 6-month and 12-month follow-up |
| EQ-5D[40 42] | Health-related quality of life | Baseline and follow-up sessions* |
| MOS-SS[46 47] | Social support | Baseline and follow-up sessions* |
| CSRI[48 49] | Health and social services use | Baseline and follow-up sessions* |
| IPAQ-SF[50 51] | Physical activity | Baseline and follow-up sessions* |
| MEDAS[53 54] | Adherence to the Mediterranean diet | Baseline and follow-up sessions* |
| PSQI[55 56] | Quality and patterns of sleep | Baseline and follow-up sessions* |
| Self-Efficacy Scale[57 62] | Self-efficacy | Baseline and follow-up sessions* |
| PAM[58 63] | Patient activation in their own health | Baseline and follow-up sessions* |
| SOC-13[59 64] | Sense of coherence | Baseline and follow-up sessions* |
| HLS-EUQ16[60 65] | Health literacy | Baseline and follow-up sessions* |
| IPS[61 66] | Procrastination | Baseline and follow-up sessions* |

*Follow-up sessions: post intervention (in a period of 2–7 days after the last session of the intervention) and 6-month and 12-month follow-up (6 and 12 months after the last session of the intervention (±2 weeks)).
BDI-II, Beck II Self-Applied Depression Inventory; CSRI, Client Service Receipt Inventory; EQ-5D, European Quality of Life-5 Dimensions Questionnaire; HLS-EUQ16, Health Literacy Europe Questionnaire; IPAQ-SF, International Physical Activity Questionnaire-Short Form; IPS, Irrational Procrastination Scale; MEDAS, 14-item Mediterranean Diet Adherence Screener; MINI, Mini-International Neuropsychiatric Interview; MOS-SS, Medical Outcomes Study Social Support Survey; PAM, Patient Activation Measure Questionnaire; PSQI, Pittsburgh Sleep Quality Index; SOC-13, Sense of Coherence Questionnaire.



BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

### Primary outcome

#### Severity of depression

The primary outcome will be measured using the BDI-II.[34] This is a self-report inventory for measuring the severity of depression, consisting of 21 multiple-choice questions with each answer being scored on a scale ranging from 0 to 3. It was translated and validated into Spanish with a reliability of 0.89.[39] The standardised cutoffs are: 0–13: minimal depression; 14–19: mild depression; 20–28: moderate depression and 29–63: severe depression.

### Secondary outcomes

#### Health-related quality of life

Health-related quality of life will be measured using the European Quality of Life-5 Dimensions Questionnaire (EQ-5D).[40 41] EQ-5D scores will be used to calculate the quality-adjusted life year (QALY) during the monitoring period by adjusting the length of time affected by the health result by the utility value. It contains five health dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and each of these has three levels (no problems, slight problems or moderate and severe problems). The EQ records the patient's self-rated health on a vertical Visual Analogue Scale (VAS) of 20 cm, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The VAS can be used as a quantitative measure of health outcome that reflect the patient's own judgement. Patients mark the point on the vertical line that best reflects their assessment of their current global health status.[42] Cronbach's alpha coefficient has been calculated in research with disease-specific populations. We highlight the study of Seoane *et al*[43] in which the overall alpha value was 0.788. Being the only study with a general population, it provides an overall mean estimate of the minimum important difference for the EQ-5D, which is 0.074.[44]

#### Comorbidity with chronic diseases

Comorbidity with chronic diseases will be determined according to the International Classification of Diseases, Tenth Revision[45]: diabetes (glucose concentration (mg/dL), glycated haemoglobin (%), creatinine, arterial hypertension and diseases of lipid metabolism. In patients with chronic heart disease, coagulation variables will be added. They will be collected from the last blood test or control measurements of the clinical history, taken by their GP or nurse (assuming they were taken over the past 3 months). Otherwise, their GP will be asked for a blood control test. It is estimated that approximately 50% of these patients will present some comorbidity.[12] Anthropometric measures will also be collected (weight, size and perimeter of the waist).

#### Social support

It will be measured by the Medical Outcomes Study Social Support Survey (MOS-SS).[46] It is a self-report instrument consisting of four subscales (emotional/informational, tangible, affectionate and positive social interaction) and an overall functional social support index. It has a good reliability (Cronbach's alpha ≥0.91) and is quite stable over time. It has 19 items, a 5-point Likert Scale. Higher scores indicate more support. We will use the Spanish validated version.[47]

#### Use of health and social services

It will be measured using the Client Service Receipt Inventory.[48] These data may be used for a wide range of applications, including estimates of the costs of service receipt. To collect information on the entire range of services and supports used by study participants. It retrospectively collects data on the use of services over the past 6 months (eg, rates of use of individual services, mean intensity of service use, rates of accommodation use over time). We will use the validated Spanish version.[49]

#### Assessment of lifestyle

##### *Physical activity*

Physical activity will be measured using the International Physical Activity Questionnaire-Short Form (IPAQ-SF).[50] It assesses the levels of habitual physical activity over the last 7 days. It has seven items and records the activity of four intensity levels: vigorous-intensity activity and moderate-intensity activity (walking and sitting). We will use the validated Spanish version.[51] IPAQ-SF has acceptable validity for the measurement of total and vigorous physical activity and poor validity for moderate activity and good reliability.[52]

##### *Adherence to the Mediterranean diet*

Adherence to the Mediterranean diet will be measured using the 14-item Mediterranean Diet Adherence Screener (MEDAS), developed within the prevention with Mediterrean diet (PREDIMED) study group.[53] It includes items on food consumption and intake habits: the use of olive oil as the main source of cooking fat, preference for white meat over red meat, servings of vegetables, portions of fruit, red meat or sausages, servings of animal fat, sugar-sweetened beverages, red wine, legumes, fish, commercial pastries and dressing food with a traditional sauce made of tomatoes, garlic, onion or leeks sautéed in olive oil. The total score ranges from 0 to 14, with a higher score indicating a better accordance with the Mediterranean diet.[54]

##### *Quality and patterns of sleep*

Quality and patterns of sleep will be measured using the Pittsburgh Sleep Quality Index (PSQI).[55] It differentiates between 'poor' and 'good' sleep by measuring seven domains: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction over the past month. It consists of 19 self-applied questions and five questions that request the evaluation of the patient's bedmate or roommate (these are not scored). Answers range from 0 (no difficulty) to 3 (severe difficulty). The overall score ranges from 0 to 21 points. In its Spanish



BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

version, the Cronbach's alpha coefficient is 0.81, sensitivity is 88.63% and specificity is 74.99%. We will use the validated Spanish version.[56]

### Personal factors on health behavior

We will assess: (1) self-efficacy[57]; (2) activation[58]; (3) sense of coherence[59]; (4) health literacy[60] and (5) procrastination.[61]

#### *Self-efficacy*

Self-efficacy will be measured using the Self-Efficacy Scale.[57] To measure General Self-Efficacy Subscale (17 items including individuals' beliefs in their ability to perform well in a variety of situations) and Social Self-Efficacy Subscale (six items). It contains 23 items that are rated on a 14-point scale (ranging from strongly agree to strongly disagree). Higher scores indicate higher levels of self-efficacy. It has a Cronbach coefficient alpha of 0.86 for General Self-Efficacy Subscale and 0.71 for the Social Self-Efficacy Subscale. The unpublished Spanish version was translated by Godoy in 1990.[62]

#### *Patient activation in their own health*

Patient activation in their own health will be measured using the Patient Activation Measure (PAM) Questionnaire with regard to the management of their health.[58] It evaluates the patient's perceived knowledge, skills and confidence to engage in self-management activities. It has 13 items with a Likert Scale from 1 (strongly disagree) to 4 (strongly agree). The resulting score (between 0 and 100) places the individual at one of four levels of activation, each of which reveals insight into a range of health-related characteristics, including behaviours and outcomes. Higher scores indicate higher levels of activation.[58] This scale is only validated in Spanish for chronic patients. It had an item separation index for the parameters of 6.64 and a reliability of 0.98.[63]

#### *Sense of coherence*

Sense of coherence will be measured using the Sense of Coherence (SOC-13) Questionnaire by Antonovsky.[59] It values the personal disposition towards the assessment of vital experiences. It measures the sense of coherence, comprehensibility, manageability and meaningfulness. It has 13 items scoring between 13 and 91 points. It has consistency rates between 0.84 and 0.93. Higher scores (after reversal of the inverted items) indicate a higher sense of coherence. We will use the validated Spanish version.[64]

#### *Health literacy*

Health literacy will be measured using the Health Literacy Europe Questionnaire (HLS-EUQ16).[60] It can indicate that the probability of functional literacy in limited health is high, a possibility of functional literacy in limited health, and functional health literacy in adequate health. It contains 16 items. Higher scores indicate better health literacy. It presents a high consistency (Cronbach's alpha of 0.982) in the Spanish validation.[65]

#### *Procrastination*

Procrastination will be measured using the Irrational Procrastination Scale (IPS).[66] To measure general procrastination (dysfunctional delay). It has nine items, rated on a 5-point Likert Scale, with higher scores (after reversal of the three procrastination-inconsistent items) indicating a higher level of procrastination. Its Cronbach's alpha value is 0.90. We will use the validated Spanish version.[61]

## Data analysis plan

### Analysis of the outcomes at baseline

First, descriptive analyses of all the variables (proportions for qualitative variables, means and SD for quantitative variables) will be performed. Then, correlation analysis will be carried out between the questionnaires that evaluate personal factors on health behaviour (Self-Efficacy Scale, PAM, SOC-13, HLS-EUQ16 and IPS), social support (MOS-SS) and depression (BDI-II). We will also analyse the correlation between personal factors on health behaviour and the questionnaires assessing lifestyle patterns (IPAQ-SF, MEDAS and PSQI). Finally, we will analyse the relation of lifestyle patterns and social support with depression. Inferential statistical analysis will be carried out using the $\chi^2$ test for qualitative variables, and Student's t-test or one-wayanalysis of variance (ANOVA) test to assess the potential relationship between qualitative and quantitative variables.

Data collection and statistical analysis will be performed using Excel software, SPSS software (V.25.0)[67] and the R statistical software environment (V.3.6.2).[68]

### Clinical effectiveness analysis

The report of the results will follow a prespecified plan, based on the Consolidated Standards of Reporting Trials guidelines[69] in order to compare the three groups using an intention-to-treat analysis and multiple imputation (MI) technique for handling missing data. Initially, a descriptive comparison (proportions, means or medians) will be carried out between groups for prognostic variables in order to establish their baseline comparability after randomisation. To analyse the clinical effectiveness, a repeated-measure linear regression will be conducted, including all evaluations over time. For this purpose, the main variable, BDI-II score, will be used as a continuous variable. The models will include adjustments for the baseline value of the BDI-II and for any other variable that would have shown differences in the baseline measurement. Possible group per time interactions will be examined using linear regression. Similar analyses will be carried out using the secondary outcomes (personal factors on health behaviour and assessment of lifestyle). To counteract the problem of multiple comparisons, we will use Bonferroni correction.

Comparisons will also be made between the LMP and LMP+ICTs groups regarding adherence to lifestyle modification requirements. Adherence will be considered as a good or beneficial score on the questionnaires assessing lifestyle patterns (IPAQ-SF, MEDAS and PSQI).



BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

In addition, we will compare the LMP and combined LMP+ICTs groups, assuming that they are comparable to each other and the two groups have significant results.

A binary variable regarding comorbidity will be created (comorbidity yes/no). We will determine if the effectiveness of the intervention differs in the subgroup presenting comorbidity and if the pathology improves. Statistical analyses will be selected based on subsample size (parametric or non-parametric tests).

As for the timepoint in which we administrate the follow-up questionnaires, we will consider the first follow-up assessment (in a period of 2–7 days after the last session of the intervention) as more relevant. We expect to find an immediate effect in the LMP and LMP+ICTs groups after attending group intervention, due to the potential social support received. In the 6-month and 12-month follow-up, we expect a beneficial change in the questionnaires assessing lifestyle, reflecting a long-lasting effect.

### Cost-effectiveness and cost-utility analysis

The effectiveness of the interventions will be estimated using the difference between the BDI-II baseline score and the score at the 6-month and 12-month follow-ups, and utility will be estimated using QALYs at the 6-month and 12-month follow-ups. QALYs will be calculated based on these scores using the Spanish EQ-5D tariffs.[70] Along with the EQ-5D utility scores, scores recorded on the EQ VAS will also be used as an outcome for the analysis.

Cost-effectiveness will be explored through the calculation of incremental cost-effectiveness ratios (ICERs) for the active intervention groups (LMP and LMP+ICTs) using the TAU group as the control. ICER is defined as the ratio between incremental costs and incremental effectiveness. In this way, cost utility will be explored by calculating incremental cost-utility ratios, which are defined as the ratio between incremental costs and incremental utilities measured on QALYs. QALYs gained in each evaluation are approximated using the area under the curve technique.[71]

Total costs will be calculated by adding direct and indirect costs. Direct costs will be calculated by adding the costs derived from the medication and the use of health services and clinical tests. The medication costs will be calculated by determining the price per milligram during the study period according to the vade-mecum of the last year of study, including value-added tax. The total cost of drug treatment will be calculated by multiplying the price per milligram by the daily dose in milligrams and the number of days the treatment is received. Costs derived from the use of health services will be calculated considering the data from the Oblikue database.[72] Indirect costs will be calculated based on the sick leave days and multiplying them by the Spanish minimum daily wage during the study period, 2019–2020.

We assume that data will be missing at random. Only patients with both cost and relevant outcome data at the 6-month and 12-month follow-ups will be included in the cost-effectiveness and cost-utility analyses. Notwithstanding this, sensitivity analysis imputing missing 6-month and 12-month data will test the robustness of cost-effectiveness and cost-utility results. The imputations will be performed using the 'mice' package,[73] freely available in the Comprehensive R Archive Network (CRAN-R).[68]

## DISCUSSION

Depression is a significant cause of morbidity having low detection and treatment rates in primary care.[74 75] Only 9% of all depressed primary care patients receive adequate treatment, and only 6% achieve remission, making depression an important management issue in primary care.[76] An effective treatment for depression that can be implemented in PHCs is brief psychotherapy (six to eight sessions programmes), which have the advantage of being performed by either mental health professionals or trained non-mental health providers.[77] In this case, the promotion of healthy lifestyles will be used to address depressive symptoms, as it has shown efficacy in a number of studies.[20–31] To ensure treatment adherence, facilitators should be used, such as the use of ICTs and the group format. They provide monitoring and social support, respectively.[33] Organising group therapies in PHCs generates a range of organisational benefits, in relation to efficient use of facilities, high therapist-to-patient ratios and potential reductions to treatment wait times.[78] Moreover, participants are just as likely to engage in group treatment as individual work and the benefits are also maintained over time.[79]

The strengths of this study include the design and the wide range of outcome measures. It will provide a wealth of information on the interplay between depression, personal factors on health behaviour and lifestyles. Study limitations include the possible attrition of participants due to session scheduling or participant refusal to participate in a group intervention or do the complete follow-ups.[80] However, the possible reasons for attrition and other issues will be registered regarding MAGI framework.[38]

Therefore, the creation of a six-session group programme addressing lifestyle modifications (plus testing the monitoring with ICTs by adding a smartwatch to one of the intervention group) appears to be a good choice for depression treatment. The long-term aim of this study is to establish intervention for patients with depression, making it accessible in their PHCs, effective and cost-effective.

### Execution dates

Initial recruitment of patients: April 2020.
Finalisation of patient recruitment: May 2020.
Finalisation of patient monitoring period: June 2021.
Publication of results: July 2021.

### Partial patient and public involvement (PPI)

PPI representatives worked with us to refine the research question; however, it was difficult to involve patients in other areas of the study design due to data protection restrictions and the very technical methods required to do a data linkage



BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

analysis. PPI representatives will write a plain language summary and design a leaflet for dissemination to their peers and distributing to patient groups.

## ETHICS APPROVAL

Ethics approval was granted by the Clinical Research Ethics Committee of Aragón (PI18/286) and the Research Ethics Committee of the Balearic Islands (IB3950/19 PI). The study has been developed in accordance with the Declaration of Helsinki. All of the subjects will sign an informed consent form, their data will be anonymised and will only be used for the purposes of the study. Participants and healthcare professionals will be informed about the results. Patients of the TAU group will be invited to participate in the LMP at the end of the study. The ethics committee will be notified of any protocol modifications.

**Author affiliations**
[1]Primary Health Care Research Group of Aragón (GAIAP), Institute for Health Research Aragón (IIS Aragón), Zaragoza, Spain
[2]Department of Psychology, University of the Balearic Islands, Palma de Mallorca, Spain
[3]Department of Psychology and Sociology, University of Zaragoza, Zaragoza, Spain
[4]Statistic and psychometric procedures implemented in Health Sciences Research Group, Balearic Islands Health Research Institute (IdISBa), Palma de Mallorca, Spain
[5]Department of Medicine, Psychiatry and Dermatology, University of Zaragoza, Zaragoza, Spain
[6]Mental disorders of high prevalence Research Group (TRAMAP), Balearic Islands Health Research Institute (IdISBa), Palma de Mallorca, Spain
[7]Department of Medicine, University of the Balearic Islands, Palma de Mallorca, Spain
[8]Research in Preventive Activities and Promotion and in Cancer Illes Balears (GRAPP-CAIB), Balearic Islands Health Research Institute (IdISBa), Palma de Mallorca, Spain

**Acknowledgements** The authors would like to thank the Primary Care Prevention and Health Promotion Network (RedIAPP-Health Institute Carlos III, Spain), Primary Health Care Research Group of Aragon (GAIAP-B21-17R) of the Department of Science, University and Knowledge Society of the Aragon (Spain) government and FEDER Funds 'Another way to make Europe'.

**Contributors** BO-B, M-JS-R and MG-T designed and developed the study and had the original idea. RMB, M-JS-R, CN and BO-B coordinated the fieldwork. AA-L and CCV undertook the fieldwork. AA-L, BO-B, EG and SB wrote the first draft of the article. The rest of the signing authors have read the manuscript critically, offering contributions and approving the final version. BO-B attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

**Funding** This work was supported by Carlos III Health Institute grant number PI18/01336, FEDER Funds 'Another way to make Europe'. The funders have no role in study design, data collection and analysis, decision to publish or manuscript preparation. The funding body will conduct audit trial once a year.

**Competing interests** None declared.

**Patient consent for publication** Not required.

**Supplemental material** This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

**ORCID iD**
Alejandra Aguilar-Latorre http://orcid.org/0000-0003-2683-7346

## REFERENCES

1 Ferrari AJ, Charlson FJ, Norman RE, *et al*. Burden of depressive disorders by country, sex, age, and year: findings from the global burden of disease study 2010. *PLoS Med* 2013.
2 Gabilondo A, Rojas-Farreras S, Vilagut G, *et al*. Epidemiology of major depressive episode in a southern European country: results from the ESEMeD-Spain project. *J Affect Disord* 2010;120:76–85.
3 Department of Information Evidence and Research WHO. WHO methods and data sources for global burden of disease estimates 2000-2015 [online]. Global Health Estimates Technical Paper WHO/HIS/IER/GHE/2017.1, 2017. Available: https://www.who.int/healthinfo/global_burden_disease/GlobalDALYmethods_2000_2015.pdf?ua=1
4 Alonso J, Angermeyer MC, Bernert S, *et al*. *Prevalence of mental disorders in Europe: results from the European study of the epidemiology of mental disorders (ESEMeD) project. Acta Psychiatrica Scandinavica, supplement*, 2004.
5 Kessler RC, Bromet EJ. The epidemiology of depression across cultures. *Annu Rev Public Health* 2013;34:119–38.
6 Vindel AC, Salguero JM, Wood CM, *et al*. La depresión en atención primaria: prevalencia, diagnóstico Y tratamiento. *Papeles del psicólogo* 2012;33:2–11.
7 Codony M, Alonso J, Almansa J, *et al*. Mental health care use in the Spanish general populations. Results of the ESEMeD-Spain study | Utilización de Los servicios de salud mental en La población General española. Resultados del estudio ESEMeD-España. *Actas españolas Psiquiatr* 2007;35:21–8.
8 Andlin-Sobocki P, Jönsson B, Wittchen HU, *et al*. Cost of disorders of the brain in Europe. *Eur J Neurol* 2005.
9 Alonso J, Angermeyer MC, Bernert S, *et al*. Use of mental health services in Europe: results from the European study of the epidemiology of mental disorders (ESEMeD) project. *Acta Psychiatr Scand Suppl* 2004:47–54.
10 In:Cassano P, Fava M. Depression and public health: an overview. *J Psychosom Res* 2002;53:849–57.
11 O'Neil A, Jacka FN, Quirk SE, *et al*. A shared framework for the common mental disorders and non-communicable disease: key considerations for disease prevention and control. *BMC Psychiatry* 2015;15.
12 Katon WJ. Clinical and health services relationships between major depression, depressive symptoms, and general medical illness. *Biol Psychiatry* 2003;54:216–26.
13 Aragonès E, Piñol JL, Labad A, *et al*. Prevalence and determinants of depressive disorders in primary care practice in Spain. *Int J Psychiatry Med* 2004;34:21–35.
14 Davidson JRT. Major depressive disorder treatment guidelines in America and Europe. *J Clin Psychiatry* 2010;71:e04.
15 Cuijpers P, van Straten A, van Schaik A, *et al*. Psychological treatment of depression in primary care: a meta-analysis. *British Journal of General Practice* 2009;59:e51–60.
16 National Collaborating Centre for Mental Health. Depression: the NICE guideline on the treatment and management of depression in adults. *Economist* 2010.
17 Wittchen HU, Jacobi F, Rehm J, *et al*. The size and burden of mental disorders and other disorders of the brain in Europe 2010. *European Neuropsychopharmacology* 2011;21:655–79.
18 Hidaka BH. Depression as a disease of modernity: explanations for increasing prevalence. *J Affect Disord* 2012;140:205–14.
19 Kupfer DJ, Frank E, Phillips ML. Major depressive disorder: new clinical, neurobiological, and treatment perspectives. *Lancet* 2012;379:1045–55.
20 Lopresti AL, Hood SD, Drummond PD. A review of lifestyle factors that contribute to important pathways associated with major depression: diet, sleep and exercise. *J Affect Disord* 2013;148:12–27.
21 Toobert DJ, Glasgow RE, Strycker LA, *et al*. Long-term effects of the Mediterranean lifestyle program: a randomized clinical trial for postmenopausal women with type 2 diabetes. *Int J Behav Nutr Phys Act* 2007;4:1.
22 García-Toro M, Ibarra O, Gili M, *et al*. Four hygienic-dietary recommendations as add-on treatment in depression a randomized-controlled trial. *J Affect Disord [Internet]* 2012;140:200–3.



BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

23 Olivan-Blázquez B, Montero-Marin J, García-Toro M, *et al*. Facilitators and barriers to modifying dietary and hygiene behaviours as adjuvant treatment in patients with depression in primary care: a qualitative study. *BMC Psychiatry* 2018;18:1–12.
24 Forsyth A, Deane FP, Williams P. A lifestyle intervention for primary care patients with depression and anxiety: A randomised controlled trial. *Psychiatry Res* 2015:1–8.
25 Harvey SB, Overland S, Hatch SL, *et al*. Exercise and the prevention of depression: results of the HUNT cohort study. *Am J Psychiatry* 2018.
26 Roca M, Kohls E, Gili M, *et al*. Prevention of depression through nutritional strategies in high-risk persons: rationale and design of the MooDFOOD prevention trial. *BMC Psychiatry* 2016;16.
27 Sánchez-Villegas A, Henríquez P, Bes-Rastrollo M, *et al*. Mediterranean diet and depression. *Public Health Nutr* 2006;9:1104–9.
28 Meerlo P, Havekes R, Steiger A. Chronically restricted or disrupted sleep as a causal factor in the development of depression. *Curr Top Behav Neurosci* 2015.
29 Coughlin JW, Smith MT. Sleep, obesity, and weight loss in adults: is there a rationale for providing sleep interventions in the treatment of obesity? *Int Rev Psychiatry* 2014.
30 Tuunainen A, Kripke DF, Endo T, *et al*. Light therapy for non-seasonal depression. *Cochrane Database Syst Rev* 2004;64:CD004050.
31 Golden RN, Gaynes BN, Ekstrom RD, *et al*. The efficacy of light therapy in the treatment of mood disorders: a review and meta-analysis of the evidence. *American Journal of Psychiatry* 2005;162:656–62.
32 Antonovsky A. The salutogenic model as a theory to guide health promotion. *Health Promot Int* 1996;11:11–18.
33 NICE. Behaviour change: individual approaches [online], 2014. Available: www.nice.org.uk/guidance/ph49
34 Beck A, Steer R, Ball R, *et al*. Comparison of beck depression 1 in psychiatric inventories -1A and - outpatients. *J Pers Assess* 1996;67:588–97.
35 Ferrando L, Bobes J, MINI GJ. Mini international neuropsychiatric interview. Versión en Español 5.0.0 DSM-IV. *Instrumentos Detección y Orientación Diagnóstica* 2000.
36 Button KS, Kounali D, Thomas L, *et al*. Minimal clinically important difference on the Beck Depression Inventory-II according to the patient's perspective. *Psychol Med* 2015.
37 Makuch R, Simon R. Sample size requirements for evaluating a conservative therapy. *Cancer Treat Rep* 1978.
38 Borek AJ, Abraham C, Greaves CJ, *et al*. Identifying change processes in group-based health behaviour-change interventions: development of the mechanisms of action in group-based interventions (MAGI) framework. *Health Psychol Rev* 2019;13:227–47.
39 Sanz J, García-Vera MP, Espinosa R, *et al*. Spanish adaptation of the Beck depression Inventory-II (BDI-II): 3. psychometric features in patiens with psychological disorders. *Clínica y Salud* 2005;16:121–42 http://www.redalyc.org/resumen.oa?id=180616104001
40 Brooks R, De Charro F. *EuroQol: the current state of play. health policy*. New York, 1996.
41 The EuroQol Group. EuroQol - a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208.
42 Badia X, Roset M, Montserrat S, *et al*. [The Spanish version of EuroQol: a description and its applications. European quality of life scale]. *Med Clin* 1999.
43 Seoane B, de la Iglesia F, Nicolás R, *et al*. Análisis factorial de la calidad de vida relacionada Con La salud de pacientes que ingresan en Una unidad de corta estancia médica. *Rev. méd. Chile* 2009;137.
44 Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. *Qual Life Res* 2005;14:1523–32.
45 WHO. International classification of diseases (ICD-10). *Fam Pract Manag* 2010.
46 Sherbourne CD, Stewart AL. The mos social support survey. *Soc Sci Med* 1991;32:705–14.
47 de la Revilla-Ahumada L, Luna del Castillo J. Bailón Muñoz E MMI. [Validation of a questionnaire to measured social support in Primary Care]. *Med Fam* 2005.
48 Knapp M. *Economic evaluation of mental health care*. In: Contemporary Psychiatry, 2001.
49 Vazquez-Barquero JL, Gaite L, Cuesta MJ, *et al*. Spanish version of the CSRI: A mental health cost evaluation interview. [Spanish version of the CSRI: A mental health cost evaluation interview]. *Archivos de Neurobiología* 1997.
50 Kim Y, Park I, Kang M. Convergent validity of the International physical activity questionnaire (IPAQ): meta-analysis. *Public Health Nutr* 2013;16:440–52.
51 Roman-Viñas B, Serra-Majem L, Hagströmer M, *et al*. International physical activity questionnaire: reliability and validity in a Spanish population. *Eur J Sport Sci* 2010;10:297–304.
52 Kurtze N, Rangul V, Hustvedt B-E. Reliability and validity of the International physical activity questionnaire in the Nord-Trøndelag health study (Hunt) population of men. *BMC Med Res Methodol* 2008;8:1–9.
53 Martínez-González Miguel Ángel, Corella D, Salas-Salvadó J, *et al*. Cohort profile: design and methods of the PREDIMED study. *Int J Epidemiol* 2012;41:377–85.
54 Schröder H, Fitó M, Estruch R, *et al*. A short screener is valid for assessing Mediterranean diet adherence among older Spanish men and women. *J Nutr* 2011;141:1140–5.
55 Buysse DJ, Reynolds CF, Monk TH, *et al*. The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989;28:193–213.
56 Royuela Rico A, Macías Fernández JA. *Propiedades clinimétricas de la versión castellana del Cuestionario de Pittsburgh*. Vigilia-Sueño, 1997.
57 Sherer M, Maddux JE, Mercandante B, *et al*. The self-efficacy scale: construction and validation. *Psychol Rep* 1982.
58 Hibbard JH, Stockard J, Mahoney ER, *et al*. Development of the patient activation measure (PAM): Conceptualizing and measuring activation in patients and consumers. *Health Serv Res* 2004;39:1005–26.
59 Antonovsky A. The structure and properties of the sense of coherence scale. *Soc Sci Med* 1993.
60 Sørensen K, Pelikan JM, Röthlin F, *et al*. Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). *Eur J Public Health* 2015;25:1053–8.
61 Guilera G, Barrios M, Penelo E, *et al*. Validation of the Spanish version of the irrational procrastination scale (iPS). *PLoS One* 2018;13:e0190806.
62 López-Torrecillas F, García J, Cañadas GA, *et al*. Validity of self-efficacy scale scores for a Spanish sample. *Psychol Rep* 2006;98:437–50.
63 Moreno Chico C, González de Paz L, Monforte Royo C, *et al*. Gallart fernández puebla A. Adaptación y validación de la escala de evaluación de la activación "Patient Activation Measure 13" (PAM13) en una muestra de pacientes crónicos visitados en CAP Rambla de MútuaTerrassa. *XXIV Premi d'infermeria* 2018;2018.
64 Moreno B, Alonso M, Álvaréz E. Sentido de coherencia, personalidad resistente, autoestima Y salud. *Rev Psicol la salud* 1997;9:115–37.
65 Nolasco A, Barona C, Tamayo-Fonseca N, *et al*. Health literacy: psychometric behaviour of the HLS-EU-Q16 questionnaire. *Gac Sanit [Internet]* 2018:8–11.
66 Arousal SP. Avoidant and decisional procrastinators: do they exist? *Pers Individ Dif* 2010.
67 IBM Corp. *Released. IBM SPSS statistics version 25.0*, 2017.
68 R Core Team. *R: a language and environment for statistical computing*, 2019.
69 Schulz KF, Altman DC, Moher D. Consort 2010 statement: updated guidelines for reporting parallel group randomised trials. *Ital J Public Health* 2010.
70 Van Hout BA, MJ A, Gordon GS, *et al*. And C/E-ratios alongside a clinical trial. *Health Econ* 1994;3:309–19.
71 Romero-Sanchiz P, Nogueira-Arjona R, García-Ruiz A, *et al*. Economic evaluation of a guided and unguided Internet-based CBT intervention for major depression: results from a multi-center, three-armed randomized controlled trial conducted in primary care. *PLoS One* 2017;12:e0172741.
72 Oblikue Consulting. Oblikue Database [online]. Available: http://www.oblikue.com/bddcostes/ [Accessed 29 Oct 2019].
73 Buuren S, Groothuis-Oudshoorn K. Mice: multivariate imputation by Chained. *J Stat Softw* 2011.
74 Smithson S, Pignone MP. Screening adults for depression in primary care. *Med Clin North Am* 2017;101:807–21.
75 Craven MA, Bland R. Depression in primary care: current and future challenges. *Can J Psychiatry* 2013;58:442–8.
76 Pence BW, O'Donnell JK, Gaynes BN. The depression treatment cascade in primary care: a public health perspective. *Curr Psychiatry Rep* 2012;14:328–35.
77 Nieuwsma JA, Trivedi RB, McDuffie J, *et al*. Brief psychotherapy for depression: a systematic review and meta-analysis. *Int J Psychiatry Med* 2012;43:129–51.
78 Piper WE. Underutilization of short-term group therapy: enigmatic or understandable? *Psychotherapy Research* 2008;18:127–38.
79 Simmonds-Buckley M, Kellett S, Waller G. Acceptability and efficacy of group behavioral activation for depression among adults: a meta-analysis. *Behav Ther* 2019;50:864–85.




BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

80 Biggs K, Hind D, Gossage-Worrall R, *et al*. Challenges in the design, planning and implementation of trials evaluating group interventions. *Trials* 2020;21:1–16.

BMJ Open: first published as 10.1136/bmjopen-2020-038457 on 28 December 2020. Downloaded from http://bmjopen.bmj.com/ on December 28, 2020 by guest. Protected by copyright.

**DOCUMENTO DE INFORMACIÓN PARA EL PARTICIPANTE**

**Título de la investigación: Efectividad y coste-utilidad de un programa de Estilo de Vida Mediterráneo en la prevención y tratamiento de la depresión subclínica, leve y moderada en Atención Primaria.**

**Promotor: Instituto de Salud Carlos III (Ministerio de Economía y Competitividad)**

**Investigador Principal: Bárbara Oliván Tfno: 976 761000 ext4547**

**Centro: Universidad de Zaragoza**

**1. Introducción:**

Nos dirigimos a usted para invitarle a participar en un proyecto de investigación que estamos realizando en Aragón y Mallorca, específicamente en Zaragoza, en los centros de salud de "Fuentes Norte", "Parque Goya" y "Arrabal", y en Mallorca, en los centros de salud de "Son Cladera", "Son Serra-La Vileta" y "Valldargent". Su participación es importante para obtener el conocimiento que necesitamos, pero antes de tomar una decisión debe:

- Leer este documento entero
- Entender la información que contiene el documento
- Hacer todas las preguntas que considere necesarias
- Consultar con su médico-persona de confianza
- Tomar una decisión meditada
- Firmar el consentimiento informado, si finalmente desea participar.

Si decide participar se le entregará una copia de este documento y del consentimiento firmado. Por favor, consérvelos por si lo necesitara en un futuro.

**2. ¿Por qué se le pide participar?**

Se le solicita su colaboración porque usted cumple los que criterios de inclusión en el estudio, que son: ser mayor de 18 años, padecer una depresión subclínica, leve o moderada con una duración de al menos dos meses.

En total en el estudio participarán 340 pacientes de estas características.

**3. ¿Cuál es el objeto de este estudio?**

El objetivo de este estudio es analizar si un tratamiento grupal sobre modificación de estilo de vida, sumando al tratamiento habitual prescrito por su médico de familia es eficaz en el tratamiento de su depresión.

**4. ¿Qué tengo que hacer si decido participar?**

Recuerde que su participación es voluntaria y si decide no participar esto no afectará a su asistencia o a su relación con el investigador y su equipo.

Si decide entrar en el estudio, su participación consistirá en la cumplimentación de un cuaderno de recogida de datos sobre su depresión, otras enfermedades que padezca (además de recoger talla, peso y tensión arterial), calidad de vida, si realiza la modificación de estilos de vida (realiza ejercicio, dieta que lleva, higiene del sueño, y apoyo social) y variables que influyen en realizar esta modificación de estilos de vida. Cumplimentar este cuestionario le costará aproximadamente entre cuarenta y cincuenta minutos. El primero que cumplimente será un poco más largo, ya que tenemos que comprobar que cumple los criterios para ser incluida en el estudio.

Posteriormente a esta primera evaluación, se le asignará de manera aleatoria, es decir, por azar, como si se lanzara una moneda al aire, a un grupo de tratamiento, que puede ser: un tratamiento grupal de 6 semanas de duración, con una sesión semanal de hora y media sobre modificación de estilos de vida; un tratamiento grupal igual que el anterior pero se le facilitará algún dispositivo para monitorizar su actividad física y horas de sueño; y grupo control, que no se le asignará a ningún tratamiento a parte del prescrito por su médico de familia. Estos tratamientos grupales consistirán en 6 sesiones y se harán una por semana. En estas sesiones se abordará el estilo de vida mediterráneo, es decir, explicaremos temas como la importancia de la dieta mediterránea, y que es recomendable comer, la importancia del ejercicio físico y cómo se debe realizar, de la exposición a la luz, de la higiene del sueño, de la activación conductual y social, para poder vencer la apatía, etc. Estas sesiones se desarrollarán en su centro de salud. Al principio de cada sesión, se tratará la cumplimentación y las dificultades de llevar a cabo el tema tratado en la sesión anterior durante 10-15 minutos. El audio de esta valoración será grabado para su posterior transcripción y análisis. Estas grabaciones serán guardadas por la investigadora principal (en su equipo informático) y no tendrá nadie más acceso a las mismas hasta su transcripción, momento en el cual serán destruidas. En dicha trascripción no se identificará a los/as autores/as de los contenidos y no serán utilizadas exclusivamente para analizar la cumplimentación y las dificultades encontradas en la modificación de estilos de vida.

En caso de que fuera asignado a este último, al finalizar el estudio, en caso de que los resultados lo aconsejaran, se le ofertará la posibilidad de realizar el tratamiento grupal sobre modificación de estilos de vida.

Posteriormente a esta intervención, se le realizará otra evaluación, así como a los 6 meses y al año de haber finalizado. La duración de estas evaluaciones tendrá una duración aproximada de media hora.

Se revisará su historia clínica en caso de que tenga alguna otra enfermedad como diabetes, insuficiencia cardiaca o hipercolesterolemia, para recoger valores de estas enfermedades en el último análisis de sangre que su médico de familia le haya realizado.

**5. ¿Qué riesgos o molestias supone?**

Tanto por la evaluación como por la intervención que se va a desarrollar en este estudio, usted no tiene ningún riesgo ni debería tener ninguna molestia. Los cuestionarios que se van a utilizar no implican ninguna prueba invasiva ni dolorosa, son cuestionarios ampliamente utilizados en investigación y en la práctica clínica. Tanto la evaluación como la intervención que se va a desarrollar va a estar dirigida por personal cualificado (psicólogos/as).

Si se detecta que usted está empeorando gravemente en su estado de depresión, se contactará con su médico de familia.

**6. ¿Obtendré algún beneficio por mi participación?**

Al tratarse de un estudio de investigación orientado a generar conocimiento es probable que no obtenga ningún beneficio por su participación si bien usted contribuirá al avance del conocimiento y al beneficio social. Usted no recibirá ninguna compensación económica por su participación.

**7. ¿Cómo se van a gestionar mis datos personales?**

Toda la información recogida se tratará conforme a lo establecido en la legislación vigente en materia de protección de datos de carácter personal. En la base de datos del estudio no se incluirán datos personales: ni su nombre, ni su nº de historia clínica ni ningún dato que le pueda identificar. Se le identificará por un código que sólo el equipo investigador podrá relacionar con su nombre.

Sólo el equipo investigador tendrá acceso a los datos de su historia clínica y nadie ajeno al centro podrá consultar su historial. En caso de que se necesite este acceso se debe especificar quién, con qué fin, durante qué periodo de tiempo, qué datos se van a revisar y solicitar consentimiento expreso para este acceso.

De acuerdo a lo que establece la legislación de protección de datos, usted puede ejercer los derechos de acceso, modificación, oposición y cancelación de datos. Además puede limitar el tratamiento de datos que sean incorrectos, solicitar una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado para el estudio. Para ejercitar sus derechos, diríjase al investigador principal del estudio. Así mismo tiene derecho a dirigirse a la Agencia de Protección de Datos si no quedara satisfecho.

Si usted decide retirar el consentimiento para participar en este estudio, ningún dato nuevo será añadido a la base de datos, pero sí se utilizarán los que ya se hayan recogido. En caso de que desee que se destruyan tanto los datos como las muestras ya recogidos debe solicitarlo expresamente y se atenderá a su solicitud.

Los datos codificados pueden ser transmitidos a terceros y a otros países pero en ningún caso contendrán información que le pueda identificar directamente, como nombre y apellidos, iniciales, dirección, nº de la seguridad social, etc. En el caso de que se produzca esta cesión, será para los mismos fines del estudio descrito o para su uso en publicaciones científicas pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente.

El promotor/investigador adoptará las medidas pertinentes para garantizar la protección de su privacidad y no permitirá que sus datos se crucen con otras bases de datos que pudieran permitir su identificación o que se utilicen para fines ajenos a los objetivos de esta investigación.

Las conclusiones del estudio se presentarán en congresos y publicaciones científicas pero se harán siempre con datos agrupados y nunca se divulgará nada que le pueda identificar.

**9. ¿Quién financia el estudio?**

Este proyecto se financia con fondos procedentes del Instituto de Salud Carlos III, perteneciente al Ministerio de Economía y Competitividad.

El conocimiento derivado de este estudio no es probable que genere en un futuro beneficios comerciales. No obstante, en caso de que generase estos beneficios, pertenecerían al equipo investigador. Los participantes no tendrán derecho a reclamar parte de ese beneficio.

**10. ¿Se me informará de los resultados del estudio?**

Usted tiene derecho a conocer los resultados del presente estudio, tanto los resultados generales como los derivados de sus datos específicos. También tiene derecho a no conocer dichos resultados si así lo desea. Por este motivo en el documento de consentimiento informado le preguntaremos qué opción prefiere. En caso de que desee conocer los resultados, el investigador le hará llegar los resultados.

**¿Puedo cambiar de opinión?**

Tal como se ha señalado, su participación es totalmente voluntaria, puede decidir no participar o retirarse del estudio en cualquier momento sin tener que dar explicaciones y sin que esto repercuta en su atención sanitaria. Basta con que le manifieste su intención al investigador principal del estudio.

Si usted desea retirarse del estudio se eliminarán los datos recogidos.

**¿Qué pasa si me surge alguna duda durante mi participación?**

En caso de duda o para cualquier consulta relacionada con su participación puede ponerse en contacto con el investigador responsable, Dña. Bárbara Oliván, en el teléfono 976 761000 ext 4547 en horario de mañanas o por correo electrónico en la dirección bolivan@unizar.es.

Muchas gracias por su atención, si finalmente desea participar le rogamos que firme el documento de consentimiento que se adjunta.

**DOCUMENTO DE CONSENTIMIENTO INFORMADO**

**Título del PROYECTO: Efectividad y coste-utilidad de un programa de Estilo de Vida Mediterráneo en la prevención y tratamiento de la depresión subclínica, leve y moderada en Atención Primaria.**

Yo, ..... (nombre y apellidos del participante)

He leído el documento de información que se me ha entregado.

He podido hacer preguntas sobre el estudio y he recibido suficiente información sobre el mismo.

He hablado con: .....(nombre del investigador)

Comprendo que mi participación es voluntaria.

Comprendo que puedo retirarme del estudio:

1) cuando quiera
2) sin tener que dar explicaciones
3) sin que esto repercuta en mis cuidados médicos

Presto libremente mi conformidad para participar en el estudio.

Deseo ser informado sobre los resultados del estudio: sí no (marque lo que proceda)

Doy mi conformidad para que mis datos clínicos sean revisados por personal ajeno al centro, para los fines del estudio, y soy consciente de que este consentimiento es revocable.

He recibido una copia firmada de este Consentimiento Informado.

Firma del participante: .....

Fecha: .....

He explicado la naturaleza y el propósito del estudio al paciente mencionado

Firma del Investigador: .....

Fecha:

Versión 4.0, de fecha 17/01/2020 6

$$n = \frac{\left(z_{\alpha} + z_{2\beta}\right)^2 \sigma_d^2}{(\Delta m)^2}$$

$\Delta m = 4.8$

α=0.05

β= 0.20

$z_{\alpha} = 1.96$

$z_{2\beta} = 1.28$

$\sigma_d^2 = 96.04$

**SLEEP DURATION AND SUNLIGHT**

| Day | Time to get up and go to bed | Sleep duration (hours) | Sunlight exposure (in minutes) |
|---|---|---|---|
| Monday | | | |
| Tuesday | | | |
| Wednesday | | | |
| Thursday | | | |
| Friday | | | |
| Saturday | | | |
| Sunday | | | |

**SLEEP DURATION AND SUNLIGHT**

| Day | Time to get up and go to bed | Sleep duration (hours) | Sunlight exposure (in minutes) |
|---|---|---|---|
| Monday | | | |
| Tuesday | | | |
| Wednesday | | | |
| Thursday | | | |
| Friday | | | |
| Saturday | | | |
| Sunday | | | |

**PHYSICAL ACTIVITY**

| Day | Activity | Sport | Duration (min) | Company | How do I feel next? |
|---|---|---|---|---|---|
| Monday | | | | | |
| Tuesday | | | | | |
| Wednesday | | | | | |
| Thursday | | | | | |
| Friday | | | | | |
| Saturday | | | | | |
| Sunday | | | | | |

**SLEEP DURATION AND SUNLIGHT**

| Day | Time to get up and go to bed | Sleep duration (hours) | Sunlight exposure (in minutes) |
|---|---|---|---|
| Monday | | | |
| Tuesday | | | |
| Wednesday | | | |
| Thursday | | | |
| Friday | | | |
| Saturday | | | |
| Sunday | | | |

**PHYSICAL ACTIVITY**

| Day | Activity | Sport | Duration (min) | Company | How do I feel next? |
|---|---|---|---|---|---|
| Monday | | | | | |
| Tuesday | | | | | |
| Wednesday | | | | | |
| Thursday | | | | | |
| Friday | | | | | |
| Saturday | | | | | |
| Sunday | | | | | |

**MEDITERRANEAN DIET**

| Day | Breakfast | Snack | Appetizer | Lunch | Snack | Dinner |
|---|---|---|---|---|---|---|
| Monday | | | | | | |
| Tuesday | | | | | | |
| Wednesday | | | | | | |
| Thursday | | | | | | |
| Friday | | | | | | |
| Saturday | | | | | | |
| Sunday | | | | | | |

# Manuscrito II. Effectiveness of a lifestyle modification programme in the treatment of depression symptoms in primary care.

frontiers | Frontiers in Medicine

TYPE Original Research
PUBLISHED 26 July 2022
DOI 10.3389/fmed.2022.954644

Check for updates

OPEN ACCESS

EDITED BY
Hans Olav Thulesius,
Linnaeus University, Sweden

REVIEWED BY
Harm Van Marwijk,
Brighton and Sussex Medical School, United Kingdom
Liang-Yu Chen,
Taipei Veterans General Hospital, Taiwan

*CORRESPONDENCE
María J. Serrano-Ripoll
mariajesus.serranoripoll@ibsalut.es

SPECIALTY SECTION
This article was submitted to Family Medicine and Primary Care, a section of the journal Frontiers in Medicine

RECEIVED 27 May 2022
ACCEPTED 07 July 2022
PUBLISHED 26 July 2022

CITATION
Aguilar-Latorre A, Pérez Algorta G, Navarro-Guzmán C, Serrano-Ripoll MJ and Oliván-Blázquez B (2022) Effectiveness of a lifestyle modification programme in the treatment of depression symptoms in primary care. *Front. Med.* 9:954644. doi: 10.3389/fmed.2022.954644

COPYRIGHT
© 2022 Aguilar-Latorre, Pérez Algorta, Navarro-Guzmán, Serrano-Ripoll and Oliván-Blázquez. This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY). The use, distribution or reproduction in other forums is permitted, provided the original author(s) and the copyright owner(s) are credited and that the original publication in this journal is cited, in accordance with accepted academic practice. No use, distribution or reproduction is permitted which does not comply with these terms.

## Effectiveness of a lifestyle modification programme in the treatment of depression symptoms in primary care

Alejandra Aguilar-Latorre[1], Guillermo Pérez Algorta[2], Capilla Navarro-Guzmán[3], María J. Serrano-Ripoll[4,5,6]* and Bárbara Oliván-Blázquez[1,7]

[1]Primary Healthcare Center Arrabal, Institute for Health Research Aragón (IIS Aragón), Zaragoza, Spain, [2]Division of Health Research, Faculty of Health and Medicine, Lancaster University, Lancaster, United Kingdom, [3]Department of Psychology, University of the Balearic Islands, Palma, Spain, [4]Primary Care Research Unit of Mallorca, Balearic Islands Health Services, Palma, Spain, [5]Research in Preventive Activities and Promotion and in Cancer Illes Balears (GRAPP-CAIB), Balearic Islands Health Research Institute (IdISBa), Palma, Spain, [6]Research Network on Chronicity, Primary Care and Health Promotion (RICAPPS), Barcelona, Spain, [7]Department of Psychology and Sociology, University of Zaragoza, Zaragoza, Spain

**Background:** Depression symptoms are prevalent in the general population, and their onset and continuation may be related to biological and psychosocial factors, many of which are related to lifestyle aspects. Health promotion and lifestyle modification programmes (LMPs) may be effective on reducing the symptoms. The objective of this study was to analyse the clinical effectiveness of a LMP and a LMP plus Information and Communication Technologies, when compared to Treatment as Usual (TAU) over 6 months. The interventions were offered as an adjuvant treatment delivered in Primary Healthcare Centers (PHCs) for people with depression symptoms.

**Methods:** We conducted an open-label, multicentre, pragmatic, randomized clinical trial. Participants were recruited from several PHCs. Those participants visiting general practitioner for any reason, who also met the inclusion criteria (scoring 10 to 30 points on the Beck II Self-Applied Depression Inventory) were invited to take part in the study. TAU+LMP consisted of six weekly 90-min group sessions focused on improving lifestyle. TAU+LMP + ICTs replicated the TAU+LMP format, plus the addition of a wearable smartwatch to measure daily minutes walked and sleep patterns. A total of 188 participants consented to participate in the study and were randomized. We used linear mixed models, with a random intercept and an unstructured covariance to evaluate the impact of the interventions compared to TAU.

**Results:** Both interventions showed a statistically significant reduction on depressive symptoms compared to TAU (TAU+LMP vs. TAU slope difference, b = −3.38, 95% CI= [−5.286, −1.474] $p$ = 0.001 and TAU+LMP+ICTs vs. TAU slope difference, b = −4.05, 95% CI = [−5.919, −2.197], p < 0.001). These reductions imply a moderate effect size. In the TAU+LMP+ICTs there was a significant increase regarding minutes walking per week (b = 99.77) and adherence to Mediterranean diet (b = 0.702). In the TAU+LMP there was a significant decrease regarding bad sleep quality (b = −1.24).

10.3389/fmed.2022.954644

**Conclusion:** TAU+LMPs administered in PHCs to people experiencing depression symptoms were effective on reducing these symptoms compared to TAU. They also have a positive impact on changing several lifestyle factors. These findings indicate that these interventions can be promising strategies for PHCs.

KEYWORDS

**depression, lifestyle modification, primary care, randomized controlled trial (RCT), health promotion**

## Introduction

It is estimated that 280 million people of all ages are currently experiencing depression symptoms and their impact (1). Due to its high prevalence in primary care settings (2), its treatment at this level of care is recommended (3, 4). One of the goals of primary care interventions is about educating people about healthy lifestyle habits (5). Lifestyle Modification Programmes (LMPs) can prevent the development of depression and are considered a successful treatment option (6–9). Regarding specific lifestyle factors, regular leisure-time exercise of any intensity has been shown to improve mental health and prevent depression (10, 11). Moreover, sleep disturbance is not only a manifestation of depression but can also be considered a prodromal symptom, therefore, its identification and treatment needs to be prioritized before, during and after experiencing depression (12, 13).

Spain has long been associated with the Mediterranean diet, which is regarded as one of the world's healthiest dietary patterns (14). This dietary pattern may be a safe and low-cost measure for depression prevention (15).

Additionally, facilitators of adherence to interventions, such as the use of Information and Communication Technologies (ICTs), should be considered in LMPs (16). In previous studies, the practice of monitoring behaviors in daily life has been useful to promote lifestyle changes in depressed people in primary care (17, 18). More specifically, wearable devices have been proven to be feasible and acceptable for use among overweight people with severe mental illness (19). These devices allow for monitoring behaviors in real-time in an unobtrusive way, enabling people to monitor and change their own activity (20).

Therefore, specifically, and as a novelty of this study, we combined and promoted several healthy lifestyles together (physical activity, sleep patterns and diet) in a face-to-face group format at the primary healthcare level with a longitudinal follow-up at 6 months in order to evaluate the effectiveness of the interventions over time.

The main objective is to analyse the clinical effectiveness of a TAU+LMP and an TAU+LMP with ICTs, when compared to Treatment as Usual (TAU) over 6 months, delivered in the context of in Primary Healthcare Centers (PHCs) as an adjuvant treatment for people experiencing depression symptoms. The second objective is to analyse if both interventions are similarly effective in improving the results of the lifestyle variables when compared to TAU.

## Methods and analysis

### Study design

An open-label, multicentre, pragmatic, randomized clinical trial (RCT) in three parallel groups was carried out: TAU as a control group, and TAU+LMP and TAU+LMP+ICTs as intervention groups in several PHCs.

### Sample size

To estimate the sample needed for this study, a Spanish study conducted with primary care patients with depression was considered as a proxy reference (18). Serrano-Ripoll et al. (18) reported an average score in BDI-II (21) at baseline of 24.5 points (SD 7.84). Following Button et al. (22) recommendation of considering a 17.5% reduction in the BDI-II as clinically relevant, we determined that a decrease of at least 4.28 points would be clinically significant and beneficial for people in Spain. Accepting a risk of 0.05 and a risk of 0.20 in a bilateral contrast, each treatment group required 35 participants. A final sample size of 42 people per each group was considered, with consideration of having a possible 20% withdrawal rate. The total sample size required was 126.

### Recruitment and participants

Participants were chosen from among those who visited a general practitioner (GP) at one of the participating PHCs for any reason and who also met the inclusion criteria described below. The recruiting time was 7 months (starting in April

10.3389/fmed.2022.954644

2020 and finishing in October 2020). By the end of the study, 188 patients from PHCs in two locations in Spain (Zaragoza and Mallorca) with subclinical, mild or moderate depression (scoring 10 to 30 points on the BDI-II) (21) were recruited for the study. Further details about the inclusion and exclusion criteria are available in the published protocol (23).

A computer-generated random number (24) administered by an independent researcher was used to allocate participants. All the study centers randomized patients to all conditions.

## Intervention development and evaluation

All participants received a general medical care from their GPs, which means that they received the care they usually get in PHC, which typically does not mean care from clinicians specialized in delivering mental health care (25). In Spain general medical care could be usual antidepressant treatment with psychological advice and / or psychotropic drugs by the GP (26).

Those allocated to TAU+LMP received 90-min session per week for 6 weeks conducted by an expert psychologist, which were also supplemented with PowerPoint presentations. The following topics were covered: 1) Psychoeducation on depression; 2) Behavior activation; 3) Sleep hygiene habits and careful exposure to sunlight; 4) Physical activity; 5) Adherence to the Mediterranean diet; and 6) Summary of previous sessions. TAU+LMP+ICTs replicated the TAU+LMP format, plus the addition that participants were given a wearable smartwatch and instructed to wear it to measure daily minutes walked and sleep patterns. Those participants not assigned to either of the two interventions were considering as part of TAU group (25).

A blinded research assistant gathered patient data by administering questionnaires at baseline (T0), immediately after the intervention (T1), and at six-month follow-up session (T2).

## Outcomes and measures

Data about gender, age, marital status, level of education, occupation and economic level were collected. Chronic comorbidities with prevalences >5% were also considered (arrhythmias, heart failure, ischemic cardiopathy, dyslipidemia, obesity, excess weight, vein and artery disease, cerebrovascular disease, diabetes, chronic bronchitis, chronic obstructive pulmonary disease (COPD), asthma, chronic kidney disease, hypo and hyperthyroidism, tobacco use, alcoholism, insomnia, attempted suicide, anemia, neoplasia, dementia, deafness, cataracts, glaucoma, arthrosis, osteoporosis, and back pain) (27).

The primary outcome was the severity of depressive symptoms, measured by the BDI-II. It consists of 21 questions, with higher scores indicating more severe depressive symptomatology (28). The internal consistency of the BDI-II in our sample was acceptable at baseline ($\alpha = 0.71$).

### Secondary outcomes

To analyse the effectiveness of the intervention in modifying lifestyles, physical activity was measured using the International Physical Activity Questionnaire-Short Form (IPAQ-SF) (29). It assesses the activity over the last seven days (30) and contains seven items. In our analysis, we use the minutes walking per week and the minutes seated per day.

Adherence to the Mediterranean diet was assessed using the 14-item Mediterranean Diet Adherence Screener (MEDAS), developed by the PREDIMED study group (31). It includes items related to food consumption and consumption habits. Higher scores indicate higher level of adherence (32).

Sleep quality and sleep patterns were measured using the Pittsburgh Sleep Quality Index (PSQI) (33), which consists of 19 questions about subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, sleep medication use and daytime dysfunction over the previous month. Higher scores indicate worse sleep quality (34). The internal consistency of the PSQI in our sample was acceptable at baseline ($\alpha = 0.75$).

## Ethics approval

Ethics approval was granted by the Research Ethics Committee of Aragón (CEICA, PI18/286) and the Research Ethics Committee of the Balearic Islands (IB3950/19 PI). The study was developed following the Helsinki Declaration. All of the subjects signed an informed consent form; their data were anonymized and were only used for the purposes of the study.

