Estudio sobre el uso de tecnología wearable para el análisis del sueño y su impacto en la vida diaria

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Acreditación de los directores de la tesis

El doctor **JAVIER PEREIRA LOUREIRO**, Profesor Titular del departamento de Fisioterapia, Medicina y Ciencias Biomédicas de la Universidade da Coruña, y subdirector del Centro de Investigación en Tecnologías de la Información y las Comunicaciones; y la doctora **MARÍA BETANIA GROBA GONZÁLEZ,** Contratada Doctora del departamento de Ciencias de la Salud de la Universidade da Coruña.

CERTIFICAN QUE:

La presente tesis doctoral titulada ***"Estudio sobre el uso de tecnología wearable para el análisis del sueño y su impacto en la vida diaria"*** presentada por Doña Patricia Concheiro Moscoso, graduada en Terapia Ocupacional por la Universidade da Coruña, fue realizada bajo nuestra dirección y reúne las condiciones teóricas, científicas y metodológicas necesarias para ser defendida públicamente, y optar al Grado de Doctora con Mención Internacional en Ciencias de la Salud por la Universidade da Coruña.

Y para que así conste a efectos oportunos, firmamos en A Coruña, 2022

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Asimismo y con el visto bueno de los directores, la doctoranda firma este documento haciendo constar la veracidad de la información,

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Acreditación de la revisión de la tesis para la mención internacional

Esta tesis doctoral fue revisada por dos expertos internacionales con el objetivo de alcanzar la mención internacional:

- la Dra. Masoumeh Amin-Emaeili, PhD, profesora titular de Psiquiatría en la University of Medical Sciences en Tehran (Irán) e investigadora postdoctoral en la Bloomberg School of Public Health de la Johns Hopkins University en Baltimore, Maryland (Estados Unidos);
- y el Dr. Guillermo López Campos, PhD, profesor contratado doctor en la Wellcome Wolfson Institute for Experimental Medicine de la School of Medicine, Dentistry and Biomedical Sciences de la Queen's University Belfast en Belfast, Irlanda del Norte (Reino Unido).

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a las que me acompañaron en este camino

y colmaron esta etapa de aprendizaje y recuerdos.

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"La vida son decisiones, dolores, placeres.
Unos momentos saboreando, otros luchando por lo que quieres"

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El grupo Redes de Neuronas Artificiales y Sistemas Adaptativos-Informática Médica y Diagnóstico Radiológico, RNASA-IMEDIR, de la Universidade da Coruña, también ofrecieron un gran apoyo a la doctoranda en los inicios de la etapa de doctorado, ya que fue el primer contacto que tuvo con el mundo de la investigación.

El Centro de Investigación en Tecnologías de la Información y las Comunicaciones, CITIC, fue un elemento clave en la trayectoria de la doctoranda al apoyar sus investigaciones y ofrecerle múltiples actividades de formación y de divulgación científica, así como oportunidades mediante bolsas de investigación.

El Hospital San Rafael, concretamente, su Unidad del Sueño, y otras entidades asociadas a la población mayor colaboraron en el desarrollo de las investigaciones llevadas a cabo por la doctoranda. Especialmente, la doctoranda quiere agradecerles tanto al personal de estos centros como a las personas participantes su contribución y dedicación en cada una de las investigaciones en las que intervinieron, ya que le aportaron grandes conocimientos y experiencias en lo laboral y lo personal.

Esta tesis doctoral fue apoyada económicamente por la Xunta de Galicia mediante las siguientes ayudas:

- Ayudas de apoyo a la etapa predoctoral en las universidades del Sistema Universitario Gallego del año 2019, en los organismos públicos de investigación de Galicia y en otras entidades del Sistema Gallego de I+D+i, cofinanciadas parcialmente por el programa operativo FSE Galicia 2014-2020 (referencia de la ayuda: ED481A-2019/069).
- Ayudas para el CITIC, financiado por la Xunta de Galicia a través del convenio de colaboración entre la Consejería de Cultura, Educación Formación Profesional y Universidades y las Universidades gallegas para el esfuerzo de los Centros de Investigación del Sistema Universitario de Galicia.
- Ayudas estructurales para la consolidación y la estructuración de unidades de investigación competitivas y otras acciones de fomento en las universidades del Sistema Universitario Gallego, en los organismos públicos de investigación de Galicia y otras entidades del Sistema Gallego de I+D+i para 2022. (referencia de la ayuda: ED431B-2022/39).

La Cátedra Handytronic (referencia: 523/2017) y el proyecto GeriaTIC, desarrollado por la Clínica Cobián, Geriatros (actualmente DomusVi) y ALDABA, y también financiado por la Agencia Gallega de Innovación (GAIN) a través del programa Conecta Peme (3ª. edición), dotado de los fondos FEDER de la Unión Europea (referencia de la ayuda: IN852A 2016/10), impulsaron varias de las investigaciones que conforman esta tesis doctoral. También, los proyectos "AssessMent and counseling to get the best efficiency and effectiveness of the Assistive TeCHnology" (MATCH) (referencia de la ayuda: PID2019-104323RB-C33) y "Heritage Efficient management through Relevant IT use (HERIT)" (referencia de la ayuda: 2020-1-BE01-KA226-VET-082730) y el proyecto "Calidad de vida para personas cuidadoras a través de una solución tecnológica centrada en la persona" (referencia de la ayuda: TED2021-130127A-I00) asociado a los "proyectos orientados a la transición ecológica y a la transición digital" en el marco del programa estatal para impulsar la investigación científico-técnica y su transferencia, del plan estatal de investigación científica, técnica y de innovación 2021-2023; apoyaron las investigaciones de esta tesis.

Finalmente, la doctoranda realizó tres estancias predoctorales, durante su etapa formativa en el Programa de Doutoramento en Ciencias da Saúde de la Universidade da Coruña. Estas estancias fueron experiencias claves en su etapa formativa.

- La primera estancia se desarrolló en el Laboratório de Reabilitação Psicossocial del Instituto Politécnico do Porto y de la Universidade do Porto, en Oporto (Portugal), durante un mes (desde el 17/05/2018 hasta el 17/06/2018), bajo la supervisión de los directores del grupo de investigación del laboratorio, los profesores y doctores Cristina Queirós y António Marques. Fue financiada por el programa IACOBUS, acción de cooperación interregional entre universidades e instituciones de la enseñanza superior de la Eurorregión Galicia-Norte de Portugal (RIS3-T), que cuenta con el apoyo de la Unión Europea a través del Programa INTERREG V-A España-Portugal (POCTEP) 2014-2020.
- La segunda estancia fue realizada en el Deparment of Mental Health de la Johns Hopkins University en Baltimore, Maryland (Estados Unidos), durante tres meses (desde el 01/09/2018 hasta el 01/12/2018). Esta estancia, gracias a la cual la doctoranda opta a la mención internacional de su tesis doctoral, fue supervisada por el profesor y doctor Adam Spira, y financiada por las ayudas para estancias predoctorales INDITEX-UDC del año 2018.
- La doctoranda llevó a cabo su última estancia de nuevo en el Laboratório de Reabilitação Psicossocial, esta vez específicamente en el laboratorio asociado a la Universidade do Porto, en Oporto (Portugal), durante tres meses (desde el 06/04/2021 hasta el 05/07/2021). Esta estancia fue supervisada por la profesora doctora Cristina Queirós y financiada por las ayudas de apoyo a la etapa predoctoral en las universidades del Sistema Universitario Gallego del año 2019 (referencia de la ayuda: ED481A-2019/069). Se destaca que un artículo científico

relacionado con esta estancia, en la que participó la investigadora doctora Cristina Queirós, obtuvo una ayuda económica mediante el programa IACOBUS-Publicaciones científicas (Papers). Dicho programa financia artículos de investigación mediante el Plan de investimentos conjuntos de la Eurorregión Galicia-Norte de Portugal 2021-2027 (PIC 21-27) y las estrategias de la Eurorregión Galicia-Norte de Portugal (RIS3-T), que cuenta con el apoyo de la Unión Europea a través del Programa INTERREG V-A España-Portugal (POCTEP) 2014-2020.

Resumen

El sueño es una ocupación significativa en la vida diaria de las personas. En los últimos años, el avance de los dispositivos ponibles (*wearables*) en la monitorización del sueño, supuso la necesidad de explorar estas herramientas por parte de la comunidad científica. La presente tesis doctoral pretende investigar sobre el rendimiento y uso de tales dispositivos *wearables*, específicamente sobre la pulsera Xiaomi Mi Band, como una posible solución tecnológica para el seguimiento del sueño.

Los hallazgos en esta tesis reflejan que el rendimiento de la Xiaomi Mi Band, analizado en 45 personas con y sin trastornos del sueño, presentó una precisión del 78 % y resultados más positivos en el grupo sin alteraciones. La combinación de este dispositivo con diferentes instrumentos de evaluación permitió analizar el estado del sueño y factores asociados en personas mayores y población trabajadora, obteniendo como resultados destacables la influencia significativa del sueño en el estado de salud y funcionamiento diario de las personas mayores.

Esta tesis concluye que el uso de dispositivos *wearables*, como la pulsera Xiaomi Mi Band, podrían ser una posible herramienta tecnológica para la monitorización del sueño. Estas investigaciones suponen un avance sobre la temática de estudio, siendo necesarios estudios más exhaustivos sobre el uso y la fiabilidad de estos dispositivos en el seguimiento del sueño en diversas poblaciones.

Resumo

O sono é unha ocupación significativa na vida diaria das persoas. Nos últimos anos, o avance dos dispositivos poñibles (*wearables*) na monitorización do sono, supuxo a necesidade de explorar estas ferramentas por parte da comunidade científica. A presente tese de doutoramento pretende investigar sobre o rendemento e uso de tales dispositivos *wearables*, especificamente sobre a pulseira Xiaomi Mi Band, como unha posible solución tecnolóxica para o seguimento do sono.

Os achados desta tese reflicten que o rendemento da Xiaomi Mi Band, analizado en 45 persoas con e sen trastornos do sono, presentou unha precisión do 78 % e resultados máis positivos no grupo sen alteracións. A combinación deste dispositivo con diferentes instrumentos de avaliación permitiu analizar o estado do sono e factores asociados en persoas maiores e poboación traballadora, obtendo como resultados destacables a influencia significativa do sono no estado de saúde e funcionamento diario das persoas maiores.

Esta tese conclúe que o uso de dispositivos *wearables*, como a pulseira Xiaomi Mi Band, poderían ser unha posible ferramenta tecnolóxica para a monitorización do sono. Estas investigacións supoñen un avance sobre a temática de estudo, sendo necesarios estudos máis exhaustivos sobre o uso e a fiabilidade destes dispositivos no seguimento do sono en diversas poboacións.

Abstract

Sleep is a significant occupation in people's daily lives. In recent years, the advance of wearable devices in sleep monitoring led to the need to explore these tools by the scientific community. This doctoral thesis aimed to research the performance and use of wearable devices, specifically the Xiaomi Mi Band wristband, as a possible technological solution for sleep monitoring.

The findings of this thesis reflect that the performance of the Xiaomi Mi Band device, analyzed in 45 people with and without sleep disorders, showed an accuracy of 78 % and more positive results in the group without sleep problems. The combination of this device with different assessment tools made it possible to analyze the state of sleep and associated factors in the older and working population, obtaining remarkable results on the significant influence of sleep on the state of health and daily functioning of the older population.

This thesis concludes that the use of wearable devices such as the Xiaomi Mi Band wristband could be a possible technological tool for sleep monitoring. These researches represent an advance on the topic of study, being necessary for more exhaustive research on the use and reliability of these devices in sleep monitoring in several populations.

Prefacio

> *"Estoy enamorado del sueño... Estoy enamorado de todo lo que el sueño es, y hace. Estoy enamorado de descubrir todo lo que queda por conocer sobre él. Estoy enamorado de comunicar su asombrosa brillantez al público. Estoy enamorado de encontrar todos, y cada uno de los métodos para reunir a la humanidad con el sueño, que tan desesperadamente necesita". Why We Sleep: Unlocking the Power of Sleep and Dreams.* Matthew Walker (2018)

La etapa formativa de la doctoranda en la Universidade da Coruña comienza con sus estudios en el grado en Terapia Ocupacional, seguido de los del Máster Universitario en Asistencia e Investigación Sanitaria. Los conocimientos y las experiencias adquiridas en ambas formaciones marcaron los inicios de su camino en el mundo de la investigación, y las considera conjuntamente una etapa de gran aprendizaje tanto en lo personal como en lo profesional.

El primer contacto que la doctoranda tiene con la investigación comienza con su contrato en el grupo de investigación Redes de Neuronas Artificiales y Sistemas Adaptativos-Informática Médica y Diagnóstico Radiológico (RNASA-IMEDIR) para desenvolver tareas de investigación en el proyecto GeriaTIC, financiado por el programa Conecta Peme, en el que colaboraron empresas e instituciones del sector tecnológico y de la salud. El objetivo de este proyecto era proporcionar una solución tecnológica, mediante la creación de una plataforma digital y el uso de dispositivos ponibles (*wearables*), por un lado, para promover la calidad de vida de las personas mayores que residían en centros gerontológicos; y, por otro, también para paliar y prevenir síndromes gerontológicos como el riesgo de caídas, la incontinencia urinaria y las alteraciones del sueño en esta población. En concreto, la doctoranda se centró en la investigación de los trastornos del sueño, lo que constituyó el punto de partida del que nace el interés por desenvolver la tesis doctoral que se presenta.

En este período, la alumna de doctorado también desempeñaba otra actividad laboral como terapeuta ocupacional en una residencia para personas mayores, donde comenzó a observar que muchas de las personas usuarias referían tener dificultades para dormir y presentaban somnolencia y otros problemas asociados al sueño. Así, la combinación de ambas experiencias laborales hizo que la doctoranda empezara a indagar sobre el sueño y los problemas asociados, debido a la influencia que tienen en la población. En este período emerge su trabajo de fin de máster sobre la influencia del sueño en la vida diaria de las personas mayores.

Dichos acontecimientos motivaron a la doctoranda para continuar su trayectoria en la investigación sobre el sueño, mediante la realización de sus estudios en el Programa de Doutoramento en Ciencias da Saúde en la Universidade da Coruña. Diferentes momentos vividos durante esta etapa definieron el diseño, la estructura y el recorrido de la presente tesis doctoral.

El primer año de doctorado, la alumna hizo una estancia predoctoral con el investigador Adam Spira en la Johns Hopkins University, situada en Baltimore, Maryland (Estados Unidos). En esta estancia acudió por primera vez a una Unidad del Sueño, donde tuvo contacto con diferentes dispositivos tecnológicos y técnicas para detectar y monitorizar problemas del sueño, como la polisomnografía o la actigrafía. Además, tuvo la posibilidad de trabajar y aprender sobre la aplicación de actígrafos a personas con y sin problemas del sueño, gracias a los miembros de este grupo de investigación. Así, la estancia comenzó a despertar en la doctoranda un mayor interés por el uso de los dispositivos para la medición del sueño.

Cabe destacar, que el grupo de investigación de la doctoranda ya tenía experiencia en el uso de dispositivos *wearables* con personas mayores y con discapacidad. Los dispositivos *wearables* permiten la monitorización en tiempo real de diferentes parámetros biomédicos, como la actividad, la frecuencia cardíaca y el sueño. Su popularidad se ha incrementado en los últimos años, por lo que las empresas tecnológicas han apostado por su desarrollo y su innovación, con el fin de hacerlos más precisos y competitivos en el mercado.

Por otra parte, la evidencia científica documenta la necesidad de estudios que validen la calidad de los datos de sueño obtenidos por este tipo de dispositivos, así como sus implicaciones y el uso que pueden tener para el seguimiento del sueño en la población. Al comienzo de la investigación de la tesis, la doctoranda apenas había encontrado estudios que se centraran en el uso de estos dispositivos en ciertas poblaciones. Por ello, en esta tesis doctoral surgió la necesidad de investigar las implicaciones del sueño y los factores asociados, concretamente en la población mayor y en personal trabajador, mediante el uso del dispositivo *wearable* Xiaomi Mi Band.

Así, el dispositivo Xiaomi Mi Band se convirtió en una herramienta valiosa y fundamental para la doctoranda, por su popularidad y su posible influencia en la gestión de la salud de la población. Además, la falta de estudios sobre la precisión y fiabilidad de este dispositivo motivó a la doctoranda y a sus directores a validarlo científicamente en una unidad del sueño.

Finalmente, cabe resaltar que uno de los momentos decisivos de la elaboración de esta tesis doctoral fue la obtención de una ayuda de apoyo a la etapa predoctoral en las universidades del Sistema Universitario Gallego en el año 2019, esto es, una bolsa predoctoral de la Xunta de Galicia que le permitió a la doctoranda poder desenvolver su formación como investigadora y docente en la Universidade da Coruña durante estos años.

Estructura y contenido de la tesis doctoral

Esta tesis doctoral está conformada por un total de siete capítulos que detallan la fundamentación y el desarrollo de las investigaciones realizadas durante el doctorado. A continuación, se explica cada uno de ellos.

- **Capítulo 1. Introducción.** En este capítulo se exponen los antecedentes que fundamentaron el desarrollo de los diferentes estudios de investigación. Está dividido en diferentes apartados que engloban el tratamiento del sueño desde una perspectiva ocupacional y biopsicosocial, los trastornos del sueño y sus características, el impacto de los trastornos del sueño en la vida diaria, y el uso de los dispositivos ponibles (*wearables*) para la medición del sueño.
- **Capítulo 2. Objetivos.** En este capítulo se presentan tanto las hipótesis como los objetivos que dieron lugar a la tesis doctoral.
- **Capítulo 3. Metodología.** Este capítulo muestra la justificación y la estructura de la tesis doctoral, las características de los estudios indexados, el procedimiento de desarrollo de estos estudios y su publicación en revistas científicas internacionales.
- **Capítulo 4. Compendio de publicaciones científicas.** Este capítulo recoge las diferentes publicaciones científicas y el manuscrito que forman esta tesis. Cada publicación cuenta con un resumen extendido en castellano.
- **Capítulo 5. Discusión.** En este capítulo se presentan los principales hallazgos de la tesis en comparación con la evidencia científica. También, se recogen las limitaciones, implicaciones y futuras líneas de investigación de esta tesis doctoral.
- ***Chapter 6. Conclusions.*** En este capítulo se destacan las principales conclusiones de la tesis, presentadas en inglés con el objetivo de lograr la mención internacional. Además, cuenta con un apartado de las conclusiones en lengua castellana (**Capítulo 6. Conclusiones**).
- **Capítulo 7. Bibliografía.** En este capítulo se recogen las principales referencias utilizadas tanto en la introducción como en la discusión general.
- **Anexos.** En los anexos se muestran diferentes materiales e información relevante de los estudios que constituyen esta tesis por compendio de artículos, junto con una copia de la primera y última página de los artículos publicados.

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Listado de abreviaturas

AASM *American Academy of Sleep Medicine*

ACIS Agencia Gallega de Conocimiento en Salud

ANSI *American National Standards Institute*

AOS/OSA Apneas obstructivas del sueño/*Obstructive sleep apneas*

AOTA *American Occupational Therapy Association*

APA *American Psychiatric Association*

AVD(s)/ADL(s) Actividades de la vida diaria/*Activities of daily living*

BMI *Body mass index*

CDC *Centers for Disease Control and Prevention*

CEIC Comité Ético de Investigación Clínica

CI Consentimiento informado

CIE-11 Clasificación Internacional de Enfermedades, versión 11

COVID-19 Coronavirus-19

CTA *Consumer Technology Association*

DSM-5 Manual diagnóstico y estadístico de los trastornos mentales, versión 5

EBE *Epoch by epoch*

ECG Electrocardiograma/*Electrocardiogram*

EDF+ *European Data Format+*

EEG Electroencelografía/*Electroencephalogram*

EMG Electromiograma/*Electromyogram*

EOG Electrooculograma/*Electrooculogram*

EQ5D-5L *EuroQol 5D-5L*

FC/HR Frecuencia Cardíaca/*Heart rate*

IA	Inteligencia artificial
ICD-3	*International Classification of Sleep Disorders*/Clasificación Internacional de los Trastornos del Sueño, versión 3
IJERPH	*International Journal of Environmental Research and Public Health*
IoT	Internet de las Cosas/ *Internet of things*
JCR	*Journal Citation Reports*
JMIR	*Journal of Medical Internet Research*
Lobo MCE	*Lobo Mini-Cognitive Examination*
M	*Mean*
MDPI	*Multidisciplinary Digital Publishing Institute*
NREM	Movimiento Ocular No Rápido/*Non rapid eyes movements*
NoSDis	Sin problemas del sueño/N*o sleep disorders*
OMS/WHO	Organización Mundial de la Salud/*World Health Organization*
PDI	Personal docente e investigador
PSG	Polisomnografía/*Polysomnography*
PSQI	*Pittsburgh Sleep Quality Index*
PSS-10	*Perceived Stress Scale-10*
REDCap	*Research Electronic Data Capture Consortium*
REM	Movimiento Ocular Rápido/*Rapid eyes movements*
SD	*Standard deviation*
SDis	Con problemas del sueño/*Sleep disorders*
SE	Eficiencia del sueño/S*leep Efficiency*
SOL	Latencia de inicio del sueño/*Sleep onset latency*
SQL Server	Lenguaje de Consulta Estructurada/*Structured Query Language*
SPIRIT	*Standard Protocol Items: Recommendations for Interventional Trials*

STAI	*State-Trait Anxiety Inventory*
TIB	*Time in bed*
TIC	Tecnologías de la Información y las Comunicaciones
TO	Terapia Ocupacional
TSPD	Duración total del periodo de sueño/*Total sleep period duration*
TST	Tiempo de sueño total/*Total sleep time*
W	*Wake*
WASO	Tiempos de vigilia posterior al inicio del sueño/*Wake time after sleep onset*

Capítulo 1. Introducción

El sueño es una función biológica con relevantes implicaciones en la vida diaria de las personas. A lo largo de la historia de la Terapia Ocupacional, el sueño es considerado una ocupación significativa y un derecho ocupacional. Desde la perspectiva biopsicosocial, la arquitectura del sueño está conformada por varios ciclos y etapas, la alteración de esta por diversos factores puede provocar el desarrollo de los trastornos del sueño. Desde el punto de vista epidemiológico, los datos refieren que un 45 % de la población global no duerme las horas recomendadas debido a diversos factores individuales y sociales. Por lo que, los trastornos del sueño son reconocidos como un problema de salud pública que necesitan ser medidos y analizados. Al respecto, la aparición de los dispositivos ponibles (*wearables*) permiten la medición en tiempo real de diferentes parámetros como el sueño. Su avance y su popularidad hacen necesarias investigaciones sobre su precisión y su rendimiento en diferentes poblaciones.