## Statistical analysis

Firstly, a descriptive analysis (frequencies for categorical variables; means and standard deviation for continuous variables) and a univariate analysis (one-way ANOVA for age, BDI-II, IPAQ-SF, PSQI, and MEDAS, and Chi-Square test for the remaining variables) were used to examine the data and tested whether there were baseline differences between groups after randomization. Secondly, to answer the main objective – whether there were differences between treatment groups regarding their effectiveness in reducing depression—we used Linear Mixed-Effects Models (LMEMs) (35). We specified a model with a random intercept and unstructured covariance. The parameter of interest was the interaction effect of treatment and time in a model that also included age as a covariate because it was the only baseline variable that was significantly different between groups. Cohen's d ($d$) is calculated from the estimated

10.3389/fmed.2022.954644

mean values of BDI-II and its standard deviations (SD) at baseline (36).

Moreover, to answer the second question—whether there were differences between treatment groups with respect to the improvement of lifestyle variables—we used LMEMs with the same previous components.

The statistical analysis was carried out per intention-to-treat analysis (ITT) (i.e., all participants who were randomized were included in the statistical analysis and were analyzed according to the group to which they were originally assigned) (37). The results from the trial were presented as a regression coefficient for predicting change in primary and secondary outcomes with 95% confidence intervals. LMEMs were tested against a Bonferroni-adjusted alpha level of 0.01 (0.05/5) (38). A statistical analysis was performed using the SPSS software (version 25.0) (39).

## Results

A total of 246 participants were evaluated for eligibility, with 14 of them failing to meet the inclusion criteria, 6 declining to participate because they were not interested, and 38 declining to participate because they had time incompatibility. Of the 246 initial participants, 58 (23.58%) did not participate. Finally, 188 participants were included (Figure 1).

Firstly, the descriptive analysis showed that of the 188 participants, 162 were female and 26 were male, and all participants were between 20 to 83 years old (mean age = 53.32, SD = 13.07). The univariate analysis subsequently revealed significant differences between the groups (p = 0.014) regarding age, specifically between the TAU and TAU+LMP+ICTs groups (p = 0.018), with the TAU+LMP+ICT participants being older. However, no significant differences were found between the groups in the other variables (Table 1).

Considering the raw scores of both intervention groups, there was a decrease in BDI-II at 6 months compared to baseline levels (TAU+LMP mean difference = −5.48, SD = 9.50 and TAU+LMP+ICTs mean difference = −7.71, SD = 11.52). Also, an increase in IPAQ–SF–Walking (TAU+LMP mean difference = 123.56, SD = 251.74 and TAU+LMP+ICTs mean difference = 189.88, SD = 350.99), a decrease in IPAQ–SF–Sedentarism (TAU+LMP mean difference = −2.56, SD = 167.48 and TAU+LMP+ICTs mean difference = −32.62, SD = 189.61), a decrease in PSQI (TAU+LMP mean difference = −3.21, SD = 4.36 and TAU+LMP+ICTs mean difference = −1.52, SD = 5.13) and a decrease and an increase in MEDAS (TAU+LMP mean difference = −0.21, SD = 2.15 and TAU+LMP+ICTs mean difference =0.92, SD = 1.64) (Table 2).

Secondly, the LMEM evidenced that both interventions could be clinically effective compared to TAU, as there was a significant interaction effect for both treatments and time on BDI–II (TAU+LMP vs. TAU slope difference: $b = -3.38$, 95% CI= [−5.286, −1.474] p =0.001; and TAU+LMP+ICTs vs. TAU slope difference: $b = -4.06$, 95% CI= [−5.919, −2.197], p <0.001) (Table 3). That reduction in BDI–II implies a moderate effect size in both TAU+LMP and TAU+LMP+ICTs groups ($d$ =0.671 and $d$ =0.779, respectively).

Moreover, LMEMs showed that the variables that measure lifestyle (IPAQ–SF–Walking, IPAQ–SF–Sedentarism, PSQI and MEDAS) changed differently when comparing TAU to the intervention group. Specifically, regarding IPAQ–SF–Walking, there was a significant increase in the TAU+LMP+ICTs group (TAU+LMP+ICTs vs. TAU slope difference: b = 99.778, 95% CI= [30.530, 169.026], $p = 0.005$) (Supplementary Table 1). That increase in IPAQ-SF-Walking implies a small effect size in the TAU+LMP+ICTs group ($d = 0.310$). Regarding IPAQ-SF-Sedentarism, there were no significant changes in any group (Supplementary Table 2). Regarding PSQI, there was a significant reduction in the TAU+LMP group (TAU+LMP vs. TAU slope difference: b = −1.240, 95% CI= [−2.126, −0.354], $p = 0.006$) (Supplementary Table 3). That decrease in PSQI implies a small effect size in the TAU+LMP group ($d = 0.268$). Finally, regarding MEDAS, there was a significant increase in the TAU+LMP+ICTs group (TAU+LMP+ICTs vs. TAU slope difference: b = 0.702, 95% CI= [.337, 1.066], $p < 0.001$) (Supplementary Table 4). That increase in MEDAS implies a small effect size in the TAU+LMP+ICTs group ($d = 0.040$).

## Discussion

The findings of this study indicate that over 6 months, TAU+LMPs were effective in decreasing depressive symptoms. Also, TAU+LMPs helped in the adoption of several healthier lifestyle behaviors when compared to TAU.

The findings of this study are consistent with other Spanish RCTs on psychoeducational group interventions delivered by PHC nurses for people with depression and physical comorbidity (40, 41). Furthermore, they are also consistent with a multidisciplinary online programmes that integrates evidence-based tactics from the fields of lifestyle medicine (42), as well as with a recent pilot RCT about a group-based lifestyle medicine for depression (43).

Recent meta-analyses of RCTs concluded that multi-component LMPs (with three lifestyle factors such as physical activity, nutritional advice, and sleep management) appeared to be effective in mitigating depressive symptoms (44, 45). A recent Spanish longitudinal cohort study (46), a cross-sectional study about health conditions, lifestyle factors and depression (47) and a recent meta-analysis of observational studies (48) have all shown that healthy lifestyles are associated with a reduced risk of depressive symptoms.

Regarding changes on lifestyle, reflecting a long-lasting effect of the interventions, people receiving the TAU+LMP+ICTs group significantly increased their total weekly minutes of

10.3389/fmed.2022.954644

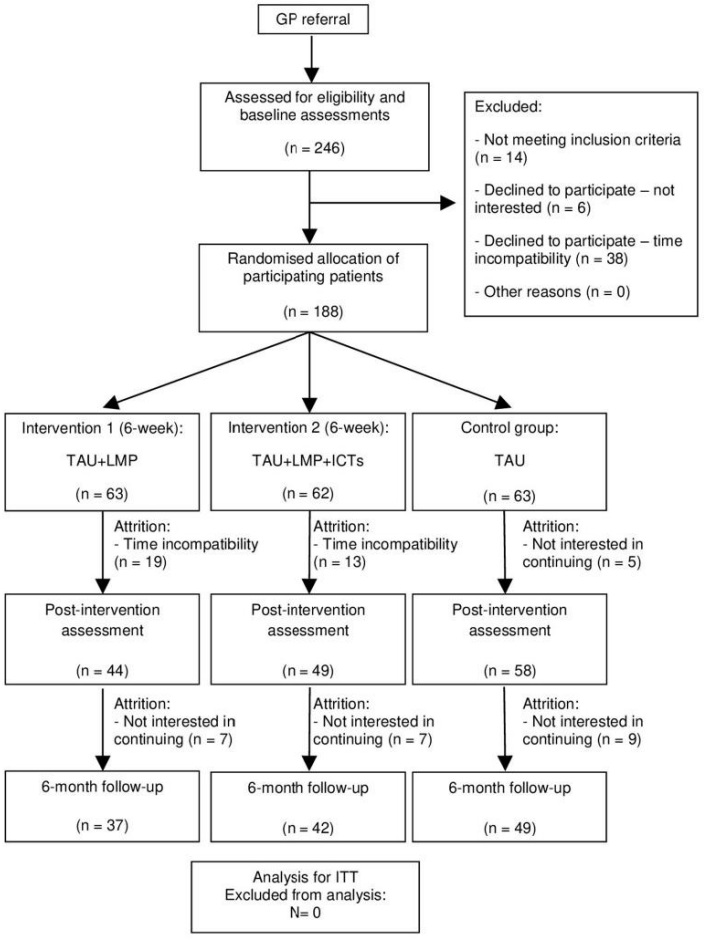



FIGURE 1
Flowchart of the study: randomization, sampling and monitoring of patients. GP, General Practitioner; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies; ITT, Intention-to-treat.

walking (approximately, 1 h and three quarters) when compared to TAU. Participants following the TAU+LMP also increased their minutes of walking (approximately 1 h), but those results only showed a certain trend toward significance. A systematic review and a meta-analysis analyzing RCTs about the treatment effect of exercise on depression (49, 50) concluded that physical exercise is an effective intervention for depression. Moreover, evidence suggests that it is not only necessary to be physically active but also to limit the number of hours spent being sedentary (51). In the same line, in a cross-sectional study with primary care patients, depression symptoms were associated with physical inactivity (52). Participants from

TABLE 1 Sociodemographic and clinical characteristics of the sample.

| Variables | Total ($n = 188$) | TAU ($n = 63$) | TAU+LMP ($n = 63$) | TAU+LMP+ICTs ($n = 62$) | $p$ |
|---|---|---|---|---|---|
| Age, *M* (*SD*) | 53.32 (13.07) | 49.54 (13.50) | 54.35 (12.97) | 56.11 (11.99) | **0.014** |
| Gender, *female n (%)* | 162 (86.2) | 52 (82.5) | 54 (85.7) | 56 (90.3) | 0.448 |
| Education | 72 (38.3) | 21 (33.3) | 22 (34.9) | 29 (46.8) | 0.241 |
| None or primary, *n (%)* | | | | | |
| Secondary or tertiary, *n (%)* | 116 (61.7) | 42 (66.7) | 41 (65.1) | 33 (53.2) | |
| Occupation | 53 (28.2) | 23 (36.5) | 17 (27) | 13 (21) | 0.150 |
| Working, *n (%)* | | | | | |
| Not working, *n (%)* | 135 (71.8) | 40 (63.5) | 46 (73) | 49 (79) | |
| Marital status | 105 (54.4) | 32 (50.8) | 34 (54) | 37 (59.7) | 0.600 |
| With a partner, *n (%)* | | | | | |
| Without a partner, *n (%)* | 88 (45.6) | 31 (49.2) | 29 (46) | 25 (40.3) | |
| Economic level | 164 (87.2) | 57 (90.5) | 51 (81) | 56 (90.3) | 0.187 |
| < 1MW to 2 IMW, *n (%)* | | | | | |
| >2 IMW, *n (%)* | 24 (12.8) | 6 (9.5) | 12 (19) | 6 (9.7) | |
| Taking antidepressants, *yes n (%)* | 132 (71.3) | 45 (71.4) | 46 (73) | 43 (69.4) | 0.776 |
| N° of chronic comorbidities, *M* (*SD*) | 4.51 (3.95) | 4.03 (4.02) | 4.41 (3.62) | 5.09 (4.18) | 0.314 |
| BDI-II, *M* (*SD*) | 24.90 (5.11) | 24.13 (5.05) | 25.00 (4.94) | 25.58 (5.29) | 0.278 |
| Number of sessions attended*, *M* (*SD*) | 4.98 (1.09) | - | 5.07 (1.02) | 4.90 (1.15) | 0.451 |
| IPAQ-SF-Walking, *M* (*SD*) | 206.46 (273.95) | 208.25 (324.92) | 233.25 (261.87) | 177.42 (226.87) | 0.524 |
| IPAQ-SF-Sedentarism, *M* (*SD*) | 289.97 (186.24) | 256.75 (212.23) | 306.67 (180.20) | 306.77 (160.72) | 0.222 |
| PSQI, *M* (*SD*) | 11.66 (4.64) | 11.57 (4.91) | 12.11 (4.34) | 11.29 (4.69) | 0.605 |
| MEDAS, *M* (*SD*) | 6.47 (1.86) | 6.41 (1.81) | 6.54 (2.08) | 6.45 (1.70) | 0.927 |

Significant differences ($p \leq 0.05$) are highlighted in bold. * Only patients in the intervention group who did not drop out were included. IMW, Interprofessional Minimum Wage. one-way ANOVA for age, n° of chronic comorbidities, BDI-II, IPAQ-SF, PSQI, and MEDAS, and Chi-Square test for the remaining variables. BDI-II, Beck II Self-Applied Depression Inventory; IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; MEDAS, Mediterranean Diet Adherence Screener; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

the TAU+LMP+ICTs group reduced their total daily minutes seated (∼45 min) almost significantly. This lack of relationship found between sedentary lifestyle and depression may be due to the fact that what the participants did while sitting was not controlled. Therefore, time spent being sedentary could have been used doing pleasant leisure activities (i.e., watching TV, reading or using the computer) (53).

An RCT associated physical activity with elevated mood and with a significant reduction in the severity of insomnia symptoms (54). In our study, there was a significant reduction in bad sleep quality among the participants from the TAU+LMP. In a recent cross-sectional study, inadequate sleep was associated with most health disabilities and major depression (55). Furthermore, a meta-analysis concluded that a lack of good sleep quality is significantly associated with depression in older adults (56), and another meta-analysis stated that certain sleep disorders (nightmares and insomnia) increase the risk of suicidal behavior in depressed patients (57).

A recent cross-sectional study observed positive associations between a healthy diet and sleep with mental health (58). Participants from the TAU+LMP+ICTs group significantly increased their adherence to the Mediterranean diet. A recent RCT determined that adherence to the Mediterranean diet was related to fewer depressive symptoms (59). A meta-analysis of RCTs determined that dietary interventions significantly reduced depressive symptoms (60). Moreover, meta-analyses of observational studies indicated that adults following a healthy dietary pattern have fewer depressive symptoms and a lower risk of developing depressive symptoms (61). In particular, adhering to the Mediterranean diet appeared to reduce the risk of depression (62).

The differences found between both interventions (TAU+LMP and TAU+LMP+ICTs) could be due to the use of the wearable smartwatch for monitoring. We have found the following advantages of its use. Firstly, the patients from the TAU+LMP+ICTs group had a more remarkable reduction in their depression and, as previously stated, this reduction of depression might be clinically relevant. Secondly, these patients had significantly increased the minutes of walking per week and they also increased their adherence to the Mediterranean diet. However, participants from this group did not have a significant improvement in their sleep quality, whereas the participants from the TAU+LMP improved their sleep. These results may have been influenced by the individual use of the

10.3389/fmed.2022.954644

TABLE 2 Outcome variables of each group in each measurement.

| Variables | TAU | TAU+LMP | TAU+LMP+ICTs |
|---|---|---|---|
| BDI-II, *M* (*SD*) | | | |
| T0 | 24.13 (5.05) | 25.00 (4.94) | 25.58 (5.29) |
| T1 | 27.45 (9.08) | 18.16 (8.53) | 19.94 (8.08) |
| T2 | 24.00 (12.72) | 18.49 (9.95) | 17.69 (11.79) |
| T1-T0 | 3.29 (7.55) | −6.43 (7.77) | −5.59 (6.74) |
| T2-T0 | −0.12 (12.06) | −5.48 (9.50) | −7.71 (11.52) |
| IPAQ-SF-walking, *M* (*SD*) | | | |
| T0 | 208.25 (324.92) | 233.25 (261.87) | 177.42 (226.87) |
| T1 | 177.93 (346.64) | 380.56 (371.98) | 367.34 (430.34) |
| T2 | 211.12 (279.09) | 368.43 (338.27) | 373.33 (351.61) |
| T1-T0 | −13.96 (410.85) | 145.34 (250.76) | 205.30 (432.34) |
| T2-T0 | 5.51 (270.41) | 123.56 (251.74) | 189.88 (350.99) |
| IPAQ-SF-sedentarism, *M* (*SD*) | | | |
| T0 | 256.75 (212.23) | 306.67 (180.20) | 306.77 (160.72) |
| T1 | 280.69 (210.17) | 240.11 (160.67) | 248.57 (150.99) |
| T2 | 302.45 (188.73) | 277.97 (172.68) | 261.67 (184.03) |
| T1-T0 | 13.96 (223.10) | −51.70 (135.25) | −52.04 (149.22) |
| T2-T0 | 49.49 (211.65) | −2.56 (167.48) | −32.62 (189.61) |
| PSQI, *M* (*SD*) | | | |
| T0 | 11.57 (4.91) | 12.11 (4.34) | 11.29 (4.69) |
| T1 | 12.29 (3.95) | 9.25 (4.12) | 10.65 (4.91) |
| T2 | 10.59 (5.74) | 8.70 (4.20) | 9.85 (5.06) |
| T1-T0 | 0.51 (3.79) | −2.68 (3.77) | −0.73 (3.25) |
| T2-T0 | −1.32 (5.11) | −3.21 (4.36) | −1.52 (5.13) |
| MEDAS, *M* (*SD*) | | | |
| T0 | 6.41 (1.81) | 6.54 (2.08) | 6.45 (1.70) |
| T1 | 5.98 (2.26) | 7.18 (1.83) | 7.20 (1.67) |
| T2 | 6.20 (1.98) | 6.78 (1.73) | 7.69 (1.52) |
| T1-T0 | −0.41 (1.69) | 0.41 (2.29) | 0.61 (1.60) |
| T2-T0 | −0.30 (1.89) | −0.21 (2.15) | 0.92 (1.64) |

BDI-II, Beck II Self-Applied Depression Inventory; IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; MEDAS, Mediterranean Diet Adherence Screener; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies; T0, Baseline assessment; T1, Post-intervention assessment; T2, Six-month follow-up.

TABLE 3 Estimates of Fixed Effects in BDI-II.

| Parameter | Estimate | 95% CI for estimated | *SE* | t | *p* |
|---|---|---|---|---|---|
| Intercept | 24.948 | [22.947, 26.949] | 1.017 | 24.524 | <0.001 |
| Time | 0.118 | [−1.158, 1.396] | 0.649 | 0.183 | 0.855 |
| Age | −0.050 | [−0.127,0.026] | 0.038 | −1.291 | 0.198 |
| TAU+LMP+ICTs | 0.307 | [−2.556, 3.171] | 1.456 | 0.211 | 0.833 |
| TAU+LMP | −0.749 | [−3.588, 2.090] | 1.443 | −0.519 | 0.604 |
| TAU+LMP+ ICTs × Time | **−4.058** | **[−5.919, −2.197]** | 0.946 | −4.289 | **<0.001** |
| TAU+LMP × Time | **−3.380** | **[−5.286, −1.474]** | 0.968 | −3.489 | **0.001** |

Significant differences ($p \leq 0.01$) are highlighted in bold. CI, confidence interval; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

smartwatch. Most of the patients from the TAU+LMP+ICTs group were very excited about using this device, however, most of them did not wear it during the night. As such, feedback about their sleep was not available. This underuse of the smartwatch could have been due to the patients' acceptance of technologies (63).

Regarding the limitations and strengths of the study, the first strength was the study's design; a pragmatic RCT with sample homogeneity between groups. As the study was developed in primary care conditions, the research results are easily transferable to practice. Another advantage is that since the randomization was blind, the evaluations and the statistical analysis provided greater validity to the results. Furthermore, and as a new characteristic, numerous aspects of healthy lifestyles were considered together and no adverse effects from the interventions were reported. In this regard, the group intervention format offered social support, a sense of belonging and the opportunity to share common difficulties (64). Finally, the participant profile was similar to regular PHC patients.

One limitation was the overlap with COVID-19 since participants found it difficult to properly implement the lifestyle guidelines during this time (65). Despite session attendance being high (5 out of the 6 sessions), another issue was the dropout rate, which was mostly due to time incompatibility or a lack of interest in answering the questionnaires during the follow-up. Furthermore, the sample was predominantly female and, as such, no analysis by gender could be performed. Finally, due to the nature of the intervention, both the psychologist who led the sessions and the participants were aware of the assigned intervention during the RCT.

Future trials with larger sample sizes could plan for subgroup analyses. For example, analyzing the effectiveness of an TAU+LMP for the different severities of depression (i.e., subclinical, mild, moderate and even severe). Moreover, recruiting more men may be beneficial to be able to make gender comparisons. Furthermore, adherence strategies (i.e., sending text messages) (66) may be considered in future RCTs. In addition, qualitative studies should be carried out to investigate the specific causes of dropout. Regarding the use of ICTs, more studies are needed to determine how to improve adherence and compliance rates so that people can wear wearable devices continuously for 24 h (20).

## Conclusion

TAU+LMPs administered in PHCs to people suffering from mainly moderate depression were effective in reducing depressive symptomatology comparing to TAU. The use of

ICTs resulted in a greater improvement in depression and in several lifestyle factors (weekly minutes of walking and adherence to the Mediterranean diet). More research is needed to enhance adherence. These promising programmes could be easily implemented in PHCs.

## Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

## Ethics statement

The studies involving human participants were reviewed and approved by Research Ethics Committee of Aragón (CEICA, PI18/286). The patients/participants provided their written informed consent to participate in this study.

## Author contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas, took part in drafting, revising or critically reviewing the article, gave final approval of the version to be published, have agreed on the journal to which the article has been submitted, and agreed to be accountable for all aspects of the work.

## Funding

This work was supported by Carlos III Health Institute grant number PI18/01336. The funders have no role in study design, data collection and analysis, decision to publish or manuscript preparation. The funding organization will audit trial conduct once a year.

## Acknowledgments

We wish to thank the Research Network on Chronicity, Primary Care and Health Promotion (RICAPPS, RD21/0016/0005) that is part of the Results-Oriented Cooperative Research Networks in Health (RICORS) (Carlos III Health Institute), the Primary Health Care Research Group of Aragon (GAIAP – B21-20R) of the Department of Science, University and Knowledge Society of the government of Aragon (Spain) and Feder Funds "Another way to make Europe". This research has been developed during a short-research term of A-AL at Lancaster University supported by *Campus de Excelencia Internacional del Valle del Ebro* (Campus Iberus), "Convenio de subvención Erasmus+ Educación Superior para prácticas Consorcio Iberus+", and *Universidad de Zaragoza*, *Fundación Bancaria Ibercaja y Fundación CAI* "Programa Ibercaja-CAI de Estancias de Investigación", grant number CM 9/21.

## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

## Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2022.954644/full#supplementary-material

## References

1. World Health Organization (WHO). *Depression*. (2021). Available online at: https://www.who.int/news-room/fact-sheets/detail/depression

2. Malhi GS, Mann JJ. Depression. *Lancet*. (2018) 392:2299–312. doi: 10.1016/S0140-6736(18)31948-2

3. Aguilera-Martín Á, Gálvez-Lara M, Cuadrado F, Moreno E, García-Torres F, Venceslá JF, et al. Cost-effectiveness and cost-utility evaluation of individual vs. group transdiagnostic psychological treatment for emotional disorders in primary care (PsicAP-Costs): a multicentre randomized controlled trial protocol. *BMC Psychiatry*. (2022) 22, 1–15. doi: 10.1186/s12888-022-03726-4

4. WHO. *International Statistical Classification of Diseases and Related Health Problems, 10th Revision ICD-10: Tabular List*. Geneva: World Health Organization (2016).

5. Malhi GS, Outhred T, Hamilton A, Boyce PM, Bryant R, Fitzgerald PB, et al. Royal australian and New Zealand college of psychiatrists clinical practice guidelines for mood disorders: Major depression summary. *Medical J Australia*. (2018) 208:175–80. doi: 10.5694/mja18.00351

6. Aguilar-Latorre A, Serrano-Ripoll MJ, Oliván-Blázquez B, Gervilla E, and Navarro C. Associations between severity of depression, lifestyle patterns, and personal factors related to health behavior: secondary

data analysis from a randomized controlled trial. *Front Psychol*. (2022) 13. doi: 10.3389/fpsyg.2022.856139

7. Forsyth A, Deane FP, Williams P. A lifestyle intervention for primary care patients with depression and anxiety : a randomised controlled trial. *Psychiatry Res*. (2015) 1–8. doi: 10.1016/j.psychres.2015.10.001

8. García-Toro M, Ibarra O, Gili M, Serrano MJ, Oliván B, Vicens E, et al. Four hygienic-dietary recommendations as add-on treatment in depression A randomized-controlled trial. *J Affect Disord*. (2012) 140:200–3. doi: 10.1016/j.jad.2012.03.031

9. Lopresti AL, Hood SD, Drummond PD. A review of lifestyle factors that contribute to important pathways associated with major depression: Diet, sleep and exercise. *J Affect Disord*. (2013) 148:12–27. doi: 10.1016/j.jad.2013.01.014

10. Harvey SB, Overland S, Hatch SL, Wessely S, Mykletun A, Hotopf M. Exercise and the prevention of depression: results of the HUNT cohort study. *Am J Psychiatry*. (2018) 175. doi: 10.1176/appi.ajp.2017.16111223

11. Lin CY, Kim B, Liao Y, Park JH. Personal, behavioral, and perceived environmental factors associated with late-life depression in older men and women. *Psychol Res Behav Manag*. (2019) 12:641–50. doi: 10.2147/PRBM.S214524

12. Asarnow LD, Soehner AM, Harvey AG. Basic sleep and circadian science as building blocks for behavioral interventions: a translational approach for mood disorders. *Behav Neurosci*. (2014) 128:360–70. doi: 10.1037/a0035892

13. Fang H, Tu S, Sheng J, Shao A. Depression in sleep disturbance: a review on a bidirectional relationship, mechanisms and treatment. *J Cell Mol Med*. (2019) 23:2324–32. doi: 10.1111/jcmm.14170

14. González-García S, Green RF, Scheelbeek PF, Harris F, Dangour AD. Dietary recommendations in Spain –affordability and environmental sustainability? *J Clean Prod*. (2020) 254. doi: 10.1016/j.jclepro.2020.120125

15. Pano O, Martínez-Lapiscina EH, Sayón-Orea C, Martinez-Gonzalez MA, Martinez JA, Sanchez-Villegas A. Healthy diet, depression and quality of life: A narrative review of biological mechanisms and primary prevention opportunities. *World J Psychiatry*. (2021) 11:997–1016. doi: 10.5498/wjp.v11.i11.997

16. NICE. *Behaviour Change: Individual Approaches*. (2014). Avavilable onlilne at: www.nice.org.uk/guidance/ph49 (accessed December 1, 2021).

17. Olivan-Blázquez B, Montero-Marin J, García-Toro M, Vicens-Pons E, Serrano-Ripoll MJ, Castro-Gracia A, et al. Facilitators and barriers to modifying dietary and hygiene behaviours as adjuvant treatment in patients with depression in primary care: A qualitative study. *BMC Psychiatry*. (2018) 18:1–12. doi: 10.1186/s12888-018-1779-7

18. Serrano-Ripoll MJ, Oliván-Blázquez B, Vicens-Pons E, Roca M, Gili M, Leiva A, et al. Lifestyle change recommendations in major depression: Do they work? *J Affect Disord*. (2015) 183. doi: 10.1016/j.jad.2015.04.059

19. Naslund JA, Aschbrenner KA, Barre LK, Bartels SJ. Feasibility of popular m-health technologies for activity tracking among individuals with serious mental Illness. *Telemed E-Health*. (2015) 21:213–6. doi: 10.1089/tmj.2014.0105

20. Lee S, Kim H, Park MJ, Jeon HJ. Current advances in wearable devices and their sensors in patients with depression. *Front Psychiat*. (2021) 12:1–8. doi: 10.3389/fpsyt.2021.672347

21. Beck A, Steer R, Ball R, Ranieri W. Comparison of beck depression 1 in psychiatric inventories—1a and - outpatients. *J Pers Assess*. (1996) 67:588–97. doi: 10.1207/s15327752jpa6703_13

22. Button K, Kounali D, Thomas L, Wiles N, Peters T, Welton N, et al. Minimal clinically important difference on the Beck Depression Inventory - II according to the patient's perspective. *Psychol Med*. (2015) 45:3269–79. doi: 10.1017/S0033291715001270

23. Aguilar-Latorre A, Navarro C, Oliván-Blázquez B, Gervilla E, Magallón Botaya R, Calafat-Villalonga C, et al. Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: a randomised clinical trial protocol. *BMJ Open*. (2020) 10. doi: 10.1136/bmjopen-2020-038457

24. Kim J, Shin W. How to do random allocation (randomization). *Clin Orthop Surg*. (2014) 6:103–9. doi: 10.4055/cios.2014.6.1.103

25. Cuijpers P, Quero S, Papola D, Cristea IA, Karyotaki E. Care-as-usual control groups across different settings in randomized trials on psychotherapy for adult depression: a meta-analysis. *Psychol Med*. (2019) 51:634–44. doi: 10.1017/S0033291719003581

26. Ministry of Health Social Services and Equality. (2014). *Clinical Practice Guideline on the Management of Major Depression in Adults. SNS Clinical Practice Guidelines*. Available online at: http://www.guideline.gov/content.aspx?id=24067&search=depression

27. Calderón-Larrañaga A, Vetrano DL, Onder G, Gimeno-Feliu LA, Coscollar-Santaliestra C, Carfi A, et al. Assessing and measuring chronic multimorbidity in the older population: a proposal for its operationalization. *J Gerontol*. (2017) 72:1417–23. doi: 10.1093/gerona/glw233

28. Sanz J, García-Vera MP, Espinosa R, Fortún M, Vázquez C, Obreg R, et al. Spanish adaptation of the Beck Depression Inventory-II (BDI-II): 3. Psychometric features in patiens with psychological disorders. *Clínica y Salud*. (2005) 16:121–42.

29. Kim Y, Park I, Kang M. Convergent validity of the International Physical Activity Questionnaire (IPAQ): meta-analysis. *In Public Health Nutrition*. (2013). doi: 10.1017/S1368980012002996

30. Roman-Viñas B, Serra-Majem L, Hagströmer M, Ribas-Barba L, Sjöström M, Segura-Cardona R. International physical activity questionnaire: Reliability and validity in a Spanish population. *Eur J Sport Sci*. (2010) 10:297–304. doi: 10.1080/17461390903426667

31. Martínez-González MÁ, Corella D, Salas-Salvadó J, Ros E, Covas MI, Fiol M, et al. Cohort profile: design and methods of the PREDIMED study. *Int J Epidemiol*. (2010) 41:377–385. doi: 10.1093/ije/dyq250

32. Schröder H, Fitó M, Estruch R, Martínez-González MA, Corella D, Salas-Salvadó J, et al. A short screener is valid for assessing mediterranean diet adherence among older Spanish men and women. *J Nutrit*. (2011) 141:1140–5. doi: 10.3945/jn.110.135566

33. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. *Psychiatry Res*. (1989). doi: 10.1037/t05178-000

34. Royuela-Rico A, Macías-Fernández JA. Propiedades clinimétricas de la versión castellana del Cuestionario de Pittsburgh. *Vigilia-Sueño*. (1997) 9:81–94.

35. Singer JD, Willett JB. *Applied Longitudinal Data Analysis: Modeling Change and Event Occurrence*. Oxford: Oxford University Press (2003).

36. Mcgough JJ, Faraone SV. Estimating the size of treatment effects: moving beyond p values. *Psychiatry*. (2009) 6:21–9.

37. McCoy CE. Understanding the intention-to-treat principle in randomized controlled trials. *West J Emerg Med*. (2017) 18:1075–8. doi: 10.5811/westjem.2017.8.35985

38. Haynes W. Bonferroni Correction. In Dubitzky W, Wolkenhauer O, Cho K-H, Yokota H, editors. *Encyclopedia of Systems Biology*. New York: Springer. (2013). doi: 10.1007/978-1-4419-9863-7_1213

39. IBM Corp. *IBM SPSS Statistics for Windows, Version 25.0*. Armonk, NY: IBM Corp (2022).

40. Casañas R, Catalán R, Raya A, Real J. Efectividad de un programa grupal psicoeducativo para la depresión mayor en atención primaria: ensayo clínico controlado aleatorizado. *Revista de La Asociación Española de Neuropsiquiatría*. (2014) 34:145–6. doi: 10.4321/S0211-57352014000100009

41. Raya-Tena A, Fernández-San-martin MI, Martin-Royo J, Casañas R, Sauch-Valmaña G, Cols-Sagarra C, et al. Effectiveness of a psychoeducational group intervention carried out by nurses for patients with depression and physical comorbidity in primary care: Randomized clinical trial. *Int J Environ Res Public Health*. (2021) 18:1–17. doi: 10.3390/ijerph18062948

42. Przybylko G, Morton D, Kent L, Morton J, Hinze J, Beamish P, et al. The effectiveness of an online interdisciplinary intervention for mental health promotion: a randomized controlled trial. *BMC Psychology*. (2021) 9:1–11. doi: 10.1186/s40359-021-00577-8

43. Ka-Yan Ip A, Yan-Yee Ho F, Yeung W-F, Chung K-F, Ng CH, Oliver G, et al. Effects of a group-based lifestyle medicine for depression: A pilot randomized controlled trial. *PLoS ONE*. (2021) 16:e0258059. doi: 10.1371/journal.pone.0258059

44. Gómez-Gómez I, Bellón J, Resurrección DM, Cuijpers P, Moreno-Peral P, Rigabert A, et al. Effectiveness of universal multiple-risk lifestyle interventions in reducing depressive symptoms: systematic review and meta-analysis. *Preventive Med*. (2020) 134:106067. doi: 10.1016/j.ypmed.2020.106067

45. Wong VWH, Ho FYY, Shi NK, Sarris J, Chung KF, Yeung WF. Lifestyle medicine for depression: a meta-analysis of randomized controlled trials. *J Affect Disord*. (2021) 284:203–16. doi: 10.1016/j.jad.2021.02.012

46. Ruiz-Estigarribia L, Martínez-González MÁ, Díaz-Gutiérrez J, Sánchez-Villegas A, Lahortiga-Ramos F, Bes-Rastrollo M. Lifestyles the risk of depression in the "Seguimiento Universidad de Navarra" cohort. *European Psychiatry*. (2019) 61:33–40. doi: 10.1016/j.eurpsy.2019.06.002

47. Cui N, Cui J, Xu X, Aslam B, Bai L, Li D, et al. Health conditions, lifestyle factors and depression in adults in qingdao, china: a cross-sectional study. *Front Psychiat. 12(May)*. (2021) 1–9. doi: 10.3389/fpsyt.2021.508810

48. Wang X, Arafa A, Liu K, Eshak ES, Hu Y, Dong JY. Combined healthy lifestyle and depressive symptoms: a meta-analysis of observational studies. *J Affect Disord*. (2021) 289:144–50. doi: 10.1016/j.jad.2021.04.030

49. Kvam S, Lykkedrang C, Hilde I, Hovland A. Exercise as a treatment for depression: A meta-analysis. *J Affect Disord.* (2016) 202:67–86. doi: 10.1016/j.jad.2016.03.063

50. Stanton R, Reaburn Exercise P, and the treatment of depression: A review of the exercise program variables. *J Sci Med Sport.* (2014) 17:177–82. doi: 10.1016/j.jsams.2013.03.010

51. De Rezende LFM, Rey-López JP, Matsudo VKR, Luiz ODC. Sedentary behavior and health outcomes among older adults: a systematic review. *BMC Public Health.* (2014) 14:1–9. doi: 10.1186/1471-2458-14-333

52. Achttien R, Van Lieshout J, Wensing M, Van Der Sanden MN, Staal JB. Symptoms of depression are associated with physical inactivity but not modified by gender or the presence of a cardiovascular disease; a cross-sectional study. *BMC Cardiovasc Disord.* (2019) 19:1–7. doi: 10.1186/s12872-019-1065-8

53. Andrade-Gómez E, García-Esquinas E, Martínez-Gómez D, Rodríguez-Artalejo F. Sedentary behaviors, physical activity, and changes in depression and psychological distress symptoms in older adults. *Depress Anxiety.* (2018) 35:884–97. doi: 10.1002/da.22804

54. Hartescu I, Morgan K, Stevinson CD. Increased physical activity improves sleep and mood outcomes in inactive people with insomnia: a randomized controlled trial. *J Sleep Res.* (2015) 24:526–34. doi: 10.1111/jsr.12297

55. Kim Y-J, Lee S-A. The relationship of lifestyle factors with the prevalence of major depressive disorder by ecological factors. *Psychiatry Investig.* (2021) 18:340–7. doi: 10.30773/pi.2020.0309

56. Becker NB, Jesus SN, João KADR, Viseu JN, Martins S. RIDepression sleep quality in older adults: a meta-analysis. *Psychology, Health and Medicine.* (2017) 22:889–95. doi: 10.1080/13548506.2016.1274042

57. Wang X, Cheng S, Xu H. Systematic review and meta-analysis of the relationship between sleep disorders and suicidal behaviour in patients with depression. *BMC Psychiatry.* (2019) 19:1–13. doi: 10.1186/s12888-019-2302-5

58. Hepsomali P, Groeger JA. Diet sleep, and mental health: insights from the uk biobank study. *Nutrients.* (2021) 13:2573. doi: 10.3390/nu13082573

59. Picard K, Senior PA, Adame Perez S, Jindal K, Richard C, Mager DR. Low Mediterranean Diet scores are associated with reduced kidney function and health related quality of life but not other markers of cardiovascular risk in adults with diabetes and chronic kidney disease. *Nutr Metab Cardiovasc Dis.* (2021) 31:1445–53. doi: 10.1016/j.numecd.2021.02.002

60. Firth J, Marx W, Dash S, Carney R, Teasdale SB, Solmi M, et al. The effects of dietary improvement on symptoms of depression and anxiety: a meta-analysis of randomized controlled trials. *Psychosom Med.* (2019) 81:265–80. doi: 10.1097/PSY.0000000000000673

61. Nicolaou M, Colpo M, Vermeulen E, Elstgeest LEM, Cabout M, Gibson-Smith D, et al. Association of a priori dietary patterns with depressive symptoms: A harmonised meta-analysis of observational studies. *Psychol Med.* (2019) 50:1872–83. doi: 10.1017/S0033291719001958

62. Lassale C, Batty GD, Baghdadli A, Jacka F, Sánchez-Villegas A, Kivimäki M, et al. Healthy dietary indices and risk of depressive outcomes: a systematic review and meta-analysis of observational studies. *Mol Psychiatry.* (2019) 24:965–86. doi: 10.1038/s41380-018-0237-8

63. Kim J, Park HA. Development of a health information technology acceptance model using consumers' health behavior intention. *J Med Internet Res.* (2012) 14:1–14. doi: 10.2196/jmir.2143

64. Guimón J. Manual de Terapias de Grupo. *Tipos, Modelos y Programas.* Madrid: Editorial Biblioteca Nueva (2003).

65. Aguilar-Latorre A, Oliván-Blázquez B, Porroche-Escudero A, Méndez-López F, García-Gallego V, Benedé-Azagra B, et al. The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain. *BMC Public Health.* (2022) 22:1–13. doi: 10.1186/s12889-022-13083-2

66. Melnyk BM, Kelly SA, Stephens J, Dhakal K, McGovern C, Tucker S, et al. Interventions to improve mental health, well-being, physical health, and lifestyle behaviors in physicians and nurses: a systematic review. *Am J Health Promot.* (2020) 34:929–41. doi: 10.1177/0890117120920451

# Supplementary

**Supplementary Table 1. Estimates of Fixed Effects in IPAQ-Walking**

| Parameter | Estimate | 95% CI for estimated | *SE* | t | *p* |
|---|---|---|---|---|---|
| Intercept | 196.860 | [119.613, 274.107] | 39.267 | 5.013 | < .001 |
| Time | 6.980 | [-40.497, 54.459] | 24.128 | .289 | .773 |
| Age | -.329 | [-3.341, 2.682] | 1.527 | -.216 | .829 |
| TAU+LMP+ICTs | 6.047 | [-104.523, 116.618] | 56.207 | .108 | .914 |
| TAU+LMP | 56.190 | [-53.383, 165.765] | 55.703 | 1.009 | .314 |
| TAU+LMP+ICTs × Time | **99.778** | **[30.530, 169.026]** | 35.195 | 2.835 | **.005** |
| TAU+LMP × Time | 61.001 | [-9.946, 131.949] | 36.063 | 1.692 | .092 |

*Note*. Significant differences (p ≤ .01) are highlighted in bold. IPAQ, Physical Activity Questionnaire; CI, confidence interval; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Supplementary Table 2. Estimates of Fixed Effects in IPAQ-Sedentarism**

| Parameter | Estimate | 95% CI for estimated | *SE* | *t* | *p* |
|---|---|---|---|---|---|
| Intercept | 254.096 | [210.366, 297.827] | 22.222 | 11.434 | < .001 |
| Time | 24.794 | [-.247, 49.835] | 12.724 | 1.948 | .052 |
| Age | -.201 | [-1.948, 1.545] | .885 | -.228 | .820 |
| TAU+LMP+ICTs | 43.470 | [-19.119, 106.059] | 31.805 | 1.367 | .173 |
| TAU+LMP | 40.656 | [-21.326, 102.640] | 31.499 | 1.291 | .198 |
| TAU+LMP+ICTs × Time | -44.318 | [-80.895, -7.740] | 18.588 | -2.384 | .018 |
| TAU+LMP × Time | -34.893 | [-72.417, 2.631] | 19.071 | -1.830 | .068 |

*Note*. IPAQ, Physical Activity Questionnaire; CI, confidence interval; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Supplementary Table 3. Estimates of Fixed Effects in PSQI**

| Parameter | Estimate | 95% CI for estimated | *SE* | t | *p* |
|---|---|---|---|---|---|
| Intercept | 11.884 | [10.758, 13.010] | .572 | 20.775 | < .001 |
| Time | -.518 | [-1.108, .070] | .299 | -1.732 | .084 |
| Age | -.011 | [-.057, .034] | .023 | -.501 | .617 |
| TAU+LMP+ICTs | -.551 | [-2.163, 1.060] | .818 | -.674 | .501 |
| TAU+LMP | -.004 | [-1.599, 1.589] | .810 | -.006 | .995 |
| TAU+LMP+ICTs × Time | -.210 | [-1.072, .652] | .438 | -.479 | .632 |
| TAU+LMP × Time | **-1.240** | **[-2.126, -.354]** | .450 | -2.755 | **.006** |

*Note*. Significant differences (p ≤ .01) are highlighted in bold. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Supplementary Table 4. Estimates of Fixed Effects in MEDAS**

| Parameter | Estimate | 95% CI for estimated | *SE* | t | *p* |
|---|---|---|---|---|---|
| Intercept | 6.441 | [5.999, 6.882] | .224 | 28.695 | < .001 |
| Time | -.159 | [-.408, .090] | .126 | -1.255 | .210 |
| Age | **.029** | **[.012, .047]** | .008 | 3.336 | **.001** |
| TAU+LMP+ICTs | -.034 | [-.666, .597] | .321 | -.108 | .914 |
| TAU+LMP | .191 | [-.434, .817] | .318 | .603 | .547 |
| TAU+LMP+ICTs * Time | **.702** | **[.337, 1.066]** | .185 | 3.793 | **< .001** |
| TAU+LMP * Time | .177 | [-.196, .551] | .189 | .934 | .351 |

*Note*. Significant differences (p ≤ .01) are highlighted in bold. MEDAS, Mediterranean Diet Adherence Screener; CI, confidence interval; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

# Manuscrito III. Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial

frontiers in Psychology

ORIGINAL RESEARCH
published: 18 March 2022
doi: 10.3389/fpsyg.2022.856139

## Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial

*Alejandra Aguilar-Latorre[1,2], Maria J. Serrano-Ripoll[2,3,4], Bárbara Oliván-Blázquez[1,2,5], Elena Gervilla[6,7] and Capilla Navarro[6]**

[1]Institute for Health Research Aragón (IIS Aragón), Zaragoza, Spain, [2]Research Network in Preventive Activities and Health Promotion (RedIAPP), Barcelona, Spain, [3]Balearic Islands Health Services, Primary Care Research Unit of Mallorca, Palma, Spain, [4]Research in Preventive Activities and Promotion and in Cancer Illes Balears (GRAPP-CAIB), Health Research Institute of the Balearic Islands (IdISBa), Palma, Spain, [5]Department of Psychology and Sociology, University of Zaragoza, Zaragoza, Spain, [6]Department of Psychology, University of the Balearic Islands, Palma, Spain, [7]Statistic and Psychometric Procedures Implemented in Health Sciences Research Group, Health Research Institute of the Balearic Islands (IdISBa), Palma, Spain

OPEN ACCESS

**Edited by:**
*Andreas Schmitt, Diabetes Zentrum Mergentheim, Germany*

**Reviewed by:**
*Hanna Kampling, Universitätsklinikum Gießen, Germany*
*Rossella Messina, University of Bologna, Italy*
*Emma Berry, Queen's University Belfast, United Kingdom*

***Correspondence:**
*Capilla Navarro*
*capilla.navarro@uib.es*

**Specialty section:**
*This article was submitted to Health Psychology, a section of the journal Frontiers in Psychology*

**Received:** *16 January 2022*
**Accepted:** *04 March 2022*
**Published:** *18 March 2022*

**Citation:**
*Aguilar-Latorre A, Serrano-Ripoll MJ, Oliván-Blázquez B, Gervilla E and Navarro C (2022) Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial. Front. Psychol. 13:856139. doi: 10.3389/fpsyg.2022.856139*

**Background:** Depression is a prevalent condition that has a significant impact on psychosocial functioning and quality of life. The onset and persistence of depression have been linked to a variety of biological and psychosocial variables. Many of these variables are associated with specific lifestyle characteristics, such as physical activity, diet, and sleep patterns. Some psychosocial determinants have an impact on people' health-related behavior change. These include personal factors such as sense of coherence, patient activation, health literacy, self-efficacy, and procrastination. This study aims to analyze the association between the severity of depression, lifestyle patterns, and personal factors related to health behavior. It also aims to analyze whether personal factors moderate the relationship between lifestyles and depression.

**Methods:** This study is a secondary data analysis (SDA) of baseline data collected at the start of a randomized controlled trial (RCT). A sample of 226 patients with subclinical, mild, or moderate depression from primary healthcare centers in two sites in Spain (Zaragoza and Mallorca) was used, and descriptive, bivariate, multivariate, and moderation analyses were performed. Depression was the primary outcome, measured by Beck II Self-Applied Depression Inventory. Lifestyle variables such as physical exercise, adherence to Mediterranean diet and sleep quality, social support, and personal factors such as self-efficacy, patient activation in their own health, sense of coherence, health literacy, and procrastination were considered secondary outcomes.

**Results:** Low sense of coherence ($\beta = -0.172$; $p < 0.001$), poor sleep quality ($\beta = 0.179$; $p = 0.008$), low patient activation ($\beta = -0.119$; $p = 0.019$), and sedentarism (more minutes seated per day; $\beta = 0.003$; $p = 0.025$) are predictors of having more depressive symptoms. Moderation analyses were not significant.

**Discussion:** Lifestyle and personal factors are related to depressive symptomatology. Our findings reveal that sense of coherence, patient's activation level, sedentarism, and sleep quality are associated with depression. Further research is needed regarding adherence to Mediterranean diet, minutes walking per week and the interrelationship between lifestyles, personal factors, and depression.

**Keywords: lifestyle, sleep quality, physical exercise, diet, personal factors, depression**

## INTRODUCTION

Depression affects an estimated 280 million people globally, making it a leading cause of disability and a major contributor to the global burden of disease [World Health Organization (WHO), 2021]. Also, depression has a significant impact on psychosocial functioning and quality of life (Malhi and Mann, 2018). The onset and persistence of depression have been linked to a variety of biological and psychosocial variables, many of which are associated with specific lifestyle characteristics (e.g., poor-quality diet, sleep disturbances, and sedentary lifestyle; Toobert et al., 2007; Hidaka, 2012; Kupfer et al., 2012; Lopresti et al., 2013). Accordingly, some healthy habits (e.g., good dietary, good sleep quality, and adequate physical activity) are linked to reduced levels of depression (Olivan-Blázquez et al., 2018; Ka-Yan Ip et al., 2021; Wong et al., 2021). Specifically, physical exercise interventions as a treatment for depression appear to have a moderate to large effect (Josefsson et al., 2014; Kvam et al., 2016). Additionally, the severity of depression and current depression diagnosis is associated with an unhealthy dietary intake, poorer dietary quality, and a lower Mediterranean diet score (Oliván-Blázquez et al., 2021). Similarly, there are also associations between mental health and having a healthy diet and a good amount of sleep (Hepsomali and Groeger, 2021). Besides that, depression positively predicted poor sleep quality over time (Wakefield et al., 2019), and likewise, sleep disorders increase the risk of suicidal behavior in depressed patients (Wang et al., 2019).

Furthermore, some personal factors are also connected to mental health. Some of these factors are self-efficacy (Sherer et al., 1982), patient activation in their own health (Hibbard et al., 2004), sense of coherence (Antonovsky, 1993), health literacy (Sørensen et al., 2015), and procrastination (Guilera et al., 2018). First, self-efficacy represents a person's confidence in their ability to self-regulate specific behaviors when confronted with various obstacles/barriers (Bandura, 1977; Sherer et al., 1982). Self-efficacy facilitates the intention to engage in preventive health behavior (Dominick et al., 2013) and is related to depression (Milanovic et al., 2018). Second, activation in their personal health is a factor present in patients with better physical and mental health, who engage in more frequent individual exercise (Hibbard et al., 2004). Patient activation is negatively associated with depression (Magnezi et al., 2014). Third, sense of coherence (SOC) is a factor that determines how well a person manages stress and stays healthy (Antonovsky, 1993), and its relationship with depression is highly reported (Konttinen et al., 2008; Giglio et al., 2015). Fourth, health literacy reflects an individual's capacity to independently engage in effective health communication and use health-related resources (Nutbeam, 2000). Individuals with adequate health literacy are more likely to participate in preventive behaviors, have more disease-specific knowledge, and have good health management skills (Dominick et al., 2013). Health literacy and depression correlate negatively (Hsu et al., 2020). Fifth, procrastination is the irrational and voluntary delaying of necessary tasks (Guilera et al., 2018) and is associated with perceived stress, depression, anxiety, and fatigue (Beutel et al., 2016). These personal factors are framed around the theory of salutogenesis (Antonovsky, 1996). The salutogenic approach aims to enhance participants' mental health and wellbeing by increasing their awareness, confidence, and ability to use their personal factors related to health behavior (Langeland and Vinje, 2016).

In light those previous associations between lifestyles, personal factors, and mental health, this study aims to analyze the association between the severity of the depression, some lifestyle patterns (physical exercise, sleep, and diet), and some personal factors related to health behavior (self-efficacy, activation in their own health, sense of coherence, health literacy, and procrastination). It also aims to analyze whether personal factors moderate the relationship between lifestyles and depression.

## METHODS AND ANALYSIS

### Study Design

This research project is a secondary data analysis (SDA; Wickham, 2019) of baseline data collected at the start of a randomized controlled trial (RCT; Aguilar-Latorre et al., 2020), whose main objective is to evaluate the effectiveness and cost-effectiveness of a lifestyle modification program in the prevention and treatment of subclinical, mild, and moderate depression in primary care settings.

### Sample Size

The sample size was established in the RCT study (Aguilar-Latorre et al., 2020). A total of 226 participants were included in this study.

### Recruitment and Participants

The selection of participants was done using individuals who consulted a general practitioner (GP) from the participating primary healthcare centers (PHCs) for any reason and who met the inclusion criteria from the RCT study. The inclusion criteria were the following: individuals over the age of 18, either male or female, scoring $\geq$10 and $\leq$30 points on the BDI-II (Beck et al., 1996), who were experiencing depression symptoms for at least 2 months, could understand written and

spoken Spanish, and also had provided their written informed consent. The exclusion criteria were the following: individuals suffering from another disease that affects the central nervous system (organic brain pathology or having suffered a traumatic brain injury of any severity, dementia); individuals with another psychiatric diagnosis or psychiatric severe illness (substance dependence or abuse, history of schizophrenia, or other psychotic disorders, eating disorders) with the exception of anxiety pathology or personality disorders [collected through a medical history and from the Mini-International Neuropsychiatric Interview (MINI; Ferrando et al., 2000)]; individuals with a severe or uncontrolled medical, infectious, or degenerative illness that may have interfered with the affective symptoms; individuals experiencing delirium or hallucinations, risk of suicide, pregnancy, or lactation; patients who had participated in another clinical trial over the past 6 months or who were in psychotherapy; individuals who practiced mindfulness, yoga, meditation, or similar practices for the preceding 6 months, and who engaged in formal training at least once a week; and the presence of any medical, psychological, or social problem that could seriously interfere with the patient's participation in the study. Recruitment started in April 2020 for a period of 7 months. A sample of 226 patients with subclinical, mild, or moderate depression was recruited from PHCs from two sites in Spain (Zaragoza and Mallorca).

Participants' data were collected in the PHCs through a structured interview carried out by Research Assistants (RA) who had received specific face-to-face training to ensure the standardization of data collection. Some RAs were involved in coding the data while others conducted the outcome assessments and data analysis. All information collected was treated following the provisions of current legislation on personal data protection.

## Study Variables

Sociodemographic data: We collected information on gender (female, male), age, marital status (without a partner: single, separated, divorced, in separation proceedings, widower or widow; and with a partner: married or living with a partner), education (none or primary and secondary or tertiary), occupation (working: active and not working: unemployment, homemaker, unpaid work, student, pensioner, sick leave, temporary job disability, permanent job disability, and other situations), and economic level (<Interprofessional Minimum Wage (IMW) to 2 IMW and >2 IMW).

Depressive symptomatology was measured using the BDI-II (Beck et al., 1996). It consists of 21 multiple-choice questions, with each response being graded on a scale ranging from 0 to 3. The validated Spanish version has a Cronbach's alpha value (α) of 0.89 (Sanz et al., 2005). The standardized cut-offs are 0–13: minimal depression; 14–19: mild depression; 20–28: moderate depression; and 29–63: severe depression. The internal consistency of the BDI-II in our sample was acceptable ($\alpha = 0.72$).

Social support was measured using the Medical Outcomes Study Social Support Survey (MOS-SS; Sherbourne and Stewart, 1991). It has 19 items, with a 5-point Likert scale, measuring four subscales (emotional/informational, tangible, affectionate, and positive social interaction) and an overall functional social support index. Higher scores indicate increased support. The validated Spanish version has good reliability ($\alpha \geq 0.91$) and has been quite stable over time (de la Revilla-Ahumada et al., 2005). The internal consistency of the MOS-SS in our sample was excellent ($\alpha = 0.95$).

Physical activity was measured using the International Physical Activity Questionnaire-Short Form (IPAQ-SF; Kim et al., 2013). It contains seven items and records the activity over the last 7 days, depending on intensity levels: vigorous-intensity activity, moderate-intensity activity, and walking and sitting. We used the validated Spanish version (Roman-Viñas et al., 2010). The IPAQ-SF had good reliability for vigorous physical activity and sitting hours, poor validity for moderate activity, and moderate reliability for walking (Kurtze et al., 2008). In our analysis, we use the minutes walking per week and the minutes seated per day.

Adherence to a Mediterranean diet was assessed using the 14-item Mediterranean Diet Adherence Screener (MEDAS), developed by the PREDIMED study group (Martínez-González et al., 2010). It includes items related to food consumption and consumption habits, such as the preference for white meat over red meat, portions of vegetables, fruit, red meat or sausages, portions of animal fat, sugar-sweetened beverages, red wine, legumes, fish, commercial pastries, and dressings made with traditional tomato sauce, garlic, onion, or leeks. The total score is between 0 and 14, with a higher score indicating better adherence to a Mediterranean diet (Schröder et al., 2011).

Quality of sleep and sleep patterns were measured using the Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989). It distinguishes between "poor" and "good" sleep by assessing seven domains: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, sleep medication use, and daytime dysfunction over the previous month. It consists of 19 self-administered questions and five questions requesting the assessment of the patient's partner or housemate (which are not scored). Responses range from 0 (no difficulty) to 3 (extreme difficulty). The total score is between 0 and 21 points. The Spanish translation has an $\alpha$ of 0.81, with a sensitivity of 88.63%, and a specificity of 74.99% (Royuela-Rico and Macías-Fernández, 1997). The internal consistency of the PSQI in our sample was acceptable ($\alpha = 0.75$).

We also assessed personal factors related to health behavior: (1) self-efficacy (Sherer et al., 1982); (2) activation (Hibbard et al., 2004); (3) sense of coherence (Antonovsky, 1993); (4) health literacy (Sørensen et al., 2015); and (5) procrastination (Guilera et al., 2018).

Self-efficacy was measured using the Self-Efficacy Scale (SES; Sherer et al., 1982), which is made up of two subscales: the General Self-Efficacy subscale (17 items assessing the individual's beliefs about their ability to perform well in various situations) and the Social Self-Efficacy subscale (6 items). It consists of 23 items, each rated on a 14-point scale (ranging from strongly agree to strongly disagree). Higher scores indicate higher levels of self-efficacy. It has an $\alpha$ value of 0.86 for the General Self-efficacy subscale and 0.71 for the Social Self-efficacy subscale. Godoy translated the unpublished Spanish version in 1990

(Lopez-Torrecillas et al., 2006). The internal consistency of the SES in our sample was good ($\alpha = 0.87$).