1.1. El sueño: una ocupación significativa y una necesidad biológica vital

1.1.1. El sueño desde una perspectiva ocupacional

El sueño es considerado una ocupación de vital importancia en la vida diaria, además de un componente clave para el equilibrio ocupacional, la salud y el bienestar (Green & Brown, 2015; Tester & Foss, 2018). A lo largo de los años, el sueño y su influencia fueron adquiriendo mayor relevancia en la salud debido a los cambios en las rutinas, los comportamientos y el estilo de vida de la sociedad (Grandner, 2017; Green, 2008).

Adolf Meyer, un reconocido psiquiatra y uno de los fundadores de la Terapia Ocupacional (TO), fue el primero en destacar el papel influyente del sueño en la vida diaria (Green & Brown, 2015; Meyer, 1983). Asimismo, otras figuras relevantes en la historia de la TO, como Charles Christiansen y Ann Wilcock, resaltaron la importancia del descanso y sueño en el equilibrio del estilo de vida, y la influencia que tienen en el desempeño del resto de ocupaciones, haciendo hincapié en el impacto que el sueño puede tener en el trabajo o la educación (Christiansen & Townsend, 2009; Wilcock & Hocking, 2015). Además, Elizabeth Townsend y Gary Kielhofner refirieron que el sueño es una ocupación necesaria para la supervivencia, que les brinda oportunidades a las personas para desenvolver otras tareas con significado y propósito (Christiansen & Townsend, 2009; Kielhofner, 2009).

En el año 2008, la *American Occupational Therapy Association* (AOTA) reconoce, en el Marco de Trabajo para la Práctica de TO, que el descanso y el sueño conforman un área de ocupación que desempeña un papel vital en el compromiso y la participación activa en el resto de actividades de la vida diaria (AVD(s)) (Boop *et al.*, 2020). Específicamente, este marco se centra en dos actividades esenciales en el sueño, como son, por un lado, la preparación para un buen descanso mediante los hábitos y rutinas del sueño; y, por otro, la participación en el sueño mediante el cuidado de las necesidades requeridas para su inicio y mantenimiento (Boop *et al.*, 2020).

El sueño también está influenciado por los aspectos culturales, los valores y las creencias que nutren la identidad de una persona, tanto a nivel individual como en la comunidad (Glaskin & Chenhall, 2013; Leive & Morrison, 2020). Las actividades asociadas al sueño y el descanso pueden adquirir un significado diferente en función del entorno y del contexto en el que se encuentra cada persona (Green & Brown, 2015). Asimismo, estas ocupaciones pueden verse alteradas por los valores y normas que tiene la sociedad, con el objetivo de preservar la identidad cultural (Glaskin & Chenhall, 2013; Iwama, 2009). Además, los patrones del sueño suelen ser modificados por factores políticos y socioeconómicos, como por ejemplo el cambio de hora o la organización de los horarios (Green & Brown, 2015; Leive & Morrison, 2020).

Por otro lado, el sueño, junto al resto de ocupaciones, es reconocido como un derecho ocupacional por la Federación Mundial de Terapeutas Ocupacionales. Así, en su declaración de posicionamiento sobre los derechos humanos establece "el derecho de todas las personas a participar en las ocupaciones que necesitan para sobrevivir, porque las definen como significativas y porque contribuyen positivamente a su propio bienestar y al de sus comunidades" (World Organization of Occupational Therapy 2020, p. 1). De igual manera, la Organización Mundial de la Salud (OMS) recoge, en su carta de Ottawa para la promoción de la salud, la necesidad del equilibrio entre el sueño/descanso, la actividad/ejercicio y la cognición/percepción para la salud y el bienestar global (World Health Organization [WHO], 1986).

1.1.2. Conceptualización del sueño desde una perspectiva biopsicosocial

El sueño es un estado neurofisiológico que ocupa entre el 20-40 % del tempo diario de las personas (Grandner, 2017). Esta necesidad biológica, organizada en varios ciclos y etapas, tiene múltiples beneficios sobre el cuerpo humano (Solet, 2016). Además, el sueño es considerado un comportamiento complejo y difícil de estudiar en los contextos clínico y científico (Stickgold & Walker, 2009). De esta manera, los avances en la tecnología, específicamente con la aparición de técnicas como la electroencefalografía (EEG), ayudaron a que los comportamientos y patrones del sueño sean cada vez más comprendidos y adquieran mayor interés en estos ámbitos (Stickgold & Walker, 2009).

En condiciones normales, el sueño se asocia con una disminución de la actividad muscular, con posturas específicas, con una suspensión de la actividad sensorial y con una baja percepción de la consciencia (Lee-Chiong, 2009). El ciclo del sueño-vigilia está controlado por dos procesos, el homeostático y el circadiano, que regulan e impulsan su inicio (Lee-Chiong, 2009). El equilibrio entre ambos procesos determina el estado de alerta, el rendimiento neuroconductual, el sueño y la somnolencia (Lee-Chiong, 2009).

Por otro lado, el sueño se compone de dos fases: el sueño de movimiento ocular no rápido (*non rapid eyes movements*, NREM) y el sueño de movimiento ocular rápido (*rapid eyes movements*, REM) (Rama *et al.*, 2009). El sueño NREM representa entre el 75-80 %, mientras que el sueño REM se manifiesta entre el 20-25 %, del tiempo de sueño total (*total sleep time*, TST) (Rentz *et al.*, 2021). Además, el sueño NREM se subdivide en tres etapas (N1, N2 y N3; esta última etapa anteriormente dividida en N3 y N4), mientras que el sueño REM puede clasificarse en dos etapas, fásica y tónica (Lee-Chiong, 2009; Stickgold & Walker, 2009).

Los ciclos NREM-REM ocurren de media cada 90 minutos y aproximadamente se tienen entre cuatro y cinco ciclos de sueño durante toda la noche (Lee-Chiong, 2009; Patel, Reddy & Araujo, 2022). La proporción de sueño NREM y REM va variando en cada ciclo a lo largo de la noche (Patel, Reddy & Araujo, 2022).

La transición de la vigilia (*wake*, W) a la fase de sueño tiene lugar en la primera fase del ciclo con la etapa NREM1. A medida que el sueño es más profundo empieza la etapa NREM2, unos 10-12 minutos después de comenzar NREM1 (Patel, Reddy, & Araujo, 2022; Rama *et al.*, 2009). La etapa más profunda del sueño, NREM3, suele comenzar tras las etapas más livianas, NREM1 y NREM2, y es más frecuente en el primer tercio de la noche (Rama *et al.*, 2009). A diferencia del sueño REM que va alargando sus episodios durante el ciclo total del sueño, predominando en el tercio final de la noche (Lee-Chiong, 2009; Patel, Reddy, & Araujo, 2020).

Las fluctuaciones de una etapa a otra se pueden deber, entre múltiples factores, a cambios en los niveles de actividad del sistema nervioso autónomo, fundamentalmente, a alteraciones en el tono muscular, en los patrones de ondas cerebrales y en los movimientos oculares (Lee-Chiong, 2009). A continuación, en la Tabla 1 se especifican las características de las diferentes etapas del sueño.

Tabla 1. Características de las etapas del sueño. Fuente: elaboración propia basada en los estudios de Lee-Chiong *et al.* (2009) y Patel *et al.* (2022)

Etapa NREM1

- Es la etapa más ligera del sueño que ocurre al comienzo o al fin del ciclo del sueño, aunque también puede aparecer en las transiciones a otras etapas.
- Su duración acostumbra a ser de entre 1 y 5 minutos, por lo que representa solo el 3-5 % del TST.

Etapa NREM2

- En esta etapa, el sueño es más profundo.
- La frecuencia cardíaca y la temperatura acostumbran a descender.
- Aparecen los "husos del sueño", que son rachas breves y potentes de actividad cerebral, y que desempeñan un papel importante en la consolidación de la memoria y en el mantenimiento del sueño.
- En esta etapa se puede dar el bruxismo, que es el hábito de apretar los dientes de manera involuntaria mediante la tensión de los músculos de la mandíbula.
- Esta etapa, que se va alargando a medida que avanza el ciclo del sueño, representa entre el 45-55 % del TST, con una duración media de 25 minutos.

Etapa NREM3

- Representa la etapa más profunda del sueño.
- Durante esta etapa, el cuerpo repara y regenera tejidos, crecen los huesos y los músculos, y se fortalece el sistema inmunológico.
- En esta etapa puede ocurrir la "inercia del sueño", que es una disminución de las capacidades cognitivas y el estado de alerta, durante aproximadamente 30 minutos o una hora.
- El sonambulismo, los terrores nocturnos y la enuresis (incontinencia nocturna) se pueden dar en esta fase.
- Esta etapa puede durar de 20 a 40 minutos, lo que representa entre el 15-25 % del TST.

Etapa REM

- En esta fase, el sueño no es reparador.
- La frecuencia cardíaca y la presión sanguínea aumentan, y el cerebro suele estar más activo durante esta etapa.
- La fase REM se asocia con los sueños y las pesadillas.
- La duración de este estadio puede variar de los 10 minutos (al comienzo del sueño) hasta una hora (al final del período), y se relaciona con el 25 % del TST.

REM: *Rapid Eyes Movements*, TST: tiempo de sueño total.

1.2. Los trastornos del sueño

A lo largo del ciclo vital, la arquitectura del sueño presenta diversas alteraciones que lo hacen más corto y superficial. En este sentido, los patrones del sueño suelen fragmentarse y aumentan los tiempos de vigilia posterior al inicio del sueño (*wake time after sleep onset*, WASO) (Crowley, 2011; Van Ryswyk *et al.*, 2018).

Asimismo, diversos parámetros del sueño también se pueden ver afectados a medida que las personas envejecen (Gulia & Kumar, 2018). En concreto, la cantidad de sueño profundo y sueño reparador suele comenzar a disminuir a finales de los 20 años y a principios de los 30. A partir de los 40 años, la falta de sueño reparador es notable. Reduciéndose entre un 60-70 % a partir de los 50 años, y entre un 80-90 % a partir de los 70 años (Pavlova & Latreille, 2019; Walker, 2017). Este factor influye en la calidad y en la eficiencia del sueño (*sleep efficiency,* SE), que es el tiempo total dormido frente el tiempo que la persona está en la cama, y suele asociarse con la latencia de inicio del sueño (*sleep onset latency*, SOL), el cual es el período de transición de la vigilia al sueño (Garbarino *et al.*, 2016; Holder & Narula, 2022).

Por todo esto, las personas pueden presentar desde edades muy tempranas dificultades para la conciliación y el mantenimiento del sueño, así como también pueden aparecer en el sueño respiraciones inadecuadas e interrupciones, entre otros problemas (Pavlova & Latreille, 2019). Estas dificultades alteran la calidad y la cantidad del sueño, y en los casos más graves provocan el desarrollo de trastornos del sueño[1] (Ramar *et al.*, 2021).

Por lo tanto, se entiende como trastornos del sueño las condiciones de salud mantenidas en el tiempo que interfieren en el adecuado funcionamiento de este fenómeno (Pavlova & Latreille, 2019). El Manual Diagnóstico y Estadístico de los Trastornos Mentales en su versión 5 (DSM-5) (American Psychiatric Association [APA], 2014), la Clasificación Internacional de Enfermedades en su versión 11 (CIE-11) (WHO, 2019) y la Clasificación Internacional de los Trastornos del Sueño en su versión 3 (*International Classification of Sleep Disorders*, ICD-3) (Sateia, 2014) incluyen los criterios diagnósticos y las características de los diferentes trastornos asociados al sueño, así como la nomenclatura empleada y su evolución a lo largo de los años.

En general, estos manuales para la práctica clínica se centran en los siguientes trastornos: insomnio; hiperinsomnio; narcolepsia; trastornos asociados a la respiración como las apneas obstructivas del sueño (AOS); trastornos del ritmo cardíaco del sueño-vigilia; parasomnias; trastornos del comportamiento del sueño REM; síndrome de las piernas inquietas y trastornos del sueño inducidos por substancias/medicamentos (APA, 2014; Sateia, 2014; WHO, 2019). La

[1] En el presente documento se emplea indistintamente los términos trastornos del sueño, problemas del sueño y alteraciones del sueño para referirse a la misma condición de salud.

evidencia refiere que los trastornos más comunes son el insomnio, las AOS, la narcolepsia y las parasomnias (Berkley, 2021; Holder & Narula, 2022; Pavlova & Latreille, 2019).

- **Insomnio**

El insomnio, que es la queja sobre el sueño más común, se define como la dificultad de conciliar y mantener el sueño que ocurre de forma repetida, y que tiene un impacto negativo en el funcionamiento diurno (APA, 2014). Cuando las quejas sobre el insomnio son manifestadas por lo menos durante tres noches a lo largo de un mes, se puede presentar insomnio crónico (Brown, 2009).

- **Apneas obstructivas del sueño**

Las AOS se asocian con esfuerzos respiratorios durante la noche (WHO, 2019). Específicamente, este trastorno se debe a una obstrucción de las vías respiratorias de forma repetitiva durante el sueño (Javaheri, 2009; Sateia, 2014). Entre los criterios diagnósticos se destaca la existencia de alteraciones en la respiración nocturna como los ronquidos, y la existencia de por lo menos cinco apneas obstructivas por cada hora de sueño (APA, 2014).

- **Narcolepsia**

La narcolepsia se caracteriza por la somnolencia diurna y la necesidad irrefrenable de dormir, aún después de tener un sueño reparador (APA, 2014; Lee-Chiong, 2009). Las personas con narcolepsia, también pueden tener parálisis del sueño y cataplejías[2] (Lee-Chiong, 2009).

- **Parasomnias**

Las parasomnias son alteraciones en la conducta y en el estado fisiológico de una persona durante el sueño (APA, 2014; Sateia, 2014). Principalmente, se trata de episodios con un despertar incompleto del sueño. Las parasomnias más comunes son el sonambulismo, los terrores nocturnos o el bruxismo (Solet, 2016).

1.2.1. Epidemiología de los trastornos del sueño

A nivel epidemiológico, la evidencia refiere que la prevalencia de los problemas del sueño es difícil de analizar ya que suelen ser trastornos infradiagnosticados que, en muchas situaciones pueden pasar desapercibidos tanto por la población como por los profesionales de la salud (Grandner, 2017; Martoni *et al.*, 2012). Además, los datos epidemiológicos de estos trastornos pueden variar en función del contexto, del sexo o del rango de edad (Ferrie *et al.*, 2011).

A nivel global, se estima que más del 45 % de la población adulta no duerme entre las 7-9 horas recomendadas por la American Academy of Sleep Medicine (AASM) (Hale *et al.*, 2019;

[2] Cataplejía: episodio de debilidad muscular asociado con la narcolepsia o con emociones intensas.

Hirshkowitz *et al.*, 2015). Entre un 35-40 % de la población menciona tener dificultades para conciliar el sueño, mientras que entre un 10-40 % refiere despertarse varias veces a lo largo de la noche y por tanto, tener somnolencia durante el día (Ferrie *et al.*, 2011; Hale *et al.*, 2019).

A nivel nacional, según los datos del Sistema Nacional de Salud, aproximadamente el 12,71 % de la población tiene un trastorno del sueño, con una prevalencia un poco mayor entre las mujeres (6,60 %) que entre los hombres (6,12 %) (García *et al.*, 2021). Además, tal y como muestra la , las personas mayores de 60 años presentan una prevalencia mayor que el resto de grupos de edad (García *et al.*, 2021).

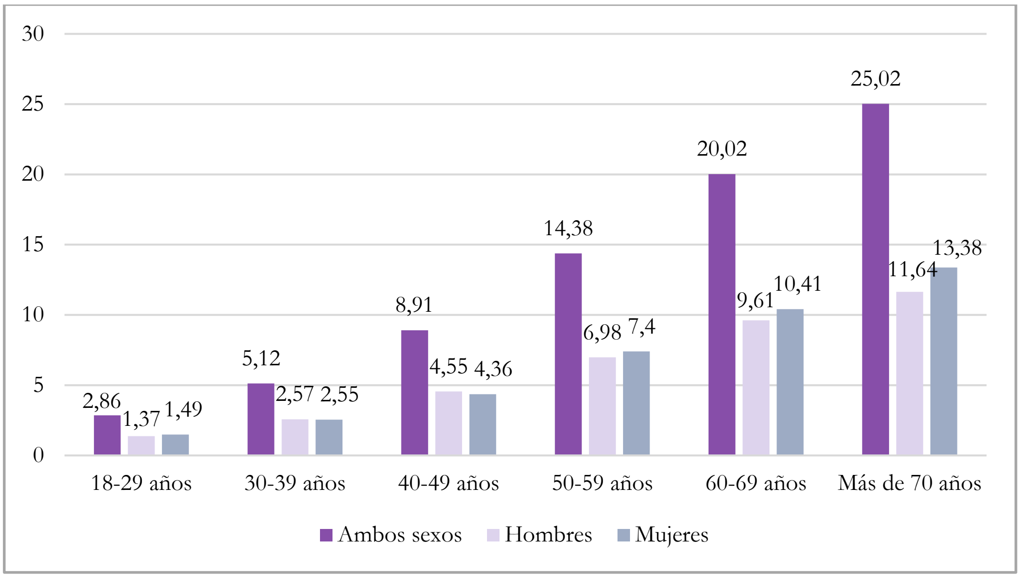


Figura 1. Prevalencia de los trastornos del sueño en la población española. Unidades: porcentaje de personas de 18 años o más. Fuente: Ministerio de Sanidad (2018)

Los estudios epidemiológicos refieren que un 40-60 % de la población mayor de 65 años presenta dificultades en el sueño, además aproximadamente un 50 % de estos trastornos no están diagnosticados en esta población (Miner & Kryger, 2017). Así, la evidencia considera que los trastornos del sueño son un síndrome asociado al fenómeno de envejecimiento progresivo de la población (Miner & Kryger, 2017).

Concretamente, el insomnio es el problema del sueño más común (Matsui *et al.*, 2021). Entre el 30-35 % de la población adulta manifiesta tener síntomas asociados con el insomnio y un 10 % cumple los criterios diagnósticos (Hale *et al.*, 2019). A medida que aumenta la edad, estos datos se incrementan (Crowley, 2011). Así, se estima que entre el 40-50 % de la población europea mayor de 60 años tiene insomnio (Pavlova & Latreille, 2019).

Las AOS también tienen una importante representación en la población, presentes en un 2-15 % de los adultos y en más de un 25 % de las personas mayores (Kaufmann *et al.*, 2017; Miner &

Kryger, 2017). En general, este trastorno afecta más a los hombres (24-31 %) que a las mujeres (9-21 %) (Isidoro *et al.*, 2015).

Por otro lado, los trastornos del sueño se asocian con otras condiciones de salud. Diversos estudios epidemiológicos obtuvieron como resultado que entre el 30-60 % de las personas con un trastorno mental desarrollaban alteraciones en su sueño (Garbarino *et al.*, 2016; Kaufmann *et al.*, 2017). En concreto, según el estudio de Chattu *et al.* (2019), el 80 % de las personas con un trastorno depresivo relataron tener síntomas asociados con el insomnio. Asimismo, el estudio de Merrill *et al.* (2022) refiere que entre un 58-74 % de la población con ansiedad tienen problemas en el sueño.

Los problemas de obesidad, diabetes e hipertensión también se relacionan con los trastornos del sueño. Por una parte, aproximadamente el 41 % de la población con obesidad tienen diagnosticado algún trastorno del sueño (Rose *et al.*, 2016), siendo las AOS el más predominante (Morsy *et al.*, 2019). Por otra parte, datos de los *Centers for Disease Control and Prevention* (CDC) refieren que las personas con un sueño insuficiente y poco reparador tienen un 40 % y un 69 % más de probabilidades de padecer diabetes e hipertensión, respectivamente (Grandner & Pack, 2011).

Además, las personas con trastornos neurodegenerativos como las demencias suelen tener trastornos del sueño. Los datos epidemiológicos muestran que aproximadamente un 25-55 % de la población con algún tipo de demencia tienen problemas en su sueño, concretamente insomnio y AOS (Gulia & Kumar, 2018; Smagula *et al.*, 2016).

Finalmente, los problemas relacionados con el sueño se incrementaron en los últimos años por causa de diversos factores como la situación generada por la pandemia derivada de la enfermedad del coronavirus de 2019 (COVID-19) (Bhat & Chokroverty, 2022). Según la Sociedad Española de Neurología, el 50-70 % de la población sufrió cambios significativos en sus patrones del sueño, debido a las alteraciones en las rutinas ocasionadas por la pandemia (Pérez, 2021). Además, el estudio desarrollado por Bhat *et al.* (2022) muestra que entre un 13-15 % de la población, con un malestar psicológico y síntomas de ansiedad y estrés debido a la pandemia, refirieron tener alteraciones en su sueño relacionados con el insomnio.

1.2.2. Etiología de los trastornos del sueño

La literatura recoge diversos factores que pueden influir negativamente en la calidad y la cantidad del sueño, y, en los casos más graves, en la aparición de trastornos del sueño en la población (Basner *et al.*, 2014). Al respecto, el modelo social-ecológico de la salud, propuesto por Bronfenbrenner (1979) y adaptado a esta temática por Michael Grandner (2019), expone que el sueño puede verse influenciado por diferentes factores integrados en tres niveles (individual, social y societario), tal y como se pode observar en la Figura 2.

Figura 2. Factores que pueden influir sobre el sueño segundo el modelo social-ecológico de la salud del sueño. Fuente: Sleep and Health. Autor: Grandner (2019)

El nivel individual está conformado por diversos factores personales, que tienen una relación con el estado del sueño y un impacto directo en él (Grandner, 2019). La evidencia refleja que los factores genéticos y fisiológicos como el sexo, los antecedentes familiares y/o la edad pueden ser factores claves en el desarrollo de trastornos del sueño como las AOS o el insomnio (APA, 2014). De igual manera, las condiciones de salud de la persona, en particular pueden incidir en el desarrollo de trastornos del sueño (Chattu *et al.*, 2019; Grandner, 2017).

Por otro lado, los comportamientos, las actitudes y el estilo de vida individuales son factores que pueden influir en la higiene del sueño[3] (Smallfield *et al.*, 2021). Así, el consumo de ciertas sustancias como la cafeína o el alcohol, la falta de hábitos y rutinas fijas, y la presencia de sedentarismo influyen negativamente en la calidad y la cantidad del sueño (Ohida *et al.*, 2001; Walker, 2017).

El nivel social está constituido por las interacciones del individuo con su entorno; como el hogar, la familia o el trabajo (Grandner, 2019). Diferentes autores manifiestan que los problemas relacionados con el contexto familiar y social de la persona, como el aislamiento social o las dificultades en la conciliación familiar, pueden tener un efecto negativo en la calidad y la cantidad del sueño de una persona (Hajj *et al.*, 2019; Miner & Kryger, 2017).

En este sentido, Li *et al.* (2018) refieren que las personas mayores institucionalizadas acostumbran presentar alteraciones del sueño por los cambios de entorno y las relaciones familiares. Además, varios estudios científicos relacionan el ámbito laboral con el sueño deficiente de los/as trabajadores/as, como consecuencia de las condiciones del puesto laboral y del estrés por el trabajo (Galant-Miecznikowska *et al.*, 2016; Nena *et al.*, 2018).

El nivel societario representa los factores que influyen en el nivel social, y consecuentemente, en el individuo (Grandner, 2019). Los factores ambientales como la temperatura, el ruido, o la luz y

[3] Higiene del sueño: actitudes y hábitos llevados a cabo para promover el sueño.

las posibles alteraciones en sus patrones pueden aumentar la vulnerabilidad a los trastornos del sueño en la población (Matsui *et al.*, 2021). Asimismo, el uso excesivo de ciertos elementos como los dispositivos tecnológicos pueden alterar los ritmos circadianos y provocar una disminución de la calidad y la cantidad del sueño (Grandner, 2019; Matsui *et al.*, 2021).

Por último, diversas situaciones a nivel global, como la situación socioeconómica o la situación ocurrida con la pandemia pueden tener un impacto negativo en el estado del sueño de la sociedad como consecuencia de los cambios en los estilos de vida y hábitos (Zhuo *et al.*, 2020).

1.2.3. Impacto de los trastornos del sueño en la vida diaria

Los trastornos del sueño son un problema para la salud pública debido a las considerables repercusiones que tienen en la vida diaria de la población, tanto en la salud como en los ámbitos social y económico (Filip *et al.*, 2017; Hale *et al.*, 2019). Al mismo tiempo, los trastornos del sueño son un reto para las organizaciones científicas, clínicas y gubernamentales, que cada vez más reconocen la relevancia del sueño y la necesidad de políticas de prevención e intervención en los trastornos asociados (Matricciani *et al.*, 2017).

La mala calidad y cantidad del sueño tiene consecuencias negativas en la salud (Fabres & Moya, 2021). El sueño insuficiente y los trastornos asociados, como el insomnio o las AOS, son un factor de riesgo para el desarrollo de ciertas enfermedades como la hipertensión, la diabetes tipo 2 o los trastornos respiratorios (APA, 2014; Hashimoto *et al.*, 2020; Morsy *et al.*, 2019; Scott, 2020).

Además, los trastornos del sueño tienen repercusiones en el bienestar físico y mental. Por una parte, las dificultades en la organización de los hábitos y rutinas, a causa de interrupciones en el sueño y despertares tardíos, pueden influir negativamente en las funciones metabólicas, lo que provoca cambios en las funciones que regulan el apetito y el gasto de energía, e incide en un exceso del peso corporal (Rose *et al.*, 2016). Por otra parte, el sueño insuficiente y los trastornos asociados pueden alterar las funciones cognitivas y la salud mental, repercutiendo en el desarrollo de diferentes tipos de demencias y de síntomas relacionados con la depresión, el estrés o la ansiedad (Crowley, 2011; Gulia & Kumar, 2018; Sivertsen *et al.*, 2021; Zhuo *et al.*, 2020).

Estas consecuencias negativas en el estado de salud tienen implicaciones en la calidad de vida y en el desempeño ocupacional de la población, especialmente en el trabajo, el ocio y la participación social (Green & Brown, 2015). En esta línea, autores como Stendardo *et al.* (2021) refieren que la combinación de la mala calidad y la cantidad del sueño junto el estrés o el síndrome de desgaste profesional (*burnout*) causa en los trabajadores dificultades en su equilibrio ocupacional (Queirós *et al.*, 2020). De esta manera, el equilibrio ocupacional es comprendido como la organización y la gestión del tiempo, la dedicación, la calidad, el compromiso y las demandas (familiares, contextuales o laborales) de una persona hacia las diferentes ocupaciones diarias que realiza (Håkansson & Ahlborg, 2017, 2018).

La evidencia también relaciona los problemas del sueño con las dificultades en la toma de decisión o el control del estado de ánimo (Green & Brown, 2015; Merrill, 2022). Estos factores pueden limitar las actividades de ocio, la participación social y aumentar el sedentarismo, sobre todo en la población mayor (Martins da Silva *et al.*, 2020; Okuyan, 2017). Del mismo modo, los trastornos del sueño como el insomnio junto a alteraciones en el estado físico y el mental limitan el desempeño de actividades básicas, como el vestido o el aseo personal, de las actividades domésticas y del cuidado de otras personas (Ho & Siu, 2018; Magnusson *et al.*, 2021; Ryuno *et al.*, 2020).

Por otro lado, la carga social y económica que estas circunstancias tienen en la población es destacable (Galant-Miecznikowska *et al.*, 2016; Garbarino *et al.*, 2016). La literatura reciente relata que el efecto negativo de los trastornos del sueño junto a otras condiciones de salud (altos niveles de estrés, presión laboral o diferentes enfermedades crónicas) hacen que se incremente el uso de los recursos sanitarios y de los tratamientos farmacológicos, con y sin receta, para paliar los síntomas (Hillman & Lack, 2013; Mohit & Wickwire, 2020).

Además, gran parte de estos costes están dirigidos a la población mayor, siendo uno de los grupos de edad más afectados por estos trastornos (Chattu *et al.*, 2019), tal y como se mencionó en apartados anteriores. De hecho, estos trastornos son un elemento que contribuye a que los/as cuidadores/as tomen la decisión de buscar apoyo en una institución residencial o centro de día (Stendardo *et al.*, 2021).

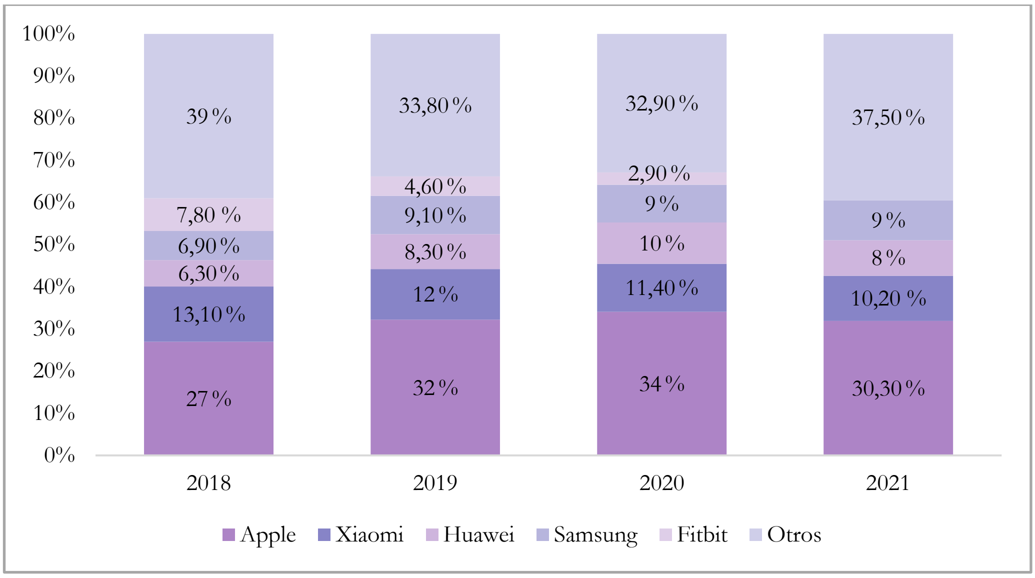
Igualmente, los problemas del sueño son considerados la segunda queja más frecuente por parte de los/as trabajadores/as (Itani *et al.*, 2022). Las implicaciones de estos problemas en el ámbito laboral pueden causar baja productividad, falta de concentración y absentismo (D'ettorre *et al.*, 2020; Itani *et al.*, 2022). A largo plazo las consecuencias empeoran, pudiendo dar lugar a accidentes laborales o enfermedades crónicas que deriven en una incapacidad laboral o permanente (D'ettorre *et al.*, 2020; Itani *et al.*, 2022). Asimismo, a nivel económico las consecuencias son significativas. Las investigaciones reflejan que la falta de sueño provoca pérdidas de hasta 2000 dólares por cada empleado/a en las empresas (Filip *et al.*, 2017; Hafner *et al.*, 2017; Walker, 2017).

Finalmente, ante las relevantes implicaciones que el sueño tiene en la sociedad, autores como Shelgikar *et al.* (2016) refieren la necesidad de conocer el impacto de los problemas del sueño en la población de forma más exhaustiva, mediante el uso de diferentes instrumentos de evaluación como los dispositivos tecnológicos.

1.3. Dispositivos wearables para la medición del sueño

Los avances en las Tecnologías de la Información y las Comunicaciones (TIC) han hecho que el Internet de las Cosas (*Internet of Things*, IoT), junto a técnicas de *Big Data* e Inteligencia Artificial (IA), permitan y faciliten el acceso a diversos parámetros biomédicos que tienen un impacto en la vida diaria (Sadek *et al.*, 2020). Estos conceptos fomentan la promoción de los hábitos de vida saludable y de la salud mediante el uso de dispositivos tecnológicos por parte de la población para la gestión y el manejo de su salud (Perez-Pozuelo *et al.*, 2020). También impulsan la "medicina/salud participativa[4]" mediante la participación, conexión y comunicación de la persona con los profesionales sanitarios u otros agentes interesados, al poder realizar un seguimiento y control de diferentes datos de la salud de forma continua (Almalki *et al.*, 2015; Nieto-Riveiro *et al.*, 2018).

Los dispositivos ponibles (*wearables*), que son complementos tecnológicos no invasivos que pueden colocarse en cualquier parte del cuerpo, forman parte de la red de dispositivos inteligentes y objetos que conforman el IoT (Sadek *et al.*, 2020). En los últimos años, estos dispositivos han incrementado su popularidad, con aproximadamente 553,56 millones de unidades vendidas en todo el mundo (Statista, 2022). Dentro de los dispositivos *wearables* destacan las pulseras de actividad, que también cuentan con una amplia aceptación en el mercado debido a la retroalimentación (*feedback*) que ofrecen, a su fácil uso y a la medición en tiempo real de diferentes parámetros de la salud que le proporcionan al consumidor (Lujan *et al.*, 2021; Statista, 2022). La Figura 3 muestra los dispositivos más vendidos en la actualidad, entre los que destacan los de las marcas Apple (30,30 %), Xiaomi (10,20 %) y Samsung (9 %) (Statista, 2022).



[4] Medicina participativa: enfoque ético de la salud cooperativa sobre la atención.

Figura 3. Pulseras de actividad más populares en el mercado a nivel mundial desde el 2018 hasta el 2021. Unidades: porcentajes. Fuente: Statista, 2022

En los últimos años, la relevancia que el papel del sueño y sus implicaciones adquirieron en la sociedad aumentó el interés por monitorizar y medir sus diferentes características y sus parámetros (Sawyer & Khayat, 2020). El sueño puede ser analizado mediante mediciones subjetivas u objetivas. Las herramientas subjetivas suelen recoger la percepción del/a usuario/a o profesional sobre la calidad y la cantidad del sueño, mediante herramientas de evaluación como la Pittsburgh Sleep Quality Index (PSQI) o los diarios del sueño (Frangopoulos *et al.*, 2021; Ibáñez-del Valle *et al.*, 2018).

Por otro lado, tanto los parámetros del sueño como los trastornos relacionados con él pueden ser medidos y diagnosticados mediante pruebas objetivas (Baron *et al.*, 2018). La polisomnografía (PSG) es el método estándar de oro en la medición de estos parámetros, ya que ofrece información detallada y precisa de la arquitectura, duración y calidad del sueño. Esta técnica puede constar de varias pruebas como un electrooculograma (EOG), un electromiograma (EMG), un electrocardiograma (ECG) y un electroencefalograma (EEG) (Marino *et al.*, 2013; Martoni *et al.*, 2012). Con todo, a pesar de que es el método más relevante para la medición del sueño, sus limitaciones promovieron la búsqueda e investigación de nuevas opciones más económicas y prácticas, como la actigrafía para la monitorización del sueño (De Zambotti *et al.*, 2019; Lee *et al.*, 2019).

Hoy en día la industria tecnológica sigue trabajando en el avance, la fiabilidad y la precisión de este tipo de dispositivos *wearables*, así como en la accesibilidad y la fácil comprensión de los datos de sueño, actividad y frecuencia cardíaca (FC) para el/la consumidor/a (Shelgikar *et al.*, 2016; Xu *et al.*, 2022). Los fabricantes de estos dispositivos trabajan en la mejora de su hardware y software con el objetivo de reducir las discrepancias y aumentar la fiabilidad de la detección de las etapas del ciclo sueño-vigilia, clasificadas generalmente como WASO, sueño ligero (NREM1 + NREM2), sueño profundo (NREM3), y sueño REM (Liang & Chapa Martell, 2018).

La evidencia reconoce los beneficios y el impacto positivo que estos dispositivos tienen en la población, al fomentar la concienciación sobre la relevancia del estado y el comportamiento del sueño, y promover la gestión y mejora de los hábitos del sueño y de los estilos de vida (De Zambotti *et al.*, 2019; Rentz *et al.*, 2021). A medida que su popularidad aumenta en la sociedad, también lo hace en el ámbito sanitario y en la investigación (Guillodo *et al.*, 2020). En este sentido, estudios recientes han hecho uso de estos dispositivos en diferentes poblaciones para el seguimiento y la medición del sueño, la actividad y la FC (Miranda-Duro *et al.*, 2021; Queirós *et al.*, 2020).

Además, algunos profesionales de la salud y sistemas sanitarios han comenzado a integrar estos dispositivos en su práctica clínica (De Zambotti *et al.*, 2019; Shelgikar *et al.*, 2016). Así, el uso de estas herramientas puede contribuir a realizar una evaluación del/a usuario/a más exhaustiva, a mejorar las intervenciones, y a poder realizar un seguimiento del sueño y otros parámetros biomédicos de forma más precisa (Chinoy *et al.*, 2021; Kwon *et al.*, 2021). Al mismo tiempo, grandes empresas y compañías de salud pueden estar interesadas en el uso de estos dispositivos para controlar y monitorizar el estado de salud de sus empleados/as o clientes/as, con el objetivo de garantizar planes de atención médica e intervenciones para prevenir trastornos del sueño o estrés laboral (Zhuo *et al.*, 2020).

En relación con el auge y el impacto que las pulseras de seguimiento del sueño y actividad están teniendo en la sociedad, la comunidad científica manifestó la necesidad de estudios de validación de estos dispositivos (Ding *et al.*, 2022; Liang & Chapa Martell, 2018). Este tipo de estudios proporcionan información sobre la precisión de los datos de estos dispositivos, y ayuda a utilizarlos de manera fiable tanto en la vida diaria como en la práctica clínica y de investigación, mediante su comparación con métodos estandarizados como la PSG (Chinoy *et al.*, 2021).

Existen pocos estudios que validen la calidad de los datos del sueño de los dispositivos *wearables* y la mayor parte de ellos se centran en las pulseras Fitbit, Jawbone y en el anillo Õura, siendo este último el más preciso hasta el momento (Cook *et al.*, 2018; Roberts *et al.*, 2020). En general, los dispositivos *wearables* suelen tener una mejor precisión (capacidad para detectar las etapas de sueño-vigilia) y sensibilidad (capacidad para detectar las etapas de sueño) que especificidad (capacidad para detectar las etapas de vigilia) (De Zambotti *et al.*, 2019).

La evolución constante y la repercusión de estos dispositivos en el mercado y en la vida diaria, hacen que sean un objetivo de investigación (Lee & Lee, 2020). Al mismo tiempo, los/as investigadores/as y expertos/as del sueño manifiestan la necesidad de seguir ampliando no solo los estudios de validación, sino también las investigaciones sobre el sueño y su transcendencia mediante el uso de estos dispositivos (De Zambotti *et al.*, 2019). Por lo tanto, esta tesis doctoral se centra en monitorizar y analizar el sueño y la calidad de los datos aportados por un dispositivo *wearable*, en diferentes poblaciones y entornos.

Capítulo 2. Objetivos

Los antecedentes y las experiencias de la doctoranda y su grupo de investigación sobre el uso de los dispositivos ponibles (*wearables*) suscitaron una serie de preguntas que dieron lugar al trabajo de esta tesis doctoral. Así, emergieron tres hipótesis de las que surge el objetivo general y los objetivos específicos, centrados en el rendimiento y el uso de los dispositivos *wearables* en diferentes poblaciones.

Los antecedentes sobre el sueño y los dispositivos ponibles (*wearables)*, explicados en el Capítulo 1. Introducción, junto a la experiencia de la doctoranda y su grupo de investigación en el uso de este tipo de dispositivos, formularon diversas inquietudes sobre el tema a tratar. Concretamente, el grupo de investigación de la doctoranda utilizó la pulsera de actividad Xiaomi Mi Band en proyectos como el GeriaTIC, centrado en diferentes síndromes gerontológicos como los trastornos del sueño. A partir de este proyecto, comenzaron a surgir varias preguntas y cuestiones de investigación en la doctoranda y en sus directores. Estas preguntas fueron plasmadas en hipótesis y objetivos, y dieron lugar a los estudios de investigación que conforman la tesis doctoral.

2.1. Hipótesis

Esta tesis doctoral cuenta con tres hipótesis de las que surge el objetivo general y los objetivos específicos. Las hipótesis, expuestas a continuación, están asociadas a los estudios de investigación que forman parte de la tesis.