Patient activation in their own health was measured using the Patient Activation Questionnaire (PAM) regarding their health management (Hibbard et al., 2004). It assesses the patient's perceived knowledge, skills, and confidence to engage in self-management activities. It consists of 23 items, each rated on a 4-point scale. Higher scores indicate higher levels of activation (Hibbard et al., 2004). This scale has been validated exclusively for chronic patients in Spanish. It had an item separation index for the parameters of 6.64 and a reliability of 0.98 (Moreno Chico et al., 2018). The internal consistency of the PAM in our sample was good ($\alpha = 0.86$).

Sense of coherence was measured using the Sense of Coherence (SOC-13) questionnaire (Antonovsky, 1993). It assesses an individual's willingness to assess vital experiences. In addition, it assesses the sense of coherence, comprehensibility, manageability, and meaningfulness. It consists of 13 items, each rated on a 7-point scale. Higher scores (after reversal of the inverted items) indicate a higher sense of coherence. It has a consistency rate of 0.84 to 0.93. We used the validated Spanish version (Moreno et al., 1997). The internal consistency of the SOC-13 in our sample was acceptable ($\alpha = 0.78$).

Health Literacy was measured using the Health Literacy Europe Questionnaire (HLS-EUQ16; Sørensen et al., 2015). Health literacy refers to individual skills used to obtain, process, and understand health information and the competencies necessary to make appropriate health-related decisions. It contains 16 items, each rated on a 4-point scale. Higher scores indicate worst health literacy. Its validated Spanish version has an α value of 0.98 (Nolasco et al., 2018). The internal consistency of the HLS-EUQ16 in our sample was excellent ($\alpha = 0.91$).

Procrastination was measured using the Irrational Procrastination Scale (IPS; Steel, 2010). To measure general procrastination (the dysfunctional action of delaying or postponing something). It contains nine items, rated on a 5-point Likert scale, with higher scores (after reversal of the inverted items) indicating a higher level of procrastination. It has an $\alpha$ value of 0.90. We used the validated Spanish version (Guilera et al., 2018). The internal consistency of the IPS in our sample was good ($\alpha = 0.83$).

## Statistical Analysis

Firstly, a descriptive analysis was performed (frequencies for categorical variables; means and standard deviation for continuous variables) to determine the characteristics of the sample. Secondly, to analyze the associations between the BDI-II score and all the variables, correlations were performed using the Pearson correlation coefficient test. Thirdly, a multiple linear regression was performed (Núñez et al., 2011), using a stepwise method to obtain a better fitting result upon statistical analysis. This stepwise regression simply repeats multiple regression, deleting the least correlated variable each time (Hamilton and James, 1994). Only the significant variables obtained in the bivariate analysis were introduced in the regression model. Finally, several hierarchical multiple regression analyses were conducted to test whether depression is associated with multiple lifestyles and personal factors, and more specifically whether personal factors (SES, PAM, SOC-13, HLS-EUQ16, and IPS) moderate the relationship between lifestyles (IPAQ-SF-Walking, IPAQ-SF-Sedentarism, PSQI, and MEDAS) and depression (BDI-II). In the first steps, two variables were included as: one of the lifestyle variables and one of the personal factors. If they accounted for a significant amount of variance in BDI-II, an interaction term between them was created. Next, the interaction term between them was added to the regression model; if it accounted for a significant proportion of BDI-II, we examined the interaction plot in order to establish the direction of the relationship.

Moderation analyses were performed using Hayes's PROCESS macro (v. 3.2; Hayes, 2018) for IBM SPSS Statistics software (version 25.0; IBM Corp., 2017). Bootstrap resampling (5.000 samples) was used to estimate 95% confidence intervals. Given that heteroscedasticity is common in cross-sectional data and that our sample consisted of less than 250 subjects, all analyses included a correction for heteroscedasticity (HC3; Long and Ervin, 2000). The Johnson-Neyman technique was used to compute the range of significance and simple slopes for the interaction analyses (Hayes, 2018). We reported unstandardized regression coefficients; all analyses were two-tailed and used conventional significance thresholds ($\alpha = 0.05$). The reliability analysis was performed using the R statistical software environment (version 3.6.2; R Core Team, 2019). The descriptive, bivariate, and multivariable analysis were performed using IBM SPSS Statistics software (version 25.0; IBM Corp., 2017).

# RESULTS

## Descriptive and Bivariate Analysis

Firstly, the descriptive analysis is shown in **Table 1**. Of the 226 participants, 185 were females and 41 were males, and all participants fell between the age range of 20 to 86 years old (mean age = 53.54, SD = 13.41).

**Table 1** shows the results of the bivariate analysis of depressive symptomatology, sociodemographic variables, lifestyle variables, and personal factors. There is a significant relationship between level of depression and age (−0.147, $p = 0.027$), sedentarism (minutes seated per day; 0.136, $p = 0.042$), sleep quality (0.344, $p < 0.001$), social support (−0.193, $p = 0.004$), self-efficacy (−0.412, $p < 0.001$), patient activation in their own health (−0.333, $p < 0.001$), sense of coherence (−0.546, $p < 0.001$), health literacy (0.150, $p = 0.024$), and procrastination (0.309, $p < 0.001$). Adherence to a Mediterranean diet was not significant (−0.089, $p = 0.181$), neither were the minutes spent walking per week (0.053, $p = 0.425$), nor the rest of sociodemographic variables.

## Multivariate Analysis

Regarding the multivariate analysis, once the stepwise regression eliminated the weakest correlated variables, the remaining variables are shown in **Table 2**. Low sense of coherence ($\beta = -0.172$; $p < 0.001$), poor sleep quality ($\beta = 0.179$; $p = 0.008$), low patient activation ($\beta = -0.119$; $p = 0.019$), and sedentarism (more minutes seated per day; $\beta = 0.003$; $p = 0.025$) are predictors of having more severe

**TABLE 1** | Demographic characteristics, lifestyle variables, and personal factors of the sample.

| Variables | Total sample ($n = 226$) | Pearson correlation coefficient with BDI-II | Value of $p$ |
|---|---|---|---|
| *Gender* | | | |
| Male, *n* (%) | 41 (18.1) | 0.117 | 0.080 |
| Female, *n* (%) | 185 (81.9) | | |
| *Education* | | | |
| None or primary, *n* (%) | 87 (38.5) | –0.010 | 0.879 |
| Secondary or tertiary, *n* (%) | 139 (61.5) | | |
| *Occupation* | | | |
| Working, *n* (%) | 67 (29.6) | 0.031 | 0.644 |
| Not working, *n* (%) | 159 (70.4) | | |
| *Marital status* | | | |
| With a partner, *n* (%) | 126 (55.8) | 0.014 | 0.836 |
| Without a partner, *n* (%) | 100 (44.2) | | |
| *Economic level* | | | |
| <IMW to 2 IMW, *n* (%) | 205 (90.7) | –0.129 | 0.052 |
| >2 IMW, *n* (%) | 21 (9.3) | | |
| Age, *years*, *M* (*SD*) | 53.54 (13.41) | **–0.147** | **0.027** |
| IPAQ-SF-Walking (minutes per week), *M* (SD) | 212.32 (285.31) | 0.053 | 0.425 |
| IPAQ-SF-Sedentarism (minutes per day), *M* (*SD*) | 288.90 (185.25) | **0.136** | **0.042** |
| PSQI, *M* (*SD*) | 11.18 (4.64) | **0.344** | **<0.001** |
| MEDAS, *M* (*SD*) | 6.38 (1.85) | –0.089 | 0.181 |
| MOS-SS, *M* (*SD*) | 12.02 (3.03) | **–0.193** | **0.004** |
| SES, *M* (*SD*) | 169.38 (47.10) | **–0.412** | **<0.001** |
| PAM, *M* (*SD*) | 40.43 (6.12) | **–0.333** | **<0.001** |
| SOC-13, *M* (*SD*) | 46.31 (12.78) | **–0.546** | **<0.001** |
| HLS-EUQ16, *M* (*SD*) | 31.55 (7.14) | **0.150** | **0.024** |
| IPS, *M* (*SD*) | 28.01 (6.95) | **0.309** | **<0.001** |

*IMW, Interprofessional Minimum Wage; BDI-II, Beck II Self-Applied Depression Inventory; IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; MEDAS, Mediterranean Diet Adherence Screener; MOS-SS, Medical Outcomes Study Social Support Survey; SES, Self-Efficacy Scale; PAM, Patient Activation Questionnaire; SOC-13, Sense of Coherence questionnaire; HLS-EUQ16, Health Literacy Europe Questionnaire; and IPS, Irrational Procrastination Scale. Significant differences ($p \leq 0.05$) are highlighted in bold font.*

**TABLE 2** | Regression model of the BDI-II scores with lifestyle variables and personal factors as predictors.

| Model | Unstandardized coefficients | | Standardized coefficients | | | | Collinearity statistics | |
|---|---|---|---|---|---|---|---|---|
| | B | *SE* | Beta | *t* | Value of *p* | 95% CI for B | Tolerance | VIF |
| (Constant) | 34.297 | 2.331 | | 14.711 | **0.000** | [29.703, 38.892] | | |
| SOC-13 | **–0.172** | 0.026 | –0.421 | –6.603 | **0.000** | [–0.223, –0.120] | 0.724 | 1.381 |
| PSQI | **0.179** | 0.067 | 0.159 | 2.675 | **0.008** | [0.047, 0.310] | 0.834 | 1.199 |
| PAM | **–0.119** | 0.050 | –0.140 | –2.366 | **0.019** | [–0.218, –0.020] | 0.844 | 1.184 |
| IPAQ-SF-Sedentarism | **0.003** | 0.002 | 0.123 | 2.258 | **0.025** | [0.000, 0.006] | 0.992 | 1.008 |

*Significant differences ($p \leq 0.05$) are highlighted in bold font. CI, confidence interval. Dependent Variable: Beck II Self-Applied Depression Inventory (BDI-II). IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; PAM, Patient Activation Questionnaire; and SOC-13, Sense of Coherence questionnaire.*

depressive symptoms. This model explains 33% of the overall variance [$R^2$ adjusted = 0.336, $F(4,221) = 29.507$, $p < 0.001$].

## Moderation Analysis

Regression coefficients were obtained for the variables that showed significant results in the bivariate analysis. In each model, one of the significant lifestyle variables (PSQI or IPAQ-SF-Sedentarism) and one of the significant personal factors (SES, PAM, SOC-13, HLS-EUQ16, or IPS) were included. Next, as all the models were significant, the interaction term between them was created and added to the regression model. At this point, only the interaction between SES and PSQI was significant, so that was the only moderation worth exploring. So, to test whether SES moderates the relationship between PSQI and depression (BDI-II), hierarchical multiple regression analyses were conducted. In the first step, two variables were included as: SES and PSQI. These two variables accounted for a significant amount of depression, $R^2 = 0.226$, $F(2, 223) = 32.517$, $p < 0.001$. The interaction term between them was added to the regression model which accounted for a significant proportion of the variance in BDI-II, $\Delta R^2 = 0.014$, $\Delta F(1, 222) = 4.07$, $p < 0.001$. However, the effect only showed a tendency $b = 0.0026$, $t(222) = 1.942$, $p = 0.053$ (**Table 3**). As this moderation was not significant, the interaction plot was not examined to establish the direction of the relationship.

**TABLE 3** | Linear regression analysis of personal factors, lifestyle variables, and the interaction between them on depression.

| Variables | $R^2$ | $F(2, 223)$ | Value of $p$ | $\Delta R^2$ | $\Delta F(1, 222)$ | Value of $p$ | Interaction |
|---|---|---|---|---|---|---|---|
| SES and PSQI | 0.226 | 32.517 | **<0.001** | 0.014 | 4.07 | **<0.001** | $b = 0.0026$, $t(222) = 1.942$, $p = 0.053$ |
| PAM and PSQI | 0.198 | 27.464 | **<0.001** | 0.009 | 2.47 | 0.118 | – |
| SOC-13 and PSQI | 0.317 | 51.686 | **<0.001** | 0.007 | 2.35 | 0.127 | – |
| HLS-EUQ16 and PSQI | 0.129 | 16.570 | **<0.001** | 0.009 | 2.37 | 0.125 | – |
| IPS and PSQI | 0.180 | 24.446 | **<0.001** | 0.003 | 0.77 | 0.381 | – |
| MOS-SS and PSQI | 0.134 | 17.231 | **<0.001** | 0.136 | 0.523 | 0.470 | - |
| SES and Sedentarism | 0.189 | 25.916 | **<0.001** | 0.000 | 0.009 | 0.926 | – |
| PAM and Sedentarism | 0.128 | 16.418 | **<0.001** | 0.004 | 1.115 | 0.292 | – |
| SOC-13 and Sedentarism | 0.310 | 50.190 | **<0.001** | 0.000 | 0.074 | 0.789 | – |
| HLS-EUQ16 and Sedentarism | 0.042 | 4.88 | **<0.001** | 0.006 | 1.374 | 0.242 | – |
| IPS and Sedentarism | 0.114 | 14.309 | **<0.001** | 0.004 | 1.000 | 0.318 | – |
| MOS-SS and Sedentarism | 0.066 | 7.833 | **<0.001** | 0.070 | 1.033 | 0.311 | – |

*Dependent Variable: Beck II Self-Applied Depression Inventory (BDI-II). IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; MEDAS, Mediterranean Diet Adherence Screener; MOS-SS, Medical Outcomes Study Social Support Survey; SES, Self-Efficacy Scale; PAM, Patient Activation Questionnaire; SOC-13, Sense of Coherence questionnaire; HLS-EUQ16, Health Literacy Europe Questionnaire; and IPS, Irrational Procrastination Scale. Significant differences ($p \leq 0.05$) are highlighted in bold font.*

## DISCUSSION

This study aimed to analyze the association between the severity of the depression, lifestyle patterns (physical exercise, sleep, and diet), and personal factors related to health behavior (self-efficacy, activation in their own health, sense of coherence, health literacy, and procrastination).

Regarding the multivariate analysis, data showed that having a low sense of coherence, poor sleep quality, low patient activation, and sedentarism were predictors of having higher depressive symptomatology. Findings as such add to the body of evidence that some lifestyles and personal factors are related to depression. In line with our results, it has been widely shown that sense of coherence is inversely related to depression, presenting a protective capacity against depressive symptoms (Plata-Muñoz et al., 2004; Skärsäter et al., 2009; Anyfantakis et al., 2015; López-Martínez et al., 2019). In line with other studies, patient activation in their own health is associated with better mental health (McCusker et al., 2016) and is negatively correlated with depression (Ngooi et al., 2017). Depressive symptoms are typically accompanied by emotions of helplessness and poor quality of life, which are then related to low patient activation scores (Magnezi et al., 2014). A sedentary lifestyle is recognized as a risk factor for depression (Porras-Segovia et al., 2019) since sedentary people tend to dedicate less time to physical exercise or social activities (Zhai et al., 2015). Sleep quality has also been shown to have significant weight in explaining depression. Sleep has been linked to depression in multiple studies since a lack of sleep is one of the most frequent symptoms that appear in depression (Wang et al., 2019).

The bivariate analysis revealed that individuals with more depressive symptoms had lower age, and a lower score in social support, self-efficacy, patient activation in their own health, sense of coherence, and lower levels of health literacy. In addition, depressive symptoms were related to a more sedentary lifestyle, poor sleep quality, and more procrastination. However, no significant relationship was found with regard to the adherence to a Mediterranean diet, nor with the minutes of walking per week. Regarding adherence to a Mediterranean diet, this non-significant association could be due to the fact that the mean score obtained in our sample was 6.38. In some studies, to consider that there is optimal adherence to a Mediterranean diet pattern, the result needed to be greater than 9 (Salvatore-Benito et al., 2019; Gregório et al., 2020). This low score has been found in several studies that show how Spain and other Mediterranean-based countries are moving away from Mediterranean diet patterns (Godoy-Izquierdo et al., 2021). Regarding minutes spent walking per week, this non-significant association could be due to the fact that the mean of minutes spent walking per week in our sample was 212.32, which is more or less the amount recommended (150 min per week of moderate aerobic physical activity or a minimum of 75 min per week of vigorous aerobic activity; World Health Organization, 2010). Our sample had an adequate amount (in minutes) of physical exercise, but the predominant physical activity was walking, which is the one with the lowest intensity. Therefore, although all physical exercise provides health benefits, the frequency, intensity, and duration of the exercise have a significant influence on its benefits (World Health Organization, 2010). This relationship requires further research as the questionnaire used (IPAQ-SF) has inherent shortcomings (i.e., individuals may have had conceptual difficulty distinguishing between terms such as vigorous or moderate physical activity; people may have had certain limits recalling weekly activities; and there may have been overestimations regarding the amount of physical activity done. In any case, IPAQ-SF reliability and validity have been rigorously verified in many countries, and it is widely used in current international research (Aibar et al., 2016)).

Furthermore, this study also aimed to analyze whether personal factors moderate the relationship between lifestyles and depression. These moderation analyses were not significant. This means that in the present sample, the relationship between the lifestyles tested (sleep quality and sedentarism) and depression does not change according to the value of the different moderators (i.e., personal factors). The interrelationship between lifestyles, personal factors, and depression should be studied further, for example,

in larger sample sizes where there may be more power to detect moderation effects, by testing other types of analysis such as mediation, and/or using longitudinal data.

The present SDA study provides data for gaining knowledge and understanding into the relationships between lifestyle, personal factors, and depression. Given the results that some lifestyle and personal factors are related to depression, some programs that modify lifestyle and personal factors might be beneficial in reducing symptoms of depression. This would be in line with recent meta-analyses of RCTs of Lifestyle Modification Programs (LMPs) suggesting that LMPs might be effective in mitigating depressive symptoms (Gómez-Gómez et al., 2020; Wong et al., 2021).

## STRENGTHS

This type of research, in which various topics about healthy lifestyles and personal factors are analyzed together in their association with depression (sleep quality, physical exercise, adherence to a Mediterranean diet, self-efficacy, patient activation in their own health, sense of coherence, health literacy, and procrastination), is scarce. This study adds to the body of evidence that some lifestyles and personal factors are related to depression. In addition, the profile of the participants corresponded with the profile of those who generally attend PHCs consultations, as the majority of patients have depression, and this type of patient is usually treated in PHCs, with only a small percentage of them being referred to a specialist.

## LIMITATIONS

Even though SDAs complement primary data collection, could be a suitable starting point for some research, and are a cost-effective way of describing the current situation (McCaston, 2005), they have some limitations. For example, we are not able to make causal inferences (Wickham, 2019), and the associations identified might be difficult to interpret (Wang and Cheng, 2020). Because this is an exploratory SDA of an RCT, there were no sample size estimates or *p*-value adjustments. So, the findings must be interpreted with caution and should only be regarded as preliminary signs that should be studied further.

## CONCLUSION

Depression is a common pathology worldwide. Lifestyle and personal factors are related to depressive symptomatology. Our findings reveal that sense of coherence, the patient's activation level, sedentarism, and sleep quality are associated with depression. Further research is needed regarding adherence to Mediterranean diet, minutes walking per week and the interrelationship between lifestyles, personal factors, and depression.

## DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

## ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Research Ethics Committee of Aragón (CEICA, PI18/286) and the Research Ethics Committee of the Balearic Islands (IB3950/19 PI). The patients/participants provided their written informed consent to participate in this study.

## AUTHOR CONTRIBUTIONS

BO-B, MS-R, and CN: conceptualization and supervision. AA-L: data curation, software, and visualization. AA-L and EG: formal analysis and methodology. BO-B: funding acquisition, project administration, and validation. AA-L, BO-B, MS-R, and CN: investigation. AA-L and BO-B: writing—original draft. EG, MS-R, and CN: writing—review and editing. All authors contributed to the article and approved the submitted version.

## FUNDING

This work was supported by Carlos III Health Institute grant number PI18/01336. The funders have no role in study design, data collection and analysis, decision to publish, and manuscript preparation. The funding body will conduct an audit trail once a year.

## ACKNOWLEDGMENTS

We wish to thank the Primary Care Prevention and Health Promotion Network (RedIAPP-Health Institute Carlos III, Spain), Primary Health Care Research Group of Aragon (GAIAP—B21-20R) of the Department of Science, University and Knowledge Society of the Aragon (Spain) government, and Feder Funds "Another way to make Europe."

## REFERENCES

Aguilar-Latorre, A., Navarro, C., Oliván-Blázquez, B., Gervilla, E., Magallón Botaya, R., Calafat-Villalonga, C., et al. (2020). Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol. *BMJ Open* 10:e038457. doi: 10.1136/bmjopen-2020-038457

Aibar, A., García-González, L., Abarca-Sos, A., Burillo, B., and Zaragoza-Casterad, J. (2016). Analizando la validación del IPAQ en jóvenes adolescentes: un protocolo modificado para la recogida de datos. *Revista Euroamericana de Ciencias Del Deporte* 5, 123–132. doi: 10.6018/264761

Antonovsky, A. (1993). The structure and properties of the sense of coherence scale. *Soc. Sci. Med.* 36, 725–733. doi: 10.1016/0277-9536(93)90033-Z

Antonovsky, A. (1996). The salutogenic model as a theory to guide health promotion. *Health Promot. Int.* 11, 11–18. doi: 10.1093/heapro/11.1.11

Anyfantakis, D., Symvoulakis, E. K., Linardakis, M., Shea, S., Panagiotakos, D., and Lionis, C. (2015). Effect of religiosity/spirituality and sense of coherence on depression within a rural population in Greece: the Spili III project. *BMC Psychiatry* 15, 1–7. doi: 10.1186/s12888-015-0561-3

Bandura, A. (1977). Self-efficacy: toward a unifying theory of behavioral change. *Psychol. Rev.* 84, 191–215. doi: 10.1037/0033-295X.84.2.191

Beck, A., Steer, R., Ball, R., and Ranieri, W. (1996). Comparison of beck depression 1 in psychiatric inventories -1A and - outpatients. *J. Pers. Assess.* 67, 588–597. doi: 10.1207/s15327752jpa6703

Beutel, M. E., Klein, E. M., Aufenanger, S., Brähler, E., Dreier, M., Müller, K. W., et al. (2016). Procrastination, distress and life satisfaction across the age range – a German representative community study. *PLoS One* 11, 1–12. doi: 10.1371/journal.pone.0148054

Buysse, D. J., Reynolds, C. F., Monk, T. H., Berman, S. R., and Kupfer, D. J. (1989). The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. *Psychiatry Res.* 28, 193–213. doi: 10.1016/0165-1781(89)90047-4

de la Revilla-Ahumada, L., Luna del Castillo, J., and Bailón Muñoz, E. (2005). Validation of a questionnaire to measured social support in primary care. *Medicina de Familia* 6, 10–18. https://www.samfyc.es/wp-content/uploads/2018/07/v6n1.pdf (accessed 1 March 2022).

Dominick, G. M., Dunsiger, S. I., Pekmezi, D. W., and Marcus, B. H. (2013). Health literacy predicts change in physical activity self-efficacy among sedentary Latinas. *J. Immigr. Minor. Health* 15, 533–539. doi: 10.1007/s10903-012-9666-7

Ferrando, L., Bobes, J., and Gibert, J. (2000). MINI. Mini International Neuropsychiatric Interview. Versión en Español 5.0.0 DSM-IV. Instrumentos de Detección y Orientación Diagnóstica.

Giglio, R. E., Rodriguez-Blazquez, C., De Pedro-Cuesta, J., and Forjaz, M. J. (2015). Sense of coherence and health of community-dwelling older adults in Spain. *Int. Psychogeriatr.* 27, 621–628. doi: 10.1017/S1041610214002440

Godoy-Izquierdo, D., Ogallar, A., Lara, R., Rodríguez-Tadeo, A., and Arbinaga, F. (2021). Association of a mediterranean diet and fruit and vegetable consumption with subjective well-being among adults with overweight and obesity. *Nutrients* 13, 1–14. doi: 10.3390/nu13041342

Gómez-Gómez, I., Bellón, J., Resurrección, D. M., Cuijpers, P., Moreno-Peral, P., Rigabert, A., et al. (2020). Effectiveness of universal multiple-risk lifestyle interventions in reducing depressive symptoms: systematic review and meta-analysis. *Prev. Med.* 134:106067. doi: 10.1016/j.ypmed.2020.106067

Gregório, M. J., Rodrigues, A. M., Salvador, C., Dias, S. S., de Sousa, R. D., Mendes, J. M., et al. (2020). Validation of the telephone-administered version of the mediterranean diet adherence screener (Medas) questionnaire. *Nutrients* 12, 1–13. doi: 10.3390/nu12051511

Guilera, G., Barrios, M., Penelo, E., Morin, C., Steel, P., and Gómez-Benito, J. (2018). Validation of the spanish version of the irrational procrastination scale (IPS). *PLoS One* 13:e0190806. doi: 10.1371/journal.pone.0190806

Hamilton, J. D., and James, D. (1994). *Time Series Analysis*. Princeton, NJ: Princeton University Press.

Hayes, A. F. (2018). Introduction to Mediation, Moderation, and Conditional Process Analysis: A Regression-Based Approach. eds. D. A., Kenny and T. D., Little (New York, NY: The Guilford Press).

Hepsomali, P., and Groeger, J. A. (2021). Diet, sleep, and mental health: insights from the UK biobank study. *Nutrients* 13:2573. doi: 10.3390/nu13082573

Hibbard, J. H., Stockard, J., Mahoney, E. R., and Tusler, M. (2004). Development of the patient activation measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv. Res.* 39, 1005–1026. doi: 10.1111/j.1475-6773.2004.00269.x

Hidaka, B. H. (2012). Depression as a disease of modernity: explanations for increasing prevalence. *J. Affective Disord.* 140, 205–214. doi: 10.1016/j.jad.2011.12.036

Hsu, Y. L., Su, D. H., and Kuo, S. C. (2020). Health literacy and depression in women with type 2 diabetes mellitus. *Clinics* 75, 1–7. doi: 10.6061/clinics/2020/e1436

IBM Corp. (2017). *IBM SPSS Statistics for Windows, Version 25.0.* Armonk, NY: IBM Corp.

Josefsson, T., Lindwall, M., and Archer, T. (2014). Physical exercise intervention in depressive disorders: meta-analysis and systematic review. *Scand. J. Med. Sci. Sports* 24, 259–272. doi: 10.1111/sms.12050

Ka-Yan Ip, A., Yan-Yee Ho, F., Yeung, W.-F., Chung, K.-F., Ng, C. H., Oliver, G., et al. (2021). Effects of a group-based lifestyle medicine for depression: a pilot randomized controlled trial. *PLoS One* 16:e0258059. doi: 10.1371/journal.pone.0258059

Kim, Y., Park, I., and Kang, M. (2013). Convergent validity of the international physical activity questionnaire (IPAQ): meta-analysis. *Public Health Nutr.* 16, 440–452. doi: 10.1017/S1368980012002996

Konttinen, H., Haukkala, A., and Uutela, A. (2008). Comparing sense of coherence, depressive symptoms and anxiety, and their relationships with health in a population-based study. *Soc. Sci. Med.* 66, 2401–2412. doi: 10.1016/j.socscimed.2008.01.053

Kupfer, D. J., Frank, E., and Phillips, M. L. (2012). Major depressive disorder: new clinical, neurobiological, and treatment perspectives. *Lancet* 379, 1045–1055. doi: 10.1016/S0140-6736(11)60602-8

Kurtze, N., Rangul, V., and Hustvedt, B. E. (2008). Reliability and validity of the international physical activity questionnaire in the Nord-Trøndelag health study (HUNT) population of men. *BMC Med. Res. Methodol.* 8, 1–9. doi: 10.1186/1471-2288-8-63

Kvam, S., Lykkedrang, C., Hilde, I., and Hovland, A. (2016). Exercise as a treatment for depression: a meta-analysis. *J. Affective Disord. J.* 202, 67–86. doi: 10.1016/j.jad.2016.03.063

Langeland, E., and Vinje, H. F. (2016). "The application of Salutogenesis in mental healthcare settings," in *The Handbook of Salutogenesis*. eds. M. Mittelmark, S. Sagy, M. Eriksson, G. Bauer, J. Pelikan, B. Lindström and G. Espnes (Berlin: Springer International Publishing), 299–305.

Long, J. S., and Ervin, L. H. (2000). Using heteroscedasticity consistent standard errors in the linear regression model. *Am. Stat.* 53, 276–281. doi: 10.1080/00031305.1999.10474474

López-Martínez, C., Frías-Osuna, A., and del-Pino-Casado, R., (2019). Sense of coherence and subjective overload, anxiety and depression in caregivers of elderly relatives. *Gac. Sanit.* 33, 185–190. doi: 10.1016/j.gaceta.2017.09.005

Lopez-Torrecillas, F., García, J., Cañadas, G. A., Ramirez Ucles, I., and de la Fuente, E. I. (2006). Validity of self-efficacy scale scores for a Spanish sample. *Psychol. Rep.* 98, 437–450. doi: 10.2466/pr0.98.2.437-450

Lopresti, A. L., Hood, S. D., and Drummond, P. D. (2013). A review of lifestyle factors that contribute to important pathways associated with major depression: diet, sleep and exercise. *J. Affect. Disord.* 148, 12–27. doi: 10.1016/j.jad.2013.01.014

Magnezi, R., Glasser, S., Shalev, H., Sheiber, A., and Reuveni, H. (2014). Patient activation, depression and quality of life. *Patient Educ. Couns.* 94, 432–437. doi: 10.1016/j.pec.2013.10.015

Malhi, G. S., and Mann, J. J. (2018). Depression. *Lancet* 392, 2299–2312. doi: 10.1016/S0140-6736(18)31948-2

Martínez-González, M. Á., Corella, D., Salas-Salvadó, J., Ros, E., Covas, M. I., Fiol, M., et al. (2010). Cohort profile: design and methods of the PREDIMED study. *Int. J. Epidemiol.* 41, 377–385. doi: 10.1093/ije/dyq250

McCaston, K. (2005). Tips for collecting, reviewing, and analyzing secondary data. Available at: https://www.ands.org.au/__data/assets/pdf_file/0003/713235/Tips_for_Collecting_Reviewing_and_Analyz.pdf

McCusker, J., Lambert, S. D., Cole, M. G., Ciampi, A., Strumpf, E., Freeman, E. E., et al. (2016). Activation and self-efficacy in a randomized trial of a depression self-care intervention. *Health Educ. Behav.* 43, 716–725. doi: 10.1177/1090198116637601

Milanovic, M., Ayukawa, E., Usyatynsky, A., Holshausen, K., and Bowie, C. R. (2018). Self efficacy in depression: bridging the gap between competence and real world functioning. *J. Nerv. Ment. Dis.* 206, 350–355. doi: 10.1097/NMD.0000000000000804

Moreno, B., Alonso, M., and Álvaréz, E. (1997). Sentido de coherencia, personalidad resistente, autoestima y salud. *Revista de Psicología de La Salud* 9, 115–137.

Moreno Chico, C., González de Paz, L., Monforte Royo, C., Navarro Rubio, M. D., and Gallart Fernández Puebla, A. (2018). Adaptación y validación de la escala de evaluación de la activación "Patient Activation Measure 13" (PAM13) en una muestra de pacientes crónicos visitados en CAP Rambla de MútuaTerrassa. XXIV Premi d'infermeria 2018.

Ngooi, B. X., Packer, T. L., Kephart, G., Warner, G., Koh, K. W. L., Wong, R. C. C., et al. (2017). Validation of the patient activation measure (PAM-13) among

adults with cardiac conditions in Singapore. *Qual. Life Res.* 26, 1071–1080. doi: 10.1007/s11136-016-1412-5

Nolasco, A., Barona, C., Tamayo-Fonseca, N., Irles, M. Á., Más, R., Tuells, J., et al. (2018). Health literacy: psychometric behaviour of the HLS-EU-Q16 questionnaire. *Gac. Sanit.* 34, 399–402. doi: 10.1016/j.gaceta.2018.08.006

Núñez, E., Steyerberg, E., and Núñez, J. (2011). Estrategias para la elaboración de modelos estadisticos de regresión. *Rev. Esp. Cardiol.* 64, 501–507. doi: 10.1016/j.recesp.2011.01.019

Nutbeam, D. (2000). Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot. Int.* 15, 259–267. doi: 10.1093/heapro/15.3.259

Oliván-Blázquez, B., Aguilar-Latorre, A., Motrico, E., Gómez-Gómez, I., Zabaleta-del-Olmo, E., Couso, S., et al. (2021). The relationship between adherence to the Mediterranean diet, intake of specific foods and depression in an adult population (45–75 years) in primary health care. A cross-sectional descriptive study. *Nutrients* 13, 1–17. doi: 10.3390/NU13082724

Olivan-Blázquez, B., Montero-Marin, J., García-Toro, M., Vicens-Pons, E., Serrano-Ripoll, M. J., Castro-Gracia, A., et al. (2018). Facilitators and barriers to modifying dietary and hygiene behaviours as adjuvant treatment in patients with depression in primary care: A qualitative study. *BMC Psychiatry* 18, 1–12. doi: 10.1186/s12888-018-1779-7

Plata-Muñoz, M. E., Castillo-Olivares, M. E., and Guevara-López, U. M. (2004). Evaluación de afrontamiento, depresión, ansiedad e incapacidad funcional en pacientes con dolor crónico. *Revista Mexicana de Anestesiologia* 27, 16–23. https://www.medigraphic.com/pdfs/rma/cma-2004/cma041d.pdf (accessed 1 March 2022).

Porras-Segovia, A., Rivera, M., Molina, E., López-Chaves, D., Gutiérrez, B., and Cervilla, J. (2019). Physical exercise and body mass index as correlates of major depressive disorder in community-dwelling adults: results from the PISMA-ep study. *J. Affect. Disord.* 251, 263–269. doi: 10.1016/j.jad.2019.01.050

R Core Team. (2019). R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing. Available at: http://www.r-project.org/

Roman-Viñas, B., Serra-Majem, L., Hagströmer, M., Ribas-Barba, L., Sjöström, M., and Segura-Cardona, R. (2010). International physical activity questionnaire: reliability and validity in a Spanish population. *Eur. J. Sport Sci.* 10, 297–304. doi: 10.1080/17461390903426667

Royuela-Rico, A., and Macías-Fernández, J. A. (1997). *Propiedades clinimétricas de la versión castellana del Cuestionario de Pittsburgh* Vigilia-Sueño.

Salvatore-Benito, A., Valero Zanuy, M. Á., Alarza Cano, M., Ruiz Alonso, A., Alda Bravo, I., Rogero Blanco, E., et al. (2019). Adherence to Mediterranean diet: a comparison of patients with head and neck cancer and healthy population. Endocrinologia, Diabetes y. *Nutricion* 66, 417–424. doi: 10.1016/j.endinu.2018.12.002

Sanz, J., García-Vera, M. P., Espinosa, R., Fortún, M., Vázquez, C., Obreg, R., et al. (2005). Spanish adaptation of the Beck depression inventory-II (BDI-II): 3. psychometric features in patiens with psychological disorders. *Clínica Salud* 32, 235–242. doi: 10.4067/S0718-48082014000300006

Schröder, H., Fitó, M., Estruch, R., Martínez-González, M. A., Corella, D., Salas-Salvadó, J., et al. (2011). A short screener is valid for assessing Mediterranean diet adherence among older Spanish men and women. *J. Nutr.* 141, 1140–1145. doi: 10.3945/jn.110.135566

Sherbourne, C. D., and Stewart, A. L. (1991). The MOS social support survey. *Soc. Sci. Med.* 32, 705–714. doi: 10.1016/0277-9536(91)90150-B

Sherer, M., Maddux, J. E., Mercandante, B., Prentice-Dunn, S., Jacobs, B., and Rogers, R. W. (1982). The self-efficacy scale: construction and validation. *Psychol. Rep.* 51, 663–671. doi: 10.2466/pr0.1982.51.2.663

Skärsäter, I., Rayens, M. K., Peden, A., Hall, L., Zhang, M., Ågren, H., et al. (2009). Sense of coherence and recovery from major depression: a 4-year follow-up. *Arch. Psychiatr. Nurs.* 23, 119–127. doi: 10.1016/j.apnu.2008.04.007

Sørensen, K., Pelikan, J. M., Röthlin, F., Ganahl, K., Slonska, Z., Doyle, G., et al. (2015). Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). *Eur. J. Pub. Health* 25, 1053–1058. doi: 10.1093/eurpub/ckv043

Steel, P. (2010). Arousal, avoidant and decisional procrastinators: do they exist? *Personal. Individ. Differ.* 48, 926–934. doi: 10.1016/j.paid.2010.02.025

Toobert, D. J., Glasgow, R. E., Strycker, L. A., Barrera, M., Ritzwoller, D. P., and Weidner, G. (2007). Long-term effects of the Mediterranean lifestyle program: a randomized clinical trial for postmenopausal women with type 2 diabetes. *Int. J. Behav. Nutr. Phys. Act.* 4:1. doi: 10.1186/1479-5868-4-1

Wakefield, J. R. H., Bowe, M., Kellezi, B., Butcher, A., and Groeger, J. A. (2019). Longitudinal associations between family identification, loneliness, depression, and sleep quality. *Br. J. Health Psychol.* 25, 1–16. doi: 10.1111/bjhp.12391

Wang, X., and Cheng, Z. (2020). Cross-sectional studies: strengths, weaknesses, and recommendations. *Chest* 158, S65–S71. doi: 10.1016/j.chest.2020.03.012

Wang, X., Cheng, S., and Xu, H. (2019). Systematic review and meta-analysis of the relationship between sleep disorders and suicidal behaviour in patients with depression. *BMC Psychiatry* 19, 303–313. doi: 10.1186/s12888-019-2302-5

Wickham, R. J. (2019). Secondary analysis research. *J. Adv. Pract. Oncol.* 10, 395–400. doi: 10.6004/jadpro.2019.10.4.7

Wong, V. W. H., Ho, F. Y. Y., Shi, N. K., Sarris, J., Chung, K. F., and Yeung, W. F. (2021). Lifestyle medicine for depression: a meta-analysis of randomized controlled trials. *J. Affect. Disord.* 284, 203–216. doi: 10.1016/j.jad.2021.02.012

World Health Organization. (2010). Global Recommendations on Physical Activity for Health (World Health Organization (ed.)). http://www.who.int/dietphysicalactivity/factsheet_recommendations/en/

World Health Organization (WHO). (2021). Depression. https://www.who.int/news-room/fact-sheets/detail/depression

Zhai, L., Zhang, Y., and Zhang, D. (2015). Sedentary behaviour and the risk of depression: a meta-analysis. *Br. J. Sports Med.* 49, 705–709. doi: 10.1136/bjsports-2014-093613

**Conflict of Interest:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

**Publisher's Note:** All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

*Copyright © 2022 Aguilar-Latorre, Serrano-Ripoll, Oliván-Blázquez, Gervilla and Navarro. This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY). The use, distribution or reproduction in other forums is permitted, provided the original author(s) and the copyright owner(s) are credited and that the original publication in this journal is cited, in accordance with accepted academic practice. No use, distribution or reproduction is permitted which does not comply with these terms.*

# Manuscrito IV. The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain

Aguilar-Latorre *et al. BMC Public Health* (2022) 22:780
https://doi.org/10.1186/s12889-022-13083-2

BMC Public Health

RESEARCH Open Access

## The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain

Alejandra Aguilar-Latorre[1], Bárbara Oliván-Blázquez[1,2*], Ana Porroche-Escudero[3], Fátima Méndez-López[1], Valentín García-Gallego[1], Belén Benedé-Azagra[1,2] and Rosa Magallón-Botaya[1,4,5]

**Abstract**

**Background and purpose:** The impact of COVID-19 and its control measures have exacerbated existing mental health conditions. Although the deleterious effects of mental health problems are well known, fewer studies have examined the links between the Social Determinants of Health (SDHs) and depression. This study provides insights into the relationship between SDHs and depression during the first strict lockdown in Spain, which lasted for a period of 7 weeks.

**Methods:** Fifty-two structured interviews were conducted with people diagnosed with depression during June 2020 in the province of Zaragoza (Spain). Interviews were conducted by telephone due to lockdown constraints. Inductive thematic content analysis was used to explore, develop, and define emergent categories of analysis, which were mapped against the SDH framework.

**Results:** Listening to people's experiences of living with depression during lockdown provided insights into their concerns and coping strategies, which are greatly influenced by the conditions in which they live, their job and their age. Examples of these factors include access to and quality of physical spaces, including housing conditions and public spaces for socialising, social support, adverse working conditions which include caring responsibilities, and access to digital technologies and healthcare services.

**Conclusion:** SDHs have played a fundamental role in shaping people's health and well-being during the COVID-19 pandemic, and this study has shown that they have a considerable effect on depression outcomes. Governments should consider implementing social welfare programs to tackle both psychosocial problems and material need during crisis situations.

**Keywords:** Social determinants of health, Depression, COVID-19, Qualitative study

### Introduction

Depression is considered to be the main worldwide cause of disability, contributing to the overall global burden of morbidity and mortality. By 2030, it is expected to be the main contributor to the burden of morbidity [1–3]. The onset and continuation of depression has been linked to numerous biological and psychosocial factors, many of which are related to different aspects of lifestyle [4]. Individual lifestyles are embedded in social and community networks and living and working conditions, related to the broader cultural and socio-economic environment [5]. Socio-economic status, education, neighbourhood and physical environment, employment, and social

*Correspondence: bolivan@unizar.es
[2] Department of Psychology and Sociology, University of Zaragoza, Zaragoza, Spain
Full list of author information is available at the end of the article

© The Author(s) 2022. **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit http://creativecommons.org/licenses/by/4.0/. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated in a credit line to the data.

support networks, as well as access to healthcare, are all Social Determinants of Health (SDHs) [6, 7]. SDHs have proven crucial for our mental health [5, 8]. Addressing SDHs is essential to improving health and reducing inequalities in health and healthcare [9]. Social analysis of health problems was evidenced in the Lalonde Report of Canada in 1974 [10]. This report proposed that we understand health as a fundamental human right, accepting the following as fundamental conditions for health: peace, education, housing, food, income, a stable ecosystem, social justice and equity [11, 12].

The coronavirus disease 2019 (COVID-19) caused by Severe Acute Respiratory Syndrome SARS-CoV-2 has caused a devastating and unprecedented worldwide health, social and economic crisis [13, 14]. Governments around the world have implemented wide-ranging public health emergency measures to cope with rapidly spreading outbreaks. These measures have included self-isolation, curfews and stay-at-home orders, physical distancing, travel restrictions, as well as the closing of borders, schools, stores, restaurants, and workplaces, as well as the cancellation of public events [15, 16].

The impact of COVID-19 and its control measures on mental well-being cannot be underestimated. Amounting evidence suggests that the pandemic has exacerbated existing mental health conditions and triggered new ones [17–20]. Physical distancing measures and social isolation have been linked to common psychological symptoms such as boredom, stress, anxiety, depression, disrupted sleep and feelings of helplessness [21–23]. It is well established that social support provides important social, emotional, and material resources, and in doing so offers a buffer against distress [24]. Thus, long periods of uncertainty and insecurity, compounded by loneliness and isolation, have been significantly associated with mental disorders and poor mental well-being [25].

Socially vulnerable groups hit harder by COVID-19 include those with pre-existing mental disorders and chronic physical diseases, frontline workers, infected or suspected patients, those living in areas with high incidence, and those who are financially less well-off [26]. It is increasingly demonstrable that SDHs such as working and living conditions, including the physical environment (e.g., housing), have had a considerable impact on mental health. SDHs have interacted with gender [27], ethnicity, class and other factors to increase COVID-19 related inequalities [28, 29]. For instance, people living in socio-economically disadvantaged neighbourhoods tend to work in low-income jobs which often entail physical proximity to other people, direct contact with the public or a lack of power to demand safe protective equipment or sick leave, thus increasing exposure to risk [30]. These people are also more likely to live in poorer quality housing (e.g. poor ventilation; poor control over housing conditions in rented flats) with higher density occupancy, which also increases the risk of transmission [30–32].

Furthermore, low income may impact on people's ability to access the internet and communication technologies such as tablets, smartphones, and laptops, as some families cannot afford such devices. This situation can exacerbate inequalities by preventing people from accessing information about the pandemic, impacting on diagnosis and follow-up [32]. Digital exclusion also reduces "social connectivity", which is supposed to promote opportunities [33]. For instance, lack of digital access will prevent people from learning about employment opportunities and their employment rights. Insufficient social services and other public resources for socio-economic support are more likely to affect low-income earners (i.e., people continue in physical work for fear of losing their source of income). In particular, people living with mental health problems and other conditions are disproportionately affected by socio-economic inequalities, impacting on their ability to comply with quarantine rules. Some people find it impossible to isolate due to the lack of a care network for people with mental illness, as do those without a family or who have been affected by the closure of day centres or suspension of social activities [32].

COVID-19 related morbidity and mortality have been unevenly distributed across geographic areas. For instance, Spain is one of the countries most affected by the disease [32], and it implemented one of the strictest lockdowns in Europe for seven weeks. During the first "State of Alarm" imposed by the central government (provisionally from March 15 to 29), people's movements were restricted to trips to specific outlets to, for example, acquire food and medicine, attend healthcare appointments, go to work, and due to force majeure (internal borders were closed a week later). During the first imposition of the stay-at-home lockdown (from March 30 to April 12), Spain rose to third and second place in the world in terms of confirmed diagnoses and catastrophic losses, respectively. After six extensions of lockdown (the last on June 7) and four transition stages in which they contemplated somewhat more relaxed measures similar to other EU countries, Spain finally moved into the "new normal" on June 21, 2020 [34]. It is in the month of June 2020 when this study was carried out, after seven weeks of strict lockdown.

Mirroring a trend in health research [35], a large amount of COVID-19 studies tend to have a biomedical or epidemiological focus [36, 37], framing health problems in terms of behaviours and individual lifestyle risk factors. This focus neglects the role of SDHs in differential exposure to the virus, differential vulnerability to the

infection and differential consequences of the disease. Qualitative methods can provide valuable insights into the experiences of people bearing the burden of COVID and the professionals managing the problem, as well as on the broader social and environmental conditions that facilitate the differential impact of COVID [38, 39]. Gaining this knowledge is essential to developing more effective prevention and management strategies. Yet, these studies are few and far between [17]. There are even fewer qualitative studies exploring the links between mental health, depression and COVID [40, 41]. This qualitative study provides insights into the relationship between SDHs and depression during the first strict lockdown in Zaragoza, Spain.

## Methods

### Study design

Fifty-two structured telephone interviews were conducted with people diagnosed with depression living in the province of Zaragoza, Spain. The SDH framework informed the interview guide. The questions were designed to explore people's experiences holistically, without assuming that some SDHs were more important than others. Thus, the questions were general enough to allow participants to explore complex and interconnected factors (Table 1).

### Participant recruitment

Patients were recruited from an existing randomised controlled trial (RCT) on a lifestyle modification programme for patients with subclinical and major depression, led by the authors AAL, BOB and RMB [42]. A trained research assistant (RA) phoned potential participants to explain this qualitative study and the patient information sheet. If participants accepted and met the eligibility criteria the RA also obtained written informed consent and booked an appointment for the interview.

The eligibility criteria were that patients had to be 18 or over, and had to have been living with subclinical, mild, moderate, or severe depression for at least two months prior to lockdown. To determine participants' mental health, the RA used the Beck II Self-Applied Depression Inventory (BDI II) [43]. Ability to understand written and spoken Spanish and provide written consent were also requirements.

The exclusion criteria were as follows: suffering from another disease that affects the brain (organic brain pathology or having suffered a traumatic brain injury of any severity, dementia); having another psychiatric diagnosis or severe psychiatric illness (substance dependence or abuse, a history of schizophrenia or other psychotic disorders, eating disorders), except for anxious pathology or personality disorders. This data was collected through a medical history and from the Mini-International Neuropsychiatric Interview (MINI) [44]. Other exclusion criteria were: the presence of a severe or uncontrolled medical, infectious or degenerative illness that may interfere with the affective symptoms; delirium or hallucinations, suicide risk, pregnancy or lactation; and the presence of any medical, psychological or social problem that could seriously interfere with the patient's participation in the study.

### Data collection

AAL interviewed participants in June 2020. She introduced herself as a trained research psychologist and adhered strictly to the script to minimise her intervention in the interview process. Data collection was conducted by telephone due to lockdown restrictions. Interviews lasted no longer than 30 min. All sessions were digitally audio-recorded, and a verbatim transcription was made to obtain the final set of qualitative data for analysis. Participants agreed to participate in the study and signed a consent form.

### Data analysis

All personally identifiable information was removed from the transcripts and replaced with an anonymised personal unique identifier. We developed a system to enable record linkage between transcripts, socio-demographics and BDI II.

**Table 1** Topic list

| |
|---|
| 1. Personal and family COVID-19 situation: Have you or someone who lives with you been infected? Has someone close to you died? Who have you lived with during lockdown? |
| 2. What type of home do you have? (Flat without terrace or balcony, flat with terrace/balcony, house with a garden, etc.) |
| 3. How has your state of mind been during lockdown? What has caused you the most suffering? (i.e., not being able to go out, not being able to be with your loved ones, the images you saw of the pandemic, etc.)? |
| 4. Do you think your state of mind is better or worse now compared to before lockdown? What do you think has made you feel better/worse? What has helped you to overcome this situation? |
| 5. What do you think the health system could have done to help you with your mood during lockdown? |

An inductive thematic content analysis was carried out to identify themes emerging from the interviews [45], while recognising that themes may also come from the preconceived SDH framework [46]. First, five researchers (AAL, FML, VG, RMB, APE) read through all the transcripts and identified emerging themes and potential subthemes which were agreed in team meetings. Secondly, four researchers (AAL, FML, VG, RMB) revised the scripts and mapped themes and subthemes against the SDH framework (Table 2). Participants' quotations were extracted, and new themes were also identified. Thirdly, the team met to discuss discrepancies as well as new themes. The interpretations of the data were discussed with interviewers and participants to obtain their consent [47]. This methodological triangulation increased consistency and rigour by combining multiple techniques and maximising the interpretations' breadth and depth. All analysis was performed iteratively using MAXQDA software (Qualitative Data Analysis) [48].

## Results

Participants' demographic characteristics and COVID-19 infection information are presented in Table 3 in numbers and percentages. Most participants were adult women (88.5%), typically with secondary and primary education, married or living with a partner, not in employment and without short/long-term disability, receiving from 1 to 2 times the Interprofessional Minimum Wage (IMW) or less, living in a house with a small balcony or terrace. Most of the participants had not been infected with COVID-19 (96.15%). One had a family member that had been infected, and two had lost a relative to the virus.

### Neighbourhood and physical environment

a. Home balconies as an extension of the street

The physical space (availability and quality) of the home was an important factor shaping well-being. Most participants appreciated their terraces and balconies during lockdown. These spaces allowed them to "leave the house" and be outdoors, which became an extension of the street for many. The positive perception that "being on the balcony makes me feel that I am out on the street" was recurrent in those living in apartments or houses with balconies. Some participants used it to walk, others to socialise with the neighbours and others to distract themselves for a while (while reading, looking outside, etc.). At 8 pm, it was customary to go out to the balcony to applaud the health professionals. Several participants mentioned this time as something positive that served to unite the neighbours since they knew that at 8 pm, they were going to see each other, and they were going to spend some time together clapping and chatting. Participants expressed that a feeling of community union emerged in the face of adversity.

> *Well, the radio provided me with company a lot of the time, and the ladies next door, or I'd just watch the balconies opposite, I used to watch life unfold on those balconies, I lived on my balcony, it was my comfort zone. Woman, aged 56.*

Only five patients live in a house with a balcony or a large garden. Two of them spent lockdown in their village, where people commonly live in a house with a large garden. They stated that having a piece of land made them feel like they were "in the countryside". It is worth mentioning that houses with balconies, and in particular houses with gardens, are not common in urban Spain.

b. The role of the street and going out

The fact of being unable "to go out" (*salir*) or "leave the house" literally paralysed people's routine. They could no longer go out to do their daily activities or

**Table 2** Overview of the themes and subthemes mapped against the SDH framework

| SDH | Themes and subthemes |
|---|---|
| Neighbourhood and physical environment | a. Public/private housing – access to the 'outdoors' within the home and quality of physical space—balcony<br>b.The outdoors/street<br>c.Outdoor exercise |
| Community, safety, and social context | d. Living together in the space<br>e. Family and social support<br>f. Extra work<br>g. Digital technologies<br>h. Home as a privilege and leisure-time activities |
| Healthcare services | |

**Table 3** Characteristics of the participants

| Variables | Patients ($n = 52$) |
|---|---|
| **Age** | 53.45 (± 14.26) |
| Young adults (18 to 39 y/o) | 10 (19.2%) |
| Middle-aged adults (40 to 49 y/o) | 7 (13.5%) |
| Mature adults (> 50 y/o) | 35 (67.3%) |
| **Gender** | |
| Male | 6 (11.5%) |
| Female | 46 (88.5%) |
| **Education** | |
| None | 5 (9.6%) |
| Primary | 21 (40.4%) |
| Secondary | 23 (44.2%) |
| Tertiary | 3 (5.8%) |
| **Occupation** | |
| Employed | 8 (15.4%) |
| Unemployed | 4 (7.7%) |
| Stay-at-home parent/unpaid worker/student/ pensioner | 20 (38.5%) |
| Sick leave/short/long-term disability/ other situations | 20 (38.5%) |
| **Marital status** | |
| Single | 5 (9,6%) |
| Married or living with a partner | 31 (59.6%) |
| Separated, divorced or in separation proceedings | 11 (21.1%) |
| Widower or widow | 5 (9,6%) |
| **Income level** | |
| < IMW | 23 (44.2%) |
| 1 to 2 × IMW | 25 (48.1%) |
| > 2 and < 4 × IMW | 4 (7.7%) |
| **Type of home** | |
| Small apartment without a balcony or terrace | 6 (11.54%) |
| Apartment with a small balcony | 23 (44.23%) |
| Apartment with a terrace | 18 (34.62%) |
| House with balconies or house with a large garden | 5 (9.61%) |
| **COVID-19 Infections** | |
| Not infected | 50 (96.15%) |
| Infected themselves | 2 (3.85%) |
| Infected relative | 1 (1.92%) |
| Loss of a relative due to COVID-19 | 2 (3.85%) |

Note: *y/o* years old, *IMW* Interprofessional Minimum Wage

meet their friends. Almost half of the participants reported that their situation worsened due to the change of routine and highlighted the importance of their daily routine:

> *It has made me feel terrible. It has made everything worse for me. It seemed like it wasn't going to affect me, but in the end it did. Not being able to go out, not being able to see the people you want to see… Nothing that would have helped could be done. Woman, aged 42.*

Since Zaragoza city has the highest rate of inward migration in the province, another recurrent complaint from people was not being able to go to their hometowns or villages (*pueblos*) to walk in the countryside and visit their families. Several participants acknowledged that they usually did not go out much, but the lack of choice made them want to go out more. For the youngest participants, online teaching and the cancelation of sport activities was emotionally challenging. In general, lockdown was perceived as the worst consequence of the pandemic for those used to doing outdoor activities. Participants also commented that seeing the streets empty and silent evoked feelings of loneliness and anxiety.

As for fear of going out due to concerns over infection, 30% of participants explained that they felt worried about going out, either due to fear of the disease itself, because they were at greater risk, or because they had relatives who were at risk.

> *But I was more afraid to go out in case I caught it [COVID-19] than of not going out. Woman, aged 55.*

c. Outdoor exercise

More than half of the participants spoke of how their exercise routines were negatively affected by not being able to leave the house, not even to go for a walk. Some said that walking helped them to 'clear their heads' and feel more cheerful by distracting them from problems. The benefits of sunbathing were also mentioned, with people stating that they tried to walk and sunbathe at the window or balcony.

> *For me, the thing that helped boost my mood the most was going for a walk and getting some sun at the window or on the balcony, 5 or 10 minutes, just letting the sun shine on my face, and when I was going to the shops, I'd try to walk in the sunlight. Woman, aged 67.*

Despite being locked down at home, some participants kept walking in their houses in an attempt to maintain their previous routines.

> *Personally, in terms of my body, what I noticed the most was that I should have gone out walking from the beginning, because I have degenerative arthrosis. My body deteriorated, I got much more tired, and I felt angry and very annoyed. I felt the impact of not being able to go out for quite a while, I felt frustrated. Woman, aged 56.*

**Community, safety, and social networks**

d. The ups and downs of living together in the same space

Ten participants stated that living with their partners and/or other relatives was a source of support and well-being. Children were also a source of support for seventeen participants.