- El dispositivo Xiaomi Mi Band es un dispositivo *wearable* que permite determinar la calidad y cantidad del sueño de las personas.
- El dispositivo Xiaomi Mi Band puede ayudar a analizar el sueño, y su influencia en la calidad de vida y en el funcionamiento diario de las personas mayores que viven en una residencia.
- Los dispositivos *wearables* como Xiaomi Mi Band permiten determinar cómo el nivel de estrés laboral puede influir en el funcionamiento ocupacional, la actividad y el sueño del personal trabajador de un entorno universitario.

2.2. Objetivos

El objetivo principal y general de esta tesis doctoral es estudiar como una posible solución tecnológica, el uso de un dispositivo *wearable* para la monitorización y medición del sueño y sus parámetros, además de sus implicaciones, en diferentes poblaciones, junto con otras herramientas de evaluación.

Los objetivos específicos son los siguientes:

- Validar la precisión y calidad de los datos del sueño del dispositivo Xiaomi Mi Band 5, en comparación con la técnica de polisomnografía (PSG) en una unidad del sueño del ámbito hospitalario.
- Analizar la aplicación del dispositivo Xiaomi Mi Band junto con otros instrumentos de evaluación en personas mayores, para conocer el estado del sueño y sus parámetros, y su influencia en la calidad de vida y en el funcionamiento diario de esta población.
- Examinar el uso del dispositivo *wearable* Xiaomi Mi Band y de las herramientas de evaluación informatizadas en personal trabajador de una universidad, para conocer el impacto del estrés

laboral en su calidad de vida y en su funcionamiento diario, especialmente en su sueño y actividad física.

Capítulo 3. Metodología

La tesis doctoral está conformada por tres investigaciones de las que surgen tres publicaciones científicas. Todas las investigaciones se centran en el uso de la Xiaomi Mi Band para la medición del sueño y factores relacionados con el mismo. Además, estos estudios fueron evaluados por un comité ético, conformado por investigadores/as expertos/as, para garantizar el cumplimiento de las consideraciones y puntos éticos necesarios para llevar a cabo una investigación.

3.1. Justificación de la tesis doctoral

Esta tesis doctoral se focaliza en el uso del dispositivo Xiaomi Mi Band para la monitorización del sueño, como eje transversal en todos los estudios. Con base en los antecedentes y los objetivos propuestos, la tesis se centró en la investigación de la calidad de los datos del sueño de uno de los dispositivos más populares, en población adulta con y sin trastornos del sueño. Por otra parte, este dispositivo se aplicó en dos poblaciones con características relacionadas estrechamente con los problemas del sueño, como son el envejecimiento y el estrés laboral. Así, se pretendió conocer las implicaciones del sueño en la vida diaria de estas poblaciones, mediante el uso del mencionado dispositivo y otros instrumentos de evaluación.

3.2. Estructura de la tesis doctoral

La tesis doctoral está conformada por tres investigaciones promovidas tanto por las hipótesis como por los objetivos expuestos en el capítulo anterior. De estas tres investigaciones surgieron cuatro publicaciones científicas, que se han agrupado y organizado en dos bloques en función de su contenido.

- **Validación del dispositivo Xiaomi Mi Band**

Este bloque está formado por la publicación científica 1 y el manuscrito, centrados en el diseño, el procedimiento y los resultados de la validación del dispositivo Xiaomi Mi Band 5, comparado con el método de la PSG en una unidad del sueño.

- **Experiencias con el dispositivo Xiaomi Mi Band**

Este bloque presenta dos publicaciones científicas, artículos 2 y 3, basadas en el uso del dispositivo Xiaomi Mi Band junto a otros instrumentos de evaluación, para medir parámetros como el sueño en diferentes poblaciones, lo que constituye una de las variables principales de ambas investigaciones.

3.3. Características de las investigaciones

La primera investigación, relacionada con el artículo científico 1 y el manuscrito, está asociada al proceso de validación del dispositivo Xiaomi Mi Band 5. Esta investigación se llevó a cabo en una unidad del sueño de un hospital de A Coruña, durante aproximadamente un año y cuatro meses (desde el 04/08/2020 hasta el 10/12/2021), y participaron en ella personas mayores de 18 años con y sin problemas del sueño. La primera publicación científica es el protocolo de esta investigación y se centra en el proceso de reclutamiento y de la recogida de datos, en los instrumentos de medición, en las consideraciones éticas y, brevemente, en el análisis estadístico empleado. A su vez, el manuscrito presenta los resultados de esta validación, las características de las personas participantes, el proceso detallado del análisis estadístico y una discusión de los datos obtenidos con la evidencia existente. En relación con este trabajo, cabe destacar que ha pasado por la primera ronda de revisión por pares y actualmente se encuentra en proceso de revisión, tras obtener revisiones menores.

La segunda investigación, ligado a la segunda publicación científica, se centra en la medición del sueño y en factores asociados al sueño que pueden tener implicaciones en la vida diaria de los/as residentes que habitan un centro gerontológico. Esta investigación se llevó a cabo durante un año (desde el 19/12/2018 hasta el 19/12/2019) en personas mayores que vivían en una residencia de A Coruña. En este artículo científico se expone el procedimiento, las características de los/as participantes, las herramientas de evaluación empleadas, los resultados obtenidos y la discusión con la literatura asociada.

La tercera investigación, vinculada a la tercera publicación científica, trata sobre el protocolo de un proyecto de estudio sobre la influencia del estrés laboral en la calidad de vida y en el funcionamiento diario del personal trabajador de un entorno universitario. Este protocolo muestra el diseño, el procedimiento, los instrumentos de evaluación, las consideraciones éticas y el proceso de análisis de esta investigación. Además, en la tesis doctoral se expone, a mayores, una síntesis de los resultados obtenidos en el estudio. En él, finalmente, participaron trabajadores/as de la Universidade da Coruña (UDC) y de la Universidade do Porto (UP) durante un mes (desde el 25/05/2021 hasta el 25/06/2021). En este sentido, es importante resaltar que los resultados de este estudio se encuentran en proceso de publicación.

3.4. Procedimiento de las investigaciones

Todos los protocolos de estas investigaciones fueron sometidas a la evaluación y aprobación del Comité Ético de Investigación Clínica (CEIC) de A Coruña-Ferrol, perteneciente a la Red Gallega de Comités de Ética de la Investigación de la Agencia Gallega de Conocimiento en Salud (ACIS). Una vez obtenido el informe favorable del CEIC de A Coruña-Ferrol, los protocolos fueron registrados en la plataforma *ClinicalTrials*, que es una base de datos de ensayos clínicos estadounidense.

En el proceso de cada estudio, se les entregó a los/as participantes una hoja de información con las características principales de la investigación y las implicaciones que tendría. También se llevó a cabo la firma del consentimiento informado (CI) con cada participante. En este sentido, como alguna de las personas participantes tenía dificultades de lectoescritura, se contó con un testigo, que solía ser un familiar, para confirmar la compresión de los procesos éticos en el estudio. Todos los documentos cumplieron con los puntos y consideraciones del CEIC.

En relación con el tratamiento de los datos de las investigaciones, se cumplieron todos los aspectos recogidos por las leyes nacionales e internacionales de protección de datos. Los datos de cada participante fueron seudonimizados en archivos con un formato .CSV, para posteriormente, ser analizados por la doctoranda en los programas R Studio y SPSS, y finalmente fueron anonimizados para su publicación.

3.5. Publicación de las investigaciones en revistas científicas internacionales

Las investigaciones que conforman esta tesis fueron publicadas en diferentes revistas científicas internacionales. Específicamente, los tres artículos científicos asociados a dichas investigaciones fueron publicados en dos revistas científicas, mientras que el manuscrito se encuentra pendiente de la decisión del editor. Estos artículos científicos le han permitido a la doctoranda presentar su tesis doctoral por compendio de publicaciones científicas. En la Tabla 2 se muestran las especificaciones y características de las revistas en las que se publicaron o se van a publicar estos trabajos: *Digital Health Journal, International Journal of Environmental Research and Public Health* (IJERPH), y *Journal of Medical Internet Research* (JMIR).

Tabla 2. Características de las revistas internacionales

Nombre	**Editorial**	**Objetivos**	***Journal Citation Reports* (JCR) y rango (2021)**
Digital Health Journal	Sage Publications	Relacionada con temas sobre el cuidado de la salud en el mundo digital. Concretamente, trata temas como la medicina personalizada, los dispositivos *wearables*, y la gestión y el manejo de datos.	JCR: 4,687. Q1 (24/109) en la categoría de ciencias y servicios de la salud.
IJERPH	MDPI	Revista asociada a temas de salud e informática, entre otros. Específicamente, contiene secciones sobre salud digital, salud global o ciencias y servicios del cuidado de la salud.	JCR: 4,614. Q1 (45/182) en la categoría de salud pública, medioambiental y ocupacional.
JMIR*	JMIR Publications	Asociada a temas sobre nuevos enfoques, métodos y dispositivos de la salud digital.	JCR: 7,093. D1 (10/109) en la categoría de ciencias y servicios de la salud.

MDPI: *Multidisciplinary Digital Publishing Institute;* *El manuscrito asociado a esta revista está pendiente de publicación.

Capítulo 4. Compendio de publicaciones científicas

Las publicaciones científicas que constituyen esta tesis fueron agrupadas en dos bloques en función de su temática. La primera publicación y el manuscrito hacen referencia a la validación de la calidad de los datos del sueño del dispositivo Xiaomi Mi Band 5. La segunda publicación se relaciona con el uso de este dispositivo en personas mayores para conocer la influencia del sueño en su vida diaria. Por último, la tercera publicación recoge el diseño y el procedimiento de un proyecto asociado con la medición del sueño y otros parámetros relacionados con el estrés laboral en población trabajadora asociada a la universidad. Además, se presenta una síntesis de los resultados obtenidos tras la aplicación de este protocolo.

Validación del dispositivo Xiaomi Mi Band

Este bloque incluye la publicación científica 1 y el manuscrito, relacionados con el procedimiento y los resultados de la validación del dispositivo Xiaomi Mi Band 5.

Publicación científica 1:

Concheiro-Moscoso P., Martínez-Martínez F.J., Miranda-Duro M.d.C., Pousada T., Nieto-Riveiro L., Groba B., Mejuto-Muiño F.J., Pereira J. (2021). Study Protocol on the Validation of the Quality of Sleep Data from Xiaomi Domestic Wristbands. *International Journal of Environmental Research and Public Health*, 18 (3), 1106. https://doi.org/10.3390/ijerph18031106

Manuscrito:

Concheiro-Moscoso P., Groba B., Álvarez-Estévez D., Miranda-Duro M.d.C., Pousada T., Nieto-Riveiro L., Mejuto-Muiño F.J., Pereira J. (2022). Quality of sleep data validation from the Xiaomi Mi Band 5 compared with Polysomnography. *Journal of Medical Internet Research.*

4.1. Study protocol on the validation of the quality of sleep data from Xiaomi domestic wristbands

4.1.1. Resumen extendido en castellano

Este protocolo de estudio está asociado a la validación del dispositivo Xiaomi Mi Band 5 y fue publicado en la revista internacional IJERPH en enero de 2021. Este protocolo cumplió con las recomendaciones marcadas por el Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2013) (véase el Anexo 3).

La investigación, observacional y prospectiva, tuvo como ámbito de estudio una unidad del sueño de un hospital de A Coruña. El perfil de los/as participantes definido fue de una persona mayor de 18 años, que acudía a este servicio para la realización de un estudio de polisomnografía (PSG), independientemente de esta investigación. Según el tamaño de la muestra calculado, se necesitaban 43 sujetos para alcanzar unos resultados estadísticamente significativos.

En relación con el procedimiento del estudio, las personas que cumplían los criterios eran invitadas a participar en la investigación. Cuando acudían a la primera consulta con el neurofisiólogo, se les explicaba la posibilidad de participar en un proyecto de investigación de la Universidade da Coruña (UDC) y se les hacía entrega de una hoja de información sobre el proyecto para que la pudiesen consultar. El día del estudio de PSG, el neurofisiólogo resolvía las dudas o preguntas que pudiesen presentar, y se llevaba a cabo el proceso de firma del consentimiento informado (CI), si aceptaban la participación.

Antes de comenzar con la prueba de PSG y el uso del dispositivo Xiaomi, el/la participante debía cubrir un cuestionario sociodemográfico y la escala de evaluación Pittsburgh Sleep Quality Index (PSQI). El equipo técnico se encargaba de poner los diferentes electrodos y dispositivos que conforman la prueba de PSG, así como el dispositivo Xiaomi en uno de los pulsos del/a usuario/a. Los datos del sueño del/a participante eran monitorizados y registrados en ambos dispositivos durante toda la noche. El equipo técnico controlaba y anotaba las posibles alteraciones o problemas que podían surgir en ambos dispositivos.

Una vez terminada la prueba, el equipo de investigación sincronizaba el dispositivo Xiaomi y descargaba los datos en un archivo .CSV. El neurofisiólogo se ocupaba de tratar los datos en bruto de la PSG y de enviarlos de forma seudonimizada al equipo investigador. Una vez obtenido en el tamaño de la muestra necesaria, se procedió al análisis, mediante la comparación de los diferentes parámetros y medidas resumidas del sueño, obtenidos en ambos dispositivos. Para este análisis, se referían diferentes pruebas estadísticas específicas para la comparación de instrumentos de medición y utilizadas para la validación de estos dispositivos.

4.1.2. Artículo original

Study protocol on the validation of the quality of sleep data from Xiaomi domestic wristbands

Abstract: (1) Background: Sleep disorders are a common problem for public health since they are considered potential triggers and predictors of some mental and physical diseases. Evaluating the sleep quality of a person may be a first step to prevent further health issues that diminish their independence and quality of life. Polysomnography (PSG) is the "gold standard" for sleep studies, but this technique presents some drawbacks. Thus, this study intends to assess the capability of the new Xiaomi Mi Smart Band 5 to be used as a tool for sleep self-assessment. (2) Methods: This study will be an observational and prospective study set at the sleep unit of a hospital in A Coruña, Spain. Forty-three participants who meet the inclusion criteria will be asked to participate. Specific statistical methods will be used to analyze the data collected using the Xiaomi Mi Smart Band 5 and PSG. (3) Discussion: This study offers a promising approach to assess whether the Xiaomi Mi Smart Band 5 correctly records our sleep. Even though these devices are not expected to replace PSG, they may be used as an initial evaluation tool for users to manage their own sleep quality and, if necessary, consult a health professional. Further, the device may help users make simple changes to their habits to improve other health issues as well. Trial registration: NCT04568408 (Registered 23 September 2020).

Keywords: sleep; health promotion; daily life activities; occupation; polysomnography; Xiaomi Mi Smart Band 5; wearable technology; participatory health; internet of things

1. Introduction

Sleep is an occupational area that has considerable implications on our daily life [1,2]. Thus, sleep disorders have become one of the most important common problems in public health [3]. The prevalence of sleep disorders increases with age [4], even though they can appear at any life stage. Bad quality and quantity of sleep, sleep arousals, and a strong will to take diurnal naps are the main complaints among the general population [5,6]. Epidemiological studies indicate that between 20% and 48% of adults between 34 and 60 years old have difficulties initiating and maintaining sleep [7]. In fact, insomnia, which is the most common sleep disorder, is present in 30–45% of the population [8].

Several studies state that sleep disorders are related to health status and quality of life in the general population [9], leading to difficulties in the performance of daily life activities, which in turn causes physical exhaustion, low productivity, a greater risk of falling, mood problems, and diurnal sleep, among many others [10–14].

These factors related to sleep disorders cause a direct and indirect economic burden, causing public health costs to rise [15,16]. Different studies have shown a direct relation between sleep disorders and costs in primary care and hospitals. Lee *et al.* indicated that the population suffering from sleep disorders regularly attends the emergency room to consult professional health workers or demands telematic assistance [9]. This is due to subjective complaints of sleep, along with factors related to stress, working pressure, and other chronic diseases [17,18].

Diverse sleep disorders are diagnosed using different tests that assess the quality and quantity of sleep [19,20]. Objective and valid diagnostic tests that evaluate the quality and quantity of sleep are a previous requisite for the control of sleep disorders [21]. Polysomnography (PSG) is considered by the scientific community as the most reliable test for the measurement of sleep parameters [22,23]. However, it has some clear drawbacks, such as its costs, operation, invasiveness, and time needed for its use [24,25]. To address these problems, actigraphy technology was designed. Actigraphy consists of the measure of sleep parameters using a wearable device created for clinical use [26]. Several studies have found similar measures from both actigraphy and PSG, proving its fitness for these studies [27–29]. Although actigraphy has become a clinically useful tool to test sleep disorders, it cannot provide feedback to people because it purpose is mainly of a research nature [26]. Thus, inspired by the actigraphy device, researchers have recently focused on the validation of different tools for sleep self-assessment, such as activity wristbands [30].

In recent years, activity wristbands have become widely accepted among the population due to their low price, easy use, smart design, and feedback that they offer to users through their fast sync with smartphones, boosting participatory health [31–33]. These devices have already reported benefits in clinics, as they reduce care burdens and facilitate the early diagnosis of health disorders [34]. They also allow the general population to acquire information on their sleep quality and physical activity, which may help in the early detection or prevention of symptoms related to sleep alterations [35–37].

Despite being limited, some studies highlight the importance of the validation of these devices not only from a technological point of view, but also for health promotion, since, by allowing sleep self-assessment, they are tightly related to improvements in life quality and daily functioning [38–41].

Recent studies have compared the measurements of these wristbands with those of actigraphy and PSG techniques. PSG involves different types of electrodes (electroencephalogram (EEG), electrooculogram (EOG), electromyogram (EMG), and electrocardiogram (ECG)) to classify the stages of sleep [42]. A few studies have shown that the usability of an ECG signal can determine the stages of sleep [43–46]. Nevertheless, some have considered the need for further research due to the insufficient quality of this classification compared to the combination of the other electrodes [47,48].

In general, wearable devices can determine the stages of sleep through a heart rate (HR) sensor, which measures the HR, and an accelerometer that detects movement. Previously validated wearable devices have shown a high precision and sensitivity, but also a low specificity and poor agreement in sleep-stage classification when compared with PSG [20,32,33,49,50]. It would be logical to expect these devices to measure sleep more accurately; however, according to these studies, there is a wide range of improvements that can still be accomplished [51,52]. As a result, this protocol has been designed to validate the Xiaomi Mi Smart Band 5 due to its low cost and high acceptance among users, as it is the best-selling fitness tracker [53]. This device has the capability of tracking the activity and HR of users and classifies the user's state as being awake or in light sleep, deep sleep, or REM sleep [54].

Therefore, this research focuses on determining whether sleep stages recorded by the new Xiaomi Mi Band 5 can effectively replace PSG sleep-stage classification in sleep-study participants. To this end, the following features will be calculated for both devices: total sleep time, sleep efficiency, sleep latency, and wake after sleep onset. Sleep stages will also be recorded.

Thus, the primary purpose of the present study is to validate the quality of the data generated by Xiaomi wearables when compared with the PSG technique from a hospital sleep unit. The secondary objectives are: (1) to determine the total sleep time, sleep efficiency, sleep latency, and wake after sleep onset from both the wearable device and PSG; and (2) to examine whether the classification of sleep stages provided by wearable devices is comparable with classifications based on PSG.

2. Materials and Methods

2.1. Study Design

This is a pilot study that aims "to demonstrate that the expected measures, data collecting instruments, and their management system are viable and effective" [55]. This is an observational and prospective study, which means that different variables from the population of interest will be observed and recorded without any direct intervention, in order to establish causality associations between these variables. It will be considered a longitudinal study, with a timeframe of six months, in which participants will stay one night at the sleep unit. They will be monitored to record their sleep through PSG and the Xiaomi wristband.

This study protocol follows the SPIRIT 2013 checklist for study protocols for clinical trials (See File S1 [Anexo 3]) [56].

2.2. Study Settings

The setting of this study will be the sleep unit of a hospital in A Coruña, Spain. This service includes a special consulting room where different sleep disorders are diagnosed and treated. Some of these disorders are sleep apnea, insomnia, restless-legs syndrome, narcolepsy, the delay and advance of sleep stages, sleep terrors, somnambulism, and bruxism. The sleep laboratory is equipped to perform different diagnostic tests: nocturnal and diurnal PSG, multiple latency tests, immobilization tests, and wakefulness maintenance tests.

2.3. Eligibility Criteria

Sample selection will be performed through an intentional sampling based on inclusion and exclusion criteria.

Participant inclusion criteria: (a) having attended the sleep unit to have any diagnostic test done; (b) having declared an age that is equal to or higher than 18 years old.

Participant exclusion criteria: (a) having a significant health complication that hinders active participation in the study; (b) suffering from skin hypersensitivity or an allergic reaction due to the materials of the wristbands that will be used in the study.