> *Now that I have my kids, I am much better. My daughters have helped me get through it. They make me see that nothing is wrong with me and that you have to try to normalise it as much as possible. Man, divorced, aged 39.*

For other participants, cohabiting during the strict lockdown was difficult since family members had to spend 'too much time together' with no opportunity to disconnect from each other. Living together was more problematic with certain relatives.

> *The worst thing has been living with my mother, who has not lived with me for such a long time in years. Woman, aged 36.*

Ten participants lived alone. The lockdown was not a problem for some of them since they were used to it and accepted the situation. However, others reported feeling lonely and unwell as a significant part of their daily routine involved seeing relatives and friends.

> *Since my husband's passing, I've gone to my daughter's on Saturdays and to my son's on Sundays. Since this [quarantine] began, well, there's been nothing, they don't come here, and I don't go there [...]. Woman, aged 75.*

e. Family and social support

Some participants reported that the support of their family members (although they did not live together) was critical to maintaining their mental well-being. Being supported and supporting others was perceived as positive. In addition, becoming aware of the people who are always with them and caring for them made them feel appreciative and strengthened their relationships. One woman who worked as a nursing assistant stated that she did not allow herself to be sad or cry to avoid worrying her family. This thought helped her keep her spirits up.

Two participants lamented that they could not say goodbye to their deceased loved ones, visit ill relatives and grieve with family members at funerals. They explained that the cancellation of these face-to-face events meant that people could not feel physically supported by their relatives at the most challenging of times.

> *What was hardest for me was when my uncle passed away. Not being able to be there physically was very hard. Woman, aged 39.*

For people who lived alone, loneliness was exacerbated by not visiting their family or friends. Participants who live alone emphasised the importance of their social life, mainly because they tend to overthink when they are alone, and they get distracted when they are with other people. In other words, being with others improved their emotional well-being.

f. Caring as extra work

For employed women with small children, the impact of motherhood and lockdown was influenced by the number of children they had, and their age. Home-schooling placed an additional burden on parents, since they had to take care of their children 24/7. Additionally, the combination of teleworking and home-schooling turned any work-life balance upside down, and some participants described an inability to completely disconnect from work/caring responsibilities:

> *One of the obstacles to following my routines that were beneficial to my mood was having a small child. I needed to pay attention to him, and I stopped doing certain things. Woman, divorced, aged 39.*

g. Digital technologies

As we can deduce from the previous paragraph, one of the most significant impacts of COVID-19 was related to socialising. Half of the participants said that not seeing or having physical closeness with some relatives was the worst aspect of lockdown.

> *The hardest thing for me was not seeing my children. We saw them on video calls, but it is not the same. Now they can come over, once a week, they have lunch at home with me. We have missed that. Man, aged 60.*

For some participants, technologies served to alleviate the suffering of not physically being with their loved ones and friends by providing an online connection. They could see them and chat to them:

> *I have kept my spirits up because I have not lost contact with my friends. I played games with them in a video call, or we called each other and worked on our End-of-Degree Projects together as if we were in*

*the library. Man, aged 22.*

Nevertheless, digital technologies came with challenges. Some older adults expressed difficulties handling mobile devices, stating clumsiness and the significant differences to face-to-face contact. As far as health is concerned, some participants stated that not being able to visit their GP face-to-face was very limiting, as they believe that the quality of care decreased, and it was difficult for them to communicate what was wrong with them verbally.

> *The medical appointments have been the worst thing I have dealt with. Having to be assessed over the phone… I have not handled it very well. How could I tell them that my shoulder hurts and where exactly! That is the worst situation I was confronted with. Woman, aged 71.*

Indeed, the lack of physical touch was missed too.

> *Not seeing my family was the hardest thing for me. Also, my great-granddaughter was born […] So, I have suffered a lot from not seeing her. Now they have brought her to me but with a distance of a metre or two, without being able to touch her, without being able to kiss her. Woman, aged 83.*

Technologies were used as a source of information on world affairs. Some participants reported that bad news in the media about COVID-19 infections and deaths greatly influenced their state of mind, even made them cry when they saw the death toll. Some complained that the images that appeared on television made them feel bad at thinking that some of their relatives at risk could be infected. For these reasons, some avoided watching TV. Although they did not feel a direct threat from COVID-19, other participants also reported feeling bad for people who had been infected or had lost a family member. This feeling would be one of empathy for what the general population was experiencing.

> *I thought continually, who remembered those who had died? I could not get it out of my head that they died alone, that their family could not see them, that at funerals they only let them stay for 10 minutes… I got really anxious and depressed… it was horrible. Woman, aged 66.*

h. Home as a privilege and leisure-time activities

A quarter of participants reported feeling well during lockdown since they were comfortable being at home. Some young and mature adults defined themselves as home-loving people, and so they did not notice much change compared to their previous life.

> *During lockdown I have been very well because we work on the computer so during the week the days passed quickly. Maybe the weekends were a bit more of a drag, but I did relaxation, meditation. The bad thing was later when they said that you could go out, I no longer felt like it… I was so comfortable. Woman, aged 62.*

Some participants stated that they did not dare to go outside and defined their apartment as a refuge. Also, they said that they found it difficult to leave home pre-COVID, so the quarantine allowed them to feel more relaxed since they did not have any schedule. Some participants said that it had been good for them to have so much time to themselves and be active at home doing manual jobs. Several women stated that they felt calmer because they knew they could not go out, nobody called them [to go out], and they were fine with that. They also would have liked it to last longer, as they did the same things that they would have done if lockdown had not been in place. In terms of routine changes, fifteen participants reported having adapted very well to lockdown, adapting to their new routines. Some participants reported feeling better in lockdown, as they felt more comfortable not having any obligations:

> *Lockdown has not affected me, on the contrary, it has been very good for me. I feel very well, very focused and very serene. Since I don't like going out, and have not felt compelled to do so, I have been living a full life with my daughter and my husband. It seems contradictory to the situation we have been living in. Woman, aged 51.*

**Healthcare services**

Thirty-five participants reported feeling satisfied with the performance of the healthcare system during lockdown. Some participants expressed that the health system had enough work caring for people sick with COVID-19 and regarded their own health problems as not being so serious. They did not mind waiting to be seen by a doctor and highly valued the healthcare workers' professionalism. Some participants also spoke of budget cuts, recognising that the healthcare system could not keep pace with demand due to a lack of resources. However, at the same time, a few people suggested ways to improve healthcare, and some others reported feeling neglected:

> *You call the health centre, they don't answer, or when they answer, a machine speaks to you saying "please call later, we cannot assist you at the moment". For*

*the elderly, or people who are a little nervous, that machine is killing us. The social worker, I call her and she does not answer, and I need to be seen right now, so I can eat. […] I do not have money for next month, nor for this month. Woman, aged 56.*

Mental healthcare was a recurrent theme. Twelve participants suggested that psychiatric and psychological mental healthcare was lacking, especially during COVID-19, and mentioned the long waiting lists. Participants explained that many people had to resort to private care, which is expensive. They demanded more psychological help from public health services, settling for online or telephone appointments if face-to-face appointments were not possible. Feelings of empathy appeared again in people's responses, as some of them emphasised how important mental health is, especially among people who have lost a relative during lockdown and have not been able to say goodbye in the usual way (i.e., being physically present in the company of relatives).

Twelve participants acknowledged having felt well-cared-for; some reported that they understood the extreme pressure the health system was under, which they said justified the neglect of mental health due to the circumstances of the pandemic. They demand closer monitoring but recognise that there are many people and that there were other priorities. Furthermore, they highlight the work of mental health associations, since thanks to them, they did not feel so alone and helpless.

### Hopelessness and hope

Specific depression symptoms such as pessimism could lead the individual to have a more negative view of events. Some participants have a negative view of what happened, with biases towards perceiving only the negative. They said that this situation was bad and that it would worsen, and they were getting worse and worse.

*I continue to feel anguish at all this that is happening and that has not yet ended, I am aware that we are existing without living. Woman, aged 66.*

In contrast, some participants highlight that their ability to cope, optimism, and adaptation has made them feel better and get a better perspective on the circumstances. They felt the pandemic made them realise that they must do things now rather than leaving them for tomorrow, as tomorrow is uncertain. It also helped them to pay more attention to positive things. The way people viewed their circumstances was influential in other cases, where social circumstances, and especially the perception people had of their personal situation, improved over time:

*What has made me feel better has been slowing down, because before the quarantine I didn't feel great, I was very badly stressed from work and everything. The break has helped me and although it has been hard … before I had no time for anything and now, I have been able to spend time with my son and spend time at home. Woman, aged 32.*

## Discussion

The results reported here highlight the role of SDHs in depression in times of COVID-19 and allow us to understand how people prioritise their needs. SDHs interact with existing non-communicable diseases (NCDs), health-related practices, and social and community networks [49]. Findings show how this interaction is exacerbated in pandemic times, as the measures adopted by the government have an immediate and unequal impact on mental health due to housing conditions, working conditions and gender-based inequalities [50].

According to participants' perceptions of their experience of depression, the living environment is one of the most influential SDHs. It is closely linked to housing, physical space and the neighbourhood [12, 51]. This study found that people living in apartments or houses with balconies or a garden could enjoy the benefits of being "out on the street" such as walking, sunbathing, and socialising with neighbours. This corroborates existing evidence suggesting that poor housing conditions, including overcrowding and little access to outside or green space, are detrimental to physical and mental health [50].

Due to Spain's first strict lockdown lasting seven weeks, the outdoors (*la calle*) lost its socialisation function. For many participants it also lost its therapeutic function as it was associated with the spread of the virus. Fear is one of the central emotional responses during a pandemic, and it has been fuelled by the negative news coming out in the media [39]. Yet participants found ways of bringing the qualities of the outdoors into the safety of the private sphere by creating new spaces for socialising such as balconies.

When queried about health-related practices, most of the participants were concerned about their lack of routine. Some greatly missed their physical activities such as walking. [52, 53]. Those who could walk on their balconies believed their mental health improved due to more exercise [17, 54]. Walking and synthesising vitamin D thanks to sun exposure have antidepressant effects both as a consequence of biochemical processes and cultural understandings of the outdoors [55]. Additionally, regular exercise prevents heart disease and, by limiting obesity, reduces the onset of diabetes, promotes a feeling of well-being, and protects the elderly from depression [24].

Future management of epidemics should take into account the importance of the living environment. Policies and public and private spaces should be provided to enhance social connectedness and enable people to access blue and green spaces, as these are associated with improved mental health in adults. Physical activity in green space is more beneficial than activity in other settings [56]. Findings confirm existing evidence that low-income areas are hit harder by the epidemic as they tend to have a lack of space [50] – in this case, balconies or gardens that integrate the benefits of the outdoors (nature and people) into the safety of the home.

The next SDH that emerges from the results is community, safety, and social networks. Social and community networks significantly impact our sense of life satisfaction and well-being [57]. Friendship, good social relationships, and strong support networks improve health at home, at work, and in the community [24].

Living together with family was described as an advantage for the majority of participants. These results align with Günther-Bel et al.'s study [58], which found that family dynamics during quarantine had improved rather than deteriorated. However, relationships appeared more harmonious when there were no children in the household [58]. Our data also shows that families with teenagers faced some tensions. What this means is that cohabitation is a double-edged sword. On the one hand, caring for others in the home can be beneficial because it helps to be active and have company. On the other hand, it can be experienced as a burden, negatively affecting both our health and the quality of care provided [59]. This may be due to the combination of emotional and physical fatigue that caring entails, increased by the pandemic situation [60], lack of resources and space and the suddenly enforced proximity with immediate family [39], especially if relationships were already strained. The weight of social norms and gender inequalities means that female caregivers, particularly low income or single parents, still experience greater levels of burden [61, 62]. We must highlight that social support protected against this burden and led to greater satisfaction with care [61].

This recommendation is even more relevant if we take into account that women are more likely to be diagnosed with depression. In addition, women suffer more from symptoms derived from quarantine measures than men [27, 63, 64]. This gender gap is widely reported in adults, with working life and family roles having a greater impact on women's mental health [65].

For people in one-person households, loneliness was accentuated, with a consequential decline in mental well-being [66]. Loneliness (perceived as social isolation) negatively affects physical and mental health [39, 57]. Self-isolation policies can increase social isolation and relationship difficulties [39]. Social isolation might be prevented by increasing the amount of contact with peers, or by sharing a common interest with others, as this could give people a sense of belonging to a community [67].

With regard to the use of digital technologies, quality (e.g. feeling 'close') was more strongly valued than quantity (e.g. dehumanised-mechanic video calls with professionals), and those with higher quality or more face-to-face or phone/video contact had fewer depressive symptoms [68]. There are also differences among seniors' perspectives and preferences when using technologies [69], making the digital literacy gap more evident [70]. Technology was important for the older population during the pandemic, facilitating meaningful relations [71]. However, the use of technologies does not fully replace traditional ways of socialising that involve 'closeness' and even physical touch or experiences such as kissing, hugging, or face-to-face conversation, which are valued positively in Western Europe [39].

When looking at the home as a privilege, and leisure activities, people who were usually more sociable or had higher empathy had more depressive symptoms during enforced reduced contact [68]. Yet, for people with depression socialising can be challenging (e.g. due to experiencing feelings of exclusion) [72]. Besides that, some participants have changed their view of life, paying more attention to other aspects they had neglected, such as spending more time with their families or taking up leisure activities. This means that they consider being at home as a privilege, instead of all the negative feelings they might also feel [20]. Stressful times such as the ones we are living through could help us to reorganise our priorities, and lead to deeper relationships and a greater appreciation of life [73]. Therefore, positive emotions also emerged due to increased leisure time and the slower pace of life during lockdown [74].

Access to healthcare is another SDH that emerged in this study. Healthcare systems take on the role of identifying and addressing patients' unmet social needs, making inroads into improving population health and health equity [75]. Examples of health system interventions include additional care and support for disadvantaged patients, additional resources for rehabilitation programmes to reduce the effects of illness on people's earning potential, and equitable healthcare financing [12]. Previous physical and mental health conditions have increased inequalities because of reduced access to healthcare services for non-COVID-19 reasons [50]. Most of our participants felt satisfied with the health system's performance during lockdown, although several mentioned the lack of mental healthcare. The general satisfaction with healthcare services might be because

of health workers' image in the media as "heroes" who deserve all the respect in the world for the great effort and work they are undertaking during the pandemic. Conformity with restrictions and the understanding shown by the population may be due to the appeal for sacrifice and cooperation by governments and the media for the good of society in general [39]. As in other studies, a strong sense of communal or civil responsibility was found [76]. Nonetheless, there is a demand for more care from the public health system; since if people have received care, it has been mainly through private associations with state-funded financial support. Mental healthcare is critical as it impacts the rest of the family. The family covers the care systems' deficiencies and weaknesses, leading to overburdening and diminishing quality of life for caregivers [77].

#### Recommendations, implications for policy and practice

There is a need to develop specific strategies to address or mitigate SDHs to reduce health inequalities [78]. For example, our study's results might have implications for urban planning, as we have seen the importance of adequate home size and some exposure to open air (i.e., balconies or terraces).

Governments should support families with young children, caregivers or people with physical or mental health problems, as people with depression are one of the groups that place the most significant burden on their caregivers [79]. Furthermore, community activities to combat social isolation should be promoted [32], as in possible future times of distress and crisis, human resilience depends on the richness and strength of social connections and active engagement in groups and communities [57].

In our study we focus specifically on people with depression. This field of research is essential as it has been acknowledged that people with mental illness and their families should participate in developing policies and thus contribute to strengthening mental healthcare systems worldwide [77]. Recommendations related to mental health would be a shared approach to vulnerability between public health services, primary care centres, hospital services, municipal health services, occupational health and mental health facilities [32]. Professional services are also needed to support people across the psychological disciplines, with face-to-face and online access and more accessible referral routes into these services as well as better connectivity with GP practices [17], especially for those with chronic diseases, diagnoses of mental health disorders, disordered substance use and highly complex patients [32]. Another recommendation regarding the management of negative emotions during quarantine periods would be providing people with clear information and basic necessities, as well as appealing to the common good [20].

#### Strengths and limitations

Despite the specific characteristics of our sample (people living with depression), the results could be highly relevant to the general population for two reasons. Firstly, our holistic approach based on the SDH framework explored people's experiences of lockdown as a whole, without assuming that people with depression would be more affected than people without depression. Secondly, our approach did not assume that some SDHs are more important than others and the analysis path was inductive. However, interviews were done by telephone due to quarantine constraints, and some non-verbal information may have been lost. Another limitation would be that inherent to the type of study, which cannot be generalized to the entire population with mental disorders.

## Conclusions

This study provides further evidence about how SDHs have played a fundamental role in shaping the experiences of people living with depression during COVID. Housing and working conditions, physical and mental health, and access to health services, health-related practices, and social and community networks were recurrent themes. The impact that these SDHs have on our mental health should not be disregarded, and governments should consider implementing social welfare programmes to tackle both psychosocial problems and material needs.

#### Acknowledgements

We wish to thank the Aragonese Primary Care Research Group (GAIAP, B21_20R) that is part of the Department of Innovation, Research and University at the Government of Aragón (Spain); the Research Network on Chronicity, Primary Care and Health Promotion (RICAPPS, RD21/0016/0005) that is part of the Results-Oriented Cooperative Research Networks in Health (RICORS) (Carlos III Health Institute); and Feder Funds "Another way to make Europe.

#### Authors' contributions

Conceptualization: BOB, APE, Data curation: AAL, APE, FML, VGG, BBA, Formal analysis: AAL, APE, FML, VGG, BBA, Funding acquisition: BOB. Investigation: AAL, APE, FML, VGG, BBA. Methodology: APE, BOB, Project administration: BOB, RMB, Resources: RMB, Software: AAL, APE, Supervision: AAL, BOB, Validation: APE, Visualization: AAL, Roles/Writing—original draft: AAL, APE, BOB, Writing—review & editing: AAL, BOB, APE, FML, VGG, BBA, RMB. All authors read and approved the final manuscript.

#### Authors' information (optional)

Alejandra Aguilar Latorre graduated with a bachelor's degree in Psychology from the University of Zaragoza and received her master's degree in Neuroscience from the University of Barcelona. Currently, she is a predoctoral researcher at the Institute for Health Research Aragón (IIS Aragón) and a Ph.D. student in Psychology (University of Zaragoza). She belongs to the Aragonese Primary Care Research Group (GAIAP, B21_20R); a consolidated group recognized by the Department of Innovation, Research and University at

the Government of Aragón. This group belongs to the Research Network on Chronicity, Primary Care and Health Promotion (RICAPPS, RD21/0016/0005) that is part of the Results-Oriented Cooperative Research Networks in Health (RICORS) (Carlos III Health Institute) [46].

**Funding**
This work was supported by Carlos III Health Institute grant number PI18/01336 and Feder Funds "Another way to make Europe". The funders had no role in study design, data collection, analysis, decision to publish, or manuscript preparation. The funding body will conduct a yearly audit.

**Availability of data and materials**
The datasets generated during and/or analysed during the current study are not publicly available due to the personal statements that have been said by the participants but are available from the corresponding author on reasonable request.

## Declarations

**Ethics approval and consent to participate**
Ethical approval was granted by the Aragon Research Ethics Committee (CEICA, PI18/286). The study has been conducted in accordance with the Helsinki Declaration. All subjects have signed an informed consent form. Their data was anonymised and was used only for the purposes of this study. Participants and healthcare professionals will be informed of the results.

**Consent for publication**
Not applicable.

**Competing interests**
The authors declare that they have no competing interests.

**Author details**
[1]Institute for Health Research Aragón (IIS Aragón), Zaragoza, Spain. [2]Department of Psychology and Sociology, University of Zaragoza, Zaragoza, Spain. [3]Lancaster Environment Centre, Lancaster University, Lancaster, UK. [4]Aragonese Healthcare Service (SALUD), Zaragoza, Spain. [5]Department of Medicine, Psychiatry and Dermatology, University of Zaragoza, Zaragoza, Spain.

Received: 1 December 2021 Accepted: 21 March 2022
Published online: 18 April 2022

**References**

1. Department of Information Evidence and Research WHO. WHO methods and data sources for global burden of disease estimates 2000–2015 [Internet]. Global Health Estimates Technical Paper WHO/HIS/IER/GHE/2017.1. 2017. Available from: https://www.who.int/healthinfo/global_burden_disease/GlobalDALYmethods_2000_2015.pdf?ua=1
2. Ferrari AJ, Charlson FJ, Norman RE, Patten SB, Freedman G, Murray CJL, et al. Burden of Depressive Disorders by Country, Sex, Age, and Year: Findings from the Global Burden of Disease Study 2010. PLoS Med. 2013;10(11):e1001547.
3. Gabilondo A, Rojas-Farreras S, Vilagut G, Haro JM, Fernández A, Pinto-Meza A, et al. Epidemiology of major depressive episode in a southern European country: Results from the ESEMeD-Spain project. J Affect Disord. 2010;120(1–3):76–85.
4. Hidaka BH. Depression as a disease of modernity: Explanations for increasing prevalence. Journal of Affective Disorders. 2012;140(3):205–14.
5. Evans T, Whitehead M, Diderichsen F, Bhuiya A, Wirth M. Challenging Inequities in Health: From Ethics to Action. New York: Oxford University Press; 2001.
6. Artiga S, Hinton E. Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity | The Henry J. Kaiser Family Foundation. Kaiser Fam Found. 2018; https://www.kff.org/disparities-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/
7. WHO. About social determinants of health. 2017 [cited 2021 Jun 15]. https://www.who.int/health-topics/social-determinants-of-health
8. Santamaría-García H, Baez S, Gómez C, Rodríguez-Villagra O, Huepe D, Portela M, et al. The role of social cognition skills and social determinants of health in predicting symptoms of mental illness. Transl Psychiatry. 2020;10(1). Available from: https://doi.org/10.1038/s41398-020-0852-4
9. Promotion Office of Disease Prevention and Health. Healthy People 2020: Social Determinants of Health. [cited 2021 Jun 15]. Available from: https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health
10. Lalonde M. A new perspective on the health of canadians: a working document. Minister of National Health and Welfare. 1974.
11. Commission on Social Determinants of Health (CSDH). Commission on Social Determinants of Health: A Conceptual Framework for Action on the Social Determinants of Health. 2007. http://minority-health.pitt.edu/757/
12. WHO. A Conceptual Framework for Action on the Social Determinants of Health [Internet]. Social Determinants of Health Discussion Paper 2 (Policy and Practice). Geneva; 2010. http://apps.who.int/iris/bitstream/10665/44489/1/9789241500852_eng.pdf?ua=1&ua=1
13. World Health Organization. Weekly operational update on COVID-19 - 16 October 2020. World Heal Organ. 2021;(66):1–10. https://www.who.int/publications/m/item/weekly-update-on-covid-19---16-october-2020
14. Zhou F, Yu T, Du R, Fan G, Liu Y, Liu Z, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. Lancet . 2020;395(10229):1054–62. https://doi.org/10.1016/S0140-6736(20)30566-3
15. Amsalem Doron, Dixon LB, Neria Y. Mental health care during the ebola virus disease outbreak in Sierra Leone. JAMA Psychiatr. 2021;78(1):9–10.
16. Arendt F, Markiewitz A, Mestas M, Scherr S. COVID-19 pandemic, government responses, and public mental health: Investigating consequences through crisis hotline calls in two countries. Soc Sci Med [Internet]. 2020;265(November). Available from: https://doi.org/10.1016/j.socscimed.2020.113532
17. Stuart K, Bidmead E, Browning R, Grimwood S, Roberts C, Winn-Reed T, et al. National Covid-19 Research. Deep Dives: Different Groups' Experiences of and Recovery Needs from Covid-19. Report Six. Carlisle: University of Cumbria; 2020.
18. Huang Y, Zhao N. Generalized anxiety disorder, depressive symptoms and sleep quality during COVID-19 outbreak in China: a web-based cross-sectional survey. Psychiatry Res . 2020;288(March):112954. https://doi.org/10.1016/j.psychres.2020.112954
19. Gao W, Ping S, Liu X. Gender differences in depression, anxiety, and stress among college students: A longitudinal study from China. J Affect Disord. 2020;263:292–300. https://doi.org/10.1016/j.jad.2019.11.121
20. Brooks SK, Webster RK, Smith LE, Woodland L, Wessely S, Greenberg N, et al. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. Lancet. 2020;395(10227):912–20. https://doi.org/10.1016/S0140-6736(20)30460-8
21. Kshirsagar MM, Dodamani AS, Dodamani GA, Khobragade VR, Deokar RN. IMPACT OF COVID-19 ON MENTAL HEALTH: AN OVERVIEW. Rev Recent Clin Trials. 2020;16(3):227–31.
22. Bozdağ F. The psychological effects of staying home due to the COVID-19 pandemic. J Gen Psychol. 2020;1–23. https://doi.org/10.1080/00221309.2020.1867494
23. Kim HH, Jung JH. Social Isolation and Psychological Distress During the COVID-19 Pandemic: A Cross-National Analysis. Gerontologist. 2021;61(1):103–13. http://www.ncbi.nlm.nih.gov/pubmed/33483692
24. WHO. Los hechos probados. Los determinantes sociales de la salud [Internet]. Vol. 2ª edicion, Los hechos probados. Los determinantes sociales de la salud. 2003. www.euro.who.int
25. Campion J, Javed A, Sartorius N, Marmot M. Addressing the public mental health challenge of COVID-19. Lancet Psychiatr. 2020;7(8):657–9.
26. Wang Y, Shi L, Que J, Lu Q, Liu L, Lu Z, et al. The impact of quarantine on mental health status among general population in China during the COVID-19 pandemic. Mol Psychiatry. 2021; http://www.ncbi.nlm.nih.gov/pubmed/33483692
27. Amendola S, Spensieri V, Hengartner MP, Cerutti R. Mental health of Italian adults during COVID-19 pandemic. Br J Health Psychol. 2021;26(2):644–56.

28. Paremoer L, Nandi S, Serag H, Baum F. Covid-19 pandemic and the social determinants of health. BMJ. 2021;372(129):1–5.
29. Burstrom B, Tao W. Social determinants of health and inequalities in COVID-19. Eur J Public Health. 2020;30(4):617–8.
30. Scientific Pandemic Influenza Group on Behaviours (SPI-B), Environmental and Modelling group (EMG). COVID-19 housing impacts. Sci Advis Gr Emergencies. 2020;1–11. https://www.gov.uk/government/publications/spi-bemg-covid-19-housing-impacts-10-september-2020.
31. Mehta S. Medact Submission to the Housing, Communities and Local Government Committee Inquiry into the Impact of COVID-19 (Coronavirus) on homelessness and the private rented sector. Medact. 2020;1-16. https://www.medact.org/wp-content/uploads/2020/05/The-impact-of-insecure-housing-on-COVID-19-transmission-%E2%94%80-Medact-May-2020-FINAL-1.pdf.
32. Spain Ministry of Health. Equidad en Salud y COVID- 19. Análisis y propuestas para abordar la vulnerabilidad epidemiológica vinculada a las desigualdades sociales. Madrid; 2020. https://www.sanidad.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Equidad_en_salud_y_covid19.pdf.
33. Boza-Kiss B, Pachauri S, Zimm C. Deprivations and Inequities in Cities Viewed Through a Pandemic Lens. Front Sustain Cities. 2021;3(March):1–7.
34. Pérez-Laurrabaquio Ó. Covid-19 en España: primera ola de la emergencia. Med Gen y Fam. 2021;10(1):1-7.
35. Inhorn MC, Whittle KL. Feminism meets the "new" epidemiologies: toward an appraisal of antifeminist biases in epidemiological research on women's health. Soc Sci Med. 2001;53(5):553–67.
36. Zhu J, Ji P, Pang J, Zhong Z, Li H, He C, et al. Clinical characteristics of 3062 COVID-19 patients: A meta-analysis. J Med Virol. 2020;92(10):1902–14.
37. Rodriguez-Morales AJ, Cardona-Ospina JA, Gutiérrez-Ocampo E, Villamizar-Peña R, Holguin-Rivera Y, Escalera-Antezana JP, et al. Clinical, laboratory and imaging features of COVID-19: A systematic review and meta-analysis. Travel Med Infect Dis. 2020;34. https://doi.org/10.1016/j.tmaid.2020.101623
38. Teti M, Schatz E, Liebenberg L. Methods in the Time of COVID-19: The Vital Role of Qualitative Inquiries. Int J Qual Methods. 2020;19:1–5.
39. Bavel JJV, Baicker K, Boggio PS, Capraro V, Cichocka A, Cikara M, et al. Using social and behavioural science to support COVID-19 pandemic response. Nat Hum Behav. 2020;4(5):460–71. https://doi.org/10.1038/s41562-020-0884-z
40. Hamm ME, Brown PJ, Karp JF, Lenard E, Cameron F, Dawdani A, et al. Experiences of American Older Adults with Pre-existing Depression During the Beginnings of the COVID-19 Pandemic: A Multicity. Mixed-Methods Study Am J Geriatr Psychiatry. 2020;28(9):924–32.
41. Chen K-L, Hung W-C, Lee M-B, Chen I-M, Wu C-Y. The Impact of the COVID-19 Pandemic on the Health and Coping Behaviors of Patients With Treatment-Resistant Depression. J Nurs. 2020;67(5):56–64.
42. Aguilar-Latorre A, Navarro C, Oliván-Blázquez B, Gervilla E, Magallón Botaya R, Calafat-Villalonga C, et al. Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol. BMJ Open. 2020;10(12):e038457.
43. Beck A, Steer R, Ball R, Ranieri W. Comparison of Beck Depression 1 in Psychiatric Inventories -1A and - Outpatients. J Pers Assess. 1996;67(3):588–97.
44. Ferrando L, Bobes J, Gibert J. MINI. Mini International Neuropsychiatric Interview. Versión en Español 5.0.0 DSM-IV. Instrumentos detección y orientación diagnóstica. Madrid; 2000. http://www.acmcb.es/files/425-5332-DOCUMENT/MINI%205%20Entrevista_Neuropsiquiatrica_Internacional.pdf.
45. Moretti F, van Vliet L, Bensing J, Deledda G, Mazzi M, Rimondini M, et al. A standardized approach to qualitative content analysis of focus group discussions from different countries. Patient Educ Couns. 2011;82(3):420–8. http://dx.doi.org/https://doi.org/10.1016/j.pec.2011.01.005
46. World Health Organization (WHO). Social Determinants of Health. 2021 [cited 2021 Feb 9]. https://www.who.int/teams/social-determinants-of-health
47. Phillips N, Hardy C. Discourse analysis. Investigating processes of social construction. Thousand Oaks: SAGE; 2002.
48. VERBI Software. MAXQDA 2020. Software. 2019.maxqda.com.
49. Dahlgren G, Whitehead M. Policies and strategies to promote social equity in health. Stockholm: Institute for future studies; 1991. https://core.ac.uk/download/pdf/6472456.pdf.
50. Bambra C, Riordan R, Ford J, Matthews F. The COVID-19 pandemic and health inequalities. J Epidemiol Community Health. 2020;74(11):964–8.
51. Chen X, Zou Y, Gao H. Role of neighborhood social support in stress coping and psychological wellbeing during the COVID-19 pandemic Evidence from Hubei. China Heal Place. 2021;69:102532.
52. Bersani FS, Ghezzi F, Maraone A, Vicinanza R, Cavaggioni G, Biondi M, et al. The relationship between Vitamin D and depressive disorders La. Riv Psichiatr. 2019;54(6):229–33.
53. Harvey SB, Overland S, Hatch SL, Wessely S, Mykletun A, Hotopf M. Exercise and the prevention of depression: Results of the HUNT cohort study. Am J Psychiatry. 2018;175(1):28–36.
54. Yang Y, Xiang X. Examine the associations between perceived neighborhood conditions, physical activity, and mental health during the COVID-19 pandemic. Heal Place. 2020;67:102505. https://doi.org/10.1016/j.healthplace.2021.102505.
55. Porroche-Escudero A. Listening to women: political narratives of breast cancer in Spain . University of Sussex; 2012. http://www.opengrey.eu/item/display/10068/993854
56. Public Health England. Improving access to greenspace: A new review for. About Public Health England. 2020;2020:1–112.
57. Bzdok D, Dunbar RIM. The Neurobiology of Social Distance. Trends Cogn Sci. 2020;24(9):717–33. https://doi.org/10.1016/j.tics.2020.05.016
58. Günther-Bel C, Vilaregut A, Carratala E, Torras-Garat S, Pérez-Testor C. A Mixed-method Study of Individual, Couple, and Parental Functioning During the State-regulated COVID-19 Lockdown in Spain. Fam Process. 2020;59(3):1060–79.
59. Koopman E, Heemskerk M, van der Beek AJ, Coenen P. Factors associated with caregiver burden among adult (19–64 years) informal caregivers – An analysis from Dutch Municipal Health Service data. Heal Soc Care Community. 2020;28(5):1578–89.
60. Navas-Martín MÁ, López-Bueno JA, Oteiza I, Cuerdo-Vilches T. Routines, time dedication and habit changes in spanish homes during the covid-19 lockdown. A large cross-sectional survey. Int J Environ Res Public Health. 2021;18(22):12176.
61. García-Mochón L, Peña-Longobardo LM, Del Río-Lozano M, Oliva-Moreno J, Larrañaga-Padilla I, Del Mar García-Calvente M. Determinants of burden and satisfaction in informal caregivers: Two sides of the same coin? the CUIDAR-SE study. Int J Environ Res Public Health. 2019;16(22):4378.
62. Men CR, Frieson K, Socheat C, Nirmita H, Mony C. Gender as a social determinant of health: Gender analysis of the health sector in Cambodia. Brazil: World Conference on Social Determinants of Health; 2011.
63. Hidalgo MD, Balluerka N, Gorostiaga A, Espada JP, Santed MÁ, Padilla JL, et al. The psychological consequences of covid-19 and lockdown in the Spanish population: An exploratory sequential design. Int J Environ Res Public Health. 2020;17(22):1–17.
64. Kimhi S, Marciano H, Eshel Y, Adini B. Resilience and demographic characteristics predicting distress during the COVID-19 crisis. Soc Sci Med. 2020;265:113389. https://doi.org/10.1016/j.socscimed.2020.113389
65. Bracke P, Delaruelle K, Dereuddre R, Van de Velde S. Depression in women and men, cumulative disadvantage and gender inequality in 29 European countries. Soc Sci Med. 2020;267. https://doi.org/10.1016/j.socscimed.2020.113354
66. Kamin T, Perger N, Debevec L, Tivadar B. Alone in a Time of Pandemic: Solo-Living Women Coping With Physical Isolation. Qual Health Res. 2020;1049732320971603. http://www.ncbi.nlm.nih.gov/pubmed/33213283
67. Lapena C, Continente X, Sánchez Mascuñano A, Pons Vigués M, Pujol Ribera E, López MJ. Qualitative evaluation of a community-based intervention to reduce social isolation among older people in disadvantaged urban areas of Barcelona. Heal Soc Care Community. 2020;28(5):1488–503.
68. Sommerlad A, Marston L, Huntley J, Livingston G, Lewis G, Steptoe A, et al. Social relationships and depression during the COVID-19 lockdown: Longitudinal analysis of the COVID-19 social study. Psychol Med. 2021;13:1–10.
69. Kavandi H, Jaana M. Factors that affect health information technology adoption by seniors: A systematic review. Heal Soc Care Community. 2020;28(6):1827–42.

70. Wheeler P, Leiper R, Akeju D, Hedgcoe L, Yameen F. Use of remote technology in research – Findings from the EPHC Diary Project. NIHR ARC NWC, editor. Lancaster: BITE Brokering Innovation Through Evidence; 2020. https://arc-nwc.nihr.ac.uk/wp-content/uploads/2020/09/Use-of-remote-technology-in-research-%E2%80%93-Findings-from-the-EPHC-Diary-Project-3.pdf.
71. von Humboldt S, Mendoza-Ruvalcaba NM, Arias-Merino ED, Costa A, Cabras E, Low G, et al. Smart technology and the meaning in life of older adults during the Covid-19 public health emergency period: a cross-cultural qualitative study. Int Rev Psychiatry. 2020;32(7–8):713–22. https://doi.org/10.1080/09540261.2020.1810643
72. Fancourt D, Baxter L. Differential participation in community cultural activities amongst those with poor mental health: Analyses of the UK Taking Part Survey. Soc Sci Med. 2020;261(March):113221. https://doi.org/10.1016/j.socscimed.2020.113221
73. Tedeschi RG, Calhoun LG. Psychological Inquiry Posttraumatic Growth: A Developmental Perspective. Psychol Inq. 2004;15(1):1–18.
74. Simblett SK, Wilson E, Morris D, Evans J, Odoi C, Mutepua M, et al. Keeping well in a COVID-19 crisis: a qualitative study formulating the perspectives of mental health service users and carers. J Ment Heal. 2021;0(0):1–10. https://doi.org/10.1080/09638237.2021.1875424
75. Gurewich D, Garg A, Kressin NR. Addressing Social Determinants of Health Within Healthcare Delivery Systems: a Framework to Ground and Inform Health Outcomes. J Gen Intern Med. 2020;35(5):1571–5.
76. Ward F. ARCBITE Brokering Innovation Through Evidence Same storm, different boats? Experience of lockdown rules during COVID-19 -findings from a diary project. NIHR ARC NWC, editor. Lancaster: BITE Brokering Innovation Through Evidence; 2020. https://arc-nwc.nihr.ac.uk/wp-content/uploads/2020/09/Use-of-remote-technology-in-research-%E2%80%93-Findings-from-the-EPHC-Diary-Project-3.pdf.
77. Carbonell Á, Navarro-Pérez JJ, Mestre MV. Challenges and barriers in mental healthcare systems and their impact on the family: A systematic integrative review. Heal Soc Care Community. 2020;28(5):1366–79.
78. Marí-Dell'olmo M, Gotsens M, Pasarín MI, Rodríguez-Sanz M, Artazcoz L, de Olalla PG, et al. Socioeconomic inequalities in COVID-19 in a European urban area: Two waves, two patterns. Int J Environ Res Public Health. 2021;18:1–12.
79. Elmståhl S, Dahlrup B, Ekström H, Nordell E. The association between medical diagnosis and caregiver burden: a cross-sectional study of recipients of informal support and caregivers from the general population study 'Good Aging in Skåne', Sweden. Aging Clin Exp Res. 2018;30(9):1023–32. https://doi.org/10.1007/s40520-017-0870-0


## Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.


**Ready to submit your research? Choose BMC and benefit from:**

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

**At BMC, research is always in progress.**

**Learn more** biomedcentral.com/submissions

# 4. DISCUSIÓN

El objetivo principal de esta tesis doctoral era el de analizar la efectividad de un Programa de Modificación de Estilos de Vida (LMP, por sus siglas en inglés) desarrollado en atención primaria de salud (APS) y ofrecido a personas con sintomatología depresiva como tratamiento adyuvante al tratamiento habitual (TAU). Este programa consistía en asistir a 6 sesiones presenciales y grupales que se impartían una vez por semana durante 6 semanas. También se pretendía analizar la efectividad de este LMP conjuntamente con el uso de un reloj de pulsera inteligente que monitorizaba los pasos caminados y los patrones de sueño de las personas participantes.

## 4.1 Efectividad de los Programas de Modificación de Estilos de Vida para la disminución de la sintomatología depresiva

Los primeros hallazgos de este estudio indicaron que, a corto plazo, ambas intervenciones fueron efectivas para disminuir los síntomas depresivos en comparación con el grupo control (TAU). Es decir, la diferencia pre-intevención y post-intervención (diferencia pre-post) del instrumento usado para medir la sintomatología depresiva (BDI-II; Sanz et al., 2005) fue significativamente mayor en los grupos de intervención (TAU+LMP y TAU+LMP+ICTs) en comparación con la diferencia pre-post del grupo control.

Lo mismo ocurrió en el seguimiento de los 6 meses, ambos grupos de intervención disminuyeron significativamente su depresión en comparación con el grupo control. A largo plazo, en el seguimiento de los 12 meses, solo el grupo TAU+LMP+ICTs disminuyó significativamente su depresión en comparación con el grupo control.

Estos resultados sobre la efectividad de los LMPs para la disminución de la sintomatología depresiva son similares a otros Ensayos Clínicos Aleatorizados (ECAs)

llevados a cabo en España, bastante novedosos e inusuales, en los cuales realizaban también intervenciones grupales psicoeducativas y de estilos de vida saludables impartidas por el personal de enfermería de Atención Primaria de Salud (APS) para personas con depresión y comorbilidad física (Casañas et al., 2014; Raya-Tena et al., 2021). Además, los resultados también son consistentes con programas *online* (en línea) multidisciplinarios que integraban tácticas basadas en la evidencia del campo de la medicina del estilo de vida (Przybylko et al., 2021). También, los resultados se alinean con los de un ECA piloto reciente en el cual las personas participantes asistían a sesiones semanales y grupales de dos horas, durante 6 semanas en las que eran instruidos sobre la dieta, el ejercicio físico, *mindfulness*, psicoeducación y control del sueño (Ka-Yan Ip et al., 2021). En este estudio de Ka-Yan Ip (2021), la disminución de la depresión en la medición post y el seguimiento a las 12 semanas tuvo un tamaño de efecto moderado, al igual que nuestro estudio.

Metaanálisis recientes en los que analizaban la efectividad de varios ECAs concluyeron que los LMPs de componentes múltiples (es decir, LMPs en los que se trabajan tres factores del estilo de vida, como la actividad física, el asesoramiento nutricional y el control del sueño) parecían ser efectivos para mitigar los síntomas depresivos (Gómez-Gómez et al., 2020; V. W. H. Wong et al., 2021). Un estudio longitudinal de cohortes reciente llevado a cabo en España (Ruiz-Estigarribia et al., 2019), un estudio transversal sobre condiciones de salud, factores de estilo de vida y depresión (N. Cui et al., 2021) y un metaanálisis reciente de estudios observacionales (Xiaowen Wang et al., 2021) han demostrado que los estilos de vida saludables están asociados con un menor riesgo de síntomas depresivos.

Por lo tanto, la adherencia a un estilo de vida saludable es esencial para disminuir los síntomas depresivos en la población general, ya que las condiciones de salud y los

factores del estilo de vida son factores de riesgo potenciales para este trastorno (N. Cui et al., 2021; V. W. H. Wong et al., 2021).

Sin embargo, el éxito de los LMPs depende de cómo se lleven a cabo las intervenciones. Algunas intervenciones sin ciertos apoyos adicionales (p. ej., solo ofrecer recomendaciones de estilo de vida por escrito, sin un formato de sesiones grupales; no monitorizar el cumplimiento a las recomendaciones; etc.), no han dado resultados satisfactorios (Serrano Ripoll et al., 2015).

## 4.2 Efectividad de los Programas de Modificación de Estilos de Vida para la mejora de los estilos de vida

A corto plazo (diferencia pre-post), las personas participantes de ambos grupos de intervención aumentaron el total de minutos que caminaban por semana, aumentaron su adherencia a la dieta mediterránea y mejoraron su calidad de su sueño, en comparación con el grupo control. Sin embargo, aunque disminuyeron los minutos que pasaban sentados diariamente (lo que hemos llamado sedentarismo), este cambio no fue estadísticamente significativo en comparación con el grupo control.

En el seguimiento de los 6 meses, las personas del grupo TAU+LMP+ICTs aumentaron significativamente el total de minutos que caminaban por semana (aproximadamente, una hora y tres cuartos) en comparación con el grupo TAU. Las personas participantes del grupo TAU+LMP también aumentaron el total de minutos que caminaban por semana (aproximadamente una hora), pero esos resultados solo fueron tendenciales. Por otro lado, las personas participantes del grupo TAU+LMP mejoraron significativamente su calidad del sueño y las personas participantes del grupo TAU+LMP+ICTs aumentaron significativamente su adherencia a la dieta mediterránea. Estos últimos, también redujeron el total de minutos que pasaban sentados diariamente (aproximadamente 40 minutos) pero solo de forma tendencial.

A largo plazo, en el seguimiento de los 12 meses, solo el grupo TAU+LMP+ICTs disminuyó significativamente el total de horas que pasaban sentados diariamente (aproximadamente, tres cuartos de hora) en comparación con el grupo TAU. Ambos grupos de intervención aumentaron el número de minutos caminados por semana y aumentaron su calidad del sueño, pero estos aumentos no fueron significativos. Por otro lado, el grupo TAU+LMP+ICTs aumentó su adherencia a la dieta mediterránea pero no significativamente.

Estos resultados sobre la efectividad de los LMPs para la mejora del estilo de vida son similares a otros estudios que se discutirán en los siguientes apartados.

### 4.2.1 Ejercicio físico

En cuanto al ejercicio físico, a corto plazo, las personas participantes de ambos grupos de intervención aumentaron el número de minutos caminados por semana, y a los 6 meses, solo las personas participantes del grupo TAU+LMP+ICTs aumentaron el número de minutos caminados, de manera significativa respecto al grupo control. A los 12 meses el aumento de minutos caminados de ambos grupos de intervención ya no fue significativo respecto al grupo control. Esta asociación entre ejercicio físico y estado de ánimo se ha reportado en la literatura. En un ECA en el que se daban clases de un tipo particular de gimnasia a las personas participantes vieron como ese programa mejoraba el bienestar físico y que el ejercicio tenía una fuerte relación con los síntomas depresivos (Schitter et al., 2016). Otro ECA asoció la actividad física con un estado de ánimo positivo y con una reducción significativa de la gravedad de los síntomas del insomnio (Hartescu et al., 2015). Un estudio transversal llevado a cabo con personas en riesgo de desarrollar una enfermedad cardiovascular concluyó que los síntomas de depresión se asociaban con la inactividad física, sin hallar diferencias en cuanto al género de las personas participantes (Achttien et al., 2019). En general, en una revisión sistemática y en un

metaanálisis en los que ponían a prueba el ejercicio físico como tratamiento y analizaban la efectividad de 5 y 23 ECAs, respectivamente (Kvam et al., 2016; Stanton & Reaburn, 2014), se concluyó que esas intervenciones eran eficaces para la depresión.

Con todo lo expuesto, queda claro que el ejercicio físico tiene un efecto antidepresivo. Esto lo consigue a través de múltiples factores biológicos y psicosociales. Diversos mecanismos biológicos han sido estudiados, por ejemplo, el factor de crecimiento del endotelio vascular (FCEV) es una neurotrofina que estimula procesos celulares, como la angiogénesis. La angiogénesis provoca cambios duraderos en la estructura cerebral que mejoran el funcionamiento de ciertas áreas implicadas en la depresión (p. ej., el hipocampo) (Kandola et al., 2019). En cuanto a los factores psicosociales, podríamos mencionar la interacción que tiene la autoestima y la autopercepción física con el ejercicio y la depresión (Kandola et al., 2019). Las personas participantes del estudio podrían haber mejorado en estos factores psicosociales, al aumentar los minutos caminados por semana y disminuir su depresión. Estas variables en concreto no se evaluaron, pero sí otros factores personales que discutiremos en el punto 4.4.

### 4.2.2 Sedentarismo

La evidencia sugiere que no solo es necesario estar físicamente activo durante al menos 150 minutos a la semana (WHO, 2010), sino también limitar la cantidad de horas de vigilia que se pasa siendo sedentario (es decir, estando sentado), ya que el sedentarismo se ha relacionado con una mala calidad de vida (De Rezende et al., 2014) y la depresión (Boulos & Salameh, 2021). Como ya se ha mencionado, en los resultados pre-post y en el seguimiento de los 6 meses, se ve una reducción en el sedentarismo de las personas participantes de los grupos de intervención, sin embargo, esta reducción no llega a ser significativa en ningún grupo. Esta falta de relación entre la mejora de la sintomatología

depresiva y el cambio en el sedentarismo puede deberse a que no se controló lo que hacían las personas participantes estando sentados. Por lo tanto, el tiempo dedicado a estar sentados podría haber sido utilizado en actividades de ocio placenteras (p. ej., ver la televisión, leer un libro o usar el ordenador) (Andrade-Gómez et al., 2018). Otra posible causa pudo ser la coincidencia de estas mediciones con la COVID-19, ya que los diversos periodos de confinamiento aumentaron notablemente el sedentarismo (Ali & Kunugi, 2020).

En cambio, en el seguimiento de los 12 meses sí que se encontró una disminución significativa del sedentarismo en comparación con el grupo control. Esto sí que se corresponde con otros estudios en los que el estilo de vida sedentario se asoció con una mayor probabilidad de tener síntomas depresivos (Mamplekou et al., 2010; Werneck et al., 2022; Zhai et al., 2015). Además, en otro estudio reciente en el que registraban con un acelerómetro el tiempo que las personas participantes pasaban sentadas se encontró que a más tiempo sentadas más número de síntomas depresivos (Biddle et al., 2021). En conclusión, estudios recientes llevados a cabo en el contexto de la pandemia por la COVID-19 abogan por contrarrestar el sedentarismo como estrategia para mejorar la salud física y mental (Ali & Kunugi, 2020).

### 4.2.3 Calidad del sueño

A corto plazo, las personas participantes de ambos grupos de intervención mejoraron la calidad de su sueño, y a medio plazo, las personas participantes del grupo TAU+LMP mejoraron significativamente su calidad del sueño. A los 12 meses la mejora de la calidad del sueño ya no fue significativa respecto al grupo control.

Esta relación entre síntomas depresivos y calidad de sueño se va reportando en la literatura de diversas maneras. Un reciente estudio transversal concluyó que unas horas de sueño inadecuadas (tanto por exceso como por defecto) están asociadas con muchos

problemas de salud y la depresión mayor (Y.-J. Kim & Lee, 2021). Por otro lado, un metaanálisis concluyó que una calidad del sueño deficiente está significativamente asociada con la depresión en los adultos mayores (Becker et al., 2017), y otro metaanálisis concluyó que ciertos trastornos del sueño (como tener pesadillas o sufrir insomnio) aumentan el riesgo de realizar conducta suicidas en personas deprimidas (Xiaofen Wang et al., 2019).

A pesar de toda la evidencia que relaciona la mala calidad del sueño con la sintomatología depresiva, los programas de educación sobre higiene del sueño en APS tienen un tamaño de efecto que va de pequeño a moderado y una evidencia limitada (Chung et al., 2018). Futuros estudios deberían garantizar la adherencia al tratamiento y asegurarse de que se cubren todas las recomendaciones de higiene del sueño, además de comparar los programas de educación sobre higiene del sueño con un grupo control (Chung et al., 2018).

### 4.2.4 Adherencia a la dieta mediterránea

De manera similar a lo que ocurrió con la calidad del sueño, a corto plazo, las personas participantes de ambos grupos de intervención mejoraron la adherencia a la dieta mediterránea, y a medio plazo, las personas participantes del grupo TAU+LMP+ICTs mejoraron significativamente su adherencia a la dieta mediterránea. A los 12 meses el aumento de la adherencia a la dieta mediterránea ya no fue significativo respecto al grupo control.

Estos resultados están en consonancia con otros estudios recientes. Un estudio transversal observó asociaciones positivas entre una dieta saludable, una buena calidad del sueño y una buena salud mental (Hepsomali & Groeger, 2021). Un metaanálisis de 16 ECAs determinó que las intervenciones dietéticas redujeron significativamente los síntomas depresivos (Firth et al., 2019). Además, un metaanálisis de estudios

observacionales indicó que los adultos que siguen un patrón dietético saludable tienen menos síntomas depresivos y un menor riesgo de desarrollar síntomas depresivos (Nicolaou et al., 2019). En esta tesis, nos centramos en la adherencia a la dieta mediterránea, ya que es uno los patrones dietéticos más saludables que reduce el riesgo de padecer síntomas depresivos, como determinó otro metaanálisis de estudios observacionales (Lassale et al., 2019) y un reciente estudio longitudinal (Picard et al., 2021).

Un estudio sobre la efectividad de una intervención grupal, que consistía en ofrecer a las personas participantes un taller de educación nutricional (basado en la dieta mediterránea) a cargo de dietistas y nutricionistas, talleres de cocina, cestas de alimentos y suplementos de aceite de pescado, todo durante 3 meses, concluyó que este programa fue altamente rentable en términos de costo/ganancia de años de vida ajustados por calidad (QALY) y costo por caso de depresión mayor resuelto (Segal et al., 2020). Esto es importante ya que, como se ha expuesto en la introducción, la depresión también tiene un impacto económico muy elevado, por lo que los tratamientos que se ponen a prueba también buscan ser rentables.

Con toda la evidencia expuesta, se aboga por el acceso de las personas con depresión mayor a programas dietéticos grupales. La relación entre la adherencia mediterránea y los síntomas depresivos está clara, sin embargo, se necesita más investigación sobre los mecanismos subyacentes que causan esta relación. En una revisión sistemática y metaanálisis sobre ECAs de intervenciones que proporcionaban ácidos grasos poliinsaturados n-3 (n-3PUFA) para tratar la depresión mayor, vieron que la suplementación con n-3PUFA tiene un tamaño de efecto de pequeño a moderado para disminuir la sintomatología depresiva, pero es poco probable que este efecto sea clínicamente significativo (Appleton et al., 2016).

En general, se ha visto una mejora significativa de los estilos de vida después de la intervención, sobre todo a corto (resultados pre-post) y medio plazo (en el seguimiento a los 6 meses). Hay que recalcar que estas mejoras significativas siempre se comprueban respecto al grupo TAU, y que a largo plazo (en el seguimiento a los 12 meses), el grupo TAU también tiene mejoras relativas, haciendo que significatividad de las diferencias se pierda. Esto no quiere decir que a largo plazo la intervención deje de ser efectiva, si no que sus efectos se ven reflejados más claramente a corto y medio plazo, y a largo plazo se difuminan. Esto puede deberse a que la intervención presencial dura 6 semanas, y luego durante el seguimiento no hay ninguna sesión de refuerzo. Futuros estudios podrían incorporar sesiones de refuerzo para seguir motivando a las personas participantes al cambio y que los cambios significativos se reflejen también a largo plazo.

## 4.3 Facilitadores de la adherencia a los Programas de Modificación de Estilos de Vida

### 4.3.1 Uso de TICs

Como se recomienda en las guías de intervención, hemos usado facilitadores para el cambio comportamental (NICE, 2014). En la presente tesis, se ha incorporado un reloj inteligente de pulsera que monitorizaba los pasos caminados por día y los patrones de sueño de las personas participantes.

En los primeros resultados obtenidos, las diferencias pre-post, no se vieron ventajas del uso del reloj inteligente por parte del grupo TAU+LMP+ICTs, ya que los resultados de ambos grupos de intervención fueron bastante similares. Incluso, el grupo TAU+LMP obtuvo una mejora más pronunciada en la calidad de vida.

Sin embargo, a los 6 meses, las diferencias encontradas entre ambas intervenciones (TAU+LMP y TAU+LMP+ICTs) podrían deberse al uso del reloj

inteligente. Hemos encontrado las siguientes ventajas de su uso: en primer lugar, las personas participantes del grupo TAU+LMP+ICTs tuvieron una reducción más notable de su depresión. En segundo lugar, estas personas habían aumentado significativamente los minutos que caminaban diariamente y también aumentaron su adherencia a la dieta mediterránea. Sin embargo, las personas participantes de este grupo no tuvieron una mejora significativa en la calidad del sueño, mientras que las personas participantes del grupo TAU+LMP mejoraron su sueño.

A los 12 meses también se han encontrado diferencias entre ambos grupos de intervención. Igualmente, el grupo TAU+LMP+ICTs consiguió una mejora significativa de los síntomas depresivos en comparación con el grupo TAU. Además, las personas participantes en ese grupo redujeron significativamente las horas que pasaban sentadas diariamente.

Estos resultados dispares pueden haber sido influenciados por el uso individual del reloj inteligente. La mayoría de las personas participantes del grupo TAU+LMP+ICTs estaban muy entusiasmadas con el uso de este dispositivo, sin embargo, la mayoría no lo usaba durante la noche. Por tanto, los datos sobre sus patrones de sueño (hora de acostarse y levantarse, y cantidad de sueño ligero y profundo) no estaban disponibles. Esta infrautilización del reloj inteligente podría deberse al nivel de aceptación de las tecnologías por parte de las personas participantes (Kim & Park, 2012).

Estos resultados concuerdan con los de otros estudios. Por ejemplo, en una reciente intervención para la mejora del estilo de vida a través de una aplicación para teléfonos inteligentes, se hallaron mejoras significativas en los síntomas depresivos y en los síntomas de insomnio, y un aumento de la calidad de vida y del tiempo que pasaban caminando, entre otras mejoras, pero no observaron diferencias significativas en relación con el sedentarismo (V. W.-H. Wong et al., 2021).

En conclusión, la incorporación de las TICs en las intervenciones para la mejora de la salud podría facilitar la promoción de la misma y la prevención de enfermedades (Haluza & Jungwirth, 2015).

### 4.3.2 Apoyo social

En general, los resultados beneficiosos obtenidos en ambos grupos de intervención en comparación con el grupo control, también podrían deberse al formato grupal de las intervenciones, ya que el apoyo social se asocia con un menor riesgo de síntomas depresivos (Du et al., 2022). En los resultados pre-post, se observó un incremento del apoyo social percibido en ambos grupos de intervención, esto tiene sentido ya que las intervenciones grupales tienen varios beneficios como el apoyo social que se da y se recibe en el mismo grupo, el sentimiento de pertenencia a un grupo y la experiencia de compartir problemas comunes (Guimón, 2003). Sin embargo, es posible que se requiera una duración más prolongada del contacto con el grupo para que las personas participantes desarrollen y establezcan una relación que les permita obtener beneficios psicosociales (Brunelli et al., 2016). De todos modos, se necesitan más ECAs de alta calidad sobre intervenciones grupales de apoyo mutuo para sacar conclusiones más firmes sobre el papel del apoyo social (Lyons et al., 2021).

En conclusión, el apoyo social, junto con las habilidades de los profesionales que llevan a cabo la intervención, son importantes para la adherencia a largo plazo de la intervención (Simmonds-Buckley et al., 2019).

En cuanto a la adherencia de ambas intervenciones (TAU+LMP y TAU+LMP+TICs), la tasa de asistencia a las sesiones por parte de las personas participantes fue alta, asistiendo de media a casi 5 de las 6 sesiones totales. Esta cifra es ligeramente superior a la obtenida en el estudio de Raya-Tena et al. (2021), en el cual

también obtuvieron una mejora de los síntomas depresivos, y reportaron una tasa media de asistencia de 7 sesiones de las 12 sesiones totales que tenía su intervención.

En cuanto a los motivos causantes de las pérdidas en ambas intervenciones, la razón principal fue la incompatibilidad horaria. En concreto, las pérdidas acumuladas en el seguimiento a los 12 meses ascendían a 21 personas en el grupo TAU, a 33 en el grupo TAU+LMP y a 27 en el grupo TAU+LMP+ICTs. Este desequilibrio entre grupos puede deberse a que la principal razón de abandono era la incompatibilidad de horarios de las personas participantes para asistir a las sesiones presenciales, por eso es mayor el número de pérdidas en los grupos de intervención y durante la medición post-intervención. En los seguimientos, el número de pérdidas de los tres grupos se asemeja, ya que la razón de abandono en esas mediciones era falta de interés en responder a los cuestionarios.

## 4.4 Los factores personales relacionados con los estilos de vida y la salud mental

Como se ha expuesto en los apartados anteriores, en la presente tesis se ha ido encontrando una relación entre la modificación del estilo de vida y los síntomas depresivos. Sin embargo, en otros estudios, las variables psicológicas fueron las que tuvieron más peso a la hora de explicar las variaciones en las puntuaciones de depresión (en torno a un 35-44%); en contraste, los factores sociodemográficos y los factores de estilo de vida explicaron solo una variación mínima (Schneider et al., 2021). Por lo tanto, se necesita más investigación para determinar el peso de cada factor para explicar la varianza de la depresión. Por ejemplo, los factores personales son mecanismos psicológicos esenciales para el cambio de comportamiento. Estas variables están íntimamente ligadas a cambiar el locus de control de externo a interno, lo que resulta en un mayor autocontrol de la persona.

En los resultados pre-post del presente estudio, la autoeficacia, la activación en salud, el sentido de coherencia y la procrastinación se mejoraron significativamente en ambas intervenciones. Sin embargo, aunque disminuyó la sintomatología depresiva, la alfabetización en salud no aumentó significativamente. Este resultado es similar a otro estudio en el que no se encontró relación entre alfabetización en salud y depresión (Baird et al., 2019).

La autoeficacia se correlaciona con el nivel de actividad física (Blom et al., 2021) y funciona como mediadora entre las intervenciones y el cambio en actividad física (Anderson et al., 2010). Por lo tanto, al ser un mecanismo crítico para cambiar a un estilo de vida más activo (Holloway & Watson, 2002), puede ser beneficioso intentar aumentar el nivel de autoeficacia en las intervenciones (Blom et al., 2021).

En cuanto a la procrastinación, ésta se asocia con mayor estrés, más depresión, ansiedad, fatiga y menor satisfacción en todos los dominios de la vida, especialmente en lo que respecta al trabajo y los ingresos (Beutel et al., 2016).

Para ahondar en estos resultados, el objetivo secundario fue el de analizar la asociación entre la gravedad de la depresión, algunos patrones de estilo de vida (ejercicio físico y sedentarismo, sueño y adherencia a la dieta mediterránea) y algunos factores personales relacionados con el comportamiento de salud (autoeficacia, activación en la propia salud, sentido de coherencia, alfabetización en salud y procrastinación). También se pretendía analizar si los factores personales moderaban la relación entre estilos de vida y depresión.

En cuanto al análisis multivariante, los resultados mostraron que un bajo sentido de coherencia, mala calidad del sueño, baja activación respecto a la salud y más nivel de sedentarismo explicaban una mayor sintomatología depresiva. Estos hallazgos se suman

a la evidencia ya existente de que algunos estilos de vida y algunos factores personales están relacionados con la depresión.

En consonancia con estos resultados, se ha demostrado ampliamente que el sentido de coherencia está inversamente relacionado con la depresión, presentando una capacidad protectora frente a los síntomas depresivos (Anyfantakis et al., 2015; López-Martínez et al., 2019; Plata-Muñoz et al., 2004; Skärsäter et al., 2009) y siendo un recurso de promoción de la salud (Masanotti et al., 2020).

Por otro lado, la activación en salud se asocia con una mejor salud mental (McCusker et al., 2016) y está correlacionada negativamente con la depresión (Ngooi et al., 2017). Los síntomas depresivos suelen ir acompañados de emociones de impotencia y con mala calidad de vida, que luego se relacionan con puntuaciones bajas de activación en salud (Magnezi et al., 2014).

Como ya se ha comentado, el sedentarismo es reconocido como un factor de riesgo para la depresión (Porras-Segovia et al., 2019) ya que las personas sedentarias tienden a dedicar menos tiempo al ejercicio físico o actividades sociales (Zhai et al., 2015). También se ha demostrado que la calidad del sueño tiene un peso significativo en la explicación de la depresión. El sueño se ha relacionado con la depresión en múltiples estudios ya que la falta de sueño es uno de los síntomas más frecuentes que aparecen en la depresión (Wang et al., 2019).

El análisis bivariado reveló que las personas participantes con más síntomas depresivos tenían menor edad y menor puntuación en apoyo social, en autoeficacia, en activación, en sentido de coherencia y en alfabetización en salud. Además, los síntomas depresivos se relacionaron con un estilo de vida más sedentario, mala calidad del sueño y más procrastinación. Sin embargo, no se encontró relación significativa con respecto a la adherencia a la dieta mediterránea, ni con los minutos caminados semanalmente.

Respecto a la adherencia a la dieta mediterránea, esta asociación no significativa podría deberse a que, a nivel basal, la puntuación media de nuestra muestra fue de 6,38. En algunos estudios, para considerar que existe una adherencia óptima a un patrón de dieta mediterránea, el resultado tiene que ser superior a 9 (Gregório et al., 2020; Salvatore-Benito et al., 2019). Esta baja puntuación se ha encontrado en varios estudios que muestran cómo España y otros países mediterráneos se están alejando de los patrones de la dieta mediterránea (Godoy-Izquierdo et al., 2021).

En cuanto a los minutos caminados semanalmente, esta asociación no significativa podría deberse a que la media de minutos caminados en nuestra muestra a nivel basal fue de 212,32 por semana, que es más o menos la cantidad recomendada por la OMS (150 minutos a la semana de actividad física aeróbica moderada, o un mínimo de 75 minutos por semana de actividad aeróbica vigorosa) (WHO, 2010). Nuestra muestra realizaba una cantidad adecuada de ejercicio físico, pero la actividad física predominante fue caminar, que es la de menor intensidad. Por tanto, aunque todo ejercicio físico aporta beneficios para la salud, la frecuencia, intensidad y duración del ejercicio también tienen una influencia significativa en sus beneficios y tienen que ser tenidos en cuenta (WHO, 2010).

Esta relación entre caminar y la sintomatología depresiva requiere más investigación, ya que el cuestionario utilizado (*International Physical Activity Questionnaire Short-Form*, IPAQ-SF) tiene ciertas limitaciones. Por ejemplo, las personas pueden haber tenido dificultades conceptuales para distinguir entre actividad física vigorosa o moderada; para recordar sus actividades semanales; y pueden haber sobreestimado o subestimado la cantidad de actividad física realizada. En cualquier caso, la fiabilidad y validez del IPAQ-SF han sido rigurosamente comprobadas en muchos países, y es ampliamente utilizado en la investigación internacional actual (Aibar et al., 2016).

Por último, también se analizó si los factores personales moderaban la relación entre los estilos de vida y la depresión. Estos resultados no fueron significativos. Lo que quiere decir que, en nuestra muestra, la intensidad de la relación entre los diferentes estilos de vida y la depresión no cambia según el valor de los diferentes factores personales.

## 4.5 Los determinantes sociales de la salud y su relación con la salud mental en tiempos de COVID-19

Finalmente, y debido a la llegada y coincidencia del ensayo clínico con la COVID-19, se decidió llevar a cabo un estudio cualitativo que evaluara el impacto del confinamiento en las personas participantes.

Los resultados obtenidos destacan el impacto exacerbado que los DSS han tenido en las personas participantes durante la COVID-19, ya que las medidas adoptadas por el gobierno tuvieron un impacto inmediato y desigual en la salud mental debido a las condiciones de vivienda, condiciones de trabajo y desigualdades basadas en el género (Bambra et al., 2020).

Según el discurso de las personas participantes, el entorno en el que viven (vivienda y barrio) ha sido uno de los DSS que más influencia ha tenido (Chen et al., 2021; Solar & Irwin, 2010). Las personas que viven en pisos o casas con balcones o jardín pueden disfrutar de los beneficios de estar "como en la calle", y pueden caminar, tomar el sol y socializar con los vecinos. Esto corrobora la evidencia existente que sugiere que las malas condiciones de vivienda, incluido el hacinamiento y el escaso acceso al exterior o a espacios verdes, son perjudiciales para la salud física y mental (Bambra et al., 2020). Durante el confinamiento, la calle perdió su función positiva y se asoció con la propagación del virus. El miedo es una de las respuestas emocionales centrales durante

una pandemia, y fue alimentado por las noticias negativas que salían en los medios (Bavel et al., 2020).

Cuando se les preguntó acerca de las prácticas relacionadas con la salud, la mayoría de las personas participantes estaban preocupadas por su falta de rutina. Algunas echaban mucho de menos las actividades físicas que realizaban, como caminar (Bersani et al., 2019; Harvey et al., 2018). Aquellos que podían caminar por sus balcones creían que su salud mental mejoraba debido a que hacían más ejercicio (Stuart et al., 2020; Yang & Xiang, 2021). Caminar y sintetizar vitamina D gracias a la exposición al sol tiene efectos antidepresivos tanto como consecuencia de los procesos bioquímicos como del peso cultural que tiene estar al aire (Porroche-Escudero, 2012). Además, el ejercicio regular previene enfermedades cardíacas, la aparición de diabetes, y nos hace sentir bien (WHO, 2003).

El siguiente DSS que apareció el discurso fue el de la importancia de la comunidad, seguridad y redes sociales. Éstas tienen un impacto significativo en nuestra satisfacción con la vida y bienestar (Bzdok & Dunbar, 2020). Las redes de apoyo social sólidas mejoran la salud en el hogar, en el trabajo y la comunidad (WHO, 2003).

La convivencia con la familia fue descrita como una ventaja por la mayoría de las personas participantes. Estos resultados se alinean con el estudio de Günther-Bel et al. (Günther-Bel et al., 2020), que encontró que la dinámica familiar durante la cuarentena había mejorado en lugar de deteriorarse. Sin embargo, las relaciones solían ser más armoniosas cuando no había niños en el hogar (Günther-Bel et al., 2020). Nuestros datos también muestran que las familias con adolescentes vivieron momentos de tensión. Lo que esto significa es que las relaciones sociales son un arma de doble filo. Por un lado, proporcionar cuidados puede ser beneficioso porque ayuda a estar activo y tener compañía. Por otro lado, puede vivirse como una carga, y esto afecta negativamente a

nuestra salud (Koopman et al., 2020). Esto puede deberse a la combinación de cansancio emocional y físico que conlleva el cuidar, incrementado por la situación de pandemia (Navas-Martín et al., 2021), la falta de recursos y espacio y la repentina convivencia forzada con la familia (Bavel et al., 2020).

Debido a las desigualdades de género, las mujeres, en particular las que tienen pocos ingresos o las madres solteras, aún experimentan mayores niveles de carga (García-Mochón et al., 2019). Este hecho es aún más relevante si tenemos en cuenta que las mujeres tienen más probabilidades de ser diagnosticadas con depresión y sufren más las consecuencias derivadas de la pandemia (Amendola et al., 2021; Hidalgo et al., 2020; Kimhi et al., 2020).

Para las personas que vivían solas, la soledad se acentuó y tuvo consecuencias negativas en su salud mental (Kamin et al., 2021). La soledad (percibida como aislamiento social) afecta negativamente a la salud física y mental (Bavel et al., 2020; Bzdok & Dunbar, 2020). Las políticas de autoaislamiento pueden aumentar el aislamiento social y dificultan las relaciones (Bavel et al., 2020). El aislamiento social se puede prevenir aumentando el número de amistades y fomentando intereses comunes con otras personas, ya que esto promueve un sentimiento de pertenencia a una comunidad (Lapena et al., 2020).

Otro aspecto comentado fue el uso de tecnologías digitales. Se valoró la importancia de la calidad de las videollamadas, ya que les hacían sentirse cerca de otras personas (Sommerlad et al., 2021; von Humboldt et al., 2020). Pero los adultos mayores tenían diferentes opiniones sobre el uso de las tecnologías, hecho que hizo más evidente la brecha de alfabetización digital (Wheeler et al., 2020). Además, el uso de las tecnologías no puede reemplazar por completo las formas tradicionales de socialización

que implican más cercanía y contacto físico, algo que se valora positivamente en Europa occidental (Bavel et al., 2020).

En general, las personas que eran más sociables experimentaron síntomas depresivos durante el confinamiento debido a las consecuencias del aislamiento (Sommerlad et al., 2021). Sin embargo, para las personas con depresión, socializar puede ser un desafío (Fancourt & Baxter, 2020), por lo que algunas se sintieron más tranquilas en sus casas.

Por otro lado, algunas personas participantes han cambiado su visión de la vida, al prestar más atención a otros aspectos de su vida que habían descuidado, como pasar más tiempo con sus familias o dedicarse a actividades de ocio. Esto significa que consideraron que estar en casa era un privilegio, en lugar de verlo como algo negativo. Momentos estresantes como los vividos por la pandemia podrían ayudarnos a reorganizar nuestras prioridades y llevarnos a crear relaciones más profundas, apreciando más la vida (Tedeschi & Calhoun, 2004). Por tanto, durante el confinamiento también surgieron emociones positivas, por el aumento del tiempo de ocio y el ritmo de vida más lento (Simblett et al., 2021).

El acceso a los servicios públicos de salud fue otro de los DSS comentado. La mayoría de las personas participantes se sintieron satisfechas con el desempeño del sistema de salud durante el confinamiento, aunque varias mencionaron la falta de atención a la salud mental. La satisfacción general puede deberse a la imagen de "héroes" que los medios de comunicación otorgaban a los profesionales de la salud. Además, como en otros estudios, se encontró un fuerte sentido de responsabilidad civil (Ward, 2020).

De todos modos, se sigue demandando mayor atención por parte del sistema público de salud; ya que si las personas participantes han recibido atención psicológica ha sido principalmente a través de asociaciones privadas. La atención de la salud mental

es crítica ya que también afecta al resto de la familia, la cual tiene que cubrir las deficiencias de los sistemas de cuidado, lo que genera una sobrecarga y una disminución de la calidad de vida de los cuidadores (Carbonell et al., 2020).

En nuestro estudio nos centramos específicamente en las personas con depresión. Este campo de investigación es fundamental ya que se ha reconocido que tanto las personas con trastornos mentales como sus familias deben participar en el desarrollo de políticas, para así contribuir a la mejora de los sistemas de salud mental en todo el mundo (Carbonell et al., 2020).

## 4.6 Fortalezas

- La primera fortaleza de esta tesis fue el diseño del estudio: un ECA pragmático con homogeneidad muestral de las principales variables entre los tres grupos (TAU, TAU+LMP y TAU+LMP+ICTs). Dado que la aleatorización, las evaluaciones y el análisis estadístico fueron ciegos, los resultados poseen mayor validez. Esto se ve fundamentado en que los ECAs con asignación aleatoria se encuentran en el nivel 1b de evidencia según la clasificación propuesta por el *Oxford Centre for Evidence- Based Medicine* (OCEBM) (Mella-Sousa et al., 2012).
- Los cuestionarios administrados fueron instrumentos validados y ampliamente usados, y se obtuvo una adecuada validez interna de los mismos en nuestra muestra.
- Como novedad, se ha creado una intervención multicomponente en la cual se analiza conjuntamente diversos factores del estilo de vida y factores personales (calidad del sueño, ejercicio físico, adherencia a la dieta mediterránea,

autoeficacia, activación en salud, sentido de coherencia, alfabetización en salud y procrastinación).

- El perfil de las personas participantes se correspondía con el de las personas que asistían habitualmente a las consultas de APS, lugar en el que se atiende al mayor porcentaje de personas con síntomas depresivos, ya solo un pequeño porcentaje son derivados a centros de salud mental especializados.
- Los hallazgos de la investigación son fácilmente transferibles a la práctica porque las intervenciones se realizaron en centros de APS y pueden ser llevadas a cabo por profesionales de la salud mental, y por facultativos/as especialistas en medicina familiar y comunitaria, personal de enfermería, o trabajadores/as sociales.
- Llevar a cabo un Análisis de Datos Secundario con los datos basales es una estrategia rentable para complementar los resultados primarios, y sirve como punto de partida para futuras investigaciones (McCaston, 2005).
- Finalmente, un número importante de personas participantes han podido ser evaluadas después un año, permitiendo obtener resultados a largo plazo.

## 4.7 Limitaciones

- En cuanto a las limitaciones de la presente tesis, se incluye la cantidad de pérdidas en los seguimientos de la intervención. Esto se debió principalmente a la incompatibilidad de horarios de las personas participantes para asistir a las sesiones presenciales o a la falta de interés en responder a todos los cuestionarios durante el período de seguimiento.

- En cualquier caso, se alcanzó el tamaño muestral establecido y los análisis se realizaron por intención de tratar. En el estudio de seguimiento de un año, se usó la técnica de imputación múltiple para tratar los datos faltantes.
- Otra limitación fue la coincidencia del estudio con la pandemia de la COVID-19, ya que podría haber dificultado que las personas participantes implementaran completamente las recomendaciones de estilo de vida durante ese período de tiempo, sobre todo durante las semanas de confinamiento, porque su rutina habitual se vio alterada. Esta limitación se intentó solventar realizando un estudio cualitativo para explorar las experiencias que las personas participantes vivieron durante el confinamiento y se vio cómo los DSS habían tenido una influencia en su salud mental.
- Debido a la naturaleza de la intervención, la profesional de salud mental que dirigió las intervenciones y las personas participantes conocían la intervención asignada durante el ECA.
- La muestra era predominantemente femenina, en consonancia con las tasas de prevalencia de la depresión, por lo que no se pudo realizar un análisis por género.
- El Análisis Secundario de Datos, a pesar de ser una estrategia adecuada, no sirve para hacer inferencias causales (Wickham, 2019), y las asociaciones identificadas pueden ser difíciles de interpretar (Wang & Cheng, 2020). Debido a la naturaleza exploratoria de este análisis, no se realizaron estimaciones del tamaño de la muestra ni ajustes del valor de *p*. Por lo tanto, los hallazgos deben interpretarse con cautela y solo deben considerarse como resultados preliminares de asociaciones que deben estudiarse más a fondo.

- Las entrevistas del estudio cualitativo se realizaron por teléfono debido a las restricciones del periodo de confinamiento, por lo que es posible que se haya perdido parte de la información no verbal.

## 4.8 Futuros estudios

- ECAs futuros podrían considerar otras estrategias de adherencia a la intervención para evitar el abandono. Por ejemplo, se ha demostrado que el envío de mensajes de texto es eficaz para aumentar la actividad física (Melnyk et al., 2020). Además, se podría ofrecer la intervención online o en diferido para vencer el problema de la incompatibilidad horaria. Por otro lado, convendría realizar estudios cualitativos para analizar más a fondo las razones de abandono de la intervención.
- En cuanto al uso de las TICs, se necesitan más estudios para determinar cómo mejorar las tasas de adherencia a las tecnologías para que las personas puedan usar dispositivos portátiles de forma continua durante 24 horas (Lee et al., 2021).
- Trabajar con tamaños de muestra más grandes podrían permitir diversos subanálisis. Por ejemplo, permitiría analizar la efectividad de la intervención según los diferentes grados de la depresión (es decir, subclínica, leve, moderada e incluso grave) o según diferentes características sociodemográficas. También, se podría analizar qué perfiles de personas podrían beneficiarse más de la intervención.
- La interrelación entre estilos de vida, factores personales y depresión debe estudiarse más a fondo, por ejemplo, probando otros tipos de análisis como la mediación y/o utilizando datos longitudinales.

# 5. CONCLUSIONES GENERALES

La evidencia científica demostrada en la presente tesis sobre la efectividad de los Programas de Modificación del Estilo de Vida (LMPs) para la mejora de los síntomas depresivos comparación con el tratamiento habitual (TAU) en centros de atención primaria de salud (APS) permite extraer las siguientes conclusiones.

Primero, a corto y a medio plazo, los LMPs realizados en APS para personas con síntomas depresivos son efectivos para disminuir la sintomatología depresiva.

Segundo, a corto plazo, los LMPs son efectivos para mejorar algunos estilos de vida (en concreto, mejorar la calidad del sueño, aumentar el número de minutos de caminata semanales y aumentar la adherencia a la dieta mediterránea) y mejorar algunos de los factores personales (en concreto, la autoeficacia, la activación de la persona en su propia salud y el sentido de coherencia).

Tercero, a medio plazo (seguimiento a los 6 meses), el TAU+LMP es efectivo para mejorar la calidad de sueño. Por otro lado, el LMP junto con el uso de un reloj inteligente (TAU+LMP+ICTs) es efectivo para aumentar el número de minutos de caminata semanales y la adherencia a la dieta mediterránea.

Cuarto, a largo plazo (seguimiento a los 12 meses), el LMP junto con el uso de un reloj inteligente (TAU+LMP+ICTs) es efectivo para mejorar los síntomas depresivos y reducir el sedentarismo.

Quinto, un bajo sentido de coherencia, un mayor nivel de activación respecto a la salud, un mayor sedentarismo y una peor calidad del sueño explican la presencia de una mayor sintomatología depresiva.

Sexto, a nivel basal, la relación de los factores del estilo de vida con la sintomatología depresiva no está moderada por los diferentes factores personales analizados.

Séptimo, los determinantes sociales de la salud han tenido un papel fundamental en las experiencias de las personas que presentan síntomas depresivos durante el confinamiento por la pandemia de la COVID-19. En concreto, estos determinantes sociales han sido: las condiciones de vivienda y trabajo, la salud física y mental, el acceso a los servicios de salud, y las redes sociales y comunitarias.

Octavo, el cumplimiento de las recomendaciones sobre estilo de vida se puede ver influenciado por el apoyo y monitorización que se brinde a las personas participantes.

# GENERAL CONCLUSIONS

The scientific evidence demonstrated in the present thesis regarding the efficacy of Lifestyle Modification Programs (LMPs) for the improvement of depressive symptoms compared to Treatment as Usual (TAU) in Primary Healthcare Centers (PHCs) allows us to draw the following conclusions:

First, in the short and medium term, the LMPs carried out in PHCs for people with depressive symptoms are effective in reducing depressive symptoms.

Second, in the short term, LMPs are effective in improving some lifestyles (specifically, improving sleep quality, increasing the number of minutes of walking per week, and increasing adherence to the Mediterranean diet) and improving some personal factors (specifically, self-efficacy, health activation and sense of coherence).

Third, in the medium term (follow-up at 6 months), TAU+LMP is effective in improving sleep quality. On the other hand, the LMP together with the use of a smartwatch (TAU+LMP+ICTs) is effective in increasing the number of minutes of walking per week and adherence to the Mediterranean diet.

Fourth, in the long term (12-month follow-up), the LMP together with the use of a smartwatch (TAU+LMP+ICTs) is effective in improving depressive symptoms and reducing sedentarism.

Fifth, a low sense of coherence, a higher level of health activation, a greater sedentarism and a worse sleep quality explain the presence of greater depressive symptoms.

Sixth, at baseline, the relationship of lifestyle factors with depressive symptomatology is not moderated by the different personal factors analyzed.

Seventh, the social determinants of health have played a fundamental role in the experiences of people who present depressive symptoms during the lockdown due to the

COVID-19 pandemic. Specifically, these social determinants of health have been: housing and work conditions, physical and mental health, access to health services, and social and community networks.

Eighth, compliance with lifestyle recommendations can be influenced by the support and monitoring provided to the participants.

# 6. BIBLIOGRAFÍA

Abdelmaksoud, A., Vojvodic, A., Ayhan, E., Dönmezdil, S., Jovicevic, T. V., Vojvodic, P., Lotti, T., & Vestita, M. (2019). Depression, isotretinoin, and folic acid: A practical review. *Dermatologic Therapy*, *32*(6), 1–5. https://doi.org/10.1111/dth.13104

Acciai, F., & Hardy, M. (2017). Depression in later life: A closer look at the gender gap. *Social Science Research*, *68*, 163–175. https://doi.org/10.1016/j.ssresearch.2017.08.003

Achttien, R., Van Lieshout, J., Wensing, M., Van Der Sanden, M. N., & Staal, J. B. (2019). Symptoms of depression are associated with physical inactivity but not modified by gender or the presence of a cardiovascular disease; A cross-sectional study. *BMC Cardiovascular Disorders*, *19*(1), 1–7. https://doi.org/10.1186/s12872-019-1065-8

Aguilar-Latorre, A., Navarro, C., Oliván-Blázquez, B., Gervilla, E., Magallón Botaya, R., Calafat-Villalonga, C., García-Toro, M., Boira, S., & Serrano-Ripoll, M. J. (2020). Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol. *BMJ Open*, *10*(12). https://doi.org/10.1136/bmjopen-2020-038457

Aguilar-Latorre, A., Oliván-Blázquez, B., Porroche-Escudero, A., Méndez-López, F., García-Gallego, V., Benedé-Azagra, B., & Magallón-Botaya, R. (2022). The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain. *BMC Public Health*, *22*(780), 1–13.

https://doi.org/10.1186/s12889-022-13083-2

Aguilar-Latorre, A., Pérez Algorta, G., Navarro-Guzmán, C., Serrano-Ripoll, M. J., & Oliván-Blázquez, B. (2022). Effectiveness of a lifestyle modification programme in the treatment of depression symptoms in primary care. *Frontiers in Medicine*, *9*, 954644. https://doi.org/10.3389/fmed.2022.954644

Aguilar-Latorre, A., Serrano-Ripoll, M. J., Oliván-Blázquez, B., Gervilla, E., & Navarro, C. (2022). Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial. *Frontiers in Psychology*, *13*, 856139. https://doi.org/10.3389/fpsyg.2022.856139

Aguilar-Shea, A. L., Muñoz Moreno-Arrones, O., Palacios-Martínez, D., & Vaño-Galván, S. (2020). Vitamina D para la práctica diaria. *Medicina de Familia. SEMERGEN*, *46*(6), 406–410. https://doi.org/10.1016/j.semerg.2020.02.008

Aguilera-Martín, Á., Gálvez-Lara, M., Cuadrado, F., Moreno, E., García-Torres, F., Venceslá, J. F., Corpas, J., Jurado-González, F. J., Muñoz-Navarro, R., González-Blanch, C., Ruiz-Rodríguez, P., Barrio-Martínez, S., Prieto-Vila, M., Carpallo-González, M., Cano-Vindel, A., & Moriana, J. A. (2022). Cost-effectiveness and cost-utility evaluation of individual vs. group transdiagnostic psychological treatment for emotional disorders in primary care (PsicAP-Costs): a multicentre randomized controlled trial protocol. *BMC Psychiatry*, *22*(1), 1–15. https://doi.org/10.1186/s12888-022-03726-4

Aibar, A., García-González, L., Abarca-Sos, A., Murillo, B., & Zaragoza, J. (2016). Analizando la validación del International Physical Activity Questionnaire en jóvenes adolescentes: Un protocolo modificado para la recogida de los datos. *SPORT*

*TK-Revista EuroAmericana de Ciencias Del Deporte*, *5*(2), 123–132. https://doi.org/10.6018/264761

Ali, A. M., & Kunugi, H. (2020). COVID-19: A pandemic that threatens physical and mental health by promoting physical inactivity. *Sports Medicine and Health Science*, *2*(4), 221–223. https://doi.org/10.1016/j.smhs.2020.11.006

Alonso, J., Angermeyer, M. C., Bernert, S., Bruffaerts, R., Brugha, T. S., Bryson, H., Girolamo, G., Graaf, R., Demyttenaere, K., Gasquet, I., Haro, J. M., Katz, S. J., Kessler, R. C., Kovess, V., Lepine, J. P., Ormel, J., Polidori, G., Russo, L. J., Vilagut, G., … Vollebergh, W. A. M. (2004a). Disability and quality of life impact of mental disorders in Europe: results from the European Study of the Epidemiology of Mental Disorders (ESEMeD) project. *Acta Psychiatrica Scandinavica*, *109*(s420), 38–46. https://doi.org/10.1111/j.1600-0047.2004.00329.x

Alonso, J., Angermeyer, M. C., Bernert, S., Bruffaerts, R., Brugha, T. S., Bryson, H., Girolamo, G., Graaf, R., Demyttenaere, K., Gasquet, I., Haro, J. M., Katz, S. J., Kessler, R. C., Kovess, V., Lepine, J. P., Ormel, J., Polidori, G., Russo, L. J., Vilagut, G., … Vollebergh, W. A. M. (2004b). Use of mental health services in Europe: results from the European Study of the Epidemiology of Mental Disorders (ESEMeD) project. *Acta Psychiatrica Scandinavica*, *109*(s420), 47–54. https://doi.org/10.1111/j.1600-0047.2004.00330.x

Amendola, S., Spensieri, V., Hengartner, M. P., & Cerutti, R. (2021). Mental health of Italian adults during COVID-19 pandemic. *British Journal of Health Psychology*, *26*(2), 644–656. https://doi.org/10.1111/bjhp.12502

American Psychiatric Association. (2013). DSM-5 Diagnostic Classification. In *Diagnostic and Statistical Manual of Mental Disorders*. American Psychiatric

Association. https://doi.org/10.1176/appi.books.9780890425596.x00DiagnosticClassification

Anderson, E. S., Winett, R. A., Wojcik, J. R., & Williams, D. M. (2010). Social cognitive mediators of change in a group randomized nutrition and physical activity intervention: Social support, self-efficacy, outcome expectations and self-regulation in the guide-to-health trial. *Journal of Health Psychology*, *15*(1), 21–32. https://doi.org/10.1177/1359105309342297

Andlin-Sobocki, P., Jonsson, B., Wittchen, H.-U., & Olesen, J. (2005). Cost of disorders of the brain in Europe. *European Journal of Neurology*, *12*(s1), 1–27. https://doi.org/10.1111/j.1468-1331.2005.01202.x

Andrade-Gómez, E., Martínez-Gómez, D., Rodríguez-Artalejo, F., & García-Esquinas, E. (2018). Sedentary behaviors, physical activity, and changes in depression and psychological distress symptoms in older adults. *Depression and Anxiety*, *35*(9), 884–897. https://doi.org/10.1002/da.22804

Anglin, R. E. S., Samaan, Z., Walter, S. D., & Sarah, D. M. (2013). Vitamin D deficiency and depression in adults: Systematic review and meta-analysis. *British Journal of Psychiatry*, *202*(2), 100–107. https://doi.org/10.1192/bjp.bp.111.106666

Antonovsky, A. (1993). The structure and properties of the sense of coherence scale. *Social Science & Medicine*, *36*(6), 725–733. https://doi.org/10.1016/0277-9536(93)90033-Z

Antonovsky, A. (1996). The salutogenic model as a theory to guide health promotion. *Health Promotion International*, *11*(1), 11–18. https://doi.org/10.1093/heapro/11.1.11

Anyfantakis, D., Symvoulakis, E. K., Linardakis, M., Shea, S., Panagiotakos, D., & Lionis, C. (2015). Effect of religiosity/spirituality and sense of coherence on depression within a rural population in Greece: The Spili III project. *BMC Psychiatry*, *15*(1), 1–7. https://doi.org/10.1186/s12888-015-0561-3

Appleton, K. M., Sallis, H. M., Perry, R., Ness, A. R., & Churchill, R. (2016). ω-3 Fatty acids for major depressive disorder in adults: an abridged Cochrane review. *BMJ Open*, *6*(e010172). https://doi.org/10.1136/bmjopen-2015-010172

Aragonès, E., Piñol, J. L., Labad, A., Masdéu, R. M., Pino, M., & Cervera, J. (2004). Prevalence and determinants of depressive disorders in primary care practice in Spain. *The International Journal of Psychiatry in Medicine*, *34*(1), 21–35. https://doi.org/10.2190/C25N-W4NY-BN8W-TXN2

Arendt, F., Markiewitz, A., Mestas, M., & Scherr, S. (2020). COVID-19 pandemic, government responses, and public mental health: Investigating consequences through crisis hotline calls in two countries. *Social Science & Medicine*, *265*(113532). https://doi.org/10.1016/j.socscimed.2020.113532

Artiga, S., & Hinton, E. (2018). Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity. In *Kaiser Family Foundation* (Issue May). https://www.kff.org/disparities-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/

Asarnow, L. D., Soehner, A. M., & Harvey, A. G. (2014). Basic sleep and circadian science as building blocks for behavioral interventions: A translational approach for mood disorders. *Behavioral Neuroscience*, *128*(3), 360–370. https://doi.org/10.1037/a0035892

Baird, B., Oh, K. M., Douglas, C., & Weinstein, A. A. (2019). Health Literacy, Depression Literacy, and Depression among Older Korean Americans. *Journal of Health Communication*, *24*(5), 525–535. https://doi.org/10.1080/10810730.2019.1632395

Bambra, C., Riordan, R., Ford, J., & Matthews, F. (2020). The COVID-19 pandemic and health inequalities. *Journal of Epidemiology and Community Health*, *74*(11), 964–968. https://doi.org/10.1136/jech-2020-214401

Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*, *84*(2), 191–215. https://doi.org/10.1037/0033-295X.84.2.191

Bavel, J. J. V., Baicker, K., Boggio, P. S., Capraro, V., Cichocka, A., Cikara, M., Crockett, M. J., Crum, A. J., Douglas, K. M., Druckman, J. N., Drury, J., Dube, O., Ellemers, N., Finkel, E. J., Fowler, J. H., Gelfand, M., Han, S., Haslam, S. A., Jetten, J., … Willer, R. (2020). Using social and behavioural science to support COVID-19 pandemic response. *Nature Human Behaviour*, *4*(5), 460–471. https://doi.org/10.1038/s41562-020-0884-z

Becker, N. B., Jesus, S. N., João, K. A. D. R., Viseu, J. N., & Martins, R. I. S. (2017). Depression and sleep quality in older adults: a meta-analysis. *Psychology, Health and Medicine*, *22*(8), 889–895. https://doi.org/10.1080/13548506.2016.1274042

Bender, A., Hagan, K. E., & Kingston, N. (2017). The association of folate and depression: A meta-analysis. *Journal of Psychiatric Research*, *95*, 9–18. https://doi.org/10.1016/j.jpsychires.2017.07.019

Bersani, F. S., Ghezzi, F., Maraone, A., Vicinanza, R., Cavaggioni, G., Biondi, M., &

Pasquini, M. (2019). The relationship between Vitamin D and depressive disorders La. *Rivista Di Psichiatria*, *54*(6), 229–233. https://doi.org/10.1708/3281.32541

Beutel, M. E., Klein, E. M., Aufenanger, S., Brähler, E., Dreier, M., Müller, K. W., Quiring, O., Reinecke, L., Schmutzer, G., Stark, B., & Wölfling, K. (2016). Procrastination, distress and life satisfaction across the age range - A German representative community study. *PLoS ONE*, *11*(2), 1–12. https://doi.org/10.1371/journal.pone.0148054

Biddle, S. J. H., Henson, J., Davies, M. J., Khunti, K., Sutton, S., Yates, T., & Edwardson, C. L. (2021). Device-assessed total and prolonged sitting time: associations with anxiety, depression, and health-related quality of life in adults. *Journal of Affective Disorders*, *287*, 107–114. https://doi.org/10.1016/j.jad.2021.03.037

Blom, V., Drake, E., Kallings, L. V, Ekblom, M. M., & Nooijen, C. F. J. (2021). The effects on self-efficacy, motivation and perceived barriers of an intervention targeting physical activity and sedentary behaviours in office workers: a cluster randomized control trial. *BMC Public Health*, *21*(1048). https://doi.org/10.1186/s12889-021-11083-2

Boelen, P. A., & O'Connor, M. (2022). Is a sense of coherence associated with prolonged grief, depression, and satisfaction with life after bereavement? A longitudinal study. *Clinical Psychology & Psychotherapy*, 1–12. https://doi.org/10.1002/cpp.2774

Boulos, C., & Salameh, P. (2021). Gender-specific factors associated with risk of depression among Lebanese older adults. *Psychogeriatrics*, *21*(4), 577–585. https://doi.org/10.1111/psyg.12708

Bozdağ, F. (2021). The psychological effects of staying home due to the COVID-19

pandemic. *The Journal of General Psychology*, *148*(3), 226–248. https://doi.org/10.1080/00221309.2020.1867494

Brooks, S. K., Webster, R. K., Smith, L. E., Woodland, L., Wessely, S., Greenberg, N., & Rubin, G. J. (2020). The psychological impact of quarantine and how to reduce it: rapid review of the evidence. *The Lancet*, *395*(10227), 912–920. https://doi.org/10.1016/S0140-6736(20)30460-8

Brunelli, A. A., Murphy, G. C., & Athanasou, J. A. (2016). Effectiveness of Social Support Group Interventions for Psychosocial Outcomes: A Meta-analytic Review. *The Australian Journal of Rehabilitation Counselling*, *22*(2), 104–127. https://doi.org/10.1017/jrc.2016.9

Burstrom, B., & Tao, W. (2020). Social determinants of health and inequalities in COVID-19. *European Journal of Public Health*, *30*(4), 617–618. https://doi.org/10.1093/eurpub/ckaa095

Bzdok, D., & Dunbar, R. I. M. (2020). The Neurobiology of Social Distance. *Trends in Cognitive Sciences*, *24*(9), 717–733. https://doi.org/10.1016/j.tics.2020.05.016

Cabello, M., Miret, M., Caballero, F. F., Chatterji, S., Naidoo, N., Kowal, P., D'Este, C., & Ayuso-Mateos, J. L. (2017). The role of unhealthy lifestyles in the incidence and persistence of depression: a longitudinal general population study in four emerging countries. *Globalization and Health*, *13*(18), 1–8. https://doi.org/10.1186/s12992-017-0237-5

Cameron, C., Habert, J., Anand, L., & Furtado, M. (2014). Optimizing the management of depression: primary care experience. *Psychiatry Research*, *220*(S1), S45–S57. https://doi.org/10.1016/S0165-1781(14)70005-8

Campion, J., Javed, A., Sartorius, N., & Marmot, M. (2020). Addressing the public mental health challenge of COVID-19. *The Lancet Psychiatry*, *7*(8), 657–659. https://doi.org/10.1016/S2215-0366(20)30240-6

Carbonell, Á., Navarro-Pérez, J. J., & Mestre, M. V. (2020). Challenges and barriers in mental healthcare systems and their impact on the family: A systematic integrative review. *Health and Social Care in the Community*, *28*(5), 1366–1379. https://doi.org/10.1111/hsc.12968

Carek, P. J., Laibstain, S. E., & Carek, S. M. (2011). Exercise for the treatment of depression and anxiety. *International Journal of Psychiatry in Medicine*, *41*(1), 15–28. https://doi.org/10.2190/PM.41.1.c

Casañas, R., Catalán, R., Raya, A., & Real, J. (2014). Efectividad de un programa grupal psicoeducativo para la depresión mayor en atención primaria: ensayo clínico controlado aleatorizado. *Revista de La Asociación Española de Neuropsiquiatría*, *34*(121), 145–146. https://doi.org/10.4321/s0211-57352014000100009

Cassano, P., & Fava, M. (2002). Depression and public health. *Journal of Psychosomatic Research*, *53*(4), 849–857. https://doi.org/10.1016/S0022-3999(02)00304-5

Chen, K.-L., Hung, W.-C., Lee, M.-B., Chen, I.-M., & Wu, C.-Y. (2020). The Impact of the COVID-19 Pandemic on the Health and Coping Behaviors of Patients With Treatment-Resistant Depression. *The Journal of Nursing*, *67*(5), 56–64. https://doi.org/https://doi.org/10.6224/JN.202010_67(5).08

Chen, X., Zou, Y., & Gao, H. (2021). Role of neighborhood social support in stress coping and psychological wellbeing during the COVID-19 pandemic: Evidence from Hubei, China. *Health & Place*, *69*, 102532.

https://doi.org/10.1016/j.healthplace.2021.102532

Chisholm, D., Sweeny, K., Sheehan, P., Rasmussen, B., Smit, F., Cuijpers, P., & Saxena, S. (2016). Scaling-up treatment of depression and anxiety: A global return on investment analysis. *The Lancet Psychiatry*, *3*(5), 415–424. https://doi.org/10.1016/S2215-0366(16)30024-4

Chung, K.-F., Lee, C.-T., Yeung, W.-F., Chan, M.-S., Chung, E. W.-Y., & Lin, W.-L. (2018). Sleep hygiene education as a treatment of insomnia: a systematic review and meta-analysis. *Family Practice*, *35*(4), 365–375. https://doi.org/10.1093/fampra/cmx122

Codony, M., Alonso, J., Almansa, J., Vilagut, G., Domingo, A., Pinto-Meza, A., Fernández, A., Usall, J., Dolz, M., & Haro, J. M. (2007). [Mental health care use in the Spanish general populations. Results of the ESEMeD-Spain study]. *Actas Españolas de Psiquiatría*, *35*(S2), 21–28. http://www.ncbi.nlm.nih.gov/pubmed/18264866

Conde-Pipó, J., Bouzas, C., Zurita-Ortega, F., Olea-Serrano, F., Tur, J. A., & Mariscal-Arcas, M. (2022). Adherence to a Mediterranean Diet Pattern, Physical Activity, and Physical Self-Concept in Spanish Older Adults. *Nutrients*, *14*(12), 1–11. https://doi.org/10.3390/nu14122404

Craven, M. A., & Bland, R. (2013). Depression in Primary Care: Current and Future Challenges. *The Canadian Journal of Psychiatry*, *58*(8), 442–448. https://doi.org/10.1177/070674371305800802

Cui, N., Cui, J., Xu, X., Aslam, B., Bai, L., Li, D., Wu, D., Ma, Z., Sun, J., & Baloch, Z. (2021). Health Conditions, Lifestyle Factors and Depression in Adults in Qingdao,

China: A Cross-Sectional Study. *Frontiers in Psychiatry*, *12*, 508810. https://doi.org/10.3389/fpsyt.2021.508810

Cui, Y., Gong, Q., Huang, C., Guo, F., Li, W., Wang, Y., & Cheng, X. (2021). The relationship between sunlight exposure duration and depressive symptoms: A cross-sectional study on elderly Chinese women. *PLOS ONE*, *16*(e0254856), 1–9. https://doi.org/10.1371/journal.pone.0254856

Cuijpers, P., van Straten, A., van Schaik, A., & Andersson, G. (2009). Psychological treatment of depression in primary care: a meta-analysis. *British Journal of General Practice*, *59*(559), e51–e60. https://doi.org/10.3399/bjgp09X395139

Davidson, J. R. T. (2010). Major Depressive Disorder Treatment Guidelines in America and Europe. *The Journal of Clinical Psychiatry*, *71*(suppl E1). https://doi.org/10.4088/JCP.9058se1c.04gry

De Rezende, L. F. M., Rey-López, J. P., Matsudo, V. K. R., & Luiz, O. D. C. (2014). Sedentary behavior and health outcomes among older adults: A systematic review. *BMC Public Health*, *14*(1), 1–9. https://doi.org/10.1186/1471-2458-14-333

Demura, S., & Sato, S. (2003). Relationships between Depression, Lifestyle and Quality of Life in the Community Dwelling Elderly: A Comparison between Gender and Age Groups. *Journal of PHYSIOLOGICAL ANTHROPOLOGY and Applied Human Science*, *22*(3), 159–166. https://doi.org/10.2114/jpa.22.159

Dominick, G. M., Dunsiger, S. I., Pekmezi, D. W., & Marcus, B. H. (2013). Health literacy predicts change in physical activity self-efficacy among sedentary Latinas. *Journal of Immigrant and Minority Health*, *15*(3), 533–539. https://doi.org/10.1007/s10903-012-9666-7

Doron Amsalem, Dixon, L. B., & Neria, Y. (2021). Mental health care during the ebola virus disease outbreak in Sierra Leone. *JAMA Psychiatry January*, *78*(1), 9–10. https://doi.org/10.2471/BLT.16.190470

Du, M., Dai, W., Liu, J., & Tao, J. (2022). Less Social Participation Is Associated With a Higher Risk of Depressive Symptoms Among Chinese Older Adults: A Community-Based Longitudinal Prospective Cohort Study. *Frontiers in Public Health*, *10*(781771), 1–12. https://doi.org/10.3389/fpubh.2022.781771

Evans, T., Whitehead, M., Diderichsen, F., Bhuiya, A., & Wirth, M. (2001). *Challenging Inequities in Health: From Ethics to Action* (T. Evans, M. Whitehead, F. Diderichsen, A. Bhuiya, & M. Wirth (eds.)). Oxford University Press. https://doi.org/10.1093/acprof:oso/9780195137408.001.0001

Fancourt, D., & Baxter, L. (2020). Differential participation in community cultural activities amongst those with poor mental health: Analyses of the UK Taking Part Survey. *Social Science & Medicine*, *261*, 113221. https://doi.org/10.1016/j.socscimed.2020.113221

Fang, H., Tu, S., Sheng, J., & Shao, A. (2019). Depression in sleep disturbance: A review on a bidirectional relationship, mechanisms and treatment. *Journal of Cellular and Molecular Medicine*, *23*(4), 2324–2332. https://doi.org/10.1111/jcmm.14170

Farzi, A., Hassan, A. M., Zenz, G., & Holzer, P. (2019). Diabesity and mood disorders: Multiple links through the microbiota-gut-brain axis. *Molecular Aspects of Medicine*, *66*, 80–93. https://doi.org/10.1016/j.mam.2018.11.003

Ferrari, A. J., Charlson, F. J., Norman, R. E., Patten, S. B., Freedman, G., Murray, C. J. L., Vos, T., & Whiteford, H. A. (2013). Burden of Depressive Disorders by Country,

Sex, Age, and Year: Findings from the Global Burden of Disease Study 2010. *PLoS Medicine*, *10*(11), e1001547. https://doi.org/10.1371/journal.pmed.1001547

Firth, J., Marx, W., Dash, S., Carney, R., Teasdale, S. B., Solmi, M., Stubbs, B., Schuch, F. B., Carvalho, A. F., Jacka, F., & Sarris, J. (2019). The Effects of Dietary Improvement on Symptoms of Depression and Anxiety: A Meta-Analysis of Randomized Controlled Trials. *Psychosomatic Medicine*, *81*(3), 265–280. https://doi.org/10.1097/PSY.0000000000000673

Frank, R. G., Huskamp, H. A., & Pincus, H. A. (2003). Aligning incentives in the treatment of depression in primary care with evidence-based practice. *Psychiatric Services*, *54*(5), 682–687. https://doi.org/10.1176/appi.ps.54.5.682

Gabilondo, A., Rojas-Farreras, S., Vilagut, G., Haro, J. M., Fernández, A., Pinto-Meza, A., & Alonso, J. (2010). Epidemiology of major depressive episode in a southern European country: Results from the ESEMeD-Spain project. *Journal of Affective Disorders*, *120*(1–3), 76–85. https://doi.org/10.1016/j.jad.2009.04.016

Gantenbein, K. V., & Kanaka-Gantenbein, C. (2021). Mediterranean Diet as an Antioxidant: The Impact on Metabolic Health and Overall Wellbeing. *Nutrients*, *13*(6), 1951. https://doi.org/10.3390/nu13061951

Gao, W., Ping, S., & Liu, X. (2020). Gender differences in depression, anxiety, and stress among college students: A longitudinal study from China. *Journal of Affective Disorders*, *263*, 292–300. https://doi.org/10.1016/j.jad.2019.11.121

García-Mochón, L., Peña-Longobardo, L. M., del Río-Lozano, M., Oliva-Moreno, J., Larrañaga-Padilla, I., & García-Calvente, M. del M. (2019). Determinants of Burden and Satisfaction in Informal Caregivers: Two Sides of the Same Coin? The

CUIDAR-SE Study. *International Journal of Environmental Research and Public Health*, *16*(22), 4378. https://doi.org/10.3390/ijerph16224378

García-Toro, M. (2014). *Estilo de vida y depresión* (1ª ed). Síntesis.

Garcia-Toro, M., Roca, M., Monzón, S., Vives, M., Oliván, B., Vicens, E., Salva, J., & Gili, M. (2012). Hygienic-dietary recommendations for major depression treatment: Study protocol of a randomized controlled trial. *BMC Psychiatry*, *12*, 2–7. https://doi.org/10.1186/1471-244X-12-201

Giglio, R. E., Rodriguez-Blazquez, C., De Pedro-Cuesta, J., & Forjaz, M. J. (2015). Sense of coherence and health of community-dwelling older adults in Spain. *International Psychogeriatrics*, *27*(4), 621–628. https://doi.org/10.1017/S1041610214002440

Gili, M., Riera-Serra, P., Roldán-Espínola, L., Castro, A., Coronado-Simsic, V., García-Toro, M., & Roca, M. (2022). Detection and treatment of depressive disorder in the spanish health system: a critical review. *Actas Españolas de Psiquiatría*, *50*(4), 187–195. http://www.ncbi.nlm.nih.gov/pubmed/35867485

Głąbska, D., Guzek, D., Groele, B., & Gutkowska, K. (2020). Fruit and Vegetable Intake and Mental Health in Adults: A Systematic Review. *Nutrients*, *12*(1), 115. https://doi.org/10.3390/nu12010115

Godoy-Izquierdo, D., Ogallar, A., Lara, R., Rodríguez-Tadeo, A., & Arbinaga, F. (2021). Association of a Mediterranean Diet and Fruit and Vegetable Consumption with Subjective Well-Being among Adults with Overweight and Obesity. *Nutrients*, *13*(4), 1342. https://doi.org/10.3390/nu13041342

Goldberg, D., Kendler, K. S., Sirovatks, P. J., & Regier, D. A. (2011). *Temas de investigación DSM-V: Depresión y trastorno de ansiedad generalizada* (1ª ed).

Panamericana.

Gómez-Donoso, C., Sánchez-Villegas, A., Martínez-González, M. A., Gea, A., Mendonça, R. de D., Lahortiga-Ramos, F., & Bes-Rastrollo, M. (2020). Ultra-processed food consumption and the incidence of depression in a Mediterranean cohort: the SUN Project. *European Journal of Nutrition*, *59*(3), 1093–1103. https://doi.org/10.1007/s00394-019-01970-1

Gómez-Gómez, I., Bellón, J., Resurrección, D. M., Cuijpers, P., Moreno-Peral, P., Rigabert, A., Maderuelo-Fernández, J. Á., & Motrico, E. (2020). Effectiveness of universal multiple-risk lifestyle interventions in reducing depressive symptoms: Systematic review and meta-analysis. *Preventive Medicine*, *134*, 106067. https://doi.org/10.1016/j.ypmed.2020.106067

González-García, S., Green, R. F., Scheelbeek, P. F., Harris, F., & Dangour, A. D. (2020). Dietary recommendations in Spain –affordability and environmental sustainability? *Journal of Cleaner Production*, *254*, 120125. https://doi.org/10.1016/j.jclepro.2020.120125

Gregório, M. J., Rodrigues, A. M., Salvador, C., Dias, S. S., de Sousa, R. D., Mendes, J. M., Coelho, P. S., Branco, J. C., Lopes, C., Martínez-González, M. A., Graça, P., & Canhão, H. (2020). Validation of the Telephone-Administered Version of the Mediterranean Diet Adherence Screener (MEDAS) Questionnaire. *Nutrients*, *12*(5), 1511. https://doi.org/10.3390/nu12051511

Grupo de Trabajo de la Guía de Práctica Clínica para el Manejo de Pacientes con Insomnio en Atención Primaria. (2009). Guía Práctica Clínica para el Manejo de Pacientes con Insomnio en Atención Primaria. In *Guia práctica Clínica en el SNS*. https://portal.guiasalud.es/wp-

content/uploads/2018/12/GPC_465_Insomnio_Lain_Entr_compl.pdf

Grupo de trabajo de la Guía de Práctica Clínica sobre el Manejo de la Depresión en el Adulto. (2014). Guía de Práctica Clínica sobre el Manejo de la Depresión Mayor en el Adulto. In *Guías de Práctica Clínica en el SNS*. https://portal.guiasalud.es/wp-content/uploads/2020/10/gpc_534_depresion_adulto_avaliat_compl_caduc.pdf

Guilera, G., Barrios, M., Penelo, E., Morin, C., Steel, P., & Gómez-Benito, J. (2018). Validation of the Spanish version of the Irrational Procrastination Scale (IPS). *PLOS ONE*, *13*(1), e0190806. https://doi.org/10.1371/journal.pone.0190806

Guimón, J. (2003). *Manual de Terapias de Grupo. Tipos, Modelos y Programas*. Biblioteca Nueva.