2.4. Recruitment Process

This project will be conducted in the sleep unit of a hospital that, regardless of this study, people attend to have PSG tests done with the aim of detecting possible alterations in their sleep. The participants will be assisted by, at a minimum, the clinical neurophysiologist responsible for the sleep unit and a member of the research team. In the first meeting with each of the users, the clinical neurophysiologist responsible for recruiting the participants and monitoring them will inform them, if they meet the selection criteria, about the possibility of participating in the study and the implications of their participation, i.e., the use of an activity bracelet during the day or night and what is involved in the PSG test that will be performed on them. In addition, the mechanisms that will be followed to guarantee their anonymity and the confidentiality of their data will be clearly stated to the participants.

After the main characteristics of the research have been explained, each potential participant will be given an information sheet so that they can consult the information and make a decision before the test is carried out. Once the users return to the unit for testing, any doubts or queries will be resolved by the clinical neurophysiologist, and the informed consent document will be signed, if applicable, by the responsible professional and the person who expresses their final interest in participating in the study. In addition, if the participant has reading and writing difficulties, a witness must be present during the entire procedure to confirm that all the ethical processes have been respected by the research team. On the day of the PSG test, participants will arrive three hours before the test to become acquainted with the room, and will turn the lights on and off based on their sleep pattern. The specialized technical staff will control the test and will attend to any possible patient demands. Figure 1-1 shows the recruitment and the assessment process.

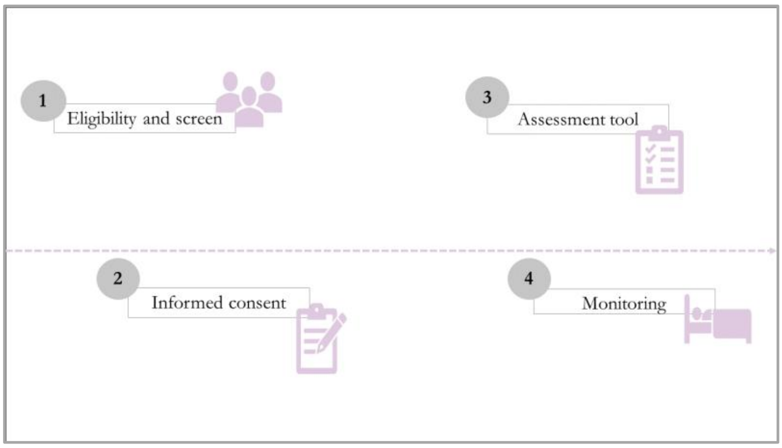


Figure 1-1. The recruitment and assessment process

2.5. Justification of Sample Size

Differences equal or greater than 15 min in deep-sleep time between the measures of both methods are considered clinically relevant. Accepting a 0.05 alpha risk and a 0.1 beta risk (90% power) in a bilateral contrast, 43 subjects are needed to detect a difference that is equal to or greater than 15 min. Conservatively, a standard deviation of 30 for mean differences is assumed, according to previous studies [21,50,57].

2.6. Outcomes

The outcomes will be the sleep-stage identification of PSG and the Xiaomi Mi Smart Band 5, and measurements of total sleep time, sleep efficiency, sleep latency, and wake after sleep onset.

2.7. Data Collection and Management

The study will focus on examining the following variables (Table 1-1): time in bed, hours of light, deep and Rapid-Eye-Movement (REM) sleep, sleep efficiency, sleep latency, wake after sleep onset, and HR. Additionally, the Pittsburgh Sleep Quality Index (PSQI) scale and a sociodemographic questionnaire will be used to assess participants' self-awareness of their sleep.

Table 1-1. Summary of the features of interest for our study

Variable	Description	Dimension
Time in Bed (TIB)	Total time the patient is laying down	min
Sleep Onset Latency (SOL)	Length of time from full wakefulness to sleep	min
Wake After Sleep Onset (WASO)	Periods of wakefulness after defined sleep onset	min
Sleep Efficiency (SE)	Time asleep / TIB *100	%
Light sleep	N1 + N2 sleep stages	min
Deep sleep	N3 sleep stages	min
Rapid Eye Movement (REM) sleep	-	min

The sociodemographic questionnaire will collect different data: gender, year of birth, weight, height, handedness, sleep pathologies, and the assessment test. These data will be pseudonymized and transferred by the hospital to the research group with the prior consent of the participant.

The PSQI will evaluate subjective sleep quality. This questionnaire consists of 24 items about the area of sleep. This tool analyzes the quantity, quality, duration, latency, and efficiency of sleep [58].

The objective sleep data will be obtained through two different devices:

Xiaomi Mi Smart Band 5: This is a wearable device focused on health and sport that measures biomedical parameters of users, among which HR and sleep measurements are the most remarkable. The wristband also requires certain personal data from the user to precisely calculate the activity, such as age, height, weight, gender, handedness, and wristband location. Wristband data will be obtained from the Mi Fit application, which is the native app of the Xiaomi Mi Band wristband. It is necessary to connect the wristband via Bluetooth to a smartphone of general use for the group, creating generic emails for each of the wristbands. The features of interest will be calculated from the data shown in this app [32].

PSG: Data obtained from diurnal and nocturnal PSG will be collected, as this is the standard test for patients who attend to the hospital's sleep unit. PSG measures sleep cycles and stages (N1, N2, N3, and REM sleep) by recording different variables, such as brain waves, eye movement, skeletal muscle activity, heart frequency and rhythm, blood pressure, oxygen level in the blood, breathing patterns, body position, limb movements, and whether there is snoring or other noise [59]. PSG parameters will be scored in 30 s epochs according to the American Academy of Sleep Medicine (AASM) guidelines [60], and PSG recordings will be exported in the European Data Format+ format [61] and interpreted by a doctor specialized in the study of sleep. Thus, sleep-stage classification based on PSG will be considered the "gold standard" for this study.

The data will be pseudonymized at the moment they are recorded; thus, the confidentiality of the data collected, and the anonymity of each participant will be maintained. Once the project has ended, each participant's data will be stored for future studies if they provide consent.

2.8. Data Analysis

The analysis will be performed by using the statistical software R. Numeric variables will be expressed as mean (M) and standard deviation (SD), including the range, minima, and maxima. Beyond simple data and study variable descriptions, inferential analysis will be performed in order to determine possible significant relationships between the variables of the study.

A paired-sample Student's t-test will be used to compare the means of the different sleep parameters of interest. T-test effect sizes are 0.2 (small effect), 0.5 (moderate effect), and 0.8 (large effect), so if the means of two groups do not differ by a 0.2 standard deviation, the difference is trivial, even if there is a statistically significant relationship [62]. Bland–Altman plots will be used to assess the concordance between both devices for each of the sleep parameters (total sleep time, sleep efficiency, and wake after sleep onset). A positive bias indicates that the device tends to underestimate a variable when compared with PSG. A negative bias indicates that a sleep variable is overestimated [63]. Point estimations will be calculated, as well as their 95% confidence interval.

An epoch-by-epoch (EBE) (min × min) analysis will be performed in order to calculate the sensitivity (the proportion of epoch segments identified as a sleep state by the PSG that are correctly identified by Xiaomi), specificity (the proportion of epoch segments identified as a waking state by the PSG that are correctly identified by the Xiaomi wristband), and the level of agreement between both devices for light sleep identification (the proportion of PSG-classified N1 + N2 stages identified as light sleep by the Xiaomi wristband), deep sleep identification (the proportion of PSG N3 + N4 stages identified as deep sleep by the Xiaomi wristband), and REM sleep identification (proportion of PSG-classified REM stages identified as REM sleep by the Xiaomi wristband) [64]. Data analysis will include the cleaning or preprocessing, description, and processing of the stored data. The final aim of this workflow will be to obtain useful information that can be used for decision-making. During preprocessing, the wrong values of the dataset will be removed or corrected to avoid bias in the results. Subsequently, obtaining a descriptive statistic study that summarizes relations and distributions in a simple way will help us to know which processing strategy needs to be taken. When processing, information extraction will be performed.

2.9. Ethics and Dissemination

This study protocol was approved by the A Coruña-Ferrol Research Ethics Committee, under the number 2020/318, on 20 July 2020. In addition, this protocol was registered in Clinical Trials Protocol Registration and Results system on 23 September 2020, available at https://clinicaltrials.gov/ct2/show/NCT04568408. In case any change in the protocol is needed, this will be communicated to the ethics committee with the assigned reference number. These modifications will also be updated in the clinical trials registry.

For each participant, the process of informed consent will be applied. Participants will receive complete verbal and written information about the characteristics of the study and about the implications derived from their participation in it. An information sheet that they can read slowly will be given to each participant, and they will be able to ask any questions they may have. Once it has been ensured that all participants fully understand the information provided, they will decide on whether or not they wish to participate in the study and, if they decide to participate, agree by signing the informed-consent document. The main researcher will maintain the confidentiality of all data collected and the anonymity of each participant. Thus, the Spanish and European Organic Law on the protection of personal data will be respected at all times [65,66]. The data of the participants will be collected, encoded, and preserved until the end of the study. Once the study is finished, each participant's data will be stored for future studies if they provide consent. The results and conclusions of this study will be disseminated through their publication in influential scientific journals and their presentation at appropriate conferences.

3. Discussion

The validation conducted in this study will allow us to evaluate whether the Xiaomi Mi Smart Band 5 is a device that can be used as a health promoter by allowing sleep self-assessment in the general population. Due to its low price, it is fairly accessible to any user who considers that they may be suffering from a sleep disorder that is potentially worsening their health [32]. Hence, if the data generated by the smart band proves to be reliable, any health professional could evaluate at a glance whether the user is suffering from a sleep disorder, and whether it influences their daily life activities [40,67]. The widespread use of these devices could help users to self-assess their sleep and connect with health professionals in the case of bad sleep quality, which would imply a better prognosis and a longer and higher-quality life expectancy. It is important to highlight some limitations and risks in studies focused on the validation of wearables, since firmware updates may modify the sleep-tracking algorithm, and the intra-wearables' sleep measurements do not perfectly match, even when multiple smart bands worn by the same user are identical.

4. Conclusions

This project contributes to the validation of the sleep data obtained through the Xiaomi Mi Band 5, making a comparison with the PSG data. Therefore, it is intended to determine whether the sleep parameters (TIB, SOL, WASO, SE, light sleep, deep sleep and REM sleep) are correctly measured through the Xiaomi Mi Band 5. The widespread use of these devices by the current society is not expected to replace the PSG. However, the information obtained by the wristbands about sleep is user-friendly in a domestic context, as this sleep data doesn't need to be processed as in the case of the PSG. Thus, the use of these devices can help the population to be able to objectively determine whether they have difficulties in their sleep or not, as well as to promote healthy lifestyle habits, and if necessary, seek the advice of a healthcare professional.

Supplementary Materials: The following are available online athttps://www.mdpi.com/1660-4601/18/3/1106/s1, File S1: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (see in Anexo 3).

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Institutional Review Board Statement: This study was approved by the Research Ethics Committee of A Coruña-Ferrol (ref. 2020/318).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the participants to publish this paper.

Data Availability Statement: Once the data collection process is finished and these have been coded, structured, and analyzed, these data will be provided, provided that the Spanish Data Protection Agency consents, to any researcher who contacts the TALIONIS group's Principal Investigator, Javier Pereira.

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Conflicts of Interest: The authors declare that they have no competing interests.

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4.2. Quality of sleep data validation from Xiaomi Mi Band 5 compared with Polysomnography

4.2.1. Resumen extendido en castellano

Este manuscrito es un artículo original, pendiente de publicarse en la revista JMIR, presenta los resultados obtenidos del estudio de validación del dispositivo Xiaomi Mi Band 5 en comparación con la técnica de la PSG. La muestra de esta investigación fue de 58 personas. Sin embargo, solo se incluyeron en el análisis los datos de 45 participantes (mayoritariamente hombres con una edad media de 53,24 ± 15,44 años), debido a la falta de datos válidos en los/as 13 participantes restantes.

Además, las personas participantes fueron divididas en dos grupos en función de la presencia en ellas de trastornos del sueño, NoSDis (sin problemas del sueño, n = 20) y SDis (con problemas del sueño, n = 25). Así, el análisis de los datos fue realizado con la totalidad de los/as participantes, por un lado, y, por otro, con los grupos que se establecieron en base a la presencia o no de un trastorno del sueño.

Con relación al procesamiento de los datos, se siguieron las recomendaciones y guías del estándar del *American National Standards Institute* y la *Consumer Technology Association* (ANSI/CTA Standard). Estas guías señalan que el análisis de validación de un dispositivo debe efectuarse con los datos de las etapas del sueño fraccionadas en épocas de 30 segundos. La PSG registra el estado del sueño en épocas de 30 segundos durante todo el período del ciclo; no obstante, los datos del sueño que ofrece la pulsera Xiaomi, tanto en su aplicación como en los archivos .CSV, son la duración total de cada etapa del sueño durante su ciclo.

Por tanto, el equipo investigador tuvo que procesar de nuevo los datos de ambos dispositivos, con el objetivo de obtener un análisis lo más preciso posible. Así, los datos fueron tratados de nuevo mediante la transformación de los archivos al formato *European Data Format*+ (EDF+) a través de un script, creado en Python con el uso de la biblioteca Python PYEDFlib. Concretamente, la obtención de los datos de la Xiaomi Mi Band en épocas de 30 segundos, se construyó en función del inicio del sueño, fijado en la PSG, y el apagado y encendido de luces, datos registrados e incluidos en el informe de la unidad del sueño.

Tras la obtención de los informes, las etapas, los parámetros y las medidas resumidas del sueño fueron analizadas en el programa estadístico R. Así, la primera prueba que marca la validación es la comparación de las medidas resumidas del sueño de ambos instrumentos mediante la prueba t-test. En este primer análisis, cabe destacar la obtención de resultados similares entre el dispositivo Xiaomi y la PSG en las variables del sueño "inicio del sueño", duración total del periodo de sueño (*total sleep period duration*, TSPD) y latencia de inicio del sueño (*sleep onset latency*, SOL) en la totalidad del grupo. Específicamente, se destacan resultados similares entre ambos dispositivos en el tiempo total del sueño (*total sleep time*, TST), tiempos de vigilia posterior al inicio del sueño (*wake time after sleep onset*, WASO) y el sueño profundo en el grupo NoDis; y en SOL y el sueño ligero en los/as participantes con trastorno del sueño.

En general, los resultados de la prueba *Bland-Altman* refirieron una sobreestimación de las medidas TST, eficiencia del sueño (*sleep efficiency*, SE), sueño ligero y el sueño profundo de la PSG por parte del dispositivo Xiaomi. Por el contrario, los resultados muestran una subestimación de la Xiaomi Mi Band 5 en las variables WASO y el sueño de movimiento ocular rápido (*rapid eyes movements*, REM) de la PSG.

En relación con los resultados obtenidos en la prueba *Epoch by epoch* (EBE) mediante el script en Python, la pulsera Xiaomi presentó, de forma general, mayor precisión (capacidad para detectar las etapas de sueño-vigilia) y sensibilidad (capacidad para detectar las etapas de sueño) que especificidad (capacidad para detectar las etapas de vigilia) en la detección de las etapas del ciclo sueño-vigilia.

En comparación con la literatura existente, se observa que los resultados obtenidos entre la pulsera Xiaomi Mi Band 5 y la PSG son similares a los estudios comparativos realizados con los dispositivos Fitbit HR, Fitbit Charge 2 o Jawbone UP. Específicamente, las diferencias entre el dispositivo Xiaomi y la PSG son menores en algunas medidas resumidas, en comparación con estos dispositivos. Además, se destaca que los resultados obtenidos en el grupo NoSDis fueron generalmente más precisos que en el grupo SDis. En este sentido, la pulsera Xiaomi Mi Band 5 podría ser una herramienta para la gestión de la salud en la población sin trastornos del sueño. No obstante, son necesarios más estudios que comparen este dispositivo con el estándar de oro, la PSG, en diferentes poblaciones con y sin trastornos del sueño, para conocer su precisión y fiabilidad.

4.2.2. Artículo original

Quality of sleep data validation from Xiaomi Mi Band 5 compared with Polysomnography

Abstract: Background: Polysomnography is the gold standard for measuring and detecting sleep patterns. In recent years, activity wristbands have become popular because they record continuous data in real time. Thereby, comprehensive validation studies are needed to analyze the performance and reliability of these devices in the recording of sleep parameters. Objective: This study compared the performance of one of the best-selling activity wristbands, the Xiaomi Mi Band 5, against polysomnography in measuring the sleep stages. Methods: This study was carried out in a hospital in A Coruña, Spain. People who attended to perform a polysomnography study in a sleep unit were recruited to wear a Xiaomi Mi Band 5 simultaneously for one night. The total sample was 45 adults with and without sleep disorders. Results: Overall, the Xiaomi Mi Band 5 had 78% accuracy, 89% sensitivity, 35% specificity, and 0.22 Cohen's kappa. It significantly overestimated polysomnography total sleep time, "light sleep" (N1+N2), and "deep sleep" (N3). In addition, it underestimated polysomnography wake after sleep onset and rapid eye movement sleep. Moreover, the Xiaomi Mi Band 5 performed better in people without sleep problems than people with sleep problems, specifically in detecting total sleep time and "deep sleep". Conclusions: The Xiaomi Mi Band 5 can be a potential device to monitor sleep and to detect changes in sleep patterns, especially for people without sleep problems. Moreover, additional studies are necessary with this device in people with different types of sleep disorders. Trial Registration: NCT04568408. Available: https://clinicaltrials.gov/ct2/show/NCT04568408 (Registered September 23, 2020).

Keywords: sleep; health promotion; occupation; polysomnography; Xiaomi Mi Band 5; internet of things

1. Background

In recent years, technological advances have made it possible to carry out diverse daily tasks, such as health management, more quickly, efficiently, and immediately [1,2]. In this context, the Internet of Things (IoT) is revolutionizing the health care system, allowing daily users to monitor their health status in real time through items such as wearable devices [2]. Thus, the IoT has spurred a digital social transformation resulting from changes in lifestyle patterns through the connection between everyday life and communication networks [3].

Activity wristbands have become more popular among consumers due to their usefulness, affordability, and attractive design [4]. Sales of these device have risen in recent years, with approximately 65.1 million units sold worldwide [5]. The technology industry has moved to brand these devices as an increasingly rigorous alternative to measure biomedical parameters [4]. Scientific evidence indicates that these wristbands can promote participatory medicine because they encourage people to be active agents in their health management [6]. Moreover, several studies consider that these devices can help stakeholders to become more aware of their health status and to improve their healthy lifestyle habits [7,8].

Activity wristbands can collect a myriad of daily health information in the user's free-living environments [9,10]. Although these devices were designed primarily to record physical activity, companies are increasingly focused on developing algorithms that record other variables such as sleep and its patterns [9,10]. So, the use of wristbands not only aims to monitor sleep patterns, but also contributes to make the population more aware of sleep relevance [11,12]. In this sense, it is important to know the details of sleep in the population because it is a vital part of daily life and a determinant of health and well-being [13-15].

Polysomnography (PSG) represents the reference method to measure sleep patterns. Its objective is the diagnosis of sleep problems by assessing the quality and quantity of sleep [16,17]. However, PSG is limited to the clinical setting due to its cost, invasiveness, the need for specialized professionals, and difficulty functioning in the user's free-living environment [15,18]. Thereby, clinicians consider actigraphy to be a common alternative to address the PSG drawbacks [19,20]. Several studies have compared actigraphy with PSG, showing that the former provides high sensitivity in detecting sleep epochs but low specificity in detecting wakefulness [20-22]. Actigraphy has poor accessibility, and a lack of feedback to users hinders its daily use in the general population [11,20]. Nevertheless, it is a validated and accepted tool for detecting certain sleep disorders at the clinical and research levels [15,21].

Based on actigraphy, activity wristbands can combine movement signals from the accelerometer and heart rate (HR) variability from sensors to detect sleep-wake cycles [23,24]. Recently, some sleep researchers have considered these devices to be a potential compliment to traditional sleep assessment methods, as they can sense long-term variations in the circadian rhythm and sleep quantity [4,25,26]. However, previous evidence indicates that the sleep data recorded by these devices are unreliable because they do not accurately detect sleep stages, being more precise in detecting sleep than wakefulness [9,19,27]. Hence, health professionals have stated that data from these devices can lead to excessive concern in consumers about getting optimal sleep, a phenomenon known as "orthosomnia" [28,29]. In addition, the lack of access to the raw data and algorithms used for sleep parameter measurements raises doubts about their use in clinical and research settings [4,27,30].

Given the above-mentioned limitations, sleep health entities, such as the American Academy of Sleep Medicine (AASM), consider it necessary to perform validation studies of activity devices to evaluate their performance and reliability against PSG, which is the gold standard [4,31,32]. In this view, it is relevant that validation studies follow some criteria to assess these devices, such as the

ANSI/CTA standard [33]. This standard is based on two levels of compliance to test how the devices classify sleep and wake stages and how they classify sleep stages (wake, rapid eye movement [REM] sleep, "light sleep," and "deep sleep") [33].