Gulliver, A., Griffiths, K. M., & Christensen, H. (2010). Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. *BMC Psychiatry*, *10*(1), 113. https://doi.org/10.1186/1471-244X-10-113

Günther-Bel, C., Vilaregut, A., Carratala, E., Torras-Garat, S., & Pérez-Testor, C. (2020). A Mixed-method Study of Individual, Couple, and Parental Functioning During the State-regulated COVID-19 Lockdown in Spain. *Family Process*, *59*(3), 1060–1079. https://doi.org/10.1111/famp.12585

Guszkowska, M. (2004). Effects of exercise on anxiety, depression and mood. *Psychiatria Polska*, *38*(4), 611–620. http://www.ncbi.nlm.nih.gov/pubmed/15518309

Haluza, D., & Jungwirth, D. (2015). ICT and the future of health care: aspects of health promotion. *International Journal of Medical Informatics*, *84*(1), 48–57. https://doi.org/10.1016/j.ijmedinf.2014.09.005

Hamm, M. E., Brown, P. J., Karp, J. F., Lenard, E., Cameron, F., Dawdani, A., Lavretsky, H., Miller, J. P., Mulsant, B. H., Pham, V. T., Reynolds, C. F., Roose, S. P., & Lenze, E. J. (2020). Experiences of American Older Adults with Pre-existing Depression During the Beginnings of the COVID-19 Pandemic: A Multicity, Mixed-Methods Study. *American Journal of Geriatric Psychiatry*, *28*(9), 924–932. https://doi.org/10.1016/j.jagp.2020.06.013

Hanna, M., Jaqua, E., Nguyen, V., & Clay, J. (2022). B Vitamins: Functions and Uses in Medicine. *The Permanente Journal*, *26*(2), 89–97. https://doi.org/10.7812/TPP/21.204

Harb, F., Hidalgo, M. P., & Martau, B. (2014). Lack of exposure to natural light in the workspace is associated with physiological, sleep and depressive symptoms. *Chronobiology International*, *32*(3), 368–375. https://doi.org/10.3109/07420528.2014.982757

Hartescu, I., Morgan, K., & Stevinson, C. D. (2015). Increased physical activity improves sleep and mood outcomes in inactive people with insomnia: A randomized controlled trial. *Journal of Sleep Research*, *24*(5), 526–534. https://doi.org/10.1111/jsr.12297

Harvey, S. B., Øverland, S., Hatch, S. L., Wessely, S., Mykletun, A., & Hotopf, M. (2018). Exercise and the Prevention of Depression: Results of the HUNT Cohort Study. *American Journal of Psychiatry*, *175*(1), 28–36. https://doi.org/10.1176/appi.ajp.2017.16111223

Hepsomali, P., & Groeger, J. A. (2021). Diet, Sleep, and Mental Health: Insights from the UK Biobank Study. *Nutrients*, *13*(8), 2573. https://doi.org/10.3390/nu13082573

Hershey, M. S., Sanchez-Villegas, A., Sotos-Prieto, M., Fernandez-Montero, A., Pano, O., Lahortiga-Ramos, F., Martínez-González, M. Á., & Ruiz-Canela, M. (2022). The Mediterranean Lifestyle and the Risk of Depression in Middle-Aged Adults. *Journal of Nutrition*, *152*(1), 227–234. https://doi.org/10.1093/jn/nxab333

Hibbard, J. H., Stockard, J., Mahoney, E. R., & Tusler, M. (2004). Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. *Health Services Research*, *39*(4p1), 1005–1026. https://doi.org/10.1111/j.1475-6773.2004.00269.x

Hidaka, B. H. (2012). Depression as a disease of modernity: Explanations for increasing prevalence. *Journal of Affective Disorders*, *140*(3), 205–214. https://doi.org/10.1016/j.jad.2011.12.036

Hidalgo, M. D., Balluerka, N., Gorostiaga, A., Espada, J. P., Santed, M. Á., Padilla, J. L., & Gómez-Benito, J. (2020). The psychological consequences of covid-19 and lockdown in the Spanish population: An exploratory sequential design. *International Journal of Environmental Research and Public Health*, *17*(22), 1–17. https://doi.org/10.3390/ijerph17228578

Hill Almeida, L. M., Flicker, L., Hankey, G. J., Golledge, J., Yeap, B. B., & Almeida, O. P. (2022). Disrupted sleep and risk of depression in later life: A prospective cohort study with extended follow up and a systematic review and meta-analysis. *Journal of Affective Disorders*, *309*, 314–323. https://doi.org/10.1016/j.jad.2022.04.133

Holloway, A., & Watson, H. E. (2002). Role of self-efficacy and behaviour change. *International Journal of Nursing Practice*, *8*(2), 106–115. https://doi.org/10.1046/j.1440-172x.2002.00352.x

Hsu, Y. L., Su, D. H., & Kuo, S. C. (2020). Health literacy and depression in women with type 2 diabetes mellitus. *Clinics*, *75*(11), 1–7. https://doi.org/10.6061/clinics/2020/e1436

Huang, Y., & Zhao, N. (2020). Generalized anxiety disorder, depressive symptoms and sleep quality during COVID-19 outbreak in China: a web-based cross-sectional survey. *Psychiatry Research*, *288*, 112954. https://doi.org/10.1016/j.psychres.2020.112954

INE. (2021). *La salud mental en la pandemia*. Cifras INE. Boletín Informativo Del Instituto Nacional de Estadística. https://www.ine.es/ss/Satellite?L=es_ES&c=INECifrasINE_C&cid=1259532254045&p=1254735116567&pagename=ProductosYServicios%2FINECifrasINE_C%2FPYSDetalleCifrasINE

Irish, L. A., Kline, C. E., Gunn, H. E., Buysse, D. J., & Hall, M. H. (2015). The role of sleep hygiene in promoting public health: A review of empirical evidence. *Sleep Medicine Reviews*, *22*, 23–36. https://doi.org/10.1016/j.smrv.2014.10.001

Jadue, L., Marín, F., Vega, J., & Iniciativa Chilena de Equidad en Salud. (2005). *Determinantes sociales de la salud en Chile: En la perspectiva de la equidad.* ICES Iniciativa Chilena de Equidad en Salud.

Jahrami, H., Bragazzi, N. L., Grant, W. B., AlFarra, H. S. M., AlFara, W. S. M., Mashalla, S., & Saif, Z. (2020). Vitamin D Doses from Solar Ultraviolet and Dietary Intakes in Patients with Depression: Results of a Case-Control Study. *Nutrients*, *12*(9), 2587. https://doi.org/10.3390/nu12092587

Josefsson, T., Lindwall, M., & Archer, T. (2014). Physical exercise intervention in

depressive disorders: Meta-analysis and systematic review. *Scandinavian Journal of Medicine and Science in Sports*, *24*(2), 259–272. https://doi.org/10.1111/sms.12050

Ka-Yan Ip, A., Yan-Yee Ho, F., Yeung, W.-F., Chung, K.-F., Ng, C. H., Oliver, G., & Sarris, J. (2021). Effects of a group-based lifestyle medicine for depression: A pilot randomized controlled trial. *Plos One*, *16*(10), e0258059. https://doi.org/10.1371/journal.pone.0258059

Kamin, T., Perger, N., Debevec, L., & Tivadar, B. (2021). Alone in a Time of Pandemic: Solo-Living Women Coping With Physical Isolation. *Qualitative Health Research*, *31*(2), 203–217. https://doi.org/10.1177/1049732320971603

Kandola, A., Ashdown-Franks, G., Hendrikse, J., Sabiston, C. M., & Stubbs, B. (2019). Physical activity and depression: Towards understanding the antidepressant mechanisms of physical activity. *Neuroscience & Biobehavioral Reviews*, *107*, 525–539. https://doi.org/10.1016/j.neubiorev.2019.09.040

Katon, W. J. (2003). Clinical and health services relationships between major depression, depressive symptoms, and general medical illness. *Biological Psychiatry*, *54*(3), 216–226. https://doi.org/10.1016/S0006-3223(03)00273-7

Kent, S. T., McClure, L. A., Crosson, W. L., Arnett, D. K., Wadley, V. G., & Sathiakumar, N. (2009). Effect of sunlight exposure on cognitive function among depressed and non-depressed participants: a REGARDS cross-sectional study. *Environmental Health*, *8*(1), 34. https://doi.org/10.1186/1476-069X-8-34

Kessler, R. C., & Bromet, E. J. (2013). The Epidemiology of Depression Across Cultures. *Annual Review of Public Health*, *34*(1), 119–138. https://doi.org/10.1146/annurev-publhealth-031912-114409

Kim, H. H., & Jung, J. H. (2021). Social Isolation and Psychological Distress During the COVID-19 Pandemic: A Cross-National Analysis. *Gerontologist*, *61*(1), 103–113. https://doi.org/10.1093/geront/gnaa168.

Kim, J.-H. (2022). Regular physical exercise and its association with depression: A population-based study short title: Exercise and depression. *Psychiatry Research*, *309*, 114406. https://doi.org/10.1016/j.psychres.2022.114406

Kim, J., & Park, H. A. (2012). Development of a health information technology acceptance model using consumers' health behavior intention. *Journal of Medical Internet Research*, *14*(5), 1–14. https://doi.org/10.2196/jmir.2143

Kim, Y.-J., & Lee, S.-A. (2021). The Relationship of Lifestyle Factors with the Prevalence of Major Depressive Disorder by Ecological Factors. *Psychiatry Investigation*, *18*(4), 340–347. https://doi.org/10.30773/pi.2020.0309

Kimhi, S., Marciano, H., Eshel, Y., & Adini, B. (2020). Resilience and demographic characteristics predicting distress during the COVID-19 crisis. *Social Science and Medicine*, *265*, 113389. https://doi.org/10.1016/j.socscimed.2020.113389

Konttinen, H., Haukkala, A., & Uutela, A. (2008). Comparing sense of coherence, depressive symptoms and anxiety, and their relationships with health in a population-based study. *Social Science and Medicine*, *66*(12), 2401–2412. https://doi.org/10.1016/j.socscimed.2008.01.053

Koopman, E., Heemskerk, M., van der Beek, A. J., & Coenen, P. (2020). Factors associated with caregiver burden among adult (19–64 years) informal caregivers – An analysis from Dutch Municipal Health Service data. *Health and Social Care in the Community*, *28*(5), 1578–1589. https://doi.org/10.1111/hsc.12982

Kshirsagar, M. M., Dodamani, A. S., Dodamani, G. A., Khobragade, V. R., & Deokar, R. N. (2021). Impact of Covid-19 on Mental Health: An Overview. *Reviews on Recent Clinical Trials*, *16*(3), 227–231. https://doi.org/10.2174/1574887115666210105122324

Kupfer, D. J., Frank, E., & Phillips, M. L. (2012). Major depressive disorder: new clinical, neurobiological, and treatment perspectives. *The Lancet*, *379*(9820), 1045–1055. https://doi.org/10.1016/S0140-6736(11)60602-8

Kvam, S., Kleppe, C. L., Nordhus, I. H., & Hovland, A. (2016). Exercise as a treatment for depression: A meta-analysis. *Journal of Affective Disorders*, *202*, 67–86. https://doi.org/10.1016/j.jad.2016.03.063

Lalonde, M. (1974). *A new perspective on the health of canadians: a working document*. Minister of Supply and Services Canada. https://www.phac-aspc.gc.ca/ph-sp/pdf/perspect-eng.pdf

Lambrinakou, S., Katsa, M. E., Zyga, S., Ioannidis, A., Sachlas, A., Panoutsopoulos, G., Pistikou, A. M., Magana, M., Kougioumtzi Dimoligianni, D. E., Kolovos, P., & Rojas Gil, A. P. (2017). Correlations Between Nutrition Habits, Anxiety and Metabolic Parameters in Greek Healthy Adults. *Advances in Experimental Medicine and Biology 987*, *987*, 23–34. https://doi.org/10.1007/978-3-319-57379-3_3

Langeland, E., & Vinje, H. F. (2016). The Application of Salutogenesis in Mental Healthcare Settings. In M. Mittelmark, S. Sagy, M. Eriksson, G. Bauer, J. Pelikan, B. Lindström, & G. Espnes (Eds.), *The Handbook of Salutogenesis* (pp. 299–305). Springer International Publishing. https://doi.org/10.1007/978-3-319-04600-6

Lapena, C., Continente, X., Sánchez Mascuñano, A., Pons Vigués, M., Pujol Ribera, E.,

& López, M. J. (2020). Qualitative evaluation of a community-based intervention to reduce social isolation among older people in disadvantaged urban areas of Barcelona. *Health and Social Care in the Community*, *28*(5), 1488–1503. https://doi.org/10.1111/hsc.12971

Lassale, C., Batty, G. D., Baghdadli, A., Jacka, F., Sánchez-Villegas, A., Kivimäki, M., & Akbaraly, T. (2019). Healthy dietary indices and risk of depressive outcomes: a systematic review and meta-analysis of observational studies. *Molecular Psychiatry*, *24*(7), 965–986. https://doi.org/10.1038/s41380-018-0237-8

Lee, S., Kim, H., Park, M. J., & Jeon, H. J. (2021). Current Advances in Wearable Devices and Their Sensors in Patients With Depression. *Frontiers in Psychiatry*, *12*, 67234. https://doi.org/10.3389/fpsyt.2021.672347

León-Muñoz, L. M., Guallar-Castillón, P., Graciani, A., López-García, E., Mesas, A. E., Aguilera, M. T., Banegas, J. R., & Rodríguez-Artalejo, F. (2012). Adherence to the mediterranean diet pattern has declined in Spanish adults. *Journal of Nutrition*, *142*(10), 1843–1850. https://doi.org/10.3945/jn.112.164616

Li, H., Li, S., Yang, H., Zhang, Y., Zhang, S., Ma, Y., Hou, Y., Zhang, X., Niu, K., Borné, Y., & Wang, Y. (2022). Association of Ultraprocessed Food Consumption With Risk of Dementia. *Neurology*, *99*(10), e1056–e1066. https://doi.org/10.1212/WNL.0000000000200871

Liao, Y., Xie, B., Zhang, H., He, Q., Guo, L., Subramanieapillai, M., Fan, B., Lu, C., & McIntyre, R. S. (2019). Efficacy of omega-3 PUFAs in depression: A meta-analysis. *Translational Psychiatry*, *9*(1), 190. https://doi.org/10.1038/s41398-019-0515-5

Lin, C.-Y., Kim, B., Liao, Y., & Park, J.-H. (2019). Personal, behavioral, and perceived

environmental factors associated with late-life depression in older men and women. *Psychology Research and Behavior Management*, *12*, 641–650. https://doi.org/10.2147/PRBM.S214524

López-Martínez, C., Frías-Osuna, A., & del-Pino-Casado, R. (2019). Sense of coherence and subjective overload, anxiety and depression in caregivers of elderly relatives. *Gaceta Sanitaria*, *33*(2), 185–190. https://doi.org/10.1016/j.gaceta.2017.09.005

Lopresti, A. L., Hood, S. D., & Drummond, P. D. (2013). A review of lifestyle factors that contribute to important pathways associated with major depression: Diet, sleep and exercise. *Journal of Affective Disorders*, *148*, 12–27. https://doi.org/10.1016/j.jad.2013.01.014

Luo, Y., Li, Y., Xie, J., Duan, Y., Gan, G., Zhou, Y., Luo, X., Wang, J., Chen, Z., Zhang, Q., & Cheng, A. S. K. (2022). Symptoms of depression are related to sedentary behavior and sleep duration in elderly individuals: A cross-sectional study of 49,317 older Chinese adults. *Journal of Affective Disorders*, *308*, 407–412. https://doi.org/10.1016/j.jad.2022.04.102

Lyons, N., Cooper, C., & Lloyd-Evans, B. (2021). A systematic review and meta-analysis of group peer support interventions for people experiencing mental health conditions. *BMC Psychiatry*, *21*(1), 315. https://doi.org/10.1186/s12888-021-03321-z

Magnezi, R., Glasser, S., Shalev, H., Sheiber, A., & Reuveni, H. (2014). Patient activation, depression and quality of life. *Patient Education and Counseling*, *94*(3), 432–437. https://doi.org/10.1016/j.pec.2013.10.015

Maher, G. M., Perry, C. P., Perry, I. J., & Harrington, J. M. (2016). Protective lifestyle

behaviours and depression in middle-aged Irish men and women : a secondary analysis. *Public Health Nutrition*, *19*(16), 2999–3006. https://doi.org/10.1017/S1368980016001105

Malhi, G. S., & Mann, J. J. (2018). Depression. *The Lancet*, *392*, 2299–2312. https://doi.org/10.1016/S0140-6736(18)31948-2

Malhi, G. S., Outhred, T., Hamilton, A., Boyce, P. M., Bryant, R., Fitzgerald, P. B., Lyndon, B., Mulder, R., Murray, G., Porter, R. J., Singh, A. B., & Fritz, K. (2018). Royal australian and New Zealand college of psychiatrists clinical practice guidelines for mood disorders: Major depression summary. *Medical Journal of Australia*, *208*(4), 175–180. https://doi.org/10.5694/mja17.00659

Mamplekou, E., Bountziouka, V., Psaltopoulou, T., Zeimbekis, A., Tsakoundakis, N., Papaerakleous, N., Gotsis, E., Metallinos, G., Pounis, G., Polychronopoulos, E., Lionis, C., & Panagiotakos, D. (2010). Urban environment, physical inactivity and unhealthy dietary habits correlate to depression among elderly living in eastern Mediterranean islands: The MEDIS (MEDiterranean ISlands elderly) study. *The Journal of Nutrition, Health & Aging*, *14*(6), 449–455. https://doi.org/10.1007/s12603-010-0091-0

Masanotti, G. M., Paolucci, S., Abbafati, E., Serratore, C., & Caricato, M. (2020). Sense of Coherence in Nurses: A Systematic Review. *International Journal of Environmental Research and Public Health*, *17*(6), 1861. https://doi.org/10.3390/ijerph17061861

McCaston, K. (2005). *Tips for Collecting, Reviewing, and Analyzing Secondary Data*. https://cyfar.org/sites/default/files/McCaston, 2005.pdf

McCusker, J., Lambert, S. D., Cole, M. G., Ciampi, A., Strumpf, E., Freeman, E. E., & Belzile, E. (2016). Activation and Self-Efficacy in a Randomized Trial of a Depression Self-Care Intervention. *Health Education and Behavior*, *43*(6), 716–725. https://doi.org/10.1177/1090198116637601

Mella-Sousa, M., Zamora-Navas, P., Mella-Laborde, M., Ballester-Alfaro, J. J., & Uceda-Carrascosa, P. (2012). Niveles de evidencia clínica y grados de recomendación. *Revista de La Sociedad Andaluza de Traumatología y Ortopedia*, *29*(1/2), 59–72. https://www.repositoriosalud.es/bitstream/10668/1568/6/Mella_Niveles.pdf

Melnyk, B. M., Kelly, S. A., Stephens, J., Dhakal, K., McGovern, C., Tucker, S., Hoying, J., McRae, K., Ault, S., Spurlock, E., & Bird, S. B. (2020). Interventions to Improve Mental Health, Well-Being, Physical Health, and Lifestyle Behaviors in Physicians and Nurses: A Systematic Review. *American Journal of Health Promotion*, *34*(8), 929–941. https://doi.org/10.1177/0890117120920451

Mikkelsen, K., Stojanovska, L., & Apostolopoulos, V. (2016). The Effects of Vitamin B in Depression. *Current Medicinal Chemistry*, *23*(38), 4317–4337. https://doi.org/10.2174/0929867323666160920110810

Milanovic, M., Ayukawa, E., Usyatynsky, A., Holshausen, K., & Bowie, C. R. (2018). Self Efficacy in Depression: Bridging the Gap between Competence and Real World Functioning. *Journal of Nervous and Mental Disease*, *206*(5), 350–355. https://doi.org/10.1097/NMD.0000000000000804

Mojtabai, R., Olfson, M., Sampson, N. A., Jin, R., Druss, B., Wang, P. S., Wells, K. B., Pincus, H. A., & Kessler, R. C. (2011). Barriers to mental health treatment: Results from the National Comorbidity Survey Replication. *Psychological Medicine*, *41*(8), 1751–1761. https://doi.org/10.1017/S0033291710002291

Murri, M. B., Ekkekakis, P., Menchetti, M., Neviani, F., Trevisani, F., Tedeschi, S., Latessa, P. M., Nerozzi, E., Ermini, G., Zocchi, D., Squatrito, S., Toni, G., Cabassi, A., Neri, M., Zanetidou, S., & Amore, M. (2018). Physical exercise for late-life depression: Effects on symptom dimensions and time course. *Journal of Affective Disorders*, *230*, 65–70. https://doi.org/10.1016/j.jad.2018.01.004

Nadal, C., Earley, C., Enrique, A., Vigano, N., Sas, C., Richards, D., & Doherty, G. (2021). Integration of a smartwatch within an internet-delivered intervention for depression: Protocol for a feasibility randomized controlled trial on acceptance. *Contemporary Clinical Trials*, *103*, 106323. https://doi.org/10.1016/j.cct.2021.106323

Naslund, J. A., Aschbrenner, K. A., Barre, L. K., & Bartels, S. J. (2015). Feasibility of popular m-health technologies for activity tracking among individuals with serious mental Illness. *Telemedicine and E-Health*, *21*(3), 213–216. https://doi.org/10.1089/tmj.2014.0105

Navas-Martín, M. Á., López-Bueno, J. A., Oteiza, I., & Cuerdo-Vilches, T. (2021). Routines, Time Dedication and Habit Changes in Spanish Homes during the COVID-19 Lockdown. A Large Cross-Sectional Survey. *International Journal of Environmental Research and Public Health*, *18*(22), 12176. https://doi.org/10.3390/ijerph182212176

Ngooi, B. X., Packer, T. L., Kephart, G., Warner, G., Koh, K. W. L., Wong, R. C. C., & Lim, S. P. (2017). Validation of the Patient Activation Measure (PAM-13) among adults with cardiac conditions in Singapore. *Quality of Life Research*, *26*(4), 1071–1080. https://doi.org/10.1007/s11136-016-1412-5

NICE. (2014). *Behaviour change: individual approaches*.

www.nice.org.uk/guidance/ph49

NICE. (2022). *Depression in adults: treatment and management*. https://www.nice.org.uk/guidance/ng222

Nicolaou, M., Colpo, M., Vermeulen, E., Elstgeest, L. E. M., Cabout, M., Gibson-Smith, D., Knuppel, A., Sini, G., Schoenaker, D. A. J. M., Mishra, G. D., Lok, A., Penninx, B. W. J. H., Bandinelli, S., Brunner, E. J., Zwinderman, A. H., Brouwer, I. A., & Visser, M. (2019). Association of a priori dietary patterns with depressive symptoms: A harmonised meta-analysis of observational studies. *Psychological Medicine*, *50*(11), 1872–1883. https://doi.org/10.1017/S0033291719001958

Nieuwsma, J. A., Trivedi, R. B., McDuffie, J., Kronish, I., Benjamin, D., & Williams, J. W. (2012). Brief Psychotherapy for Depression: A Systematic Review and Meta-Analysis. *Int J Psychiatry Med*, *43*(2), 129–151. https://doi.org/10.1038/jid.2014.371

Null, G., & Pennesi, L. (2017). Diet and lifestyle intervention on chronic moderate to severe depression and anxiety and other chronic conditions. *Complementary Therapies in Clinical Practice*, *29*, 189–193. https://doi.org/10.1016/j.ctcp.2017.09.007

Nutbeam, D. (2000). Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promotion International*, *15*(3), 259–267. https://doi.org/10.1093/heapro/15.3.259

O'Neil, A., Jacka, F. N., Quirk, S. E., Cocker, F., Taylor, C. B., Oldenburg, B., & Berk, M. (2015). A shared framework for the common mental disorders and Non-Communicable Disease: key considerations for disease prevention and control. *BMC*

*Psychiatry*, *15*(1), 15. https://doi.org/10.1186/s12888-015-0394-0

Olivan-Blázquez, B., Montero-Marin, J., García-Toro, M., Vicens-Pons, E., Serrano-Ripoll, M. J., Castro-Gracia, A., Sarasa-Bosque, M. C., Mendive-Arbeloa, J. M., López-del-Hoyo, Y., & Garcia-Campayo, J. (2018). Facilitators and barriers to modifying dietary and hygiene behaviours as adjuvant treatment in patients with depression in primary care: A qualitative study. *BMC Psychiatry*, *18*(1), 1–12. https://doi.org/10.1186/s12888-018-1779-7

Olivan-Blázquez, B., Rubio-Aranda, E., García-Sanz, O., & Magallón-Botaya, R. (2016). Correlación entre el diagnóstico de depresión y la sintomatología presentada en pacientes de Atención Primaria. *Actas Españolas de Psiquiatría*, *44*(2), 55–64. https://doi.org/https://actaspsiquiatria.es/repositorio/18/100/ESP/18-100-ESP-55-63-220189.pdf

Opie, R., Abbott, G., Crawford, D., & Ball, K. (2021). Exploring the associations of depressive symptoms with healthy eating self-efficacy over time amongst women in the READI cohort study. *International Journal of Behavioral Nutrition and Physical Activity*, *18*(1), 1–10. https://doi.org/10.1186/s12966-021-01233-5

Pano, O., Martínez-Lapiscina, E. H., Sayón-Orea, C., Martinez-Gonzalez, M. A., Martinez, J. A., & Sanchez-Villegas, A. (2021). Healthy diet, depression and quality of life: A narrative review of biological mechanisms and primary prevention opportunities. *World Journal of Psychiatry*, *11*(11), 997–1016. https://doi.org/10.5498/wjp.v11.i11.997

Paremoer, L., Nandi, S., Serag, H., & Baum, F. (2021). Covid-19 pandemic and the social determinants of health. *The BMJ*, *372*(129), 1–5. https://doi.org/10.1136/bmj.n129

Pence, B. W., O'Donnell, J. K., & Gaynes, B. N. (2012). The Depression Treatment Cascade in Primary Care: A Public Health Perspective. *Curr Psychiatry Rep*, *14*(4), 328–335. https://doi.org/doi:10.1007/s11920-012-0274-y.

Penckofer, S., Kouba, J., Byrn, M., & Estwing Ferrans, C. (2010). Vitamin D and depression: Where is all the sunshine. *Issues in Mental Health Nursing*, *31*(6), 385–393. https://doi.org/10.3109/01612840903437657

Pérez-Laurrabaquio, Ó. (2021). COVID-19 en España: primera ola de la emergencia. *Medicina General y de Familia*, *10*(1), 3–9. https://doi.org/10.24038/mgyf.2021.007

Picard, K., Senior, P. A., Adame Perez, S., Jindal, K., Richard, C., & Mager, D. R. (2021). Low Mediterranean Diet scores are associated with reduced kidney function and health related quality of life but not other markers of cardiovascular risk in adults with diabetes and chronic kidney disease. *Nutrition, Metabolism and Cardiovascular Diseases*, *31*(5), 1445–1453. https://doi.org/10.1016/j.numecd.2021.02.002

Piper, W. E. (2008). Underutilization of short-term group therapy: Enigmatic or understandable? *Psychotherapy Research*, *18*(2), 127–138. https://doi.org/10.1080/10503300701867512

Plata-Muñoz, M. E., Castillo-Olivares, M. E., & Guevara-López, U. M. (2004). Evaluación de afrontamiento, depresión, ansiedad e incapacidad funcional en pacientes con dolor crónico. *Revista Mexicana de Anestesiologia*, *27*(1), 16–23. https://doi.org/https://www.medigraphic.com/pdfs/rma/cma-2004/cma041d.pdf

Porras-Segovia, A., Rivera, M., Molina, E., López-Chaves, D., Gutiérrez, B., & Cervilla, J. (2019). Physical exercise and body mass index as correlates of major depressive

disorder in community-dwelling adults: Results from the PISMA-ep study. *Journal of Affective Disorders*, *251*, 263–269. https://doi.org/10.1016/j.jad.2019.01.050

Porroche-Escudero, A. (2012). *Listening to women: political narratives of breast cancer in Spain* [University of Sussex]. http://www.opengrey.eu/item/display/10068/993854

Promotion Office of Disease Prevention and Health. (2020). *Healthy People 2020: Social Determinants of Health*. https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health

Przybylko, G., Morton, D., Kent, L., Morton, J., Hinze, J., Beamish, P., & Renfrew, M. (2021). The effectiveness of an online interdisciplinary intervention for mental health promotion: a randomized controlled trial. *BMC Psychology*, *9*(1), 1–11. https://doi.org/10.1186/s40359-021-00577-8

Raya-Tena, A., Fernández-San-Martin, M. I., Martin-Royo, J., Casañas, R., Sauch-Valmaña, G., Cols-Sagarra, C., Navas-Mendez, E., Masa-Font, R., Casajuana-Closas, M., Foguet-Boreu, Q., Fernández-Linares, E. M., Mendioroz-Peña, J., González-Tejón, S., Martín-López, L. M., & Jiménez-Herrera, M. F. (2021). Effectiveness of a Psychoeducational Group Intervention Carried Out by Nurses for Patients with Depression and Physical Comorbidity in Primary Care: Randomized Clinical Trial. *International Journal of Environmental Research and Public Health*, *18*(6), 2948. https://doi.org/10.3390/ijerph18062948

Roca, M., Kohls, E., Gili, M., Watkins, E., Owens, M., Hegerl, U., van Grootheest, G., Bot, M., Cabout, M., Brouwer, I. A., Visser, M., & Penninx, B. W. (2016). Prevention of depression through nutritional strategies in high-risk persons: rationale and design of the MooDFOOD prevention trial. *BMC Psychiatry*, *16*(1), 192.

https://doi.org/10.1186/s12888-016-0900-z

Rodriguez-Morales, A. J., Cardona-Ospina, J. A., Gutiérrez-Ocampo, E., Villamizar-Peña, R., Holguin-Rivera, Y., Escalera-Antezana, J. P., Alvarado-Arnez, L. E., Bonilla-Aldana, D. K., Franco-Paredes, C., Henao-Martinez, A. F., Paniz-Mondolfi, A., Lagos-Grisales, G. J., Ramírez-Vallejo, E., Suárez, J. A., Zambrano, L. I., Villamil-Gómez, W. E., Balbin-Ramon, G. J., Rabaan, A. A., Harapan, H., … Sah, R. (2020). Clinical, laboratory and imaging features of COVID-19: A systematic review and meta-analysis. *Travel Medicine and Infectious Disease*, *34*, 101623. https://doi.org/10.1016/j.tmaid.2020.101623

Ruiz-Estigarribia, L., Martínez-González, M. Á., Díaz-Gutiérrez, J., Sánchez-Villegas, A., Lahortiga-Ramos, F., & Bes-Rastrollo, M. (2019). Lifestyles and the risk of depression in the "Seguimiento Universidad de Navarra" cohort. *European Psychiatry*, *61*, 33–40. https://doi.org/10.1016/j.eurpsy.2019.06.002

Salvatore-Benito, A., Valero Zanuy, M. Á., Alarza Cano, M., Ruiz Alonso, A., Alda Bravo, I., Rogero Blanco, E., Maíz Jiménez, M., & León Sanz, M. (2019). Adherence to Mediterranean diet: A comparison of patients with head and neck cancer and healthy population. *Endocrinologia, Diabetes y Nutricion*, *66*(7), 417–424. https://doi.org/10.1016/j.endinu.2018.12.002

Sánchez-Villegas, A., Henríquez, P., Bes-Rastrollo, M., & Doreste, J. (2006). Mediterranean diet and depression. *Public Health Nutrition*, *9*(8A), 1104–1109. https://doi.org/10.1017/S1368980007668578

Santamaría-García, H., Baez, S., Gómez, C., Rodríguez-Villagra, O., Huepe, D., Portela, M., Reyes, P., Klahr, J., Matallana, D., & Ibanez, A. (2020). The role of social cognition skills and social determinants of health in predicting symptoms of mental

illness. *Translational Psychiatry*, *10*(1), 165. https://doi.org/10.1038/s41398-020-0852-4

Sanz, J., García-Vera, M. P., Espinosa, R., Fortún, M., Vázquez, C., Obreg, R., Erika, M., Godeleva, O., Ortiz, R., Martínez, A. J., & Diario Oficial. (2005). Spanish adaptation of the Beck Depression Inventory-II (BDI-II): 3. Psychometric features in patiens with psychological disorders. *Clínica y Salud*, *16*(2), 121–142. https://doi.org/10.4067/S0718-48082014000300006

Sarasa-Bosque, C., Oliván-Blázquez, B., & García-Toro, M. (2017). *El estilo de vida como tratamiento contra la tristeza patológica: La importancia de los estilos de vida en la depresión*. Editorial Academica Española.

Schitter, A. M., Nedeljkovic, M., Ausfeld-Hafter, B., & Fleckenstein, J. (2016). Changes in self-reported symptoms of depression and physical well-being in healthy individuals following a Taiji beginner course - Results of a randomized controlled trial. *Brain and Behavior*, *6*(4), 1–7. https://doi.org/10.1002/brb3.429

Schneider, G., Köhnke, C., Teismann, H., & Berger, K. (2021). Childhood trauma and personality explain more variance in depression scores than sociodemographic and lifestyle factors – Results from the BiDirect Study. *Journal of Psychosomatic Research*, *147*, 110513. https://doi.org/10.1016/j.jpsychores.2021.110513

Segal, L., Twizeyemariya, A., Zarnowiecki, D., Niyonsenga, T., Bogomolova, S., Wilson, A., O'Dea, K., & Parletta, N. (2020). Cost effectiveness and cost-utility analysis of a group-based diet intervention for treating major depression – the HELFIMED trial. *Nutritional Neuroscience*, *23*(10), 770–778. https://doi.org/10.1080/1028415X.2018.1556896

Serrano Ripoll, M. J., Oliván-Blázquez, B., Vicens-Pons, E., Roca, M., Gili, M., Leiva, A., García-Campayo, J., Demarzo, M. P., & García-Toro, M. (2015). Lifestyle change recommendations in major depression: Do they work? *Journal of Affective Disorders*, *183*, 221–228. https://doi.org/10.1016/j.jad.2015.04.059

Sherer, M., Maddux, J. E., Mercandante, B., Prentice-Dunn, S., Jacobs, B., & Rogers, R. W. (1982). The Self-Efficacy Scale: Construction and Validation. *Psychological Reports*, *51*(2), 663–671. https://doi.org/10.2466/pr0.1982.51.2.663

Silventoinen, K., Vuoksimaa, E., Volanen, S.-M., Palviainen, T., Rose, R. J., Suominen, S., & Kaprio, J. (2022). The genetic background of the associations between sense of coherence and mental health, self-esteem and personality. *Social Psychiatry and Psychiatric Epidemiology*, *57*(2), 423–433. https://doi.org/10.1007/s00127-021-02098-6

Simblett, S. K., Wilson, E., Morris, D., Evans, J., Odoi, C., Mutepua, M., Dawe-Lane, E., Jilka, S., Pinfold, V., & Wykes, T. (2021). Keeping well in a COVID-19 crisis: a qualitative study formulating the perspectives of mental health service users and carers. *Journal of Mental Health*, *30*(2), 138–147. https://doi.org/10.1080/09638237.2021.1875424

Simmonds-Buckley, M., Kellett, S., & Waller, G. (2019). Acceptability and Efficacy of Group Behavioral Activation for Depression Among Adults: A Meta-Analysis. *Behavior Therapy*, *50*(5), 864–885. https://doi.org/10.1016/j.beth.2019.01.003

Skärsäter, I., Rayens, M. K., Peden, A., Hall, L., Zhang, M., Ågren, H., & Prochazka, H. (2009). Sense of Coherence and Recovery From Major Depression: A 4-Year Follow-up. *Archives of Psychiatric Nursing*, *23*(2), 119–127. https://doi.org/10.1016/j.apnu.2008.04.007

Smithson, S., & Pignone, M. P. (2017). Screening Adults for Depression in Primary Care. *Medical Clinics of North America*, *101*(4), 807–821. https://doi.org/10.1016/j.mcna.2017.03.010

Solar, O., & Irwin, A. (2010). A Conceptual Framework for Action on the Social Determinants of Health. In *Social Determinants of Health Discussion Paper 2 (Policy and Practice)*. http://apps.who.int/iris/bitstream/10665/44489/1/9789241500852_eng.pdf?ua=1&ua=1

Sommerlad, A., Marston, L., Huntley, J., Livingston, G., Lewis, G., Steptoe, A., & Fancourt, D. (2021). Social relationships and depression during the COVID-19 lockdown: longitudinal analysis of the COVID-19 Social Study. *Psychological Medicine*, 1–10. https://doi.org/10.1017/S0033291721000039

Song, T. M., An, J., Hayman, L. L., Woo, J., & Yom, Y.-H. (2014). Stress, Depression, and Lifestyle Behaviors in Korean Adults: A Latent Means and Multi-Group Analysis on the Korea Health Panel Data. *Behavioral Medicine*, *42*(2), 72–81. https://doi.org/10.1080/08964289.2014.943688

Sørensen, K., Pelikan, J. M., Röthlin, F., Ganahl, K., Slonska, Z., Doyle, G., Fullam, J., Kondilis, B., Agrafiotis, D., Uiters, E., Falcon, M., Mensing, M., Tchamov, K., Van Den Broucke, S., & Helmut Brand. (2015). Health literacy in Europe: Comparative results of the European health literacy survey (HLS-EU). *European Journal of Public Health*, *25*(6), 1053–1058. https://doi.org/10.1093/eurpub/ckv043

Spain Ministry of Health. (2020). *Equidad en Salud y COVID- 19. Análisis y propuestas para abordar la vulnerabilidad epidemiológica vinculada a las desigualdades sociales*.

https://www.sanidad.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Equidad_en_salud_y_COVID-19.pdf

Stanton, R., & Reaburn, P. (2014). Exercise and the treatment of depression: A review of the exercise program variables. *Journal of Science and Medicine in Sport*, *17*(2), 177–182. https://doi.org/10.1016/j.jsams.2013.03.010

Stuart, K., Bidmead, E., Browning, R., Grimwood, S., Roberts, C., Winn-reed, T., & Pac, A. (2020). *Deep Dives: Different Groups' Experiences of and Recovery Needs from Covid-19 Report Six*. https://www.health.org.uk/sites/default/files/2021-08/Deep Dives Different Groups' Experiences of and Recovery Needs from Covid-19.pdf

Tao, L., Jiang, R., Zhang, K., Qian, Z., Chen, P., Lv, Y., & Yao, Y. (2020). Light therapy in non-seasonal depression: An update meta-analysis. *Psychiatry Research*, *291*, 113247. https://doi.org/10.1016/j.psychres.2020.113247

Tedeschi, R. G., & Calhoun, L. G. (2004). Psychological Inquiry Posttraumatic Growth: A Developmental Perspective. *Psychological Inquiry*, *15*(1), 1–18. https://doi.org/10.1207/s15327965pli1501

Teti, M., Schatz, E., & Liebenberg, L. (2020). Methods in the Time of COVID-19: The Vital Role of Qualitative Inquiries. *International Journal of Qualitative Methods*, *19*. https://doi.org/10.1177/1609406920920962

Thomas, J., & Al-Anouti, F. (2017). Sun Exposure and Behavioral Activation for Hypovitaminosis D and Depression: A Controlled Pilot Study. *Community Mental Health Journal*, *54*(6), 860–865. https://doi.org/10.1007/s10597-017-0209-5

Toobert, D. J., Glasgow, R. E., Strycker, L. A., Barrera, M., Ritzwoller, D. P., & Weidner, G. (2007). Long-term effects of the Mediterranean lifestyle program: a randomized

clinical trial for postmenopausal women with type 2 diabetes. *International Journal of Behavioral Nutrition and Physical Activity*, *4*(1), 1. https://doi.org/10.1186/1479-5868-4-1

van Dammen, L., Wekker, V., de Rooij, S. R., Groen, H., Hoek, A., & Roseboom, T. J. (2018). A systematic review and meta-analysis of lifestyle interventions in women of reproductive age with overweight or obesity: the effects on symptoms of depression and anxiety. *Obesity Reviews*, *19*(12), 1–9. https://doi.org/10.1111/obr.12752

van der Rhee, H. J., de Vries, E., & Coebergh, J. W. (2016). Regular sun exposure benefits health. *Medical Hypotheses*, *97*, 34–37. https://doi.org/10.1016/j.mehy.2016.10.011

Veleva, B. I., van Bezooijen, R. L., Chel, V. G. M., Numans, M. E., & Caljouw, M. A. A. (2018). Effect of ultraviolet light on mood, depressive disorders and well-being. *Photodermatology Photoimmunology and Photomedicine*, *34*(5), 288–297. https://doi.org/10.1111/phpp.12396

Vindel, A. C., Salguero, J. M., Wood, C. M., Dongil, E., Latorre, J. M., Antonio, C., & Vindel, C. (2012). La depresión en atención primaria: prevalencia, diagnóstico y tratamiento. *Papeles Del Psicólogo*, *33*(1), 2–11. https://www2.papelesdelpsicologo.es/pdf/2030.pdf

von Humboldt, S., Mendoza-Ruvalcaba, N. M., Arias-Merino, E. D., Costa, A., Cabras, E., Low, G., & Leal, I. (2020). Smart technology and the meaning in life of older adults during the Covid-19 public health emergency period: a cross-cultural qualitative study. *International Review of Psychiatry*, *32*(7–8), 713–722. https://doi.org/10.1080/09540261.2020.1810643

Wakefield, J. R. H., Bowe, M., Kellezi, B., Butcher, A., & Groeger, J. A. (2019). Longitudinal associations between family identification, loneliness, depression, and sleep quality. *British Journal of Health Psychology*, *25*(1), 1–16. https://doi.org/10.1111/bjhp.12391

Wang, J., Um, P., Dickerman, B., & Liu, J. (2018). Zinc, Magnesium, Selenium and Depression: A Review of the Evidence, Potential Mechanisms and Implications. *Nutrients*, *10*(5), 584. https://doi.org/10.3390/nu10050584

Wang, Xiaofen, Cheng, S., & Xu, H. (2019). Systematic review and meta-analysis of the relationship between sleep disorders and suicidal behaviour in patients with depression. *BMC Psychiatry*, *19*(1), 303. https://doi.org/10.1186/s12888-019-2302-5

Wang, Xiaofeng, & Cheng, Z. (2020). Cross-Sectional Studies. *Chest*, *158*(1), S65–S71. https://doi.org/10.1016/j.chest.2020.03.012

Wang, Xiaowen, Arafa, A., Liu, K., Eshak, E. S., Hu, Y., & Dong, J.-Y. (2021). Combined healthy lifestyle and depressive symptoms: a meta-analysis of observational studies. *Journal of Affective Disorders*, *289*, 144–150. https://doi.org/10.1016/j.jad.2021.04.030

Ward, F. (2020). *Same storm, different boats? Experience of lockdown rules during COVID-19 -findings from a diary project* (Issue September). https://arc-nwc.nihr.ac.uk/wp-content/uploads/2020/09/Same-storm-different-boats-Experience-of-lockdown-rules-during-COVID-19-–-findings-from-a-diary-project-1-1.pdf

Werneck, A. O., Vancampfort, D., Stubbs, B., Silva, D. R., Cucato, G. G., Christofaro,

D. G. D., Santos, R. D., Ritti-Dias, R. M., & Bittencourt, M. S. (2022). Prospective associations between multiple lifestyle behaviors and depressive symptoms. *Journal of Affective Disorders*, *301*, 233–239. https://doi.org/10.1016/j.jad.2021.12.131

Wheeler, P., Leiper, R., Akeju, D., Hedgcoe, L., & Yameen, F. (2020). *Use of remote technology in research – Findings from the EPHC Diary Project*. https://arc-nwc.nihr.ac.uk/wp-content/uploads/2020/09/Use-of-remote-technology-in-research-–-Findings-from-the-EPHC-Diary-Project-3.pdf

WHO. (2003). *Social determinants of health. The solid facts. Second edition* (WHO (ed.)). https://www.euro.who.int/__data/assets/pdf_file/0005/98438/e81384.pdf

WHO. (2007). *A Conceptual Framework for Action on the Social Determinants of Health* (Issue April). https://apps.who.int/iris/handle/10665/44489

WHO. (2010). *Global recommendations on physical activity for health* (WHO (ed.)). http://www.who.int/dietphysicalactivity/factsheet_recommendations/en/

WHO. (2017a). *About social determinants of health*. https://www.who.int/health-topics/social-determinants-of-health

WHO. (2017b). WHO methods and data sources for global burden of disease estimates 2000-2015. In *Global Health Estimates Technical Paper* (Issue January). https://www.who.int/healthinfo/global_burden_disease/GlobalDALYmethods_2000_2015.pdf?ua=1

WHO. (2021a). *Depression*. https://www.who.int/news-room/fact-sheets/detail/depression

WHO. (2021b). *Weekly operational update on COVID-19 - 4 August 2021*. *66*, 1–13.

https://www.who.int/publications/m/item/weekly-update-on-covid-19---16-october-2020

Wickham, R. J. (2019). Secondary Analysis Research. *Journal of the Advanced Practitioner in Oncology*, *10*(4), 395–400. https://doi.org/10.6004/jadpro.2019.10.4.7

Wittchen, H. U., Jacobi, F., Rehm, J., Gustavsson, A., Svensson, M., Jönsson, B., Olesen, J., Allgulander, C., Alonso, J., Faravelli, C., Fratiglioni, L., Jennum, P., Lieb, R., Maercker, A., van Os, J., Preisig, M., Salvador-Carulla, L., Simon, R., & Steinhausen, H.-C. (2011). The size and burden of mental disorders and other disorders of the brain in Europe 2010. *European Neuropsychopharmacology*, *21*(9), 655–679. https://doi.org/10.1016/j.euroneuro.2011.07.018

Wong, V. W.-H., Ho, F. Y.-Y., Shi, N.-K., Tong, J. T.-Y., Chung, K.-F., Yeung, W.-F., Ng, C. H., Oliver, G., & Sarris, J. (2021). Smartphone-delivered multicomponent lifestyle medicine intervention for depressive symptoms: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*, *89*(12), 970–984. https://doi.org/10.1037/ccp0000695

Wong, V. W. H., Ho, F. Y. Y., Shi, N. K., Sarris, J., Chung, K. F., & Yeung, W. F. (2021). Lifestyle medicine for depression: A meta-analysis of randomized controlled trials. *Journal of Affective Disorders*, *284*, 203–216. https://doi.org/10.1016/j.jad.2021.02.012

Xie, F., Huang, T., Lou, D., Fu, R., Ni, C., Hong, J., & Ruan, L. (2022). Effect of vitamin D supplementation on the incidence and prognosis of depression: An updated meta-analysis based on randomized controlled trials. *Frontiers in Public Health*, *10*, 903547. https://doi.org/10.3389/fpubh.2022.903547

Yang, Y., & Xiang, X. (2021). Examine the associations between perceived neighborhood conditions, physical activity, and mental health during the COVID-19 pandemic. *Health & Place*, *67*, 102505. https://doi.org/10.1016/j.healthplace.2021.102505

Zhai, L., Zhang, Y., & Zhang, D. (2015). Sedentary behaviour and the risk of depression: A meta-analysis. *British Journal of Sports Medicine*, *49*(11), 705–709. https://doi.org/10.1136/bjsports-2014-093613

Zhang, M.-M., Ma, Y., Du, L.-T., Wang, K., Li, Z., Zhu, W., Sun, Y.-H., Lu, L., Bao, Y.-P., & Li, S.-X. (2022). Sleep disorders and non-sleep circadian disorders predict depression: A systematic review and meta-analysis of longitudinal studies. *Neuroscience & Biobehavioral Reviews*, *134*, 104532. https://doi.org/10.1016/j.neubiorev.2022.104532

Zhou, F., Yu, T., Du, R., Fan, G., Liu, Y., Liu, Z., Xiang, J., Wang, Y., Song, B., Gu, X., Guan, L., Wei, Y., Li, H., Wu, X., Xu, J., Tu, S., Zhang, Y., Chen, H., & Cao, B. (2020). Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *The Lancet*, *395*(10229), 1054–1062. https://doi.org/10.1016/S0140-6736(20)30566-3

Zhu, J., Ji, P., Pang, J., Zhong, Z., Li, H., He, C., Zhang, J., & Zhao, C. (2020). Clinical characteristics of 3062 COVID-19 patients: A meta-analysis. *Journal of Medical Virology*, *92*(10), 1902–1914. https://doi.org/10.1002/jmv.25884

# Anexo I. Effectiveness of a lifestyle modification programme in the treatment of depression in primary care: randomised clinical trial pre-post results



**Title:** Effectiveness of a lifestyle modification programme in the treatment of depression in primary care: randomised clinical trial pre-post results

**Authors:**

Alejandra Aguilar-Latorre[1,2], Capilla Navarro[3], María Jesús Serrano-Ripoll[2,4,5], Elena Gervilla[2,6], Mauro García-Toro[7,8], Bárbara Oliván-Blázquez[1,9*]

[1] Institute for Health Research Aragón (IIS Aragón), Zaragoza, Spain.

[2] Research Network on Chronicity, Primary Care and Health Promotion (RICAPPS), Barcelona, Spain

[3] Department of Psychology, University of the Balearic Islands, Palma, Balearic Islands, Spain.

[4] Primary Care Research Unit of Mallorca, Balearic Islands Health Services, Palma, Spain,

[5] Research in Preventive Activities and Promotion and in Cancer Illes Balears (GRAPP-CAIB), Balearic Islands Health Research Institute (IdISBa), Palma, Spain,

[6] Statistic and psychometric procedures implemented in Health Sciences Research Group, Health Research Institute of the Balearic Islands (IdISBa), Palma, Balearic Islands, Spain.

[7] Mental disorders of high prevalence Research Group (TRAMAP), Health Research Institute of the Balearic Islands (IdISBa), Palma, Balearic Islands, Spain.

[8] Department of Medicine, University of the Balearic Islands, Palma, Balearic Islands, Spain.

[9] Department of Psychology and Sociology, University of Zaragoza, Zaragoza, Spain.

* Corresponding author:

Bárbara Oliván-Blázquez, PhD

E-mail address: bolivan@unizar.es

**Abstract:**

Background: Major depression is a highly prevalent pathology. Its onset and continuation may be related to biological and psychosocial factors, many of which are related to lifestyle aspects. This study aims to analyse the clinical effectiveness of a Lifestyle Modification Programme (LMP) and an LMP with Information and Communication Technologies (LMP+ICTs) as compared to Treatment as Usual (TAU) as an adjunctive treatment for the depressive symptoms of primary care patients.

Methods: We conducted a randomized, multicentre pragmatic clinical trial. Interventions were: 1. TAU. 2. TAU+LMP, which consisted of six weekly 90-minute group sessions focused on improving lifestyle and led by an experienced psychologist. 3. TAU+LMP+ICTs replicated the LMP format, plus the addition of a wearable smartwatch. A total of 188 people were randomised. Depression was the primary outcome. Lifestyle variables (i.e., physical exercise, adherence to Mediterranean diet and sleep quality), quality of life, social support, and personal factors (i.e., self-efficacy, patient activation in their own health, sense of coherence, health literacy and procrastination) were considered secondary outcomes. The questionnaires were administered at baseline and after the intervention. Descriptive and univariate analyses and ANCOVAs were performed to determine statistically significant differences between the three groups.

Results: There was a clinically significant reduction of BDI-II in both intervention groups compared to TAU. There was also a significant effect on lifestyle change and personal factors change in both intervention groups. However, only the TAU+LMP group showed a significant effect on quality of life, and only the TAU+LMP+ICTs group showed a significant effect on procrastination. Furthermore, there is no significant effect in sedentarism or health literacy in any group.

Conclusion: LMPs conducted in primary healthcare centres for patients with depression were effective in reducing depressive symptomatology and improving lifestyle and personal factors over the short term.

**Keywords:** Depression, Lifestyle modifications, Diet, Exercise, Sleep patterns

**Trial registration number:** ClinicalTrials.gov Registry (NCT03951350).

**Strengths and limitations of this study:**

- The study was a multicentre, pragmatic, randomised clinical trial (RCT) in three parallel groups.

- The time demands of attending for the face-to-face interventions led o most of the drop-out.

- Due to the nature of the intervention, the psychologist who led the intervention and participants were not blinded.

**Introduction**

Currently, depression affects an estimated 280 million people globally.[1] The prevalence of depression ranges between 4.2% and 9.3%,[2] with the 12-month prevalence of major depressive disorder being approximately 6% on a global level. It has been stated that depression is the second most common cause of disability, considered a public health problem.[3] Women are more likely than men to experience stress and depression and, in general, the prevalence of depression is higher in the adult population than in the youth.[3–8]

The onset and continuation of depression have been linked to numerous biological and psychosocial factors, many of which are related to distinct lifestyle aspects.[9–12] Healthy lifestyles are associated with lower levels of depression;[13,14] therefore, many of the strategies promoting a healthier lifestyle could serve as antidepressants.[11,15–17] Specifically, moderate exercise has been found to have benefits, decreasing and even preventing depressive symptoms.[18–21] In addition, diet-related interventions have been shown to result in improvements in depression.[15,22–26] Nutrients linked to depression prevention are included in the Mediterranean Dietary Pattern, since it provides an adequate intake of fruit, nuts, vegetables, cereals, legumes and fish.[27,28] A lack of good sleep quality has been significantly related to depression[29] and constitutes an independent risk factor for developing the disorder.[30,31] Careful exposure to sunlight has been shown to alleviate depressive symptoms.[32–34] A lack of exposure to sunlight is related to high cortisol levels and lower melatonin levels at night.[35] Furthermore, low vitamin D concentration has been associated with depression.[36]

Framed around the theory of salutogenesis,[37] personal resources are psychosocial determinants affecting behaviour modification carried out by an individual. Personal resources include self-efficacy,[38] activation in one's health,[39] a sense of coherence,[40] health literacy,[41] and procrastination.[42]

Factors that can make it difficult to accept or adhere to treatment include a self-perceived low need for treatment, poor mental health literacy, increased self-reliance, and a fear of

stigmatization.[43,44] Nevertheless, personal factors and facilitators should be considered in Lifestyle Modification Programmes (LMPs). Information and Communication Technologies (ICTs) and social support have been shown to improve motivation.[45] Specifically, smartwatches might improve self-monitoring by addressing challenges in recalling sleep and physical activity.[46] Adherence may be facilitated by following simple guidelines, adapted through motivational interviews, with a prolonged and intense follow-up during the different stages of the disorder and receiving appropriate feedback.[16]

Primary Care (PC) services play a critical role in identifying and treating depression. Approximately 60% of all mental health treatment distribution takes place in PC settings,[47] yet it remains underdiagnosed and undertreated.[48,49] Even in developed countries, most people having common mental illnesses fail to receive treatment, with less treatment being received by those with anxiety (20%) than depression (28%).[50] Therefore, the management of depression in primary care settings is advocated,[51] for example, through brief psychoeducational group interventions, which have the advantage of being effective and cost-effective for depression, and may be carried out by mental health professionals or trained non-mental health providers.[52–54]

The promotion of individual healthy lifestyles to address depressive symptoms has shown efficacy in many studies.[21,27,28,30,55–58] However, their success depends on how the intervention is carried out. Some unsupported interventions may not be sufficient (e.g., only offering written lifestyle recommendations, without support).[59] Therefore, specifically, and as a novelty of this study, we have promoted combined healthy lifestyles (physical activity, sleep patterns, and diet) in a face-to-face group format and at the primary healthcare level.

**Aims of the Study**

This study aims to analyse the clinical effectiveness of a Lifestyle Modification Programme (TAU+LMP) group and an LMP with Information and Communication Technologies (TAU+LMP+ICTs) group as compared to a Treatment as Usual (TAU) group as an adjunctive treatment for the depressive symptoms of primary care patients suffering from depression.

**Methods and analysis**

**Study design**

We conducted a multicentre, pragmatic, randomised clinical trial (RCT) in three parallel groups: TAU as a control group, TAU+LMP, and TAU+LMP+ICTs, both as intervention groups, in primary healthcare centres (PHCs).

**Sample size**

A first sample size was established in the clinical trial protocol,[60] which anticipated a 17% reduction in the Beck II Self-Applied Depression Inventory (BDI-II)[61]. To further specify the sample size, a change has been made in the calculation, anticipating a 17.5% reduction in the BDI-II to be considered clinically relevant.[62] According to a prior study conducted by our team with primary care patients, the average BDI-II score at the onset of the study was 24.5 points (SD 7.84).[59] Therefore, we considered that a reduction of at least 4.28 points would have clinical significance and would benefit the patient. Accepting an $\alpha$ risk of 0.05 and a $\beta$ risk of 0.20 in a bilateral contrast, 35 subjects were required for each group. A withdrawal rate of 20% was assumed, meaning that the sample size needed approximately 42 patients in each group. The total sample necessary was 126 subjects. Finally, 188 participants were included, exceeding the required sample size.

**Recruitment and participants**

The study was presented in several PHCs situated in two areas of Spain (Zaragoza and Mallorca). The PHCs were chosen by convenience sampling (i.e., the PHCs where we had easy access and where we were able to make a first dissemination of the study were chosen).[63] Selection of participants was carried out amongst subjects who consulted a blinded general practitioner (GP) of the participating PHCs for any reason and met the inclusion criteria. The recruitment period

was 7 months, halted due to the COVID-19 pandemic, with recruitment beginning in April 2020 and ending in October 2020. Thus, a sample of 188 patients with subclinical, mild, or moderate depression (scoring ≥ 10 and ≤ 30 points on the BDI II Spanish version[64]) from PHCs in two areas of Spain (Zaragoza and Mallorca) were recruited for the study.

The following inclusion criteria were used: individuals of both sexes over the age of 18, with a duration of depression symptoms extending over at least two months, who understand written and spoken Spanish, and who have provided their informed consent. The following exclusion criteria were used: suffering from another disease affecting the central nervous system (organic brain pathology or having suffered a traumatic brain injury of any severity, dementia); having another psychiatric diagnosis or psychiatric severe illness (substance dependence or abuse, history of schizophrenia or other psychotic disorders, eating disorders) with the exception of anxious pathology or personality disorders (collected through a medical history); the presence of a severe or uncontrolled medical, infectious or degenerative illness that may interfere with the affective symptoms; the presence of delirium or hallucinations, risk of suicide, pregnancy or lactation; patients who have participated in another clinical trial over the past 6 months or who are currently in psychotherapy; or those who practiced mindfulness, yoga, meditation or similar practices over the past 6 months, engaging in formal training at least once a week; and the presence of any medical, psychological or social problem that could seriously interfere with the patient's participation in the study.

A computer-generated random number[65] administered by an independent researcher was used to allocate participants. The randomisation was carried out using a list of patients from Zaragoza and Mallorca. They were not blind to their allocation, being informed of the nature of the intervention. Participants' data entry and coding was carried out by a blind Research Assistant (RA). Another blind RA conducted the outcome assessments and data analysis. All the collected information was treated according to the provisions of current laws on personal data protection.

**Intervention development and evaluation**

Patients assigned to the first arm (control group) received general medical care from their GP (treatment-as-usual, TAU).[66] Patients in the second arm (1st intervention group) followed the TAU and Lifestyle Modification Programme (LMP). This programme consisted of 6 weekly group sessions (lasting 90 minutes each) led by an experienced psychologist and complemented by PowerPoint presentations. Finally, patients in the third arm (2nd intervention group) followed the TAU and LMP programmes and were monitored using a wearable smart wristwatch that tracked their daily sleep patterns and physical activity (TAU+LMP+ICTs). Group size was continually adjusted in accordance with the preventive regulations of COVID-19 and sessions were held between May 2020 and November 2020.