Few studies have analyzed the sleep data performance of activity wristbands. Most of these studies focused on validation of the Fitbit [34-37], Jawbone UP [10,38], and Õura ring [39,40] devices. In general, compared with PSG these devices have good accuracy in sleep versus wake differentiation (between 65% and 91%) and high sensitivity (between 96% and 97%) but low specificity (between 42% and 51%) [10,34-39]. These devices overestimate PSG total sleep time (TST) and sleep efficiency (SE), but they underestimate PSG wake after sleep onset (WASO) and sleep onset latency (SOL) [10,34-39,41,42].

Some of these validated devices can also identify sleep stages. The Fitbit Charge 2 overestimates PSG N1+N2 sleep and underestimated N3 sleep [36,37]. However, the Õura ring overestimates PSG REM sleep and underestimates N3 sleep [39]. Additionally, the authors of some comparative studies claim that it is essential to know the performance of these devices in people with sleep disorders, considering that most studies have only included healthy populations [23,34,36]. Kahawage *et al.* [34] and Moreno-Pino *et al.* [36] used the Fitbit Alta HR in a population with obstructive sleep apnea (OSA) and insomnia. Both studies showed similar concordance against PSG, with high sensitivity and low specificity [34,36].

According to the literature, it is necessary to continue testing the validity of wearable devices [11,30]. Therefore, this research focused on the Xiaomi Mi Band (Xiaomi Inc., Pekin, China), which is one of the most popular activity wristbands on the market due to its low cost and suitable quality [4,5]. The Xiaomi Mi Band is not a device that is frequently used in scientific research, unlike other devices, such as those manufactured by Fitbit [4,7,9]. However, recent studies have used the Xiaomi Mi Band as an objective tool to record physical activity and sleep in older populations [43-45] and work environments [46,47]. Moreover, previous research compared the sleep data of the Xiaomi devices, specifically the Xiaomi Mi Bands 2 and 3, with other devices, concluding that the Xiaomi devices do not correctly identify the TST and WASO periods [9,30]. Nevertheless, researchers have not comprehensively assessed the Xiaomi Mi Band against PSG and specifically analyzed how it records sleep stages in people with and without sleep disorders. Therefore, this study is the first to address validation of the Xiaomi Mi Band 5 against PSG.

This study aimed to compare the performance of the Xiaomi Mi Band 5 in measuring the sleep-wake stages compared with PSG performed in a hospital sleep unit. The secondary objectives were: (1) to determine the agreement between sleep measures from PSG and the Xiaomi Mi Band 5; (2) to assess the accuracy, specificity, and sensitivity for classifying sleep and wake stages by the Xiaomi Mi Band 5 compared with PSG; and (3) to determine the performance level of the Xiaomi

Mi Band 5 for detecting sleep stages (wake, "light sleep", "deep sleep", and REM sleep) compared with PSG.

2. Methods

2.1. Participants

This study was carried out from August 2020 to December 2021. Participants were recruited from the sleep unit of a hospital located in A Coruña, Spain. These people attended the sleep unit to perform a PSG study independent of this project; it was intended to detect possible sleep alterations. All participants had access to a study information sheet and gave written informed consent for their participation. The study was approved by the A Coruña-Ferrol Ethics Committee, with approval number is 2020/318. In addition, the protocol study was registered in the Clinical Trials Protocol Registration and Results System (NCT04568408) and published in an international journal, where the design and recruitment process of the study is detailed [48]. The research group maintained anonymization of all data recorded and obtained from each participant, following and respecting the European (UE 2018/1725) and Spanish (BOE-A-2018-16673) laws on personal data protection at all times.

Fifty-eight people participated in the Xiaomi Mi Band 5 validation project. However, data from 13 participants of the study were not used in the sleep analysis due to different factors such as Xiaomi device malfunction (n = 10), not meeting the inclusion criteria (n = 2), or did not perform a PSG (n = 1). Therefore, the final sample comprised 45 people (23 males, age 23-81 years, mean 53.24 (15.44) years, body mass index [BMI] 27.86 (4.44) kg/m2). Of those participants, 25 were diagnosed with a sleep disorder after they had undergone PSG. Sleep diagnoses were OSA syndrome (n = 18), insomnia (n = 4), narcoleptic syndrome (n = 1), a combination of hypersomnia and narcoleptic syndrome (n = 1), and a combination of sleep apnea syndrome and hypoventilation syndrome (n = 1). For this reason, sleep measures were also analyzed in two groups according to whether there was a sleep disorder. The demographic characteristics of the "no sleep disorders" ("No SDis") (n = 20) and the "sleep disorders" ("SDis") (n = 25) groups are shown in Table 2-1.

Table 2-1. Sample Characteristics

Characteristics	No SDis group	SDis group
	N (%)/Mean (SD)	**N (%)/Mean (SD)**
Sex (females/males)	12/8	10/15
Age, years	49.7 (14.22)	56.08 (16.06)
BMI (Kg/m^2)	26.55 (3.67)	28.91 (4.79)
PSQI	10.30 (4.66)	9.8 (4.07)

BMI, body mass index; PSQI, Pittsburgh Sleep Quality Index; SDis, sleep disorder; SD, standard deviation.

2.2. Procedure

All participants slept in the sleep unit for one night. On the day of the recording, participants did not drink liquid for 3 hours before PSG, and they attended the sleep unit a few hours before to become acquainted with the bedroom. The technical team of the sleep unit was in charge of supervising, preparing the participant for PSG, and meeting the possible demands of participants. Regarding PSG, the technicians placed the sensors with electrode gel on the participants and connected them to start the test. Participants wore the Xiaomi Mi Band 5 during the recording test, and its location on the wrist was noted by the technicians. During the registration, the technical team supervised PSG and the Xiaomi device worn by the participant, making notes and marking alterations that emerged throughout the night for subsequent analysis. The lights-out and lights-on times, the temperature, and the sound were controlled in the room by the technicians. PSG and Xiaomi data were collected and synchronized simultaneously. The data coincided with the lights-off and lights-on times, providing a record of approximately 8 hours of time in bed (TIB).

2.3. Polysomnography

PSG was performed using the NicoletOne EEG (NATUS Medical Incorporated, CA, USA). This device uses several recordings that included an electroencephalogram (EEG) (6 lead: FP1/FP2, F3/F4, C3/C4, O1/O2 referenced by the contralateral mastoid); a submental (P3, P4) and bilateral anterior tibial (2 electrodes on each leg to assess leg movements); electromyogram (EMG); a bilateral electrooculogram (EOG); and an electrocardiogram (ECG) [16]. EEG, EMG, EOG, and ECG signals were sampled at 256 Hz. The EEG and EOG signals were filtered at 0.3-35 Hz, the EMG signal was filtered at 10-100 Hz, and the ECG signal was filtered at 0.3-70 Hz. At the same time, other biomedical parameters such as respiratory movements and efforts (thoracic and abdominal bands), nasal and oral airflow (nasal cannula), arterial oxygen saturation (pulse oximeter), cardiac activity, and body movement band were recorded to provide relevant information for a potential sleep disturbance diagnosis [16]. PSG parameters were interpreted by the specialized doctor of the sleep unit to obtain the cycles and stages of sleep (wake time, N1, N2, N3, and REM sleep) and was scored in 30-second epochs according to the standards of the AASM [49].

2.4. Xiaomi Mi Band 5

The Xiaomi Mi Band 5 includes an accelerometer (3-axis), a gyroscope (3-axis), an HR sensor, and a ppg sensor to measure some biomedical parameters. This device contains updated software that records daily activity (e.g., steps, distance, activity time, and calories), sleep (e.g., light sleep, deep sleep, REM sleep, wake, TST, start and end of the sleep period, and naps), and HR continuously [50]. The device also calculates and classifies the stress level (classification in the terms "relaxed," "mild," "moderate," and "high") through HR data. In addition, the wristband requires a series of personal data such as age, gender, weight, height, handedness, and wristband location. The Xiaomi Mi Band connects to its application, the Zepp Life app, via Bluetooth, where the recording data is transferred and displayed [50]. The Zepp Life app allows the export of activity data (broken down into total activity, minute-by-minute activity, and activity stage), total sleep data (start and end sleep period, WASO, "light sleep", "deep sleep", and REM sleep), HR data (broken down into total HR; minimum, maximum, and mean HR; and minute-by-minute HR), sports data, and body data in CSV files [50]. In the current study, some modes of the Xiaomi device were activated, such as automatic HR, sleep assistant, and night mode, to obtain accurate data and to not disturb the participant. Moreover, there were no problems with the charging or with the wristband battery.

2.5. Processing of the data from PSG and Xiaomi Mi Band 5

The Xiaomi Mi Band 5 and PSG source data were originally available in different formats. The Xiaomi Mi Band 5 data were collected from the Zepp Life app manually and exported to an Excel sheet, as Xiaomi's app did not allow downloading the raw data from the wristband. PSG data, on the other hand, consisted of CSV text files that contained the manually scored sleep stages, and the corresponding reports with clinical sleep diagnostic parameters, available in Word format, both exported using the NicoletOne EEG software. Hence, to enable performance analysis, data were transformed to a common format using the European Data Format + (EDF+) [51]. For this purpose, a Python script (version 3.10.5; Python Software Foundation, the Netherlands) was developed with help of the PyEDFlib library [52].

To carry out this process, "Start time," "lights off," "lights on," and "end of the test" markers were set according to expert annotations available in the corresponding PSG reports. Sleep stages were coded using EDF+ standard texts following the AASM guidelines [49]. For the Xiaomi data, it was necessary to adjust the resolution to standard 30-second epochs as the device originally reports on the basis of 1-minute periods only. This was achieved by splitting each 1-minute epoch into two corresponding epochs of 30 seconds sharing the same sleep stage. Likewise, the Xiaomi hypnogram information does not consider N1 and N2 stages separately. For this reason, epoch-by-epoch (EBE) performance analysis was carried out using a four-way classification (wake, light sleep, deep sleep/N3, and REM) by merging the corresponding N1 and N2 labels from PSG in the corresponding "light sleep" category. Performance analysis was carried out using information within the TIB periods. It should be noted that the Xiaomi Mi Band 5 only starts reporting after the first sleep period is identified by the device, therefore assuming that periods before (after) the first (last) sleeping periods detected by the device within TIB are scored as wakefulness.

After this process, and using the corresponding EDF+ annotation files, different standard sleep parameters were calculated and compared [53]. More specifically, TIB (minutes), total sleep period duration (TSPD) (minutes, a measure containing the duration of both sleep and wake cycles), TST (minutes), WASO (minutes), Awakenings (number), SOL (minutes), SE (%), "light sleep" (minutes), "deep sleep" (minutes), REM sleep (minutes), and awake (minutes) were analyzed for both instruments in this study. Normative values for some of these parameters have been proposed based on consensus of a panel of experts in regard to objective assessment of sleep quality [41].

2.6. Statistical Analysis

Statistical analysis was performed using R Version 4.1.2 (GNU project: Auckland). The analysis was carried out with the total sample (n = 45). Likewise, data were analyzed with the participants grouped depending on the existence of a sleep disorder to determine the differences between PSG and the Xiaomi Mi Band 5.

Summary measures of PSG and the Xiaomi Mi Band 5 equivalents were compared using the paired t-test [54] and the Mann-Whitney-Wilcoxon test [54]. The choice of the test was based on whether the data were normally distributed, determined by using the Shapiro-Wilk normality test. Normally distributed data were analyzed by the parametric t-test, while non-normally distributed data were analyzed by the Mann-Whitney-Wilcoxon test. Moreover, the effect size was measured using Cohen's d, classified as 0.2 (small effect), 0.5 (moderate effect), and 0.8 (large effect) [54].

Furthermore, the Bland-Altman method was employed to determine the agreement between PSG and the Xiaomi Mi Band 5 for each the sleep parameter. The mean difference (or bias) between the methods, the standard deviation, the 95% confidence interval [CI], and the lower and upper agreements limits (mean difference (±1.96 standard deviations [SD]) were calculated. A positive bias indicates that the Xiaomi Mi Band 5 tends to underestimate a variable when compared with the gold standard (i.e., PSG). A negative bias indicates that a sleep variable is overestimated [55].

EBE analysis was performed according to the two levels of compliance by the ANSI/CTA performance evaluation guidelines [33]. The first level analyzed the performance of the devices in a 2-way classification for detecting sleep-wake stages using a confusion matrix. For this purpose, accuracy (proportion of correctly classified sleep and wake epochs), sensitivity (proportion of epoch segments identified as sleep by Xiaomi Mi Band 5 of those classified as sleep by the PSG), specificity (proportion of epoch segments identified as wake by Xiaomi Mi Band 5 of those classified as wake by the PSG), and Cohen's kappa (agreement corrected by chance between the two devices) were analyzed [33]. The standard label definitions used to classify Cohen's kappa were used: 0-0.2 (slight); 0.21-0.40 (fair); 0.41-0.60 (moderate); 0.61-0.80 (substantial); and >0.80 (almost perfect) [56]. The second level analyzed how the device detected sleep stages using a 4-way classification (wake, REM sleep, "light sleep," and "deep sleep"). For this purpose, accuracy and Cohen's kappa were analyzed [33].

3. Results

3.1. Comparison PSG and Xiaomi Mi Band 5 sleep measures

The sleep parameters obtained from PSG and the Xiaomi Mi Band 5 were compared with Student's t-test or the Mann-Whitney-Wilcoxon test. Table 2-2 provides the sleep outcomes for PSG and the Xiaomi Mi Band 5 in the total sample. Overall, there were no significant differences between the methods in the "initial sleep onset," TSPD, and SOL measures. However, the Xiaomi Mi Band 5 significantly overestimated PSG TST (z = -2.73; P = 0.009), the percentage of PSG SE (z = -2.59; P = 0.032), PSG "light sleep" (t = -2.49; P = 0.005), and PSG "deep sleep" (t = -2.58; P = 0.013). It also underestimated PSG WASO (z = 2.96; P = 0.005), PSG awakenings (z= 7.72; P = 0.001), PSG REM sleep (t = 3.59; P = 0.001), and PSG awake (z = 2.61, P = 0.012).

Table 2-2. Comparison of polysomnography (PSG) and Xiaomi Mi Band 5 sleep measures in the total sample

	PSG		Xiaomi Mi Band 5		t	z	*P*	d
	Mean (SD)	±95% CI	Mean (SD)	±95% CI				
Lights-on (hh:mm)	07:01 (00:17)	06:56-07:10	-	-	-	-	-	-
Lights-off (hh:mm)	23:36 (00:40)	22:29-01:03	-	-	-	-	-	-
Initial sleep onset (hh:mm)	00:29 (01:31)	22:47-01:33	00:11 (01:05)	23:55-00:31	1.12	**-**	**0.266**	0.208*
TIB (minutes)	443.58 (44.98)	430.07-457.1	-	-	-	-	-	-
TSPD (minutes)	408.05 (57.13)	390.88-425.23	406.16 (51.27)	390.75-421.56	0.28	-	**0.778**	0.250*
TST (minutes)	344.62 (79.58)	320.71-368.53	374.17 (72.42)	352.42-395.93	-	-2.73	0.009	-0.407*
WASO (minutes)	63.42 (57.42)	46.17-80.68	31.99 (51.64)	16.47-47.50	-	2.96	0.005	0.442*
Awakenings (> 5 minutes) (number per night)	3.64 (2.27)	4.33-2.96	0.69 (0.94)	0.97-0.40	-	7.72	0.001	1.15***
SOL (minutes)	31.64 (33.97)	21.43-41.84	40.26 (42.59)	27.47-53.06	-	-1.07	**0.288**	-0.206*
SE (%)	78.32 (16.56)	73.35-83.30	84.14 (15.70)	79.42-88.86	-	-2.59	0.032	-0.329*
Time in N1 (minutes)	12.65 (9.21)	9.9-15.42	-	-	-	-	-	-
Time in N2 (minutes)	202.14 (57.47)	184.87-219.40	-	-	-	-	-	-
Time in N1+N2 ("light sleep") (minutes)	214.79 (55.12)	198.23-231.35	244.62 (56.59)	227.61-261.62	-2.49	-	0.005	-0.439*
Time in N3 ("deep sleep") (minutes)	60.72 (29.41)	51.88-69.56	75.37 (31.73)	65.83-84.90	-2.58	-	0.013	-0.385*
Time in REM (minutes)	69.11 (28.08)	60.67-77.54	49.61 (30.7)	40.01-59.22	3.59	-	0.001	0.536**
Awake (minutes)	94.86 (71.88)	116.46-73.27	66.51 (66.22)	86.40-46.61	-	2.61	0.012	0.390*

CI, confidence interval; REM, rapid-eye-movement; SE, sleep efficiency; SOL, sleep onset latency; TIB, time in bed; TSPD, total sleep period duration; TST, total sleep time; WASO, wake after sleep onset.
t values correspond to t-tests. z values correspond to the Mann-Whitney-Wilcoxon test. d values correspond to Cohen's d: small effect (*), moderate effect (**), or large effect (***).

Table 2-3 shows the results of sleep measures for the devices in the "No SDis" and "SDis" groups. There were no significant differences between PSG and the Xiaomi Mi Band 5 for the "initial sleep onset" and TSPD variables in either group. However, the Xiaomi Mi Band 5 differed significantly from PSG in the rest of the sleep measures depending on whether the participants presented or did not present sleep disorders. In the "No SDis" group, this device overestimated PSG SOL (z = -1.83; P = 0.046) and PSG "light sleep" (t = -3.23; P = 0.004), and it underestimated PSG awakenings (z = 5.50; P = <0.001) and PSG REM sleep (t = 2.66; P = 0.015). In contrast, in the "SDis" group it overestimated PSG TST (z = -2.70; P = 0.007), PSG SE (z = -2.19; P = 0.028), and PSG "deep sleep" (t = -3.97; P = 0.000), and it underestimated PSG WASO (z = 2.35; P = 0.019), PSG awakenings (z = 5.35; P = <0.001), PSG REM sleep (t = 2.37; P = 0.026), and PSG awake time (z = 3.13; P = 0.005).

Table 2-3. Comparison of polysomnography (PSG) and the Xiaomi Mi Band 5 sleep measures in the no sleep disorders ("No SDis") and sleep disorder ("SDis") groups

		PSG		**Xiaomi Mi Band 5**		t	z	*P*	d
		Mean (SD)	±95% CI	Mean (SD)	±95% CI				
Lights-on (hh:mm)	*No SDis*	07:02 (00:11)	06:57-07:07	-	-	-	-	-	-
	SDis	07:01 (00:45)	06:52-07:10	-	-	-	-	-	-
Lights-off (hh:mm)	*No SDis*	23:32 (00:48)	23:09-23:54	-	-	-	-	-	-
	SDis	23:42 (00:32)	23:28-23:55	-	-	-	-	-	-
Initial sleep onset (hh:mm)	*No SDis*	00:37 (02:00)	23:41-01:33	00:10 (00:56)	23:43-00:37	0.91	-	**0.374**	0.204*
	SDis	00:22 (01:02)	23:56-00:48	00:12 (01:13)	23:42-00:43	0.64	-	**0.523**	0.230*
TIB (minutes)	*No SDis*	446.66 (50.37)	423.09-470.24	-	-	-	-	-	-
	SDis	441.12 (41.06)	424.16-458.07	-	-	-	-	-	-
TSPD (minutes)	*No SDis*	442.80 (42.35)	402.97-442.62	410.56 (50.66)	386.84-434.27	2.12	-	**0.474**	0.475*
	SDis	396.26 (65.11)	369.38-423.13	402.64 (52.51)	380.96-424.32	-0.58	-	**0.567**	-0.508**
TST (minutes)	*No SDis*	363.55 (68.20)	331.63-395.47	378.26 (70.98	345.04-411.49	-0.83	-	**0.414**	-0.208*
	SDis	329.48 (85.97)	293.99-364.97	370.90 (74.84)	340-401.79	-	-2.70	0.007	-0.625**
WASO (minutes)	*No SDis*	59.25 (56.44)	32.83-85.66	32.30 (54.31)	6.87-57.71	-	1.98	**0.123**	0.361*
	SDis	66.77 (59.14)	42.36-91.18	31.75 (50.53)	10.89-52.61	-	2.35	0.019	0.504**
Awakenings (>5 minutes) (number per night)	*No SDis*	3.90 (2.38)	5.01-2.78	0.65 (0.98)	1.11-0.18	-	5.50	<.001	1.20***
	SDis	3.44 (2.22)	4.35-2.52	0.72 (0.93)	1.10-0.33	-	5.35	<.001	1.07***
SOL (minutes)	*No SDis*	26.47 (15.19)	19.36-33.58	38.75 (32.46)	23.56-53.95	-	-1.83	0.046	-0.478*
	SDis	35.78 (43.50)	17.82-53.73	41.48 (49.88)	20.89-62.07	-	-0.25	**0.797**	-0.474*
SE (%)	*No SDis*	81.02 (13.67)	74.63-87.42	84.61 (15.24)	77.47-91.74	-	-1.46	**0.368**	-0.206*
	SDis	76.17 (18.56)	68.51-83.83	83.77 (16.36)	77.02-90.53	-	-2.19	0.028	-0.421*
Time in N1 (minutes)	*No SDis*	13.85 (10.05)	9.14-18.55	-	-	-	-	-	-
	SDis	11.70 (8.56)	8.16-15.23	-	-	-	-	-	-

Table 2-3. Comparison of polysomnography (PSG) and the Xiaomi Mi Band 5 sleep measures in the no sleep disorders ("No SDis") and sleep disorder ("SDis") groups. (Continued)

		PSG		Xiaomi Mi Band 5		t	z	*P*	d
		Mean (SD)	±95% CI	Mean (SD)	±95% CI				
Time in N2 (minutes)	*No SDis*	198.74 (52.72)	174.06-223.42	-	-	-	-	-	-
	SDis	204.86 (61.95)	179.28-230.43	-	-	-	-	-	-
Time in N1+N2 ("light sleep") (minutes)	*No SDis*	212.59 (48.09)	190.08-235.10	254.63 (52.78)	229.93-279.33	-3.23	-	0.004	-0.724**
	SDis	216.56 (61.09)	191.34-241.77	236.59 (59.29)	212.12-261.07	-1.34	-	**0.193**	-0.268*
Time in N3 ("deep sleep") (minutes)	*No SDis*	77.05 (20.68)	67.37-86.73	73.88 (30.54)	59.59-88.17	0.42	-	**0.672**	-0.345*
	SDis	47.66 (29.11)	35.64-59.67	76.55 (33.22)	62.84-90.27	-3.97	-	0.000	-0.796**
Time in REM (minutes)	*No SDis*	73.90 (23.56)	62.88-84.94	49.85 (27.20)	37.12-62.58	2.66	-	0.015	0.597**
	SDis	65.26 (31.17)	52.39-78.13	49.43 (35.89)	34.62-64.24	2.37	-	0.026	0.475*
Awake (minutes)	*No SDis*	85.72 (62.81)	115.12-56.33	71.01 (73.04)	105.21-36.83	-	0.83	**0.415**	0.218*
	SDis	102.18 (78.90)	134.75-69.61	60.77 (62.39)	86.53-35.01	-	3.13	0.005	0.625**

CI, confidence interval; REM, rapid-eye-movement; SE, sleep efficiency; SOL, sleep onset latency; TIB, time in bed; TSPD, total sleep period duration; TST, total sleep time; WASO, wake after sleep onset.
t values correspond to t-tests. z values correspond to the Mann-Whitney-Wilcoxon test. d values correspond to Cohen's d: small effect (*), moderate effect (**), or large effect (***).

3.2. Bland-Altman plots

Table 2-4 shows Bland-Altman biases, SD, ±95% CI, and the lower and upper agreement limits. Figure 2-1 provides Bland-Altman plots for the main sleep measures. In the total sample, the Xiaomi Mi Band 5 significantly overestimated PSG TST by 29.54 minutes, PSG SE by 5.82 points, PSG "light sleep" by 29.81 minutes, and PSG "deep sleep" by 14.64 minutes. On the other hand, it underestimated PSG WASO by 31.44 minutes, PSG awakenings by 2.95 epochs, PSG REM sleep by 19.49 minutes, and PSG awake time by 28.36 minutes.

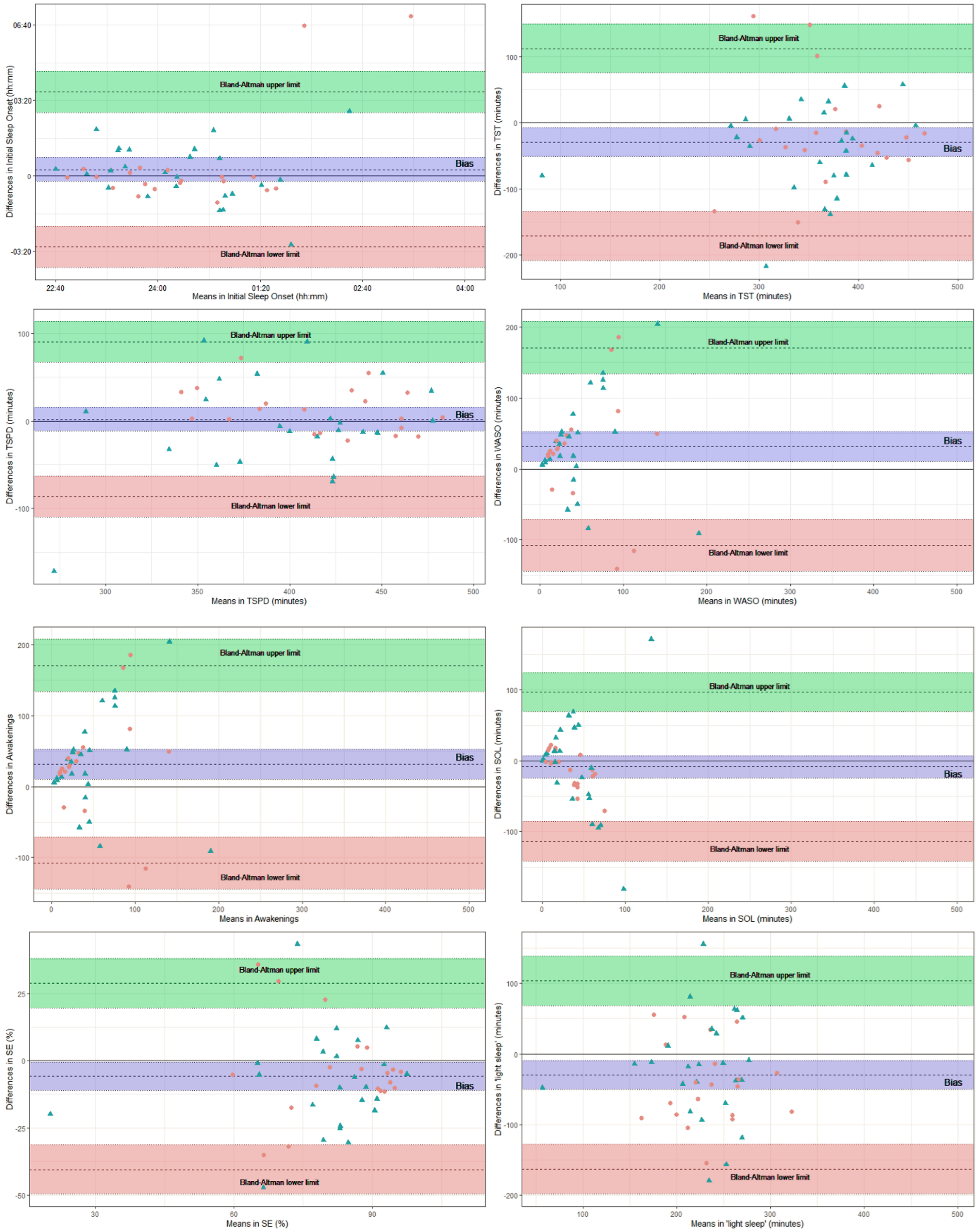
There were also differences between the sleep groups. The Xiaomi Mi Band 5 significantly overestimated PSG "light sleep" by 42.02 minutes and PSG SOL by 12.28 minutes in the "No SDis" group. It also underestimated PSG awakenings by 3.25 epochs and PSG REM sleep by 24.05 minutes in this group. However, in the "SDis" group, the Xiaomi Mi Band 5 overestimated PSG TST by 41.41 minutes, PSG SE by 7.60 points, and PSG "deep sleep" by 28.89 minutes. It underestimated PSG WASO by 35.03 minutes, PSG awakenings by 2.72 epochs, PSG REM sleep time by 15.83 minutes, and PSG awake time by 41.41 minutes.

On average, the Bland-Altman agreement limits were exceeded every four and two participants for the total sample, especially in TST, WASO, Awakening, and SE measures. The participants with sleep problems were the ones that mainly exceeded these aggregation limits.

Table 2-4. Bland-Altman parameters for the comparison between polysomnography (PSG) and the Xiaomi Mi Band 5 in the total sample, and the no sleep disorder ("No SDis") and sleep disorder ("SDis") groups

		Bias (SD)	±95% CI of the Bias	Lower agreement limit	Upper agreement limit	Number of participants exceeding the agreement limits
Initial sleep onset (hh:mm)	*Total sample*	00:17 (01:44)	00:49-00:13	-03:06	03:40	2
	No SDis	00:27 (02:13)	01:29-00:35	-01:36	02:30	2
	SDis	00:09 (01:17)	00:41-00:21	-02:22	02:40	0
TST (minutes)	*Total sample*	-29.54 (72.54)	-7.75-51.33	-171.72	112.63	3
	No SDis	-14.71 (78.94)	-51.66-22.23	-169.44	140.01	1
	SDis	-41.41 (66.20)	-68.73-14.08	-171.18	88.36	2
TSPD (minutes)	*Total sample*	1.89 (44.97)	-11.61-15.40	-86.25	90.04	1
	No SDis	12.24 (25.75)	0.19-24.29	-38.24	62.73	0
	SDis	-6.38 (54.97)	-29.07-16.31	-114.14	101.37	1
WASO (minutes)	*Total sample*	31.44 (71.13)	10.07-52.81	-107.97	170.86	4
	No SDis	26.96 (61.92)	-8-61.93	-119.47	173.40	1
	SDis	35.03 (69.48)	6.35-63.71	-101.15	171.21	3
Awakenings (>5 minutes) (number per night)	*Total sample*	2.95 (2.57)	3.73-2.18	-2.07	3.73	4
	No SDis	3.25 (2.63)	4.48-2.01	-1.91	8.41	3
	SDis	2.72 (2.54)	3.77-1.67	-2.26	7.70	1
SOL (minutes)	*Total sample*	-8.62 (53.76)	-24.77-7.53	-114	96.75	2
	No SDis	-12.28 (25.69)	-24.31-0.26	-62.65	38.08	0
	SDis	-5.7 (68.97)	-34.17-22.77	-140.88	129.48	2
SE (%)	*Total sample*	-5.82 (17.67)	-11.13-0.51	-40.46	28.82	4
	No SDis	-3.85 (17.37)	-11.71-4.54	-37.63	30.46	2
	SDis	-7.60 (18.06)	-15.06-0.14	-43	27.80	2
Time in N1+N2 ("light sleep") (minutes)	*Total sample*	-29.81 (67.98)	-50.24-9.39	-163.07	103.44	2
	No SDis	-42.04 (58.04)	-69.20-14.87	-155.81	71.72	0
	SDis	-20.03 (74.72)	-50.88-10.81	-166.49	126.42	2
Time in N3 ("deep sleep") (minutes)	*Total sample*	-14.64 (59.97)	-26.08-3.20	-89.27	59.98	0
	No SDis	3.17 (33)	-12.28-18.62	-61.53	67.86	0
	SDis	-28.89 (36.32)	-43.88-13.90	-100.08	36.32	0
Time in REM (minutes)	*Total sample*	19.49 (36.40)	8.55-30.42	-51.85	90.84	2
	No SDis	24.05 (40.30)	5.20-42.92	-54.93	103.05	0
	SDis	15.83 (33.34)	2.07-29.60	-49.52	81.20	2
Awake (minutes)	*Total sample*	28.36 (72.69)	50.20-6.52	-114.11	170.84	3
	No SDis	14.71 (78.93)	51.65-22.23	-140	169.43	2
	SDis	41.41 (66.21)	14.08-68.74	-88.36	171.18	1

CI, confidence interval; REM, rapid-eye-movement; SE, sleep efficiency; SOL, sleep onset latency; TSPD, total sleep period duration; TST, total sleep time; WASO, wake after sleep onset.


Bland-Altman upper limit
Bias
Bland-Altman lower limit
Differences in Initial Sleep Onset (hh:mm)
Means in Initial Sleep Onset (hh:mm)
Differences in TST (minutes)
Means in TST (minutes)
Differences in TSPD (minutes)
Means in TSPD (minutes)
Differences in WASO (minutes)
Means in WASO (minutes)
Differences in Awakenings
Means in Awakenings
Differences in SOL (minutes)
Means in SOL (minutes)
Differences in SE (%)
Means in SE (%)
Differences in 'light sleep' (minutes)
Means in 'light sleep' (minutes)

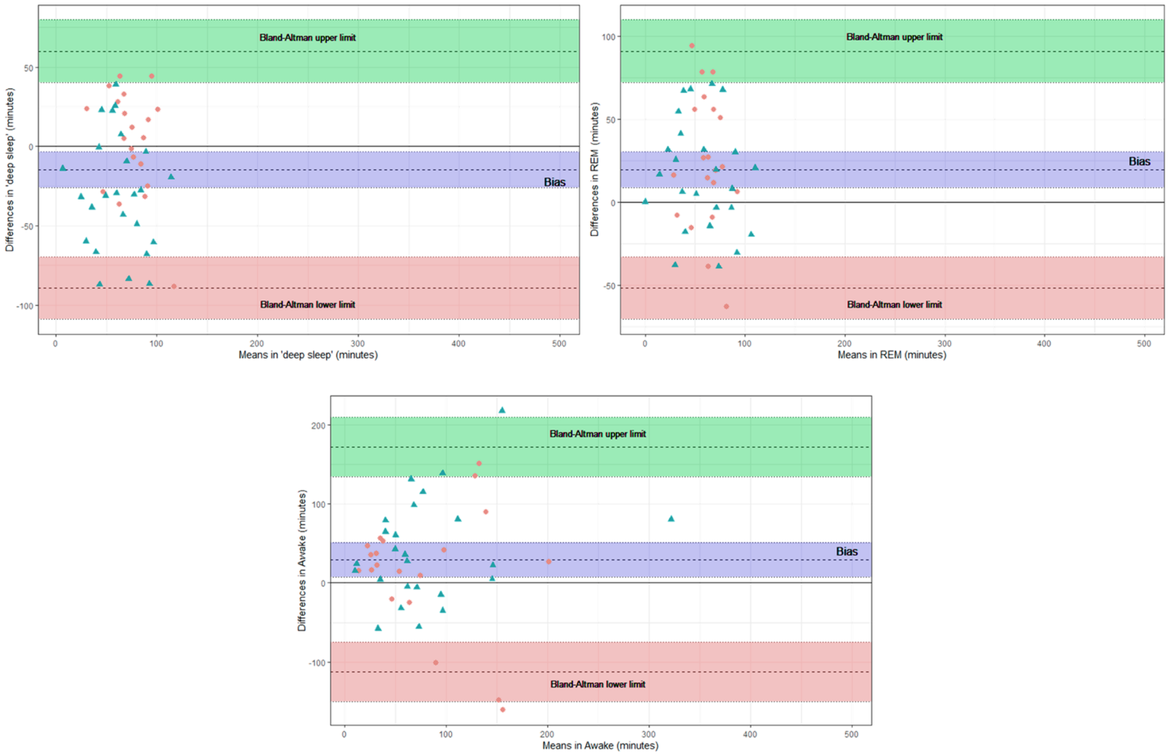


Figure 2-1. Bland Altman Plots for "Initial Sleep Onset", TST, WASO, Awakening, SOL, SE, "light sleep", "deep sleep", REM sleep and Awake time. PSG-Xiaomi Mi Band 5 differences for sleep parameters (y-axis) are plotted as a function of the PSG-Xiaomi Mi Band 5 means (x-axis) for sleep parameters. Circles represent participants without sleep disorders ("No SDis") (n=20), and triangles represent participants with sleep disorders ("SDis") (n=25). Zero lines are marked and represent the perfect agreement. The dotted lines represent the biases and Bland Altman agreement limits (means ±1.96*SD)

3.3. Epoch by Epoch analysis

Table 2-5 shows the confusion matrices resulting from the 2-way (sleep vs. wake) classification of 30-second epochs between PSG and the Xiaomi Mi Band 5 device. Results are shown separately for the total sample as well as for the "No SDis" and the "SDis" groups. The derived metrics of accuracy and Cohen's kappa are shown in Table 2-7.

According to the results, the Xiaomi Mi Band 5 correctly classified both sleep and wake in 30,805 out of the 39,568 (78 %) available epochs. It correctly detected 27,786 out of the 31,024 sleep epochs, thus resulting in 0.89 sensitivity for the sleep class, and it was able to identify 3,019 out of the 8,544 wake stages, leading to corresponding 0.35 specificity for the same class. Because of the binary classification, the respective sensitivity and specificity values for the wake class derive immediately as 0.35 and 0.89. Based on Cohen's kappa, the level of concordance between PSG and the Xiaomi Mi Band 5 was 0.22.

These results were similar in the “No SDis” and “SDis” groups. Xiaomi Mi Band 5 had an accuracy of 0.80 and 0.76 in the “No SDis” and “SDis” groups, respectively. The sensitivity for the sleep class was of 0.89 for both groups, and the corresponding sensitivity was of 0.38 for “No SDis” and 0.33 for the “SDis” group. Cohen’s kappa for the Xiaomi Mi Band 5 was 0.27 in the “No SDis” group and 0.26 in the “SDis” group.

Table 2-5. Confusion matrix for 2-way (wake vs sleep) epoch by epoch classification for a) total sample, b) no sleep disorder (“No SDis”), and c) sleep disorder ("SDis”) groups

a)

		Xiaomi	
		Wake	**Sleep**
PSG	**Wake**	3019	5525
	Sleep	3238	27786

b)

		Xiaomi	
		Wake	**Sleep**
PSG	**Wake**	1305	2117
	Sleep	1528	13018

c)

		Xiaomi	
		Wake	**Sleep**
PSG	**Wake**	1714	3408
	Sleep	1710	14786

Table 2-6 shows the corresponding confusion matrices for the 4-way sleep stage classification between the PSG and the Xiaomi Mi Band 5. In general, the accuracy level was 0.44. More specifically, the agreement with PSG was 0.48 for the detection of wakefulness, 0.51 for “light sleep”, 0.33 for “deep sleep”, and 0.26 for REM sleep. The “No SDis” and “SDis” groups had outcomes similar to the total sample. Moreover, the Xiaomi Mi Band 5 misidentified PSG epochs 40-70% of the time. It should be noted that the Xiaomi device misclassified 3,957 out of the 8,544 (46%) wake epochs and 4,044 out of the 6,221 (65 %) REM stages as “light sleep” in the total sample. In addition, it misclassified 1,945 out of the 2,975 (65 %) and 2,099 out of the 3,264 (64 %) REM epochs in the “No SDis” and “SDis” groups, respectively, as “light sleep”.

Table 2-6. Confusion matrix for 4-way (wake, “light sleep”, “deep sleep” and REM) epoch by epoch classification for a) total sample, b) no sleep disorder (“No SDis”), and c) sleep disorder ("SDis”) groups

a)

		Xiaomi			
		Wake	**“Light sleep”**	**“Deep sleep”**	**REM**
PSG	**Wake**	3019	3957	1020	548
	“Light sleep”	2236	11366	3468	2274
	“Deep sleep”	537	2653	1775	494
	REM	465	4044	519	1193

Table 2 6. Confusion matrix for 4-way (wake, "light sleep", "deep sleep" and REM) epoch by epoch classification for a) total sample, b) no sleep disorder ("No SDis"), and c) sleep disorder ("SDis") groups. (Continued)

b)

		Xiaomi			
		Wake	**"Light sleep"**	**"Deep sleep"**	**REM**
PSG	**Wake**	1305	1630	272	215
	"Light sleep"	872	5142	1438	1055
	"Deep sleep"	422	1469	982	209
	REM	234	1945	263	515

c)

		Xiaomi			
		Wake	**"Light sleep"**	**"Deep sleep"**	**REM**
PSG	**Wake**	1714	2327	748	333
	"Light sleep"	1364	6224	2030	1219
	"Deep sleep"	115	1184	793	285
	REM	231	2099	256	678

Table 2-7 shows that Kappa coefficients for the 4-way epoch classification ranged 0.11-015 for agreement between PSG and the Xiaomi Mi Band 5 among the three groups, indicating that most of the accuracy agreement is due to chance.

Table 2-7. Overall accuracy and kappa statistics for 2-way and 4-way epoch by epoch classification for total sample, no sleep disorder ("No SDis"), and sleep disorder ("SDis") groups

	2-way		**4-way**	
	Accuracy	**Kappa**	**Accuracy**	**Kappa**
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Total sample	0.78 (0.13)	0.22 (0.23)	0.44 (0.10)	0.12 (0.13)
No SDis	0.80 (0.13)	0.27 (0.21)	0.45 (0.10)	0.15 (0.12)
SDis	0.76 (0.12)	0.26 (0.25)	0.43 (0.10)	0.11 (0.14)

Cohen's Kappa (k): 0-0.2 (slight); 0.21-0.40 (fair); 0.41-0.60 (moderate); 0.61-0.80 (substantial); > 0.80 (almost perfect)

4. Discussion

4.1. Main findings

The Xiaomi Mi Band 5 is one of the most popular wristbands among consumers around the world [4,5]. Its use has increased because it can continuously record different parameters such as sleep [4,5]. Nevertheless, it was not developed for clinical or scientific purposes in the diagnosis of sleep disorders or sleep monitoring, a factor that could influence its performance [11,28]. Thus, the authors of this study considered it necessary to determine the quality and accuracy of sleep data obtained from this device, comparing it against PSG performed in a clinical sleep unit. To the authors' knowledge, this is the first study that has validated the ability of the Xiaomi Mi Band 5 device to measure sleep parameters in people with and without sleep disorders.