During the group sessions, the following topics were covered: 1) Presentation of the project and psychoeducation on depression. 2) Behaviour activation (as well as the importance of establishing, maintaining, and monitoring activities and explanation on the use of the wearable smart wristwatch for the TAU+LMP+ICTs group). 3) Sleep hygiene habits and careful exposure to sunlight. 4) Physical activity. 5) Adherence to the Mediterranean diet. 6) Summary of previous sessions with final practical suggestions.

The psychologist provided patients with self-registration tables at the end of each session. They completed them, including details on their everyday routines related to the suggested lifestyle changes: their wake-up and bedtime hours, sleep length, time spent in direct sunlight, diet pattern, physical activity and sports played, social support, and subjective perceptions of satisfaction following these activities.

Two experienced psychologists carried out the intervention, one in Zaragoza and the other in Mallorca. They were graduated with a bachelor's degree in Psychology, had a master's degree and had worked as a health psychologist for at least one year. They adhered to the planned content (i.e., they kept the content on the slide). The full intervention was created by the research team taking into account previous interventions already tested[15,16,59] and can be accessed through the following link: https://www.gaiap.es/proyecto/5195/

**Outcomes and measures**

A blinded RA collected patient data using the questionnaires administered at baseline (pre intervention, T0), and immediately after the intervention (in a period of 2 to 7 days after the last intervention session) (post intervention, T1). The same time period was used for all three groups.

The following variables were collected for this study:

Sociodemographic data: We collected information on sex (female, male), age, marital status (without a partner: single, separated or divorced or in separation proceedings, widower or widow; and having a partner: married or living with a partner), education (none or primary; and secondary or tertiary), occupation (working: active; and not working: unemployed, housewife, unpaid work, student, pensioner, sick leave, temporary job disability, permanent job disability, other situations), economic level (< Interprofessional Minimum Wage (IMW) to 2 IMW, and> 2 IMW).

Chronic comorbidities: We collected information on chronic comorbidities with prevalence rates larger than 5% (arrhythmias, heart failure, ischemic cardiopathy, dyslipidemia, obesity, excess weight, vein and artery disease, cerebrovascular disease, diabetes, chronic bronchitis, chronic obstructive pulmonary disease (COPD), asthma, chronic kidney disease, hypo and hyperthyroidism, tobacco use, alcoholism, insomnia, attempted suicide, anemia, neoplasia, dementia, deafness, cataracts, glaucoma, arthrosis, osteoporosis, and back pain).[67] The problem was that due to COVID-19, it was very difficult for us to send the participants to go to their GP for a blood test. In addition, it was also difficult to maintain close physical contact to measure their weight, size and perimeter of the waist. So, we have collected the comorbidity information at baseline, self-reported, but not the other measures stated in the protocol.[60]

The primary outcome is the level of depressive symptomatology, measured by the BDI-II.[61] It consists of 21 multiple-choice questions. The Spanish validation has a Cronbach's alpha value (α) of .89.[64] The standardised cut-offs are 0–13: minimal depression; 14–19: mild depression;

20–28: moderate depression; 29–63: severe depression. The internal consistency of the BDI-II in our sample is acceptable at baseline (T0) (α = 0.71).

Secondary outcomes

Health-related quality of life was measured using the European Quality of Life-5 Dimensions Questionnaire (EQ-5D).[68,69] The EQ-5D quantitatively assesses the patient's self-rated health using a vertical visual analogue scale (VAS), with endpoints labelled "The best health you can imagine" (= 100) and "The worst health you can imagine" (= 0).[70] Its α value is .788 in a study with disease-specific populations.[71] The only study with a general population provides an overall mean estimate of the Minimum Important Difference (MID) for the EQ-5D, which is .074.[72]

Social support was measured using the Medical Outcomes Study Social Support Survey (MOS-SS).[73] It has 19 items, measuring four subscales and an overall functional social support index. Higher scores indicate increased support. The Spanish validation has good reliability (α ≥ .91) and is quite stable over time.[74] The internal consistency of the MOS-SS in our sample is excellent at T0 (α = 0.95).

Physical activity was measured using the International Physical Activity Questionnaire-Short Form (IPAQ-SF).[75] It contains seven items and records the activity over the last seven days, depending on intensity levels. We used the validated Spanish version.[76] The IPAQ-SF has good reliability for vigorous physical activity and sitting hours, poor validity for moderate activity and moderate reliability for walking.[77]

Adherence to the Mediterranean diet was assessed using the 14-item Mediterranean Diet Adherence Screener (MEDAS), developed by the PREDIMED study group.[78] The total score is between 0 and 14, with a higher score indicating a better adherence to the Mediterranean diet.[79]

Quality and sleep patterns were measured using the Pittsburgh Sleep Quality Index (PSQI).[80] It distinguishes between "poor" and "good" sleep by assessing seven domains over the previous month. It consists of 19 self-administered questions and five questions requesting the assessment of the patient's partner or housemate (which are not scored). The total score is between 0 and 21 points. The Spanish translation has an α of .81, with a sensitivity of 88.63% and a specificity of 74.99%.[81] The internal consistency of the PSQI in our sample is acceptable at T0 (α = 0.75).

We also assessed personal factors related to health behaviour: 1) self-efficacy; 2) activation; 3) sense of coherence; 4) health literacy; and 5) procrastination.

Self-Efficacy was measured using the Self-Efficacy Scale (SES),[38] which is made up of two subscales: the General Self-Efficacy subscale and the Social Self-Efficacy subscale. It consists of 23 items, each rated on a 14-point scale. Higher scores indicate higher levels of self-efficacy. It has an α value of .86 for the General Self-efficacy subscale and .71 for the Social Self-efficacy subscale. Godoy translated the unpublished Spanish version in 1990.[82] The internal consistency of the SES in our sample is good at T0 (α = 0.87).

Patient activation in their own health was measured using the Patient Activation Questionnaire (PAM) on their health management.[39] It contains 13 items. The resulting score (between 0 and 100) assigns an individual to one of four activation levels, each of which provides insight into various health-related characteristics, including behaviours and outcomes. Higher scores indicate higher activation levels.[39] This scale has been validated exclusively for chronic patients in Spanish. It contained an item separation index for the parameters of 6.64 and a reliability of .98.[83] The internal consistency of the PAM in our sample is good at T0 (α = 0.85).

Sense of coherence was measured using the Sense of Coherence (SOC-13) questionnaire by Antonovsky.[40] It assesses the sense of coherence, comprehensibility, manageability, and meaningfulness. It contains 13 items ranging from 13 to 91 points. It has a consistency rate of .84 to .93. Higher scores indicate a higher sense of coherence. We used the validated Spanish version.[84] The internal consistency of the SOC-13 in our sample is acceptable at T0 (α = 0.78).

Health Literacy was measured using the Health Literacy Europe Questionnaire (HLS-EUQ16).[41] Health Literacy refers to individual skills used to obtain, process and understand health information and the competencies necessary to make appropriate health-related decisions. It contains 16 items. Higher scores indicate worse health literacy. Its Spanish validation has an α value of .982.[85] The internal consistency of the HLS-EUQ16 in our sample is excellent at T0 (α = 0.90).

We used the Irrational Procrastination Scale (IPS)[86] to measure general procrastination (dysfunctional delay). It contains nine items, rated on a 5-point Likert scale, with higher scores indicating a higher level of procrastination. Its α value is 0.90. We used the validated Spanish version.[42] The internal consistency of the IPS in our sample is good at T0 (α = 0.83).

**Statistical Analysis**

Firstly, a descriptive analysis (frequencies and percentages for categorical variables; means and standard deviation, and median and interquartile range for continuous variables) and a univariate analysis (one-way ANOVA for age, Kruskal-Wallis test for Nº of chronic comorbidities, BDI-II, IPAQ-SF, PSQI, MEDAS, EQ-5D-VAS, MOS-SS, SES, PAM, SOC-13, HLS-EUQ16 and IPS, and Chi-Square test for the remaining variables) were used to examine the data and tested whether there were baseline differences between groups after randomisation.

Secondly, to analyse the differences between both intervention groups (TAU+LMP and TAU+LMP+ICTs) comparing to TAU regarding the pre-post change of the primary outcome (BDI-II) and the secondary outcomes (IPAQ-SF-Walking, IPAQ-SF-Sedentarism PSQI, MEDAS, EQ-5D-VAS, MOS-SS, SES, PAM, SOC-13, HLS-EUQ16 and IPS), General Linear Modelling (specifically, ANCOVAs) were used. ANCOVAs were adjusted by their baseline score and by the variables showing significant differences in the baseline measurement (in our case, only age). To overcome possible problems of asymmetry in the distribution of the variables and sources of inaccuracy, a wild bootstrapping analysis with 5,000 samples[87,88] and with the bias-corrected-and-accelerated (BCa) bootstrap method[89] was carried out. Moreover, as considered

in the sample size calculation, a reduction of at least 17.5% from the baseline BDI-II score would be clinically relevant and would benefit the patient.[62] So, this specific reduction of each intervention group (TAU+LMP and TAU+LMP+ICTs) will be also tested. Statistical analysis was performed using IBM SPSS Statistics software (version 25.0)[90].

**Results**

A total of 246 participants were evaluated for eligibility, with 14 of them failing to meet the inclusion criteria, 6 declining to participate because they were not interested, and 38 declining to participate because they had time incompatibility. Of the 246 initial participants, 58 (23.58%) did not participate. Regarding the BDI-II results, no significant differences were found between those who participated in the study and those who did not ($p = 0.949$). Finally, 188 participants were included, exceeding the necessary sample size (Figure 1).

[Figure 1 here]

Firstly, the descriptive analysis showed that of the 188 participants, 162 were female (F) and 26 were male (M), and all participants were between 20 to 83 (mean age = 53.32, SD = 13.07) at T0. There were 63 (52 F and 11 M) participants in the treatment-as-usual group (TAU) (mean age = 49.54, SD = 13.50), 63 (54 F and 9 M) in the TAU+LMP group (mean age = 54.35, SD = 12.97) and 62 (56 F and 6 M) in the TAU+LMP+ICTs group (mean age = 56.11, SD = 11.98).

The univariate analysis subsequently revealed that the randomization produced similar groups in the primary and secondary outcomes (Table 1). The only difference is in the age, with the TAU+LMP+ICT participants being older compared to TAU participants ($p = 0.018$), which is probably due to chance as multiple tests were performed and no correction was made.

[Table 1 here]

Secondly, ANCOVAs revealed that there was a significant effect of both intervention groups on BDI-II compared to TAU (TAU+LMP vs. TAU mean pre-post change, $b$ = -9.703, 95% CI = [-12.762, -6.348] and TAU+LMP+ICTs vs. TAU mean pre-post change $b$ = -8.742, 95% CI = [-11.601, -5.781]). Considering the raw score of the mean pre-post change, there was an increase in BDI-II in the TAU group ($M$ = 3.29, $SD$ = 7.55), a decrease in the TAU+LMP group ($M$ = -6.43, $SD$ = 7.77) and in the TAU+LMP+ICTs group ($M$ = -5.59, $SD$ = 6.74). Additionally, in the TAU+LMP group a reduction of at least 4.37 points would have clinical significance, and in the TAU+LMP+ICTs group would be a reduction of at least 4.47 points. So, the reduction of the BDI-II in both groups have clinical significance (Table 2).

Moreover, there was a significant effect of both intervention groups in IPAQ-SF-Walking, PSQI, MEDAS, MOS-SS, SES, PAM, and SOC-13. In contrast, there was no significant change of any intervention group in IPAQ-SF-Sedentarism or HLS-EUQ16. And finally, there was a significant effect of TAU+LMP in EQ-5D-VAS and there was a significant effect of TAU+LMP+ICTs in IPS (Table 2).

[Table 2 here]

**Discussion**

The findings of this study indicate that, over the short term, the intervention is effective in decreasing depressive symptoms and adopting healthier lifestyles, as compared to TAU. Using this programme as an adjunctive treatment makes depressive symptoms improve more quickly.

Our results regarding effectiveness in depressive symptoms are similar to the RCTs conducting psychoeducational and healthy lifestyle aspect interventions.[53,91,92] In addition, recent studies have shown that healthy lifestyles are associated with a reduced risk of depressive symptoms.[93,94] Therefore, adherence to a healthy overall lifestyle is essential to prevent depression in the general population, since health conditions and lifestyle factors are potential risk factors for this disorder.[95,96]

Participants in the intervention groups increased their total weekly minutes of walking, increased their adherence to the Mediterranean diet and improved the quality of their sleep. However, even with a reduced amount of time spent seated, the change was not significant as compared to the TAU group. Regarding recent studies addressing the different lifestyles separately, a Mediterranean diet adherence group programme for treating major depression proved to be highly cost-effective in terms of cost/QALY gain and cost per case of major depression resolved.[97] Poor diet quality is associated with poor quality of life and depression,[98] but further research is necessary on the underlying effects, as well as the effect of n-3PUFAs as a treatment for major depression.[99] Physical well-being was shown to have a strong relationship with depressive symptoms.[100] In primary care settings, depression symptoms were associated with physical inactivity.[101] Personalised lifestyle advice to increase physical activity is a promising intervention against anhedonia.[102] Evidence suggests that it is not only necessary to be physically active for at least 150 min a week, but also to limit the number of waking hours spent being sedentary (i.e., sitting), since large amounts of time spent sitting have been linked to poor health[103] and depression.[104] Inadequate sleep (both too much and too little) is associated with most health disabilities and major depression.[105]

Although our study found a relationship between lifestyle modification and depressive symptoms, in some other studies, psychological variables explained the most variance in depression scores (35–44%); in contrast, sociodemographic and lifestyle factors explained only minimal variance.[106] Thus, further research is necessary to determine the weight of each factor in explaining the variance of depression. For example, personal factors as psychological mechanisms are essential for behaviour change. These variables are closely linked to changing the locus of control from the external to the internal, thus resulting in greater self-control. In this study, self-efficacy, patient activation, sense of coherence, and procrastination have been modified significantly after the intervention. In other study, self-efficacy is correlated with the level of physical activity[107] and has been shown to mediate the association between intervention and behaviour change in physical activity.[108] Thus, it may be a critical mechanism

in changing to a more active lifestyle,[109] and therefore it may be beneficial to attempt to increase the level of self-efficacy in interventions.[107] In a study in PHCs, low patient activation in their own health scores was strongly associated with increased depressive symptoms and a poorer quality of life.[110] Several studies have confirmed that SOC is inversely related to depression, presenting a protective capacity against depressive symptoms.[111] In addition, higher SOC levels are associated with better mental health outcomes and may be a health-promoting resource.[112] Procrastination was consistently associated with higher stress, more depression, anxiety, fatigue, and reduced satisfaction across life domains, especially regarding work and income.[113] In our study, health literacy was not significantly modified after the intervention, although the level of depression decreased. This result is similar to another study in which no relationship was found between health literacy and depression.[114] However, another study established that physical activity and higher health literacy protect against anxiety and depression and were associated with higher health-related quality of life.[115] Moreover, in our study, health literacy[116] worsens significantly with age, consistent with the results of a European health literacy survey.[41]

As recommended,[45] we used facilitators (in this case, a wearable smartwatch) for monitoring. The advantages of this use have not been reported in our study, since the results on both intervention groups are pretty similar. This may be due to differences in acceptance of wearable devices and adherence.[117] Moreover, only the TAU+LMP group obtained higher scores on the VAS as compared to the TAU. Another facilitator is the group intervention format since its benefits include social support, the feeling of belonging to a group, and the experience of sharing common problems.[118] Our results indicate an increase in perceived social support (higher score on the MOS-SS). Participants are just as likely to engage in group treatment as individual work, and the benefits are most likely to be maintained over time.[118] In this study, lifestyle changes took place in 6 weeks; in order for changes to become habits, they must be maintained for at least one year.[45]

In a recent study on exercise programmes,[119] adherence to the intervention groups was associated with improved coping and role fulfilment and keeping up with essential life areas. The professionals' skills, how the instructor tailored group instruction, and social support were found to be very important to the participants' adherence to long-term intervention.[119] In our study, session attendance by patients who did not drop out of the intervention group was high, attending almost 5 out of the 6 sessions. This figure is slightly higher than that obtained by Raya-Tena et al. (2021), who reported a mean of seven sessions out of 12,[53] and in which there was also a decrease in the BDI-II scores in the intervention group. As for dropout, the main reason was time incompatibility, accounting for 25.6% of the dropout rate in the intervention groups. In order to decrease the dropout rate, other adherence strategies may be considered. For example, sending text messages has been proven effective to increased physical activity.[120] So, for future research, we propose incorporating text messages, since the watch did not make significant changes over the short term.

Regarding the limitations and strengths of the study, the first strength was the study's design, an RCT with sample homogeneity between the TAU, TAU+LMP, and TAU+LMP+ICTs. Since the randomisation was blinded, the evaluations and statistical analysis provided greater validity to the results. The evidence existing in this field is limited since an RCT was used to evaluate the effectiveness of the programme on lifestyle modification in PHCs, in which various topics on healthy lifestyles are analysed together: psychoeducation, sleep quality and sunlight exposure, physical exercise, and adherence to the Mediterranean diet. In addition, the participant profile corresponded to that of patients who typically attended PHC consultations, and they are mostly patients with symptoms of depression since this type of patient tends to be treated in PHCs, with only a small percentage of them being referred to specialized mental health services. One limitation was the coincidence with COVID-19. Spain was one of the countries that were most strongly affected by the pandemic and it implemented one of the strictest initial lockdowns in Europe, extending over seven weeks.[121] Therefore, during this period, participants were unable to properly practice the lifestyle recommendations. However, this may have a greater effect in the

follow-up assessments as opposed to the pre-post assessment. Moreover, due to the nature of the intervention, the psychologist who led the interventions and participants were aware of the assigned intervention during the trial. Finally, attrition was due to time incompatibility with the face-to-face intervention and could be a source of bias. In any case, we have reached the sample size established in the protocol and no individual data was missing. In the one-year follow-up study, Multiple Imputation technique (MI) for handling missing data should be considered.

LMPs conducted in PHCs for patients with depression were found to be effective for depression remission, improvement in lifestyles (improved sleep quality, weekly minutes of walking, and Mediterranean diet adherence), and improvement of personal factors (self-efficacy, activation in their own health, and sense of coherence) over the short term. However, sedentarism and health literacy did not significantly change in both groups following the intervention (TAU+LMP and TAU+LMP+ICTs), quality of life only changed in the TAU+LMP group and procrastination only changed in the TAU+LMP+ICTs group. In light of these results, it is recommended that these effective programmes be implemented in PHCs.

**Ethics approval**: Ethics approval was granted by the Research Ethics Committee of Aragón (CEICA, PI18/286) and the Research Ethics Committee of the Balearic Islands (IB3950/19 PI). The study was developed following the Helsinki Declaration. All of the subjects signed an informed consent form; their data were anonymised and were only used for the purposes of the study.

**Partial Patient and Public Involvement**: PPI representatives worked with us to refine the research question; however, it was difficult to involve patients in other areas of the study design due to data protection restrictions and the very technical methods required to do a data linkage analysis. PPI representatives wrote a plain language summary and designed a leaflet for dissemination to their peers and distributing to patient groups.

**Funding:** This work was supported by Carlos III Health Institute grant number PI18/01336. The funders have no role in study design, data collection and analysis, decision to publish or manuscript preparation. The funding organisation will audit trial conduct once a year.

**Competing interests:** None declared.

**Acknowledgements:** We wish to thank the Aragonese Primary Care Research Group (GAIAP, B21_20R) that is part of the Department of Innovation, Research and University at the Government of Aragón (Spain); the Research Network on Chronicity, Primary Care and Health Promotion (RICAPPS, RD21/0016/0005) that is part of the Results-Oriented Cooperative Research Networks in Health (RICORS) (Carlos III Health Institute); and Feder Funds "Another way to make Europe".

**Data Availability Statement:** The data that support the findings of this study are available from the corresponding author upon reasonable request.

**Author Contributions**

Conceptualization: BOB, CN, MJSR and MGT
Data curation: AAL
Formal analysis: AAL, EG
Funding Acquisition: BOB
Investigation: AAL, CN, MJSR and BOB
Methodology: AAL, EG
Project administration: BOB
Software: AAL
Supervision: BOB, CN and MJSR
Validation: BOB
Visualization: AAL
Writing – original draft: AAL and BOB
Writing – review & editing: CN, MJSR, EG and MGT

**References**


1 OMS. Depression. 2021.https://www.who.int/news-room/fact-sheets/detail/depression (accessed 21 Feb 2022).

2 Sjöberg L, Karlsson B, Atti AR, *et al*. Prevalence of depression: Comparisons of different depression definitions in population-based samples of older adults. *J Affect Disord* 2017;**221**:123–31. doi:10.1016/j.jad.2017.06.011

3 World Health Organisation. Depression and other common mental disorders: global health estimates. *World Heal Organ* 2017.

4 Demura S, Sato S. Relationships between Depression , Lifestyle and Quality of Life in the Community Dwelling Elderly : A Comparison between Gender and Age Groups. *J Physiol Anthropol Appl Human Sci* 2003;**22**:159–166.

5 Song TM, An J, Hayman LL, *et al.* Stress, Depression, and Lifestyle Behaviors in Korean Adults: A Latent Means and Multi-Group Analysis on the Korea Health Panel Data. *Behav Med* 2014;**42**:72–81. doi:10.1080/08964289.2014.943688

6 Acciai F, Hardy M. Depression in later life: A closer look at the gender gap. *Soc Sci Res* 2017;**68**:163–75. doi:10.1016/j.ssresearch.2017.08.003

7 Maher GM, Perry CP, Perry IJ, *et al.* Protective lifestyle behaviours and depression in middle-aged Irish men and women : a secondary analysis. *Public Health Nutr* 2016;**19**:2999–3006. doi:10.1017/S1368980016001105

8 Cabello M, Miret M, Caballero FF, *et al.* The role of unhealthy lifestyles in the incidence and persistence of depression: a longitudinal general population study in four emerging countries. *Global Health* 2017;**13**:18. doi:10.1186/s12992-017-0237-5

9 Hidaka BH. Depression as a disease of modernity: Explanations for increasing prevalence. *J Affect Disord* 2012;**140**:205–14. doi:10.1016/j.jad.2011.12.036

10 Kupfer DJ, Frank E, Phillips ML. Major depressive disorder: New clinical, neurobiological, and treatment perspectives. Lancet. 2012. doi:10.1016/S0140-6736(11)60602-8

11 Lopresti AL, Hood SD, Drummond PD. A review of lifestyle factors that contribute to important pathways associated with major depression: Diet, sleep and exercise. *J Affect Disord* 2013;**148**:12–27. doi:10.1016/j.jad.2013.01.014

12 Toobert DJ, Glasgow RE, Strycker LA, *et al.* Long-term effects of the Mediterranean lifestyle program: A randomized clinical trial for postmenopausal women with type 2 diabetes. *Int J Behav Nutr Phys Act* Published Online First: 2007. doi:10.1186/1479-5868-4-1

13 Null G, Pennesi L, Feldman M. Nutrition and Lifestyle Intervention on Mood and Neurological Disorders. *J Evid Based Complementary Altern Med* 2016;:1–7. doi:10.1177/2156587216637539

14 Aguilar-Latorre A, Serrano-Ripoll MJ, Oliván-Blázquez B, *et al.* Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial. *Front Psychol* 2022;**13**. doi:10.3389/fpsyg.2022.856139

15 García-Toro M, Ibarra O, Gili M, *et al.* Four hygienic-dietary recommendations as add-on treatment in depression A randomized-controlled trial. *J Affect Disord* 2012;**140**:200–3. doi:10.1016/j.jad.2012.03.031

16 Olivan-Blázquez B, Montero-Marin J, García-Toro M, *et al.* Facilitators and barriers to modifying dietary and hygiene behaviours as adjuvant treatment in patients with depression in primary care: A qualitative study. *BMC Psychiatry* 2018;**18**:1–12. doi:10.1186/s12888-018-1779-7

17 Forsyth A, Deane FP, Williams P. A lifestyle intervention for primary care patients with

depression and anxiety: A randomised controlled trial. *Psychiatry Res* Published Online First: 2015. doi:10.1016/j.psychres.2015.10.001

18 Andrade-Gómez E, García-Esquinas E, Martínez-Gómez D, *et al*. Sedentary behaviors , physical activity , and changes in depression and psychological distress symptoms in older adults. Published Online First: 2018. doi:10.1002/da.22804

19 Kvam S, Lykkedrang C, Hilde I, *et al*. Exercise as a treatment for depression: A meta-analysis. *J Affect Disord J* 2016;**202**:67–86. doi:10.1016/j.jad.2016.03.063

20 Carek PJ, Laibstain SE, Carek SM. Exercise for the treatment of depression and anxiety. *Int J Psychiatry Med* 2011;**41**:15–28. doi:10.2190/PM.41.1.c

21 Harvey SB, Overland S, Hatch SL, *et al.* Exercise and the prevention of depression: Results of the HUNT cohort study. *Am J Psychiatry* 2018;**175**. doi:10.1176/appi.ajp.2017.16111223

22 Segal L, Twizeyemariya A, Zarnowiecki D, *et al.* Cost effectiveness and cost-utility analysis of a group-based diet intervention for treating major depression – the HELFIMED trial. *Nutr Neurosci* 2020;**23**:770–8. doi:10.1080/1028415X.2018.1556896

23 Null G, Pennesi L. Diet and lifestyle intervention on chronic moderate to severe depression and anxiety and other chronic conditions. *Complement Ther Clin Pract* Published Online First: 2017. doi:10.1016/j.ctcp.2017.09.007

24 Farzi A, Hassan AM, Zenz G, *et al.* Molecular Aspects of Medicine Diabesity and mood disorders : Multiple links through the microbiota-gut- brain axis. *Mol Aspects Med* 2018;:0–1. doi:10.1016/j.mam.2018.11.003

25 Dammen L Van, Wekker V, Rooij SR De, *et al.* Obesity Comorbidity / Lifestyle Intervention A systematic review and meta-analysis of lifestyle interventions in women of reproductive age with overweight or obesity : the effects on symptoms of depression and anxiety. *Obes Rev* Published Online First: 2018. doi:10.1111/obr.12752

26 Lambrinakou S, Katsa ME, Zyga S, *et al*. Correlations Between Nutrition Habits , Anxiety and Metabolic Parameters in Greek Healthy Adults. *Adv Exp Med Biol 987,* 2016;**987**:23–34. doi:10.1007/978-3-319-57379-3

27 Roca M, Kohls E, Gili M, *et al*. Prevention of depression through nutritional strategies in high-risk persons: Rationale and design of the MooDFOOD prevention trial. *BMC Psychiatry* Published Online First: 2016. doi:10.1186/s12888-016-0900-z

28 Sánchez-Villegas A, Henríquez P, Bes-Rastrollo M, *et al*. Mediterranean diet and depression. In: *Public Health Nutrition*. 2006. doi:10.1017/S1368980007668578

29 Becker NB, Jesus SN, João KADR, *et al*. Depression and sleep quality in older adults: a meta-analysis. *Psychol Heal Med* 2017;**22**:889–95. doi:10.1080/13548506.2016.1274042

30 Meerlo P, Havekes R, Steiger A. Chronically restricted or disrupted sleep as a causal factor in the development of depression. *Curr Top Behav Neurosci* Published Online First: 2015. doi:10.1007/7854_2015_367

31 Zhai L, Zhang H, Zhang D. Sleep duration and depression among adults: A meta-analysis of prospective studies. *Depress Anxiety* 2015;**32**:664–70. doi:10.1002/da.22386

32 Thomas J, Al-Anouti F. Sun Exposure and Behavioral Activation for Hypovitaminosis D and Depression: A Controlled Pilot Study. *Community Ment Health J* 2017;**54**:860–5. doi:10.1007/s10597-017-0209-5

33 Penckofer S, Kouba J, Byrn M, *et al.* Vitamin D and depression: Where is all the sunshine. *Issues Ment Health Nurs* 2010;**31**:385–93. doi:10.3109/01612840903437657

34 Veleva BI, van Bezooijen RL, Chel VGM, *et al.* Effect of ultraviolet light on mood, depressive disorders and well-being. *Photodermatol Photoimmunol Photomed* 2018;**34**:288–97. doi:10.1111/phpp.12396

35 Harb F, Hidalgo MP, Martau B. Lack of exposure to natural light in the workspace is associated with physiological, sleep and depressive symptoms. *Chronobiol Int* 2014;**32**:368–75. doi:10.3109/07420528.2014.982757

36 Anglin RES, Samaan Z, Walter SD, *et al.* Vitamin D deficiency and depression in adults: Systematic review and meta-analysis. *Br J Psychiatry* 2013;**202**:100–7. doi:10.1192/bjp.bp.111.106666

37 Antonovsky A. The salutogenic model as a theory to guide health promotion. *Health Promot Int* 1996;**11**. doi:10.1093/heapro/11.1.11

38 Sherer M, Maddux JE, Mercandante B, *et al.* The Self-Efficacy Scale: Construction and Validation. *Psychol Rep* Published Online First: 1982. doi:10.2466/pr0.1982.51.2.663

39 Hibbard JH, Stockard J, Mahoney ER, *et al.* Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. *Health Serv Res* 2004;**39**:1005–26. doi:10.1111/j.1475-6773.2004.00269.x

40 Antonovsky A. The structure and properties of the sense of coherence scale. *Soc Sci Med* Published Online First: 1993. doi:10.1016/0277-9536(93)90033-Z

41 Sørensen K, Pelikan JM, Röthlin F, *et al.* Health literacy in Europe: Comparative results of the European health literacy survey (HLS-EU). *Eur J Public Health* 2015;**25**:1053–8. doi:10.1093/eurpub/ckv043

42 Guilera G, Barrios M, Penelo E, *et al.* Validation of the spanish version of the irrational procrastination scale (IPS). *PLoS One* Published Online First: 2018. doi:10.1371/journal.pone.0190806

43 Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: A systematic review. *BMC Psychiatry* 2010;**10**. doi:10.1186/1471-244X-10-113

44 Mojtabai R, Olfson M, Sampson NA, *et al.* Barriers to mental health treatment: Results from the National Comorbidity Survey Replication. *Psychol Med* 2011;**41**:1751–61. doi:10.1017/S0033291710002291

45 NICE. Behaviour change: individual approaches. 2014.www.nice.org.uk/guidance/ph49

46 Nadal C, Earley C, Enrique A, *et al.* Integration of a smartwatch within an internet-delivered intervention for depression: Protocol for a feasibility randomized controlled trial on acceptance. *Contemp Clin Trials* 2021;**103**:106323. doi:10.1016/j.cct.2021.106323

47 Frank RG, Huskamp HA, Pincus HA. Aligning incentives in the treatment of depression in primary care with evidence-based practice. *Psychiatr Serv* 2003;**54**:682–7. doi:10.1176/appi.ps.54.5.682

48 Craven MA, Bland R. Depression in Primary Care: Current and Future Challenges. *Can J Psychiatry* 2013;**58**:442–8.www.TheCJP.ca

49 Smithson S, Pignone MP. Screening Adults for Depression in Primary Care. *Med Clin North Am* 2017;**101**:807–21. doi:10.1016/j.mcna.2017.03.010

50 Chisholm D, Sweeny K, Sheehan P, *et al.* Scaling-up treatment of depression and anxiety: A global return on investment analysis. *The Lancet Psychiatry* 2016;**3**:415–24. doi:10.1016/S2215-0366(16)30024-4

51 World Health Organization. mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings: mental health Gap Action Programme (mhGAP), version 2.0. *World Heal Organ* 2016;:1–173.

52 Cameron C, Habert J, Anand L, *et al.* Optimizing the management of depression: primary care experience. *Psychiatry Res* 2014;**220**:S45–57. doi:10.1016/S0165-1781(14)70005-8

53 Raya-Tena A, Fernández-San-martin MI, Martin-Royo J, *et al.* Effectiveness of a psychoeducational group intervention carried out by nurses for patients with depression and physical comorbidity in primary care: Randomized clinical trial. *Int J Environ Res Public Health* 2021;**18**:1–17. doi:10.3390/ijerph18062948

54 Nieuwsma JA, Trivedi RB, McDuffie J, *et al.* Brief Psychotherapy for Depression: A Systematic Review and Meta-Analysis. *Int J Psychiatry Med* 2012;**43**:129–151. doi:10.1038/jid.2014.371

55 Tuunainen A, Kripke DF, Endo T. Light therapy for non-seasonal depression. *Cochrane Database Syst Rev* Published Online First: 19 April 2004. doi:10.1002/14651858.CD004050.pub2

56 Golden RN, Gaynes BN, Ekstrom RD, *et al.* The efficacy of light therapy in the treatment of mood disorders: A review and meta-analysis of the evidence. Am. J. Psychiatry. 2005. doi:10.1176/appi.ajp.162.4.656

57 Forsyth A, Deane FP, Williams P. A lifestyle intervention for primary care patients with depression and anxiety : A randomised controlled trial. *Psychiatry Res* 2015;:1–8. doi:10.1016/j.psychres.2015.10.001

58 Coughlin JW, Smith MT. Sleep, obesity, and weight loss in adults: Is there a rationale for providing sleep interventions in the treatment of obesity? *Int Rev Psychiatry* Published Online First: 2014. doi:10.3109/09540261.2014.911150

59 Serrano-Ripoll MJ, Oliván-Blázquez B, Vicens-Pons E, *et al.* Lifestyle change recommendations in major depression: Do they work? *J Affect Disord* 2015;**183**. doi:10.1016/j.jad.2015.04.059

60 Aguilar-Latorre A, Navarro C, Oliván-Blázquez B, *et al.* Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial

protocol. *BMJ Open* 2020;**10**. doi:10.1136/bmjopen-2020-038457

61 Beck A, Steer R, Ball R, *et al*. Comparison of Beck Depression 1 in Psychiatric Inventories -1A and - Outpatients. *J Pers Assess* 1996;**67**:588–97. doi:10.1207/s15327752jpa6703

62 Button KS, Kounali D, Thomas L, *et al.* Minimal clinically important difference on the Beck Depression Inventory-II according to the patient's perspective. *Psychol Med* Published Online First: 2015. doi:10.1017/S0033291715001270

63 Galloway A. Non-Probability Sampling. *Encycl Soc Meas* 2005;**2**:859–64.

64 Sanz J, García-Vera MP, Espinosa R, *et al.* Spanish adaptation of the Beck Depression Inventory-II (BDI-II): 3. Psychometric features in patiens with psychological disorders. *Clínica y Salud* 2005;**16**:121–42. doi:10.4067/S0718-48082014000300006

65 Kim J, Shin W. How to do random allocation (randomization). *Clin Orthop Surg* 2014;**6**:103–9. doi:10.4055/cios.2014.6.1.103

66 Cuijpers P, Quero S, Papola D, *et al*. Care-as-usual control groups across different settings in randomized trials on psychotherapy for adult depression: A meta-analysis. *Psychol Med* 2019;**51**:634–44. doi:10.1017/S0033291719003581

67 Calderón-Larrañaga A, Vetrano DL, Onder G, *et al*. Assessing and Measuring Chronic Multimorbidity in the Older Population: A Proposal for Its Operationalization. *Journals Gerontol Med Sci* 2017;**72**:1417–23. doi:10.1093/GERONA/GLW233

68 Brooks R, De Charro F. EuroQol: The current state of play. *Health Policy (New York)* Published Online First: 1996. doi:10.1016/0168-8510(96)00822-6

69 The EuroQol Group. EuroQol - a new facility for the measurement of health-related quality of life. *Health Policy (New York)* 1990;**16**:199–208. doi:10.1016/0168-8510(90)90421-9

70 Badia X, Roset M, Montserrat S, *et al.* [The Spanish version of EuroQol: a description and its applications. European Quality of Life scale]. *Med Clin (Barc)* 1999.

71 Seoane B, de la Iglesia F, Nicolás R, *et al.* Análisis factorial de la calidad de vida relacionada con la salud de pacientes que ingresan en una unidad de corta estancia médica. *Rev Med Chil* Published Online First: 2009. doi:10.4067/s0034-98872009000900004

72 Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. *Qual Life Res* 2005;**14**:1523–32. doi:10.1007/s11136-004-7713-0

73 Sherbourne CD, Stewart AL. The MOS social support survey. *Soc Sci Med* Published Online First: 1991. doi:10.1016/0277-9536(91)90150-B

74 de la Revilla-Ahumada L, Luna del Castillo J, Bailón Muñoz E. [Validation of a questionnaire to measured social support in Primary Care]. *Med Fam* 2005;**6**:10–8.

75 Kim Y, Park I, Kang M. Convergent validity of the International Physical Activity Questionnaire (IPAQ): Meta-analysis. Public Health Nutr. 2013. doi:10.1017/S1368980012002996

76 Roman-Viñas B, Serra-Majem L, Hagströmer M, *et al.* International physical activity questionnaire: Reliability and validity in a Spanish population. *Eur J Sport Sci* 2010;**10**:297–304. doi:10.1080/17461390903426667

77 Kurtze N, Rangul V, Hustvedt BE. Reliability and validity of the international physical activity questionnaire in the Nord-Trøndelag health study (HUNT) population of men. *BMC Med Res Methodol* 2008;**8**:1–9. doi:10.1186/1471-2288-8-63

78 Martínez-González MÁ, Corella D, Salas-salvadó J, *et al.* Cohort profile: Design and methods of the PREDIMED study. *Int J Epidemiol* 2012;**41**:377–85. doi:10.1093/ije/dyq250

79 Schröder H, Fitó M, Estruch R, *et al.* A Short Screener Is Valid for Assessing Mediterranean Diet Adherence among Older Spanish Men and Women. *J Nutr* 2011;**141**:1140–5. doi:10.3945/jn.110.135566

80 Buysse DJ, Reynolds CF, Monk TH, *et al.* The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. *Psychiatry Res* Published Online First: 1989. doi:10.1016/0165-1781(89)90047-4

81 Royuela-Rico A, Macías-Fernández JA. Propiedades clinimétricas de la versión castellana del Cuestionario de Pittsburgh. *Vigilia-Sueño* 1997;**9**:81–94.

82 Lopez-Torrecillas F, García J, Cañadas GA, *et al.* Validity of self-efficacy scale scores for a spanish sample. *Psychol Rep* 2006;**98**:437–50.

83 Moreno-Chico C, González-de Paz L, Monforte-Royo C, *et al.* Adaptation to European Spanish and psychometric properties of the Patient Activation Measure 13 in patients with chronic diseases. *Fam Pract* 2017;**34**:627–34. doi:10.1093/fampra/cmx022

84 Moreno B, Alonso M, Álvaréz E. Sentido de coherencia, personalidad resistente, autoestima y salud. *Rev Psicol la salud* 1997;**9**:115–37.

85 Nolasco A, Barona C, Tamayo-Fonseca N, *et al.* Health literacy: psychometric behaviour of the HLS-EU-Q16 questionnaire. *Gac Sanit* 2018;:8–11. doi:10.1016/j.gaceta.2018.08.006

86 Steel P. Arousal, avoidant and decisional procrastinators: Do they exist? *Pers Individ Dif* Published Online First: 2010. doi:10.1016/j.paid.2010.02.025

87 Hardle W, Marron JS. Bootstrap Simultaneous Error Bars for Nonparametric Regression. *Ann Stat* 1991;**19**:778–96.

88 Wu CFJ. Jackknife, Bootstrap and Other Resampling Methods in Regression Analysis. *Ann Stat* 1986;**14**:1261–95. doi:https://doi.org/10.1214/aos/1176350142

89 Efron B. Better Bootstrap Confidence Intervals. *J Am Stat Assoc* 1987;**82**:171–85. doi:10.1080/01621459.1987.10478410

90 IBM Corp. Released. IBM SPSS Statistics version 25.0. 2017. 2017.

91 Casañas R, Catalán R, Raya A, *et al*. Efectividad de un programa grupal psicoeducativo para la depresión mayor en atención primaria: ensayo clínico controlado aleatorizado. *Rev la Asoc Española Neuropsiquiatría* 2014;**34**:145–6. doi:10.4321/s0211-57352014000100009

92 Przybylko G, Morton D, Kent L, *et al*. The effectiveness of an online interdisciplinary intervention for mental health promotion: a randomized controlled trial. *BMC Psychol* 2021;**9**:1–11. doi:10.1186/s40359-021-00577-8

93 Wang X, Arafa A, Liu K, *et al*. Combined healthy lifestyle and depressive symptoms: a meta-analysis of observational studies. *J Affect Disord* 2021;**289**:144–50. doi:10.1016/j.jad.2021.04.030

94 Ruiz-Estigarribia L, Martínez-González MÁ, Díaz-Gutiérrez J, *et al*. Lifestyles and the risk of depression in the "Seguimiento Universidad de Navarra" cohort. *Eur Psychiatry* 2019;**61**:33–40. doi:10.1016/j.eurpsy.2019.06.002

95 Wong VWH, Ho FYY, Shi NK, *et al*. Lifestyle medicine for depression: A meta-analysis of randomized controlled trials. *J Affect Disord* 2021;**284**:203–16. doi:10.1016/j.jad.2021.02.012

96 Cui N, Cui J, Xu X, *et al*. Health Conditions, Lifestyle Factors and Depression in Adults in Qingdao, China: A Cross-Sectional Study. *Front Psychiatry* 2021;**12**:1–9. doi:10.3389/fpsyt.2021.508810

97 Segal L, Twizeyemariya A, Zarnowiecki D, *et al*. Cost effectiveness and cost-utility analysis of a group-based diet intervention for treating major depression–the HELFIMED trial. *Nutr Neurosci* 2020;**23**:770–8. doi:10.1080/1028415X.2018.1556896

98 Picard K, Senior PA, Adame Perez S, *et al.* Low Mediterranean Diet scores are associated with reduced kidney function and health related quality of life but not other markers of cardiovascular risk in adults with diabetes and chronic kidney disease. *Nutr Metab Cardiovasc Dis* 2021;**31**:1445–53. doi:10.1016/j.numecd.2021.02.002

99 Appleton KM, Sallis HM, Perry R, *et al.* ω-3 fatty acids for major depressive disorder in adults: An abridged Cochrane review. *BMJ Open* 2016;**6**. doi:10.1136/bmjopen-2015-010172

100 Schitter AM, Nedeljkovic M, Ausfeld-Hafter B, *et al.* Changes in self-reported symptoms of depression and physical well-being in healthy individuals following a Taiji beginner course - Results of a randomized controlled trial. *Brain Behav* 2016;**6**:1–7. doi:10.1002/brb3.429

101 Achttien R, Van Lieshout J, Wensing M, *et al.* Symptoms of depression are associated with physical inactivity but not modified by gender or the presence of a cardiovascular disease; A cross-sectional study. *BMC Cardiovasc Disord* 2019;**19**:1–7. doi:10.1186/s12872-019-1065-8

102 Schmitter M, van Roekel E, Heininga VE, *et al.* Personalized lifestyle advice alters affective reactivity to negative events in anhedonic young adults. *J Affect Disord* 2021;**291**:118–25. doi:10.1016/j.jad.2021.04.036

103 De Rezende LFM, Rey-López JP, Matsudo VKR, *et al.* Sedentary behavior and health outcomes among older adults: A systematic review. *BMC Public Health* 2014;**14**:1–9. doi:10.1186/1471-2458-14-333

104 Boulos C, Salameh P. Gender-specific factors associated with risk of depression among Lebanese older adults. *Psychogeriatrics* 2021;:1–9. doi:10.1111/psyg.12708

105 Kim Y-J, Lee S-A. The Relationship of Lifestyle Factors with the Prevalence of Major Depressive Disorder by Ecological Factors. *Psychiatry Investig* 2021;**18**:340–7.

doi:10.30773/pi.2020.0309

106 Schneider G, Köhnke C, Teismann H, *et al.* Childhood trauma and personality explain more variance in depression scores than sociodemographic and lifestyle factors – Results from the BiDirect Study. *J Psychosom Res* 2021;**147**:110513. doi:10.1016/j.jpsychores.2021.110513

107 Blom V, Drake E, Kallings L V, *et al.* The effects on self-efficacy, motivation and perceived barriers of an intervention targeting physical activity and sedentary behaviours in office workers: a cluster randomized control trial. *BMC Public Health* 2021;**21**:1–9.

108 Anderson ES, Winett RA, Wojcik JR, *et al.* Social cognitive mediators of change in a group randomized nutrition and physical activity intervention: Social support, self-efficacy, outcome expectations and self-regulation in the guide-to-health trial. *J Health Psychol* 2010;**15**:21–32. doi:10.1177/1359105309342297

109 Holloway A, Watson HE. Role of self-efficacy and behaviour change. *Int J Nurs Pract* 2002;**8**:106–15. doi:10.1046/j.1440-172x.2002.00352.x

110 Magnezi R, Glasser S, Shalev H, *et al.* Patient activation, depression and quality of life. *Patient Educ Couns* 2014;**94**:432–7. doi:10.1016/j.pec.2013.10.015

111 Schäfer SK, Schanz CG, Sopp MR, *et al.* Pre-rehabilitation sense of coherence as a predictor of symptom change after rehabilitation. *Stress Heal* 2020;**36**:546–54. doi:10.1002/smi.2949

112 Masanotti GM, Paolucci S, Abbafati E, *et al.* Sense of coherence in nurses: A systematic review. *Int J Environ Res Public Health* 2020;**17**. doi:10.3390/ijerph17061861

113 Beutel ME, Klein EM, Aufenanger S, *et al.* Procrastination, distress and life satisfaction across the age range - A German representative community study. *PLoS One* 2016;**11**:1–12. doi:10.1371/journal.pone.0148054

114 Baird B, Oh KM, Douglas C, *et al.* Health Literacy, Depression Literacy, and Depression among Older Korean Americans. *J Health Commun* 2019;**24**:525–35. doi:10.1080/10810730.2019.1632395

115 Tran T V., Nguyen HC, Pham L V., *et al.* Impacts and interactions of COVID-19 response involvement, health-related behaviours, health literacy on anxiety, depression and health-related quality of life among healthcare workers: A cross-sectional study. *BMJ Open* 2020;**10**:1–13. doi:10.1136/bmjopen-2020-041394

116 Torres Cubeiro M. Ignorancia y complejidad: la sociología de la enfermedad mental. *Acciones e Investig Soc* 2021;**42**:43–75. doi:https://doi.org/10.26754/ojs_ais/ais.2021426228

117 Lee S, Kim H, Park MJ, *et al.* Current Advances in Wearable Devices and Their Sensors in Patients With Depression. *Front Psychiatry* 2021;**12**:1–8. doi:10.3389/fpsyt.2021.672347

118 Guimón J. *Manual de Terapias de Grupo. Tipos, Modelos y Programas*. Madrid (Spain): : Biblioteca Nueva 2003.

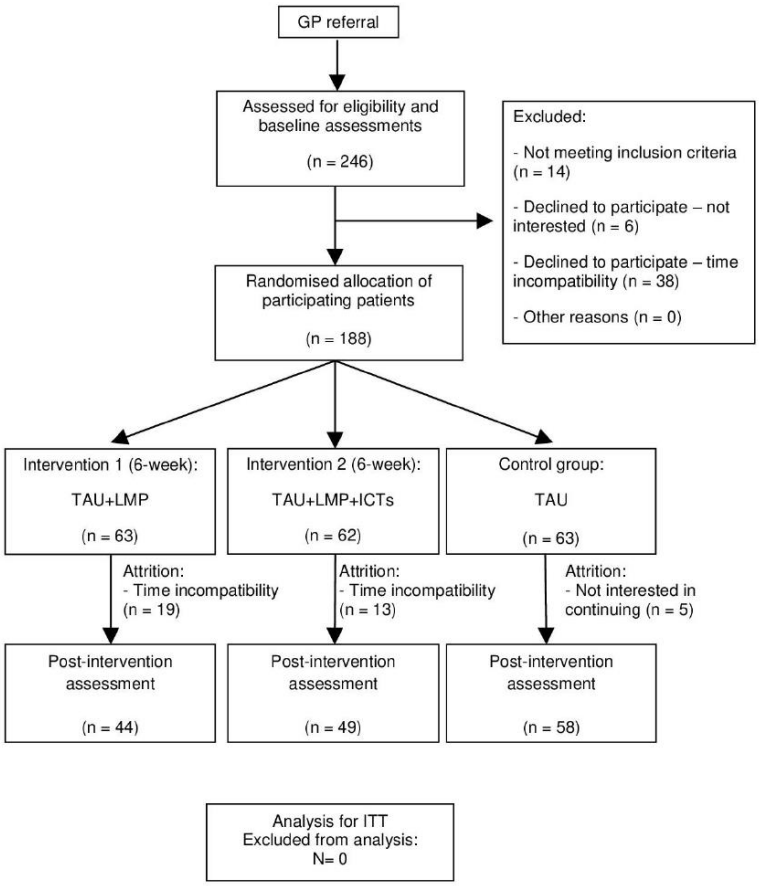
119 Simmonds-Buckley M, Kellett S, Waller G. Acceptability and Efficacy of Group Behavioral Activation for Depression Among Adults: A Meta-Analysis. *Behav Ther* 2019;**50**:864–85. doi:10.1016/j.beth.2019.01.003

120 Stødle IV, Debesay J, Pajalic Z, *et al.* The experience of motivation and adherence to group-based exercise of Norwegians aged 80 and more: A qualitative study. *Arch Public Heal* 2019;**77**:1–12. doi:10.1186/s13690-019-0354-0

121 Spain Ministry of Health. Update No 303. Coronavirus Disease (COVID-19). 02.02.2021. Madrid (Spain): 2020. https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/Actualizacion_223_COVID-19.pdf

34

**Figure 1. Flowchart of the study: randomisation, sampling and monitoring of patients.**




GP, General Practitioner; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Table 1. Sociodemographic and clinical characteristics of the sample at baseline**

| Variables | Total (n = 188) | TAU (n = 63) | TAU+LMP (n = 63) | TAU+LMP+ICTs (n = 62) | *F, H or* $X^2$ |
|---|---|---|---|---|---|
| Age, *M* (*SD*) | 53.32 (13.07) | 49.54 (13.50) | 54.35 (12.97) | 56.11 (11.99) | 4.399* |
| Gender, *female n (%)* | 162 (86.2) | 52 (82.5) | 54 (85.7) | 56 (90.3) | 1.60 |
| Education | | | | | |
| None or primary, *n (%)* | 72 (38.3) | 21 (33.3) | 22 (34.9) | 29 (46.8) | 2.84 |
| Secondary or tertiary, *n (%)* | 116 (61.7) | 42 (66.7) | 41 (65.1) | 33 (53.2) | |
| Occupation | | | | | |
| Working, *n (%)* | 53 (28.2) | 23 (36.5) | 17 (27) | 13 (21) | 3.79 |
| Not working, *n (%)* | 135 (71.8) | 40 (63.5) | 46 (73) | 49 (79) | |
| Marital status | | | | | |
| With a partner, *n (%)* | 105 (54.4) | 32 (50.8) | 34 (54) | 37 (59.7) | 1.02 |
| Without a partner, *n (%)* | 88 (45.6) | 31 (49.2) | 29 (46) | 25 (40.3) | |
| Economic level | | | | | |
| < IMW to 2 IMW, *n (%)* | 164 (87.2) | 57 (90.5) | 51 (81) | 56 (90.3) | 3.35 |
| >2 IMW, *n (%)* | 24 (12.8) | 6 (9.5) | 12 (19) | 6 (9.7) | |
| Taking antidepressants, *yes n (%)* | 132 (71.3) | 45 (71.4) | 46 (73) | 43 (69.4) | .39 |
| Nº of chronic comorbidities, *Mdn (IQR)* | 4 (6) | 3 (6) | 4 (5) | 4.5 (7.25) | 2.51 |
| Number of sessions attended**, *M* (*SD*) | 4.98 (1.09) | - | 5.07 (1.02) | 4.90 (1.15) | 2.04 |
| BDI-II, *Mdn (IQR)* | 27 (7) | 26 (7) | 27 (8) | 28 (6) | 5.19 |
| IPAQ-SF-Walking, *Mdn (IQR)* | 97.5 (341.25) | 70 (280) | 180 (410) | 82.5 (280) | 2.74 |
| IPAQ-SF-Sedentarism, *Mdn (IQR)* | 285 (240) | 240 (240) | 300 (180) | 300 (195) | 5.93 |
| PSQI, *Mdn (IQR)* | 11 (7.75) | 12 (7) | 12 (7) | 11 (7) | .87 |
| MEDAS, *Mdn (IQR)* | 6 (3) | 6 (3) | 6 (3) | 6 (2) | .08 |
| EQ-5D-VAS, *Mdn (IQR)* | 50 (20) | 50 (30) | 50 (30) | 50 (25) | 1.09 |
| MOS-SS, *Mdn (IQR)* | 72 (28) | 76 (29) | 72 (29) | 72 (27) | 1.35 |
| SES, *Mdn (IQR)* | 164.5 (58) | 177 (56) | 165 (61) | 159.5 (48.75) | 2.86 |
| PAM, *Mdn (IQR)* | 39 (7.75) | 41 (10) | 39 (6) | 39 (8) | 2.82 |
| SOC-13, *Mdn (IQR)* | 43.5 (18) | 45 (14) | 44 (16) | 42 (20) | .38 |
| HLS-EUQ16, *Mdn (IQR)* | 33 (8.75) | 33 (12) | 32 (10) | 34 (6) | 5.21 |
| IPS, *Mdn (IQR)* | 28 (10) | 27 (11) | 30 (10) | 28.5 (9.25) | .86 |

Note. *p<.05 **Only patients in the intervention group who did not drop out were included in this analysis. IMW, Interprofessional Minimum Wage. *F* value of the one-way ANOVA for age, *H* value of the Kruskal-Wallis test for Nº of chronic comorbidities, BDI-II, IPAQ-SF, PSQI, MEDAS, EQ-5D-VAS, MOS-SS, SES, PAM, SOC-13, HLS-EUQ16 and IPS. Chi-Square test ($X^2$) for the remaining variables. BDI-II, Beck II Self-Applied Depression Inventory; IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; MEDAS, Mediterranean Diet Adherence Screener; EQ-5D-VAS, European Quality of Life-5 Dimensions Questionnaire; MOS-SS, Medical Outcomes Study Social Support Survey; SES, Self-Efficacy Scale; PAM, Patient Activation Questionnaire; SOC-13, Sense of Coherence questionnaire; HLS-EUQ16, Health Literacy Europe Questionnaire; IPS, Irrational Procrastination Scale; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Table 2. Mean pre-post changes for each group and mean pre-post change comparing to TAU.**

| | *M* | *SD* | 95% CI for *M* | *B* | *SE* | 95% CI for *B* |
|---|---|---|---|---|---|---|
| **BDI-II** | | | | $R^2$ adj = .398, $F(4, 146) = 25.750$, $p < .001$ | | |
| TAU | 3.29 | 7.55 | [1.30, 5.27] | - | - | - |
| TAU+LMP | -6.43 | 7.77 | [-8.79, -4.06] | -9.703*** | 1.541 | [-12.762, -6.348] |
| TAU+LMP + ICTs | -5.59 | 6.74 | [-7.52, -3.65] | -8.742*** | 1.417 | [-11.601, -5.781] |
| **IPAQ-SF-Walking** | | | | $R^2$ adj = .173, $F(4, 146) = 8.83$, $p < .001$ | | |
| TAU | -13.96 | 410.85 | [-121.99, 94.06] | - | - | - |
| TAU+LMP | 145.34 | 250.76 | [69.10, 221.57] | 175.548** | 57.616 | [62.703, 284.378] |
| TAU+LMP + ICTs | 205.30 | 432.34 | [81.12, 329.48] | 198.704** | 70.071 | [61.185, 335.619] |
| **IPAQ-SF-Sedentarism** | | | | $R^2$ adj = .283, $F(4, 146) = 15.81$, $p < .001$ | | |
| TAU | 13.96 | 223.10 | [-44.69, 72.62] | - | - | - |
| TAU+LMP | -51.70 | 135.25 | [-92.82, -10.58] | -54.649 | 31.882 | [-116.350, 6.188] |
| TAU+LMP + ICTs | -52.04 | 149.22 | [-94.90, -9.17] | -51.095 | 33.994 | [-117.528, 14.099] |
| **PSQI** | | | | $R^2$ adj = .503, $F(4, 146) = 39.02$, $p < .001$ | | |
| TAU | .51 | 3.79 | [-.48, 1.51] | - | - | - |
| TAU+LMP | -2.68 | 3.77 | [-3.82, -1.53] | -3.222*** | .641 | [-4.515, -1.931] |
| TAU+LMP + ICTs | -.73 | 3.25 | [-1.67, .20] | -1.506* | .597 | [-2.680, -.393] |
| **MEDAS** | | | | $R^2$ adj = 333., $F(4, 146) = 19.72$, $p < .001$ | | |
| TAU | -.41 | 1.69 | [-.85, .03] | - | - | - |
| TAU+LMP | .41 | 2.29 | [-.28, 1.10] | .986** | .354 | [.281, 1.658] |
| TAU+LMP + ICTs | .61 | 1.60 | [.15, 1.07] | 1.106*** | .312 | [.517, 1.705] |
| **EQ-5D-VAS** | | | | $R^2$ adj = .278, $F(4, 146) = 15.40$, $p < .001$ | | |
| TAU | 2.17 | 19.30 | [-2.90, 7.24] | - | - | - |
| TAU+LMP | 11.79 | 19.71 | [5.80, 17.78] | 10.217** | 3.385 | [3.818, 17.004] |
| TAU+LMP + ICTs | 8.22 | 19.11 | [2.73, 13.71] | 5.548 | 3.512 | [-1.229, 12.533] |
| **MOS-SS** | | | | $R^2$ adj = .448, $F(4, 146) = 31.47$, $p < .001$ | | |
| TAU | -4.34 | 13.05 | [-7.77, -.91] | - | - | - |
| TAU+LMP | 9.77 | 18.50 | [4.14, 15.39] | 13.588*** | .000 | [7.860, 19.483] |
| TAU+LMP + ICTs | 2.36 | 14.05 | [-1.66, 6.40] | 6.419** | .009 | [1.897, 10.890] |
| **SES** | | | | $R^2$ adj = .385, $F(4, 146) = 24.45$, $p < .001$ | | |
| TAU | -16.48 | 50.54 | [-29.77, -3.19] | - | - | - |
| TAU+LMP | 14.97 | 47.18 | [.63, 29.32] | 34.266*** | 8.944 | [16.586, 51.461] |
| TAU+LMP + ICTs | 13.04 | 32.29 | [3.76, 22.31] | 27.458** | 7.742 | [11.704, 43.391] |
| **PAM** | | | | $R^2$ adj = .333, $F(4, 146) = 19.72$, $p < .001$ | | |
| TAU | -2.53 | 6.05 | [-4.12, -.94] | - | - | - |
| TAU+LMP | 2.97 | 6.04 | [1.14, 4.81] | 5.390*** | 1.027 | [3.315, 7.453] |
| TAU+LMP + ICTs | 1.32 | 6.22 | [-.46,3.11] | 3.500** | 1.020 | [1.421, 5.763] |
| **SOC-13** | | | | $R^2$ adj = .462, $F(4, 146) = 33.24$, $p < .001$ | | |
| TAU | -1.51 | 11.11 | [-4.43, 1.40] | - | - | - |
| TAU+LMP | 3.75 | 12.29 | [.01, 7.48] | 5.704* | 2.349 | [1.048, 10.338] |
| TAU+LMP + ICTs | 3.73 | 9.63 | [.96, 6.50] | 4.751* | 2.060 | [.441, 9.209] |
| **HLS-EUQ16** | | | | $R^2$ adj = .201, $F(4, 146) = 10.43$, $p < .001$ | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| TAU | -.55 | 7.33 | [-2.48, 1.37] | - | - | - |
| TAU+LMP | .27 | 7.18 | [-1.91, 2.45] | .572 | .654 | [-1.846, 2.972] |
| TAU+LMP + ICTs | -1.59 | 8.10 | [-3.92, .73] | -.199 | .866 | [-2.656, 2.390] |
| **IPS** | | | | $R^2$ adj = .229, $F(4, 146) = 12.11$, $p < .001$ | | |
| TAU | 1.70 | 7.66 | [-.30, 3.72] | - | - | - |
| TAU+LMP | -1.20 | 8.13 | [-3.67, 1.27] | -2.416 | 1.294 | [-5.002, .120] |
| TAU+LMP + ICTs | -.97 | 4.09 | [-2.15, .19] | -2.107* | .989 | [-4.060, -.077] |

*Note*. *B*: unstandardized regression coefficient for the pre-post change of the TAU+LMP and TAU+LMP+ICTs comparing to TAU. *SE*: bootstrapped standard error. 95% CI for *B*: bootstrapped lower-level/upper-level for 95% confidence interval (calculations based on 5,000 bootstrap samples). ***p<.001; **p<.01; *p<.05. CI, confidence interval; BDI-II, Beck II Self-Applied Depression Inventory; IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; MEDAS, Mediterranean Diet Adherence Screener; EQ-5D-VAS, European Quality of Life-5 Dimensions Questionnaire; MOS-SS, Medical Outcomes Study Social Support Survey; SES, Self-Efficacy Scale; PAM, Patient Activation Questionnaire; SOC-13, Sense of Coherence questionnaire; HLS-EUQ16, Health Literacy Europe Questionnaire; IPS, Irrational Procrastination Scale.

# Anexo II. One-year follow-up of the effectiveness of a lifestyle modification programme as an adjuvant treatment of depression in primary care: a randomised clinical trial



ORIGINAL RESEARCH

**ONE-YEAR FOLLOW-UP OF THE EFFECTIVENESS OF A LIFESTYLE MODIFICATION PROGRAMME AS AN ADJUVANT TREATMENT OF DEPRESSION IN PRIMARY CARE: A RANDOMISED CLINICAL TRIAL**

**Alejandra Aguilar-Latorre[1], Bárbara Oliván-Blázquez[1,2*], Guillermo Pérez Algorta[3], Maria J. Serrano-Ripoll[4,5,6], Alberto Turón-Lanuza[7]**

[1]Institute for Health Research Aragón (IIS Aragón), Zaragoza, Spain.

[2]Department of Psychology and Sociology, University of Zaragoza, Zaragoza, Spain.

[3]Division of Health Research, Faculty of Health and Medicine, Lancaster University, Lancaster, United Kingdom.

[4]Balearic Islands Health Services, Primary Care Research Unit of Mallorca, Palma, Balearic Islands, Spain.

[5]Research in Preventive Activities and Promotion and in Cancer Illes Balears (GRAPP-CAIB), Health Research Institute of the Balearic Islands (IdISBa), Palma, Balearic Islands, Spain.

[6]Research Network in Preventive Activities and Health Promotion (RedIAPP), Barcelona, Spain.

[7]Department of Applied Economics, University of Zaragoza, Zaragoza, Spain.

* Correspondence:

Bárbara Oliván-Blázquez

E-mail: bolivan@unizar.es

Address: University of Zaragoza. St. Violante de Hungria 23. ZIP: 50009. City: Zaragoza. Country: Spain. Telephone: 876554547 (Ext: 844547).

**Funding**

This work was supported by Carlos III Health Institute grant number PI18/01336. The funders have no role in study design, data collection and analysis, decision to publish or manuscript preparation. The funding organisation will audit trial conduct once a year.

**Conflicts of interest**

None.

**Data Availability Statement**

The data that support the findings of this study are available from the corresponding author upon reasonable request.

**Acknowledgements**

We wish to thank the Primary Care Prevention and Health Promotion Network (RedIAPP-Health Institute Carlos III, Spain), the Primary Health Care Research Group of Aragon (GAIAP – B21-20R) of the Department of Science, University and Knowledge Society of the government of Aragon (Spain) and Feder Funds "Another way to make Europe". This research has been developed during a short-research term of AAL at Lancaster University supported by *Campus de Excelencia Internacional del Valle del Ebro* (Campus Iberus), "Convenio de subvención Erasmus+ Educación Superior para prácticas Consorcio Iberus+", and *Universidad de Zaragoza*, *Fundación Bancaria Ibercaja y Fundación CAI* "Programa Ibercaja-CAI de Estancias de Investigación", grant number CM 9/21.

**Author Contributions**

Conceptualization: BOB, and MJSR

Data curation: AAL

Formal analysis: AAL, GPA, AT

Funding Acquisition: BOB

Investigation: AAL, MJSR, and BOB

Methodology: AAL, GPA, AT

Project administration: BOB

Software: AAL

Supervision: BOB, and MJSR

Validation: BOB

Visualization: AAL

Writing – original draft: AAL and BOB

Writing – review & editing: GPA, AT, and MJSR

**Abstract:**

Background: An estimated 280 million individuals suffer from depression. Brief group interventions in Primary Healthcare Centres (PHCs) are recommended. One goal of these interventions is to educate people about healthy lifestyle habits, as they prevent the development of depression. This study aims to analyse the one-year follow-up results about the effectiveness of a Lifestyle Modification Programme (LMP) and an LMP plus Information and Communication Technologies (LMP+ICTs) when compared to Treatment as Usual (TAU).

Methods: We conducted an open-label, multicentre, pragmatic, randomised clinical trial. A total of 188 individuals that visited a general practitioner and met the inclusion criteria were randomised. LMP consisted of six weekly 90-minute group sessions focusing on lifestyle improvement. LMP+ICTs was a hybrid of the LMP format with the inclusion of a wearable smartwatch. We used linear mixed models (with a random intercept and an unstructured covariance) to evaluate the effectiveness of the interventions, and an intention-to-treat analysis and Multiple Imputation technique for handling missing data.

Results: LMP+ICTs showed a statistically significant reduction on depressive symptoms (*b* = -2.68, 95% CI= [-4.239, -1.133] p = .001) and sedentarism (b = -37.38, 95% CI [-62.930, -11.833], p = .004) compared to TAU.

Limitations: Most of the dropouts were due to time restrictions.

Conclusions: In long-term, LMPs plus ICTs administered in PHCs to people suffering from depression were effective in reducing depressive symptomatology and sedentarism comparing to TAU. More research is needed to enhance adherence to lifestyle recommendations. These promising programmes could be easily implemented in PHCs.

**Keywords:** Depression, Lifestyle modification, Diet, Physical Exercise, Sleep quality, Primary Care

**Trial registration number:** ClinicalTrials.gov Registry (NCT03951350).

**Highlights**

- This paper demonstrates the effectiveness in the long-term of a Lifestyle Modification Programme in a face-to-face group format at the primary healthcare level.

- It confirms the relationship between several lifestyles and depression.

6

**Introduction**

Depression is the second most prevalent cause of disability globally (WHO, 2017), and it is a serious public health problem that affects an estimated 280 million people of all ages (WHO, 2021). Depression management at Primary Healthcare Centres (PHCs) is encouraged due to its high incidence (WHO, 2016), as one out of every ten patients at that level of care exhibits depressed symptoms (Malhi & Mann, 2018).

Brief group interventions have various advantages in PHCs, for example, they can be offered by either trained mental health professionals or experienced non-mental health caregivers (Nieuwsma et al., 2012). One of the aims of these interventions is to educate individuals about healthy living habits (Malhi et al., 2018) since Lifestyle Modification Programmes (LMPs) are considered a beneficial therapeutic strategy to prevent the development of depression (Aguilar-Latorre, Serrano-Ripoll, et al., 2022; Forsyth et al., 2015; García-Toro et al., 2012; Lopresti et al., 2013).

In terms of particular lifestyle variables, interventions that support healthier dietary practices may contribute to reducing depressive symptoms (Opie et al., 2021). In particular, the Mediterranean diet has been associated with improved symptoms of depression (Pano et al., 2021), and beyond that, there is evidence that the Mediterranean lifestyle may be a more effective prevention strategy for depression (Hershey et al., 2022). Regarding physical activity, there is a negative relationship between regular exercise and depressive symptoms (Kim, 2022). Moreover, including exercise in antidepressant drug treatment may offer significant advantages over affective symptoms of depression (Murri et al., 2018). In this line, sedentary behavior and short sleep duration in older adults are associated with depressive symptoms (Luo et al., 2022). Furthermore, there is a higher risk of depression among older people with sleep problems than without them (Hill et al., 2022; Zhang et al., 2022).

Besides that, previous research has suggested that monitoring of everyday behaviors promotes lifestyle modifications in depressed primary care patients (Olivan-Blázquez et al., 2018; Serrano-Ripoll et al., 2015). Therefore, the use of Information and Communication Technologies (ICT), such as wearable devices, is recommended to improve adherence (NICE, 2014).

This study aims to analyse the one-year follow-up results about the effectiveness of an LMP and an LMP plus Information and Communication Technologies (LMP+ICTs) when compared to Treatment as Usual (TAU).

**Methods and analysis**

***Study design***

An open-label, multicentre, pragmatic, randomised clinical trial (RCT) in three parallel groups (TAU as a control group, and LMP and LMP+ICTs as intervention groups) was carried out in several PHCs. Trial registration number: NCT03951350.

***Sample size***

A Spanish study with primary care patients was used as a proxy reference to determine the sample size for this research. Serrano-Ripoll et al (2015) reported an average BDI-II score (Beck et al., 1996) of 24.5 points (SD 7.84) (Serrano-Ripoll et al., 2015). We determined that a decrease of at least 4.28 points would be clinically significant and beneficial for people in Spain, based on Button et al (2015) (Button et al., 2015) proposal of considering a 17.5 percent reduction in the BDI-II as clinically relevant. Accepting a risk of 0.05 and a risk of 0.20 in a bilateral contrast, each treatment group required 35 participants. With a hypothetical 20% withdrawal rate, a final sample size of 42 participants per group was considered. A total sample size of 126 participants was required.

***Recruitment and participants***

Participants were selected from individuals who saw a general practitioner (GP) at one of the participating PHCs for any reason and satisfied the inclusion criteria outlined below. By the end of the study, 188 patients had been recruited from PHCs in two sites in Spain (Zaragoza and Mallorca).

The inclusion criteria were the following: individuals with depression (scoring 10 to 30 points on the BDI-II) (Beck et al., 1996), of both sexes over the age of 18, with a duration of depression symptoms extending over at least two months, and who understood written and spoken Spanish. The exclusion criteria were the following: suffering from another disease affecting the central nervous system (organic brain pathology or having suffered a traumatic brain injury of any severity, dementia) determined by people self-report; having another psychiatric diagnosis or psychiatric severe illness (substance dependence or abuse, history of schizophrenia or other psychotic disorders, eating disorders) with the exception of anxious pathology or personality disorders (collected through a medical history); the presence of a severe or uncontrolled medical, infectious or degenerative illness that may have interfered with the affective symptoms; the presence of delirium or hallucinations, risk of suicide, pregnancy or lactation; patients who had participated in another clinical trial during the previous 6 months or who were in psychotherapy at the time of the study; those who practiced mindfulness, yoga, meditation or similar practices during the previous 6 months, engaging in formal training at least once a week; and the presence of any medical, psychological or social problem that could have seriously interfered with the patient's participation in the study.

An independent researcher assigned participants using a computer-generated random number (J. Kim & Shin, 2014). Patients were randomly assigned to one of three conditions at each PHC. Because they were informed of the intervention, participants were not blinded to their allocation. Data from participants was entered and coded by a

blinded Research Assistant (RA). Another blinded RA assessed the outcomes and analysed the data. All information gathered was handled in compliance with current personal data protection rules.

***Intervention development and evaluation***

GPs provided general medical care (TAU) to all participants (Cuijpers et al., 2019; Ministry of Health Social Services and Equality, 2014).

Those assigned to LMP had a 90-minute session each week for six weeks, which was complemented with PowerPoint presentations. The following subjects were addressed: 1) Psychoeducation on depression; 2) Behaviour activation; 3) Sleep hygiene habits and careful exposure to sunlight; 4) Physical activity; 5) Adherence to the Mediterranean diet; and 6) Summary of previous sessions. LMP+ICTs reproduced the LMP format, with the addition of participants receiving a wearable wristwatch and being asked to use it to track daily minutes walked and sleep habits. Participants who were not assigned to any of the two interventions were part of the TAU group. The published protocol provides further information (Aguilar-Latorre et al., 2020).

At baseline (T0), immediately following the intervention (T1), six-month follow-up (T2), and twelve-month follow-up (T3), patient data was gathered by a blinded RA.

***Outcomes and measures***

Gender, age, marital status, level of education, occupation, and economic level were collected.

The BDI-II was used to assess the severity of depression symptoms as the primary outcome. It is made up of 21 questions, with higher scores indicating more severe depression symptoms (Sanz et al., 2005). At baseline, the internal consistency of the BDI-II in our sample was acceptable ($\alpha = 0.71$).

Secondary outcomes:

The International Physical Activity Questionnaire-Short Form (IPAQ-SF) (Y. Kim et al., 2013) was used to assess the physical activity over the last seven days (Roman-Viñas et al., 2010). It contains seven items and has good reliability for vigorous physical activity and sitting hours, poor validity for moderate activity and moderate reliability for walking (Kurtze et al., 2008). The minutes walked per week and the minutes sat per day were use in the present study.

The 14-item Mediterranean Diet Adherence Screener (MEDAS), developed by the PREDIMED study group (Martínez-González et al., 2010), was used to assess food intake and consumption patterns related to the Mediterranean diet. A higher score indicates a higher level of adherence (Schröder et al., 2011).

The Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989) was used to assess sleep quality and sleep patterns. It contains 19 items. Higher scores indicate worse sleep quality (Royuela-Rico & Macías-Fernández, 1997). The internal consistency of the PSQI in our sample was acceptable at baseline ($\alpha = 0.75$).

***Statistical Analysis***

Firstly, a descriptive analysis (frequencies for categorical variables; means and standard deviation for continuous variables) and a univariate analysis (one-way ANOVA for age, BDI-II, IPAQ-SF, PSQI, and MEDAS, and Chi-Square test for the remaining variables) were used to examine the data and determined whether there were baseline differences between groups after randomisation. Secondly, to answer the main objective – whether there were differences between treatment groups regarding their effectiveness in reducing depression – we used Linear Mixed-Effects Models (LMEMs) (Singer & Willett, 2003). We specified a model with a random intercept and unstructured covariance. The

parameter of interest was the interaction effect of treatment and time in a model that also included age as a covariate because it was the only baseline variable that was significantly different between groups. Cohen's d (*d*) is calculated from the estimated mean values of BDI-II and its standard deviations (SD) at baseline (Mcgough & Faraone, 2009).

Moreover, to answer the second question – whether there were differences between treatment groups with respect to the improvement of lifestyle variables – we used LMEMs with the same previous components.

The results from the trial were presented as a regression coefficient for predicting change in primary and secondary outcomes with 95% confidence intervals. LMEMs were tested against a Bonferroni-adjusted alpha level of 0.01 (0.05/5) (Haynes, 2013). We used an intention-to-treat analysis (ITT) (McCoy, 2017) and Multiple Imputation technique (MI) for handling missing data. The statistical analyses were performed using the SPSS software (version 25.0) (IBM Corp., 2017) and the imputations were performed using the "mice" package (Buuren & Groothuis-Oudshoorn, 2011), freely available in the Comprehensive R Archive Network (CRAN-R) of the R statistical software environment (version 3.6.2) (R Core Team, 2019).

**Ethics approval**

Ethics approval was granted by the Research Ethics Committee of Aragón (CEICA, PI18/286) and the Research Ethics Committee of the Balearic Islands (IB3950/19 PI). The study was developed following the Helsinki Declaration. All of the subjects signed an informed consent form; their data were anonymised and were only used for the purposes of the study.

**Results**

A total of 246 participants were evaluated for eligibility, with 14 of them failing to meet the inclusion criteria, 6 declining to participate because they were not interested, and 38 declining to participate because they had time incompatibility. Of the 246 initial participants, 58 (23.58%) did not participate. Finally, 188 participants were included (Figure 1) (Moher et al., 2001).

[Figure 1 here]

Firstly, the descriptive analysis showed that of the 188 participants, 162 were female and 26 were male, and all participants were between 20 to 83 years old (mean age = 53.32, SD = 13.07) at T0. The univariate analysis subsequently revealed significant differences between the groups (p = 0.014) regarding age, specifically between the TAU and LMP+ICTs groups (p = 0.018), with the LMP+ICT participants being older. However, no significant differences were found between the groups in the other variables (Table 1).

[Table 1 here]

Secondly, the LMEM evidenced that there was a significant effect on BDI-II in the LMP+ICTs (LMP+ICTs vs. TAU slope difference, *b* = -2.68, 95% CI= [-4.239, -1.133] p = .001) (Table 2). That reduction in BDI-II implies a moderate effect size in the LMP+ICTs (*d* = .519).

[Table 2 here]

Moreover, LMEMs showed that the variables that measure lifestyle (IPAQ-SF-Walking, IPAQ-SF-Sedentarism, PSQI and MEDAS) changed differently when comparing TAU to the intervention group. Specifically, regarding IPAQ-SF-Sedentarism, there was a significant decrease in the LMP+ICTs group (LMP+ICTs vs. TAU slope difference, b = -37.38, 95% CI [-62.930, -11.833], p = .004) (Supplementary Table 1). That decrease in

IPAQ-SF-Sedentarism implies a small effect size in the LMP+ICTs ($d$ = .198). Regarding IPAQ-SF-Walking, PSQI and MEDAS there were no significant changes in any group (Supplementary Table 3, 4 and 5).

**Discussion**

The findings of this study indicate that over 12 months, LMP+ICTs were effective in decreasing depressive symptoms. Also, LMP+ICTs helped in the reduction of minutes seated per day.

These results are in line with other studies. For example, a smartphone-delivered multicomponent lifestyle medicine intervention revealed significant improvements in depressive symptoms (Wong et al., 2021). Regarding changes on lifestyle, reflecting a long-lasting effect of the intervention, people receiving the LMP+ICTs group significantly decreased their total daily minutes seated (approximately, three quarters of an hour) when compared to TAU. Sedentary lifestyle were associated with higher likelihood of having depressive symptoms (Mamplekou et al., 2010; Werneck et al., 2022; Zhai et al., 2015). Moreover, a study evaluating sitting time using a wearable device found that total and prolonged sitting time was associated with depression (Biddle et al., 2021). So, counteracting the sedentarism may restore mental health (Mohammed Ali & Kunugi, 2020).

The differences found between both interventions (LMP and LMP+ICTs) could be due to the use of the wearable smartwatch for monitoring. Some of the advantages of this use have been reported in our study. Firstly, the patients from the LMP+ICTs group had significant reduction in their depression. Secondly, these patients had significantly decreased the minutes sitting per day. So, as reported in other studies, ICT-based health

solutions could facilitate health promotion and disease prevention (Haluza & Jungwirth, 2015).

The beneficial results could also have been due to the group format of the interventions, since social support is associated with a lower risk of depressive symptoms (Du et al., 2022).

Concerning the study's strengths, the first strength was that the research findings were easily transferrable to practise because it was conducted in primary care settings and any health practitioner could carry out the intervention. Furthermore, and as a novel feature, a variety of components of healthy lifestyles were addressed combined, with no observed harmful effects from the treatments. Finally, the participants of the intervention have been able to be evaluated for one year, allowing the present analysis of long-term results.

**Limitations**

One limitation was the overlap with COVID-19, which might have made it difficult for participants to fully implement the lifestyle recommendations during this time period because they couldn't go out to do their normal routines (Aguilar-Latorre et al., 2022). Another concern was the dropout rate, which was mostly due to time constraints or a lack of interest in responding questionnaires throughout the follow-up period. This limitation was addressed by employing the multiple imputation technique for missing data.

Future trials could consider adherence strategies for avoiding drop-out. Also, analyzing the effectiveness of LMPs for different sociodemographic factors might be planned for future trials with larger sample sizes.

**Conclusion**

In long-term, LMPs+ICTs administered in PHCs to people suffering from depression were effective in reducing depressive symptomatology and sedentarism comparing to TAU. More research is needed to enhance adherence to lifestyle recommendations. These promising programmes could be easily implemented in PHCs.

**References**

Aguilar-Latorre, A., Navarro, C., Oliván-Blázquez, B., Gervilla, E., Magallón Botaya, R., Calafat-Villalonga, C., García-Toro, M., Boira, S., & Serrano-Ripoll, M. J. (2020). Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol. *BMJ Open*, *10*(12). https://doi.org/10.1136/bmjopen-2020-038457

Aguilar-Latorre, A., Oliván-Blázquez, B., Porroche-Escudero, A., Méndez-López, F., García-Gallego, V., Benedé-Azagra, B., & Magallón-Botaya, R. (2022). The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain. *BMC Public Health*, *22*(780), 1–13. https://doi.org/10.1186/s12889-022-13083-2

Aguilar-Latorre, A., Serrano-Ripoll, M. J., Oliván-Blázquez, B., Gervilla, E., & Navarro, C. (2022). Associations Between Severity of Depression , Lifestyle Patterns , and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial. *Frontiers in Psychology*, *13*(856139). https://doi.org/10.3389/fpsyg.2022.856139

Beck, A., Steer, R., Ball, R., & Ranieri, W. (1996). Comparison of Beck Depression 1 in Psychiatric Inventories -1A and - Outpatients. *Journal of Personality Assessment*, *67*(3), 588–597. https://doi.org/10.1207/s15327752jpa6703

Biddle, S. J. H., Henson, J., Davies, M. J., Khunti, K., Sutton, S., Yates, T., & Edwardson, C. L. (2021). Device-assessed total and prolonged sitting time: associations with anxiety, depression, and health-related quality of life in adults. *Journal of Affective Disorders*, *287*(March), 107–114.

https://doi.org/10.1016/j.jad.2021.03.037

Button, K. S., Kounali, D., Thomas, L., Wiles, N. J., Peters, T. J., Welton, N. J., Ades, A. E., & Lewis, G. (2015). Minimal clinically important difference on the Beck Depression Inventory-II according to the patient's perspective. *Psychological Medicine*. https://doi.org/10.1017/S0033291715001270

Buuren, S., & Groothuis-Oudshoorn, K. (2011). mice: Multivariate Imputation by Chained. *Journal of Statistical Software*.

Buysse, D. J., Reynolds, C. F., Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. *Psychiatry Research*. https://doi.org/10.1016/0165-1781(89)90047-4

Cuijpers, P., Quero, S., Papola, D., Cristea, I. A., & Karyotaki, E. (2019). Care-as-usual control groups across different settings in randomized trials on psychotherapy for adult depression: A meta-analysis. *Psychological Medicine*, *51*(4), 634–644. https://doi.org/10.1017/S0033291719003581

Du, M., Dai, W., Liu, J., & Tao, J. (2022). Less Social Participation Is Associated With a Higher Risk of Depressive Symptoms Among Chinese Older Adults: A Community-Based Longitudinal Prospective Cohort Study. *Frontiers in Public Health*, 1–12. https://doi.org/10.3389/fpubh.2022.781771

Forsyth, A., Deane, F. P., & Williams, P. (2015). A lifestyle intervention for primary care patients with depression and anxiety : A randomised controlled trial. *Psychiatry Research*, 1–8. https://doi.org/10.1016/j.psychres.2015.10.001

García-Toro, M., Ibarra, O., Gili, M., Serrano, M. J., Oliván, B., Vicens, E., & Roca, M. (2012). Four hygienic-dietary recommendations as add-on treatment in depression

A randomized-controlled trial. *Journal of Affective Disorders*, *140*(2), 200–203. https://doi.org/10.1016/j.jad.2012.03.031

Haluza, D., & Jungwirth, D. (2015). ICT and the future of health care: Aspects of health promotion. *International Journal of Medical Informatics*, *84*(1), 48–57. https://doi.org/10.1016/j.ijmedinf.2014.09.005

Haynes, W. (2013). Bonferroni Correction. In W. Dubitzky, O. Wolkenhauer, K.-H. Cho, & H. Yokota (Eds.), *Encyclopedia of Systems Biology* (p. 154). Springer New York. https://doi.org/10.1007/978-1-4419-9863-7_1213

Hershey, M. S., Sanchez-Villegas, A., Sotos-Prieto, M., Fernandez-Montero, A., Pano, O., Lahortiga-Ramos, F., Martínez-González, M. Á., & Ruiz-Canela, M. (2022). The Mediterranean Lifestyle and the Risk of Depression in Middle-Aged Adults. *Journal of Nutrition*, *152*(1), 227–234. https://doi.org/10.1093/jn/nxab333

Hill, L. M., Flicker, L., Hankey, G. J., Golledge, J., Yeap, B. B., & Almeida, O. P. (2022). Disrupted sleep and risk of depression in later life : A prospective cohort study with extended follow up and a systematic review and meta-analysis. *Journal of Affective Disorders*, *309*(April), 314–323. https://doi.org/10.1016/j.jad.2022.04.133

IBM Corp. (2017). *IBM SPSS Statistics for Windows, Version 25.0*. IBM Corp.

Kim, J. H. (2022). Regular physical exercise and its association with depression: A population-based study. *Psychiatry Research*, *309*(September 2020), 114406. https://doi.org/10.1016/j.psychres.2022.114406

Kim, J., & Shin, W. (2014). How to do random allocation (randomization). *Clinics in Orthopedic Surgery*, *6*(1), 103–109. https://doi.org/10.4055/cios.2014.6.1.103

Kim, Y., Park, I., & Kang, M. (2013). Convergent validity of the International Physical Activity Questionnaire (IPAQ): Meta-analysis. In *Public Health Nutrition*. https://doi.org/10.1017/S1368980012002996

Kurtze, N., Rangul, V., & Hustvedt, B. E. (2008). Reliability and validity of the international physical activity questionnaire in the Nord-Trøndelag health study (HUNT) population of men. *BMC Medical Research Methodology*, *8*, 1–9. https://doi.org/10.1186/1471-2288-8-63

Lopresti, A. L., Hood, S. D., & Drummond, P. D. (2013). A review of lifestyle factors that contribute to important pathways associated with major depression: Diet, sleep and exercise. *Journal of Affective Disorders*, *148*, 12–27. https://doi.org/10.1016/j.jad.2013.01.014

Luo, Y., Li, Y., Xie, J., Duan, Y., Gan, G., Zhou, Y., Luo, X., Wang, J., Chen, Z., Zhang, Q., & Cheng, A. S. K. (2022). Symptoms of depression are related to sedentary behavior and sleep duration in elderly individuals: A cross-sectional study of 49,317 older Chinese adults. *Journal of Affective Disorders*, *308*(April), 407–412. https://doi.org/10.1016/j.jad.2022.04.102

Malhi, G. S., & Mann, J. J. (2018). Depression. *The Lancet*, *392*, 2299–2312. https://doi.org/10.1016/S0140-6736(18)31948-2

Malhi, G. S., Outhred, T., Hamilton, A., Boyce, P. M., Bryant, R., Fitzgerald, P. B., Lyndon, B., Mulder, R., Murray, G., Porter, R. J., Singh, A. B., & Fritz, K. (2018). Royal australian and New Zealand college of psychiatrists clinical practice guidelines for mood disorders: Major depression summary. *Medical Journal of Australia*, *208*(4), 175–180. https://doi.org/10.5694/mja17.00659

Mamplekou, E., Bountziouka, V., Psaltopoulou, T., Zeimbekis, A., Tsakoundakis, N., Papaerakleous, N., Gotsis, E., Metallinos, G., Pounis, G., Polychronopoulos, E., Lionis, C., & Panagiotakos, D. (2010). Urban environment, physical inactivity and unhealthy dietary habits correlate to depression among elderly living in eastern mediterranean islands: The MEDIS (Mediterranean Islands Elderly) study. *Journal of Nutrition, Health and Aging*, *14*(6), 449–455. https://doi.org/10.1007/s12603-010-0091-0

Martínez-González, M. Á., Corella, D., Salas-Salvadó, J., Ros, E., Covas, M. I., Fiol, M., Wärnberg, J., Arós, F., Ruíz-Gutiérrez, V., Lamuela-Raventós, R. M., Lapetra, J., Muñoz, M. Á., Martínez, J. A., Sáez, G., Serra-Majem, L., Pintó, X., Mitjavila, M. T., Tur, J. A., del Puy Portillo, M., & Estruch, R. (2010). Cohort profile: Design and methods of the PREDIMED study. *International Journal of Epidemiology*, *41*(2), 377–385. https://doi.org/10.1093/ije/dyq250

McCoy, C. E. (2017). Understanding the intention-to-treat principle in randomized controlled trials. *Western Journal of Emergency Medicine*, *18*(6), 1075–1078. https://doi.org/10.5811/westjem.2017.8.35985

Mcgough, J. J., & Faraone, S. V. (2009). Estimating the size of treatment effects: moving beyond p values. *Psychiatry*, *6*(10), 21–29. https://doi.org/10.1007/s13239-015-0213-2

Ministry of Health Social Services and Equality. (2014). Clinical practice guideline on the management of major depression in adults. *SNS Clinical Practice Guidelines*. http://www.guideline.gov/content.aspx?id=24067&search=depression

Mohammed Ali, A., & Kunugi, H. (2020). COVID-19: A pandemic that threatens physical and mental health by promoting physical inactivity. *Sports Medicine and*

*Health Science Journal*, *2*, 221–223.

Moher, D., Schulz, K. F., & Altman, D. G. (2001). The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet*, *357*, 1191–94. https://doi.org/10.1024/0036-7281.145.6.291

Murri, M. B., Ekkekakis, P., Menchetti, M., Neviani, F., Trevisani, F., Tedeschi, S., Latessa, P. M., Nerozzi, E., Ermini, G., Zocchi, D., Squatrito, S., Toni, G., Cabassi, A., Neri, M., Zanetidou, S., & Amore, M. (2018). Physical exercise for late-life depression: Effects on symptom dimensions and time course. *Journal of Affective Disorders*, *230*(January), 65–70. https://doi.org/10.1016/j.jad.2018.01.004

NICE. (2014). *Behaviour change: individual approaches*. www.nice.org.uk/guidance/ph49

Nieuwsma, J. A., Trivedi, R. B., McDuffie, J., Kronish, I., Benjamin, D., & Williams, J. W. (2012). Brief Psychotherapy for Depression: A Systematic Review and Meta-Analysis. *Int J Psychiatry Med*, *43*(2), 129–151. https://doi.org/10.1038/jid.2014.371

Olivan-Blázquez, B., Montero-Marin, J., García-Toro, M., Vicens-Pons, E., Serrano-Ripoll, M. J., Castro-Gracia, A., Sarasa-Bosque, M. C., Mendive-Arbeloa, J. M., López-del-Hoyo, Y., & Garcia-Campayo, J. (2018). Facilitators and barriers to modifying dietary and hygiene behaviours as adjuvant treatment in patients with depression in primary care: A qualitative study. *BMC Psychiatry*, *18*(1), 1–12. https://doi.org/10.1186/s12888-018-1779-7

Opie, R., Abbott, G., Crawford, D., & Ball, K. (2021). Exploring the associations of

depressive symptoms with healthy eating self-efficacy over time amongst women in the READI cohort study. *International Journal of Behavioral Nutrition and Physical Activity*, *18*(1), 1–10. https://doi.org/10.1186/s12966-021-01233-5

Pano, O., Martínez-Lapiscina, E. H., Sayón-Orea, C., Martinez-Gonzalez, M. A., Martinez, J. A., & Sanchez-Villegas, A. (2021). Healthy diet, depression and quality of life: A narrative review of biological mechanisms and primary prevention opportunities. *World Journal of Psychiatry*, *11*(11), 997–1016.

R Core Team. (2019). *R: A language and environment for statistical computing*. R Foundation for Statistical Computing. http://www.r-project.org/

Roman-Viñas, B., Serra-Majem, L., Hagströmer, M., Ribas-Barba, L., Sjöström, M., & Segura-Cardona, R. (2010). International physical activity questionnaire: Reliability and validity in a Spanish population. *European Journal of Sport Science*, *10*(5), 297–304. https://doi.org/10.1080/17461390903426667

Royuela-Rico, A., & Macías-Fernández, J. A. (1997). Propiedades clinimétricas de la versión castellana del Cuestionario de Pittsburgh. *Vigilia-Sueño*, *9*(2), 81–94.

Sanz, J., García-Vera, M. P., Espinosa, R., Fortún, M., Vázquez, C., Obreg, R., Erika, M., Godeleva, O., Ortiz, R., Martínez, A. J., & Diario Oficial. (2005). Spanish adaptation of the Beck Depression Inventory-II (BDI-II): 3. Psychometric features in patiens with psychological disorders. *Clínica y Salud*, *16*(2), 121–142. https://doi.org/10.4067/S0718-48082014000300006

Schröder, H., Fitó, M., Estruch, R., Martínez-González, M. A., Corella, D., Salas-Salvadó, J., Lamuela-Raventós, R., Ros, E., Salaverría, I., Fiol, M., Lapetra, J., Vinyoles, E., Gómez-Gracia, E., Lahoz, C., Serra-Majem, L., Pintó, X., Ruiz-

Gutierrez, V., & Covas, M. (2011). A Short Screener Is Valid for Assessing Mediterranean Diet Adherence among Older Spanish Men and Women. *The Journal of Nutrition*, *141*(6), 1140–1145. https://doi.org/10.3945/jn.110.135566

Serrano-Ripoll, M. J., Oliván-Blázquez, B., Vicens-Pons, E., Roca, M., Gili, M., Leiva, A., García-Campayo, J., Demarzo, M. P., & García-Toro, M. (2015). Lifestyle change recommendations in major depression: Do they work? *Journal of Affective Disorders*, *183*, 221–228. https://doi.org/10.1016/j.jad.2015.04.059

Singer, J. D., & Willett, J. B. (2003). *Applied Longitudinal Data Analysis: Modeling Change and Event Occurrence*. Oxford University Press.

Werneck, A. O., Vancampfort, D., Stubbs, B., Silva, D. R., Cucato, G. G., Christofaro, D. G. D., Santos, R. D., Ritti-Dias, R. M., & Bittencourt, M. S. (2022). Prospective associations between multiple lifestyle behaviors and depressive symptoms. *Journal of Affective Disorders*, *301*(December 2021), 233–239. https://doi.org/10.1016/j.jad.2021.12.131

Wong, V. W.-H., Ho, F. Y.-Y., Shi, N.-K., Tong, J. T.-Y., Chung, K.-F., Yeung, W.-F., Ng, C. H., Oliver, G., & Sarris, J. (2021). Smartphone-delivered multicomponent lifestyle medicine intervention for depressive symptoms: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*, *89*(12), 970–984. https://doi.org/https://doi.org/10.1037/ccp0000695

World Health Organization. (2016). mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings: mental health Gap Action Programme (mhGAP), version 2.0. *World Health Organization*, 1–173.

World Health Organization (WHO). (2017). *Depression and Other Common Mental*

*Disorders: Global Health Estimates*.

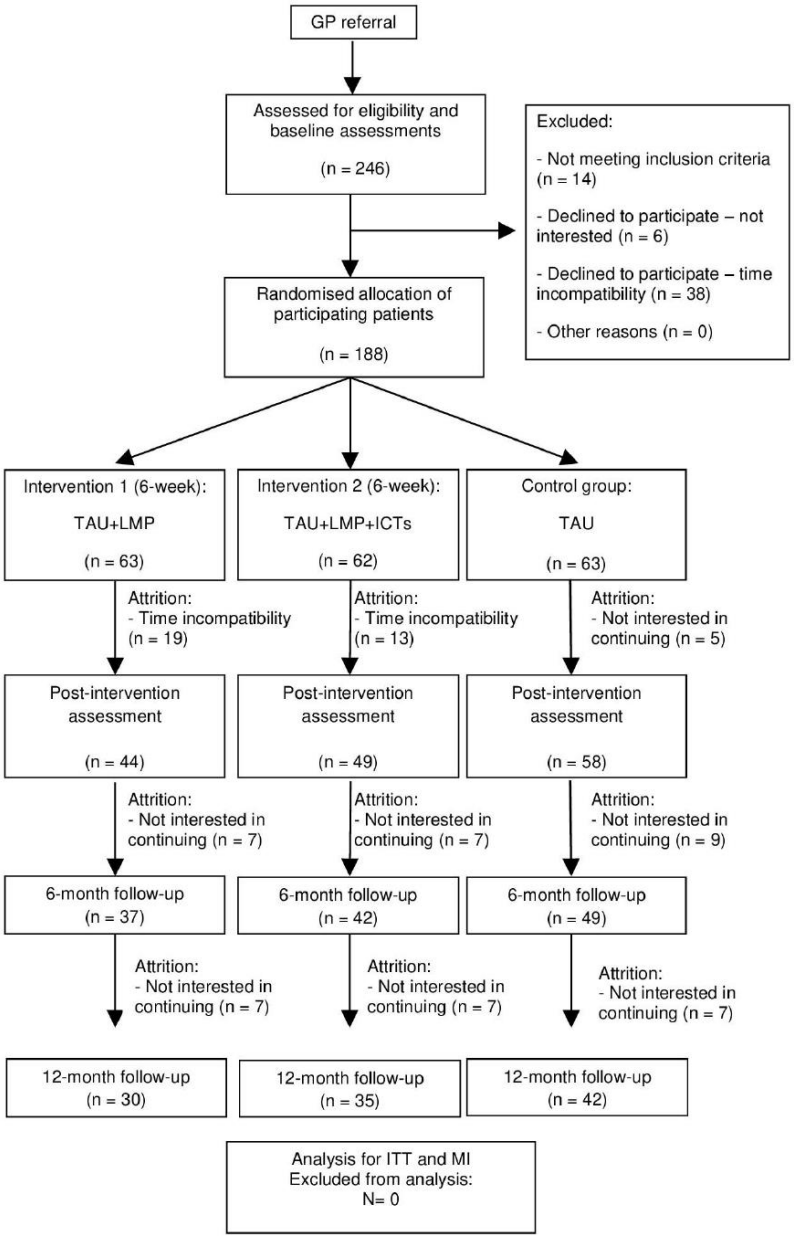
World Health Organization (WHO). (2021). *Depression*. https://www.who.int/news-room/fact-sheets/detail/depression

Zhai, L., Zhang, Y., & Zhang, D. (2015). Sedentary behaviour and the risk of depression: A meta-analysis. *British Journal of Sports Medicine*, *49*(11), 705–709. https://doi.org/10.1136/bjsports-2014-093613

Zhang, M. M., Ma, Y., Du, L. T., Wang, K., Li, Z., Zhu, W., Sun, Y. H., Lu, L., Bao, Y. P., & Li, S. X. (2022). Sleep disorders and non-sleep circadian disorders predict depression: A systematic review and meta-analysis of longitudinal studies. *Neuroscience and Biobehavioral Reviews*, *134*(January), 104532. https://doi.org/10.1016/j.neubiorev.2022.104532

25

**Figure 1. Flowchart of the study: randomisation, sampling and monitoring of patients**



GP, General Practitioner; TAU, Treatment as Usual; LMP, Lifestyle Modification Program; ICTs, Information and Communication Technologies; ITT, Intention-to-treat; MI, Multiple Imputation Technique.

**Table 1. Sociodemographic and clinical characteristics of the sample**

| Variables | Total (n = 188) | TAU (n = 63) | LMP (n = 63) | LMP+ICTs (n = 62) | *F or* $X^2$ |
|---|---|---|---|---|---|
| Age, *M* (*SD*) | 53.32 (13.07) | 49.54 (13.50) | 54.35 (12.97) | 56.11 (11.99) | 4.399* |
| Gender, *female n (%)* | 162 (86.2) | 52 (82.5) | 54 (85.7) | 56 (90.3) | 1.60 |
| Education | | | | | |
| None or primary, *n (%)* | 72 (38.3) | 21 (33.3) | 22 (34.9) | 29 (46.8) | 2.84 |
| Secondary or tertiary, *n (%)* | 116 (61.7) | 42 (66.7) | 41 (65.1) | 33 (53.2) | |
| Occupation | | | | | |
| Working, *n (%)* | 53 (28.2) | 23 (36.5) | 17 (27) | 13 (21) | 3.79 |
| Not working, *n (%)* | 135 (71.8) | 40 (63.5) | 46 (73) | 49 (79) | |
| Marital status | | | | | |
| With a partner, *n (%)* | 105 (54.4) | 32 (50.8) | 34 (54) | 37 (59.7) | 1.02 |
| Without a partner, *n (%)* | 88 (45.6) | 31 (49.2) | 29 (46) | 25 (40.3) | |
| Economic level | | | | | |
| < IMW to 2 IMW, *n (%)* | 164 (87.2) | 57 (90.5) | 51 (81) | 56 (90.3) | 3.35 |
| >2 IMW, *n (%)* | 24 (12.8) | 6 (9.5) | 12 (19) | 6 (9.7) | |
| Taking antidepressants, *yes n (%)* | 132 (71.3) | 45 (71.4) | 46 (73) | 43 (69.4) | .39 |
| BDI-II, *M* (*SD*) | 24.90 (5.11) | 24.13 (5.05) | 25.00 (4.94) | 25.58 (5.29) | 1.28 |
| Number of sessions attended**, *M* (*SD*) | 4.98 (1.09) | - | 5.07 (1.02) | 4.90 (1.15) | .57 |
| IPAQ-SF-Walking, *M* (*SD*) | 206.46 (273.95) | 208.25 (324.92) | 233.25 (261.87) | 177.42 (226.87) | .64 |
| IPAQ-SF-Sedentarism, *M* (*SD*) | 289.97 (186.24) | 256.75 (212.23) | 306.67 (180.20) | 306.77 (160.72) | 1.51 |
| PSQI, *M* (*SD*) | 11.66 (4.64) | 11.57 (4.91) | 12.11 (4.34) | 11.29 (4.69) | .50 |
| MEDAS, *M* (*SD*) | 6.47 (1.86) | 6.41 (1.81) | 6.54 (2.08) | 6.45 (1.70) | .07 |

*Note*. *p<.05. **Only patients in the intervention group who did not drop out were included. IMW, Interprofessional Minimum Wage. one-way ANOVA for age, BDI-

II, IPAQ-SF, PSQI, and MEDAS, and Chi-Square test for the remaining variables. BDI-II, Beck II Self-Applied Depression Inventory; IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; MEDAS, Mediterranean Diet Adherence Screener; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Table 2. Estimates of Fixed Effects in BDI-II**

| Parameter | Estimate | *SE* | t | *p* | 95% CI for estimated |
|---|---|---|---|---|---|
| Intercept | 25.497 | 1.257 | 20.283 | < .001 | [23.027, 27.967] |
| Time | -.749 | .556 | -1.345 | .179 | [-1.843, .344] |
| Age | -.079 | .042 | -1.893 | .060 | [-.162, .003] |
| LMP+ICTs | -.299 | 1.792 | -.167 | .868 | [-3.820, 3.221] |
| LMP | -1.116 | 1.775 | -.629 | .529 | [-4.604, 2.370] |
| LMP+ICTs * Time | **-2.686** | .790 | -3.397 | **.001** | [-4.239, -1.133] |
| LMP * Time | -1.015 | .787 | -1.290 | .198 | [-2.562, .531] |

*Note.* Significant differences (p ≤ .01) are highlighted in bold. CI, confidence interval; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

## Supplementary

**Supplementary Table 1. Estimates of Fixed Effects in IPAQ-Sedentarism**

| Parameter | Estimate | *SE* | *t* | *p* | 95% CI for estimated |
|---|---|---|---|---|---|
| Intercept | 247.511 | 21.852 | 11.327 | < .001 | [204.566, 290.456] |
| Time | 37.301 | 9.160 | 4.072 | < .001 | [19.308, 55.294] |
| Age | -.899 | .761 | -1.183 | .238 | [-2.401, .601] |
| LMP+ICTs | 43.793 | 31.162 | 1.405 | .161 | [-17.449, 105.036] |
| LMP | 44.106 | 30.852 | 1.430 | .154 | [-16.526, 104.739] |
| LMP+ICTs * Time | **-37.382** | 13.007 | -2.874 | **.004** | [-62.930, -11.833] |
| LMP * Time | -26.531 | 12.954 | -2.048 | .041 | [-51.977, -1.085] |

*Note.* Significant differences (p ≤ .01) are highlighted in bold. IPAQ, Physical Activity Questionnaire; CI, confidence interval; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Supplementary Table 2. Estimates of Fixed Effects in IPAQ-Walking**

| Parameter | Estimate | *SE* | t | *p* | 95% CI for estimated |
|---|---|---|---|---|---|
| Intercept | 202.934 | 41.905 | 4.843 | .000 | [120.612, 285.257] |
| Time | 24.693 | 19.056 | 1.296 | .196 | [-12.737, 62.124] |
| Age | -.843 | 1.372 | -.614 | .540 | [-3.550, 1.864] |
| LMP+ICTs | 46.243 | 59.729 | .774 | .439 | [-71.095, 163.583] |
| LMP | 109.024 | 59.176 | 1.842 | .066 | [-7.226, 225.275] |
| LMP+ICTs * Time | 15.596 | 27.058 | .576 | .565 | [-37.551, 68.744] |
| LMP * Time | 21.238 | 26.950 | .788 | .431 | [-31.696, 74.173] |

*Note.* IPAQ, Physical Activity Questionnaire; CI, confidence interval; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Supplementary Table 3. Estimates of Fixed Effects in PSQI**

| Parameter | Estimate | *SE* | t | *p* | 95% CI for estimated |
|---|---|---|---|---|---|
| Intercept | 12.056 | .619 | 19.464 | < .001 | [10.839, 13.273] |
| Time | -.290 | .165 | -1.751 | .080 | [-.616, .035] |
| Age | -.012 | .020 | -.594 | .553 | [-.053, .028] |
| LMP+ICTs | .066 | .883 | .075 | .940 | [-1.668, 1.801] |
| LMP | -.084 | .874 | -.096 | .924 | [-1.802, 1.634] |
| LMP+ICTs * Time | -.399 | .235 | -1.698 | .090 | [-.862, .062] |
| LMP * Time | -.527 | .234 | -2.247 | .025 | [-.987, -.066] |

*Note.* PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

**Supplementary Table 4. Estimates of Fixed Effects in MEDAS**

| Parameter | Estimate | *SE* | t | *p* | 95% CI for estimated |
|---|---|---|---|---|---|
| Intercept | 6.308 | .230 | 27.386 | < .001 | [5.855, 6.761] |
| Time | -.050 | .092 | -.548 | .584 | [-.232, .131] |
| Age | .027 | .008 | 3.389 | .001 | [.011, .044] |
| LMP+ICTs | .229 | .328 | .699 | .485 | [-.416, .875] |
| LMP | .334 | .325 | 1.028 | .305 | [-.305, .973] |
| LMP+ICTs * Time | .070 | .131 | .533 | .594 | [-.188, .328] |
| LMP * Time | -.182 | .131 | -1.392 | .164 | [-.440, .074] |

*Note.* MEDAS, Mediterranean Diet Adherence Screener; CI, confidence interval; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

# Anexo III. Información adicional sobre los manuscritos que se recogen en la tesis

**Manuscrito I**

Aguilar-Latorre, A., Navarro, C., Oliván-Blázquez, B., Gervilla, E., Magallón Botaya, R., Calafat-Villalonga, C., García-Toro, M., Boira, S., & Serrano-Ripoll, M. J. (2020). Effectiveness and cost-effectiveness of a lifestyle modification programme in the prevention and treatment of subclinical, mild and moderate depression in primary care: A randomised clinical trial protocol. *BMJ Open, 10*(12). https://doi.org/10.1136/bmjopen-2020-038457

Factor de Impacto (JCR 2020): 2,692 (Q2)

Área temática: MEDICINE, GENERAL & INTERNAL

Justificación de la contribución de la doctoranda: Tal y como se menciona en el manuscrito publicado, la doctoranda hizo una contribución significativa en la investigación, encargándose de llevar a cabo el trabajo de campo, de la redacción del borrador original y posterior revisión y edición de éste.

**Manuscrito II**

Aguilar-Latorre, A., Pérez Algorta, G., Navarro-Guzmán, C., Serrano-Ripoll, M. J., & Oliván-Blázquez, B. (2022). Effectiveness of a lifestyle modification programme in the treatment of depression symptoms in primary care. *Frontiers in Medicine, 9*(954644), 1–10. https://doi.org/10.3389/fmed.2022.954644

Factor de Impacto (JCR 2021): 5,058 (Q2)

Área temática: MEDICINE, GENERAL & INTERNAL

Justificación de la contribución de la doctoranda: Tal y como se menciona en el manuscrito publicado, la doctoranda hizo una contribución significativa en la investigación, encargándose de la conceptualización, curación de datos, análisis formal, investigación, metodología, software, visualización, supervisión, redacción del borrador original y posterior revisión y edición de éste.

**Manuscrito III**

Aguilar-Latorre, A., Serrano-Ripoll, M. J., Oliván-Blázquez, B., Gervilla, E., & Navarro, C. (2022). Associations Between Severity of Depression, Lifestyle Patterns, and Personal Factors Related to Health Behavior: Secondary Data Analysis From a Randomized Controlled Trial. *Frontiers in Psychology, 13*(856139). https://doi.org/10.3389/fpsyg.2022.856139

Factor de Impacto (JCR 2021): 4,232 (Q1)

Área temática: PSYCHOLOGY, MULTIDISCIPLINARY

Justificación de la contribución de la doctoranda: Tal y como se menciona en el manuscrito publicado, la doctoranda hizo una contribución significativa en la investigación, encargándose de la curación de datos, análisis formal, investigación, metodología, software, visualización, supervisión, redacción del borrador original y posterior revisión y edición de éste.

**Manuscrito IV**

Aguilar-Latorre, A., Oliván-Blázquez, B., Porroche-Escudero, A., Méndez-López, F., García-Gallego, V., Benedé-Azagra, B., & Magallón-Botaya, R. (2022). The impact of the COVID-19 lockdown on depression sufferers: a qualitative study from the province of Zaragoza, Spain. *BMC Public Health, 22*(780), 1–13. https://doi.org/10.1186/s12889-022-13083-2

Factor de Impacto (JCR 2021): 4,135 (Q2)

Área temática: PUBLIC, ENVIRONMENTAL & OCCUPATIONAL HEALTH

Justificación de la contribución de la doctoranda: Tal y como se menciona en el manuscrito publicado, la doctoranda hizo una contribución significativa en la investigación, encargándose de la curación de datos, análisis formal, investigación, software, visualización, supervisión, redacción del borrador original y posterior revisión y edición de éste.

**Anexo I**

Aguilar-Latorre, A., Navarro, C., Serrano-Ripoll, M. J., Gervilla, E., García-Toro, M., Oliván-Blázquez, B. (2022). Effectiveness of a lifestyle modification programme in the treatment of depression in primary care: randomised clinical trial pre-post results. *BMJ Open, XX*(XX). Aceptado 24/08/2022.

Factor de Impacto (JCR 2021): 3,017 (Q2)

Área temática: MEDICINE, GENERAL & INTERNAL

Justificación de la contribución de la doctoranda: Tal y como se menciona en el manuscrito aceptado provisionalmente, la doctoranda hizo una contribución significativa en la investigación, encargándose de la curación de datos, análisis formal, investigación, metodología, software, visualización, redacción del borrador original y posterior revisión y edición de éste.

Copia de la carta de aceptación provisional:

Gmail Alejandra Aguilar <alejandra31392@gmail.com>

## Your submission to BMJ Open has been accepted

9 mensajes

**BMJ Open** <onbehalfof@manuscriptcentral.com> 24 de agosto de 2022, 17:57
Responder a: info.bmjopen@bmj.com
Para: aaguilar@iisaragon.es

24-Aug-2022
bmjopen-2021-057792.R3 - Effectiveness of a lifestyle modification programme in the treatment of depression in primary care: randomised clinical trial pre-post results

Dear Ms. Aguilar-Latorre:

We are pleased to accept your article for publication in BMJ Open.

Within 2-3 working days, you will receive an email with payment options and instructions from BMJ's e-commerce partner, Copyright Clearance Center. You will be able to choose either to pay by credit card or invoice. If you are not making the payment yourself, you may forward the email to the person or organisation that will be paying on your behalf. Your article will not be processed by production until you have paid the article processing charge or requested an invoice. For more details on open access publication please visit our Author Hub: https://authors.bmj.com/open-access/.

Please note, that if your institution is part of one of BMJ's Publish and Read or prepay agreements your request for funding will be automatically processed based on this acceptance and you will only receive an email accepting or denying your funding request. To find out if your institution is part of a Publish and Read or prepay agreement visit BMJ's open access agreements page: https://authors.bmj.com/open-access/institutional-programme/.

Once payment is confirmed and your article is sent to Production, copyediting and typesetting will be completed. We will email you a proof to check via our online tool usually within 10-15 days of this time; please check your junk mail folder.

The proof is your opportunity to check for typesetting errors and the completeness and accuracy of the text; including author names and affiliations, tables and figures; including legends, numerical, mathematical, or other scientific expressions. We ask that you only make minor corrections at this stage. Please provide any comments within 48 hours. There will be no further opportunities to make corrections prior to publication.

See https://authors.bmj.com/after-submitting/accepted/ for more information about what to expect once your article has been accepted.

We publish most articles online in their final form around three weeks after acceptance. See https://authors.bmj.com/after-submitting/online-publication/ for more information about online publication. BMJ will deposit your article in all indexes affiliated with the journal.

Any final comments from the reviewer(s) are included at the foot of this email. The comments are for your information only, but in the case of minor requests (e.g. typos) these can be corrected when you receive your proof. These comments will be included in the peer review history published alongside your article.

If your article is selected for press release by BMJ's Press Office you will be informed as soon as possible.

If you have any queries, please contact the Editorial Office at info.bmjopen@bmj.com.

Kind regards,
Ms. Amy Branch-Hollis

https://bmjopen.bmj.com/