This study investigated the agreement in sleep measures from PSG and the Xiaomi Mi Band 5. Overall, the Xiaomi Mi Band 5 had some limitations in the detection of several sleep measures. There were no significant differences detected among "initial sleep onset", TSPD, and SOL measures relative to PSG. However, the Xiaomi Mi Band 5 significantly overestimated TST, SE, "light sleep," and "deep sleep". It also significantly underestimated WASO, the number of awakenings, REM sleep and awake time. These results are similar to previous studies that validated activity wristbands such as the Fitbit Alta HR [34], Fitbit Charge HR [57], Fitbit Charge 2 [37], and Jawbone UP [38] devices.

The Bland-Altman analysis showed the biases between the Xiaomi Mi Band 5 and PSG in general, which ranged from 1.89 to 31.44 minutes. Unlike other devices, the Xiaomi Mi Band 5 more accurately estimated some summary measures of sleep relative to PSG (see Multimedia Appendix 1 [Anexo 5]). PSG TST was overestimated by approximately 25-30 minutes more by the Jawbone UP (59.1 minutes) [38] and the Fitbit Alta HR (53.33 minutes) [34] than by the Xiaomi Mi Band 5 (29.54 minutes). Moreover, the Xiaomi Mi Band 5 overestimated PSG "light sleep" by 29.81 minutes, but the Fitbit Charge 2 overestimated it by 34 minutes [37]. Likewise, the Xiaomi Mi Band 5 underestimated PSG WASO by 31.44 minutes and PSG awake time by 28.36 minutes, while the Fitbit Alta HR underestimated WASO by 48.37 minutes and awake time by 41.93 minutes [34,36]. On the other hand, the Fitbit Charge HR underestimated WASO by 5.6 minutes [35] less than the Xiaomi Mi Band 5.

Furthermore, two studies evaluated previous versions of the Xiaomi wristband against other devices. However, the authors did not comprehensively compare the sleep parameters of the Xiaomi devices against PSG. Ameen *et al.* [30] used the Xiaomi Mi Band 2 alongside other devices to determine the reliability of sleep data, concluding that the Xiaomi device overestimated TST by 69.64 minutes and SE by 13.25%, and it underestimated WASO by 33.57 minutes. Topalidis *et al.* [9] compared the Xiaomi Mi Band 3 sleep data with the GT3X scientific actigraphy devices, showing low concordance between the devices in the waking period and TST. Thus, these authors reports result similar to ours, but TST, SE, and WASO sleep measurement estimates by the Xiaomi Mi Band 5 were more accurate than in previous Xiaomi versions [9,30].

The Bland-Altman limits of agreement (Table 2-4) were generally high, especially for the TST, WASO, number of awakenings, and SE variables. These limits are similar to those reported in studies that compared the Jawbone UP or the Fitbit Alta HR with PSG [34,38]. However, they differ from those obtained in the Fitbit Charge 2 wristband or the Õura Ring validation studies, whose limits of agreement were narrower for all sleep measures [37,39]. In the present study, between 8.8 % and 4.4 % of the participants exceeded the limits of agreement, mainly for the TST, WASO, number of awakenings, and SE measures. In fact, some of these participants coincide with the disagreement on the limits on these sleep measures. Likewise, several studies have reported a similar number of participants (8 %-12 % of subjects) who exceeded the aggregation limits [35,38,39].

The Xiaomi Mi Band 5 showed an accuracy of 78 % for identifying sleep and wake stages. It had a sensitivity of 89 % for detecting sleep epochs. Nevertheless, this device showed a specificity of 35 %. These findings are similar to previous studies, highlighting that, in general, these devices have high accuracy and sensitivity but low specificity [37,38,58]. Kappa analysis nevertheless revealed that most of the accuracy was due to chance (K = 0.22) with 78 % of all the available epochs in the total sample belonging to the "sleep" class according to the PSG. In this line, some authors suggest that poor detection of wakefulness time could be due to difficulties the wristbands have in detecting periods of immobility [11,39,59].

Moreover, the present study analyzed the level of performance to identify the sleep stages using a 4-way classification by the Xiaomi Mi Band 5. The device obtained accuracy of 44 % for this task. Specifically, the Xiaomi Mi Band 5 was more accurate in detecting wake (48 %) and "light sleep" (51 %) than in identifying "deep sleep" (34 %) and REM sleep (28 %), misclassifying these stages as "light sleep" and vice versa. Overall, other validated devices seem to have greater accuracy in identifying sleep stages than the Xiaomi Mi Band 5 [11,37,39,60], except for the Fitbit Charge 2, which showed lower accuracy in detecting "deep sleep" (49 %) than the Xiaomi Mi Band 5 [37].

Cohen's kappa corrects the agreement due to chance between the Xiaomi Mi Band 5 and PSG. Overall, the obtained values hovered around 0.11-0.27 for the different 2-way (sleep/wake) and 4-way stage classifications and patient groups. Thus, the levels of agreement between the two devices were slight to fair. Conversely, other authors reported that the Fitbit Alta HR and the Fitbit Charge 2 devices had kappa coefficients of 0.52 to 0.66, indicating a moderate agreement with PSG [36,37,61].

Experts who have validated other devices have concluded the need to focus on the population with sleep problems due to their increased prevalence during the COVID-19 pandemic [14,62]. The existing literature that validated these devices in people with sleep problems reflects the myriad difficulties that come with measuring sleep parameters [34,36,58]. In the present study, the total sample was divided into two groups, namely one with sleep disorders ("SDis") and one without sleep disorders ("No SDis").

Both groups presented similar results for the "initial sleep onset" and TSPD measures, showing only slight biases with the PSG measures. However, in the rest of the measures, there were relevant differences between the two sleep groups. Specifically, the Xiaomi Mi Band 5 showed almost no variation compared with PSG for the TST, SE, "deep sleep" and awake time variables in the "No SDis" group. However, in the “SDis” group, the Xiaomi Mi Band 5 overestimated several parameters compared with PSG, namely TST and “deep sleep” by 28-41 minutes and SE by 7.60 points in the “SDis” group. In addition, it underestimated PSG WASO more in the “SDis” group than the "No SDis" group.

The estimations of these sleep measures are consistent with those made by the Jawbone or Fitbit in a group of people with sleep disorders [36,38]. However, the Jawbone and Fitbit biases compared with PSG are greater than those obtained in this study [36,38]. Conversely, unlike the group without disorders, the "SDis" group did not present significant differences with PSG in the sleep variables "light sleep" and SOL. In addition, REM PSG was mainly underestimated by the "No SDis" group than by the "SDis" group.

Moreover, both groups presented similar results in the performance of sleep/wake stage detection, but participants with sleep problems presented lower values. Overall, kappa coefficients were also lower in the group with sleep disorders. Specifically, the Xiaomi Mi Band 5 misidentified more epochs in the "SDis" than in the "No SDis" group. This device misclassified “light sleep” epochs as awake, “deep sleep," and REM in the "SDis" group, and to a lesser extent in the “No SDis" group.

Overall, the outcomes obtained from people without sleep disorders were more similar to the general performance. Consistent with the literature, devices such as the Xiaomi Mi Band 5 may be an alternative for health management in people without sleep disorders because the data are more reliable than in people with sleep disorders [8,11,41,61].

However, the outcomes of the “SDis” group could be influenced by the inclusion of multiple sleep disorders (rather than a single disorder), with OSA being the most prevalent syndrome. Similarly to other studies, performance of this activity wristband can be lower among people diagnosed with this sleep disorder. There are reports that devices like the Xiaomi Mi Band 5 had worse outcomes in this population than in populations with other conditions [36]. In this study, the biases between the Xiaomi device and PSG differed between participants with OSA and other sleep disorders (see Multimedia Appendix 2 [Anexo 5]). Our results show better performance in detecting waking sleep stages, but higher biases were detected for sleep variables in the “other sleep disorders” group.

4.2. Limitations

There are some limitations that could have negatively influenced the main findings of the present study. The first limitation is the loss of participants: Only 45 of the 58 participants completed the study. Participants did not complete the study due to difficulties with the use of the wristband and/or data collection. Hence, the sample was heterogeneous, and the size of the groups ("SDis" and "NoSDis") was small. In addition, how the participants were monitored might have influenced the data because it was not in the usual context in which people sleep. Moreover, participants should be followed up for more days for better assessment of the performance of the Xiaomi Mi Band 5.

There are other limitations to this study. Specifically, the Xiaomi Mi Band 5 and other devices only combine movement and HR to classify sleep parameters, while PSG includes several sensors, so the accuracy of the data collected by wearable devices could be lower than the data collected by PSG. These devices present more limitations in the detection of WASO, "light sleep", and REM sleep. Moreover, it would be necessary to have access to raw data in 30-second epochs and to the algorithm that Xiaomi uses to classify the data; this additional information would improve data analysis [11]. Although synchronization of the Xiaomi Mi Band 5 and PSG was simultaneous, there may be certain deviations that could affect the results of the study, specifically those obtained in the EBE analysis [11].

5. Conclusions

In conclusion, the very popular Xiaomi Mi Band 5 may be an acceptable activity wristband in terms of quality and price. Moreover, its use can promote greater awareness of the importance of sleep and promote good healthy lifestyle habits, so people get more quality sleep. Likewise, this device could be considered a tool to monitor sleep and to screen changes in its patterns through which health professionals could determine the state of people's sleep. Specifically, it could be a potential tool for use in populations without sleep disorders, especially to identify TST and "deep sleep". Future research must study the performance of this device in various populations, such as people with OSA, insomnia, and other conditions.

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Experiencias con el dispositivo Xiaomi Mi Band

Este bloque incluye las publicaciones científicas 2 y 3, relacionadas con el uso del dispositivo Xiaomi Mi Band para la monitorización del sueño y el análisis de sus implicaciones en la vida diaria de diferentes poblaciones de estudio.

Publicación científica 2:

Concheiro-Moscoso P., Groba B., Martínez-Martínez F.J., Miranda-Duro M.dC., Nieto-Riveiro L., Pousada T., Pereira J. (2022). Use of the Xiaomi Mi Band for sleep monitoring and its influence on the daily life of older people living in a nursing home. *Digital Health*, 8. https://doi.org/10.1177/2055207622112116

Publicación científica 3:

Concheiro-Moscoso P., Groba B., Martínez-Martínez F.J., Miranda-Duro M.dC., Nieto-Riveiro L., Pousada T., Queirós C., Pereira J. (2021). Study for the Design of a Protocol to Assess the Impact of Stress in the Quality of Life of Workers. *International Journal of Environmental Research and Public Health*, 18 (4), 1413. https://doi.org/10.3390/ijerph18041413

4.3. Use of the Xiaomi Mi Band for sleep monitoring and its influence on the daily life of older people living in a nursing home

4.3.1. Resumen extendido en castellano

Este artículo científico muestra el procedimiento seguido en una investigación sobre el sueño y su influencia en la vida diaria de los/as residentes de una institución gerontológica, junto con los resultados obtenidos en ella. Este estudio fue publicado en agosto de 2022 en la revista internacional *Digital Health*. La investigación consistió en un estudio longitudinal en el que participaron 21 personas mayores que vivían en una residencia gerontológica situada en un entorno rural. Los 21 participantes, sobre todo mujeres con una edad media de 86,38 ± 9,26 años, debían llevar el dispositivo Xiaomi Mi Band 2 las 24 horas del día durante un año, este aspecto era un criterio de inclusión del estudio.

Al comienzo y al final del estudio, los/as participantes tuvieron que completar una serie de herramientas de evaluación asociadas coa calidad de vida (*EuroQol 5D-5L*) y la calidad del sueño (PSQI), con apoyo del equipo investigador. Además, los/as investigadores/as se encargaron de cubrir tres escalas de evaluación para conocer el estado del/a participante, relacionadas con el nivel del estado cognitivo (Mini Examen Cognoscitivo de Lobo), el nivel de dependencia en las actividades de la vida diaria (AVD(s)) (índice de Barthel) y el riesgo de caídas (escala de Tinetti). También consultaron la base de datos de la residencia para obtener diferentes datos sociodemográficos y registraron los cambios en los productos de apoyo, la presencia de caídas y las alteraciones en la estancia de los/as participantes a lo largo del año.

En relación con el uso del dispositivo Xiaomi, el equipo investigador se encargó de sincronizar y cargar el dispositivo, así como de exportar los datos durante toda la investigación. Asimismo, los/as investigadores/as pudieron extraer algunos datos ambientales relacionados con la temperatura, la humedad, la lluvia, las horas de sol y la presión atmosférica mediante un dispositivo de la unidad de observación y predicción meteorológica de la Xunta de Galicia.

En total, fueron registrados 61 320 datos de actividad (pasos, distancia, e calorías) y sueño (TST, sueño ligero, sueño profundo y sueño REM). En general, el 76,21 % de la población de estudio caminaba menos de 3000 pasos diarios, mientras que el 90,47 % dormía menos de 8 horas diarias. Mediante la aplicación de un modelo mixto, se obtuvo que la cantidad de sueño podría ser un vaticinador de la actividad, aspecto que apoya la literatura. Del mismo modo, mediante correlaciones de Spearman, se observa que los parámetros del sueño se asociaban débilmente con las puntuaciones obtenidas en las herramientas de evaluación. Este resultado está relacionado con algunos estudios, que refieren que los problemas del sueño pueden ser factores de riesgo en el desarrollo de deterioro cognitivo o de dificultades en el desempeño de las AVD(s).

También mediante correlaciones de Spearman, se halló que los factores ambientales como la temperatura, la humedad, las horas de sol y la lluvia tuvieron una relación significativa con el sueño y sus parámetros. Finalmente, las fluctuaciones a lo largo del estudio, obtenidas mediante un test de Wilcoxon, influyeron significativa pero débilmente en el estado de salud, el sueño y la actividad de los/as participantes mayores.

Por consiguiente, la calidad y la cantidad del sueño presentan importantes implicaciones en la vida diaria de las personas mayores residentes de un centro gerontológico. En este sentido, los problemas en el sueño pueden influir negativamente en la calidad de vida y el desempeño ocupacional de estas personas. Finalmente, se considera que el dispositivo Xiaomi Mi Band 2 podría ser una herramienta de evaluación del sueño y la actividad en esta población.

4.3.2. Artículo original

Use of the Xiaomi Mi Band for sleep monitoring and its influence on the daily life of older people living in a nursing home

Abstract: Background: Lower quantity and poorer sleep quality are common in most older adults, especially for those who live in a nursing home. The use of wearable devices, which measure some parameters such as the sleep stages, could help to determine the influence of sleep quality in daily activity among nursing home residents. Therefore, this study aims to analyse the influence of sleep and its changes concerning the health status and daily activity of older people who lived in a nursing home, by monitoring the participants for a year with Xiaomi Mi Band 2. Methods: This is a longitudinal study set in a nursing home in Galicia, Spain. The Xiaomi Mi Band 2 will be used to measure biomedical parameters and different assessment tools will be administered to participants for evaluating their quality of life, sleep quality, cognitive state, and daily functioning. Results: A total of 21 nursing home residents participated in the study, with a mean age of 86.38 ± 9.26. The main outcomes were that sleep may influence daily activity, cognitive state, quality of life, and level of dependence in activities of daily life. Moreover, environmental factors and the passage of time could also impact sleep. Conclusions: Xiaomi Mi Band 2 could be an objective tool to assess the sleep of older adults and know its impact on some factors related to health status and quality of life of older nursing homes residents. Trial Registration: NCT04592796 (Registered 16 October 2020) Available on: https://clinicaltrials.gov/ct2/show/NCT04592796

Keywords: sleep; participatory health; quality of life; activities of daily life; occupational therapy; wearable technology; Xiaomi mi smart band 2

1. Introduction

Sleep is considered an occupation that performs a vital role in people's health and well-being.[1] As people age, the duration and quality of sleep are negatively influenced by alterations in its sleep-wake cycle, with less restful deep sleep and sleep stages fragmented by increased nocturnal awakenings.[2,3] Likewise, changes associated with the passage of time, such as changes in roles, environment, or healthy lifestyle habits, affect sleep status.[4,5] In the aging stage, sleep problems are often underdiagnosed, and their prevalence depends on social and environmental factors and daily habits and routines.[2,6] Globally, it is estimated that 40%–60% of the older population has poor sleep quality and sleep difficulties.[7] Therefore, sleep problems have become a problem associated with the growing aging phenomenon,[8,9] and a relevant public health problem, mainly affecting older people's quality of life.[7,8]

Sleep problems can be a risk factor for the development of cardiovascular diseases or diabetes, digestive diseases, and respiratory diseases.[10] Also, insufficiency of restful sleep and its poor quality is associated with a higher prevalence of cognitive impairment,[3] mental disorders (specifically depression, anxiety, or fatigue),[4,11] risk of falling,[12] and decreased daily functioning[13] and physical activity.[6,12] Specifically, the presence of sleep disorders and their relation to different diseases or alterations in the health of older adults can have a significant impact on their occupational performance,[1] such as in the development of daily routines or their participation in society.[1,14] In most cases, older adults present difficulties in their daily living, requiring third-party care, such as family members or other caregivers,[15] greater attention and frequency of health resources, and a greater need of institutional resources, like nursing homes, for older adults.[8,15]

Nursing homes tend to be the most frequented and required resources for the older population in need of some sort of assistance.[13,16] These resources are increasingly in demand in countries with high rates of older adults, such as Spain, where 81.5% of the older people live in nursing home.[16] Residents of these resources are exposed to changes in the environment and routines, lack of social participation, more time in bed, and are poorly exposed to the sun, which can cause the increase or appearance of sleep disorders and associated factors.[4,17] It is estimated that 65% of nursing home residents can have sleep problems.[17] Some studies report that older people in nursing homes have excessive daytime sleepiness, disturbed nighttime sleep, and high levels of sedentary lifestyle.[13,18] Martins da Silva *et al.*[14] refer that older institutionalized with poor sleep quality have low levels of activity and social participation, difficulties in carrying out leisure activities, and need support for performing their activities of daily living (ADLs).

Due to this situation and the increased prevalence of sleep problems in the older population, it is required the development of strategies for planning the care and services that nursing home residents need.[19] As well as, for health professionals to work in an interdisciplinary way to improve the quality of sleep and its influence on the daily life of the older population.[19]

Therefore, some studies report that the development of longitudinal studies about different geriatric syndromes is necessary to explore the impact of disorders such as sleep disturbances on the quality of life of older adults.[20,21] The development of these studies combining objective and subjective measurements can provide health professionals and governmental agents with the necessary information to promote organizational and environmental changes and development interventions in nursing homes to improve their sleep quality and quality of life.[22] Therefore, in contrast to previous studies, this study intends to analyse the quality and quantity of sleep and its influence, using subjective and objective measures.

The most common subjective measures are assessment tools.[21] Regarding objective measurements, there are a variety of instruments that analyse the quality and quantity of sleep. The clinical tool used to detect possible sleep difficulties is polysomnography (PSG).[23] PSG, considered the 'Gold Standard,' is the most reliable sleep test available and the most used in sleep units.[23] However, its cost and invasiveness have led to the use of other devices such as actigraphy, which is scientifically recognized as an objective instrument to study sleep.[24] So, some studies focused on sleep measurement use actigraphy.[24,25] But with time, new devices that are handy to society have been emerging and appearing on the market, such as wearable devices.[24] Today, these devices are used by the majority of the population, and there is evidence in the literature of previous works that have used them to evaluate mainly physical activity.[26,27]

Some studies report that wearable devices can promote healthy lifestyle habits and help people to be more aware of their health status, specifically the activity they perform and the quality of their sleep.[20,28] In addition, the remote monitoring of people in their daily environment is highlighted as a positive point in these devices, providing crucial information about people's health to health care professionals.[20,28,29] Likewise, the study performed by Chong *et al.*[28] refers that wearable devices are helpful tools that stand out for four aspects: the discretion of the device, the motivation they provide, responsibility, and sleep hygiene. Kondama Reddy *et al.*[27] refers that it would be interesting to know the impact of these devices on the population in the long term. However, no study has used wearable devices in the long term in a specific population.

Many wearable devices have validation studies, comparing them with PSG, and many others are in process, with previous results showing similarity of the data from these devices with PSG.[24,30,31] Within the variety of wearable devices, the Xiaomi Mi Band devices are one of the most attractive to the public due to their quality-price ratio.[32] Some research has used this device to measure the health status of different populations. Both Miranda-Duro *et al.*[12] and Domingo *et al.*[33] focussed on investigating the risk of falling and physical activity in older people using the Xiaomi Mi Band 2. Queirós *et al.*[34] focused on studying the impact of stress in the work environment using the Xiaomi Mi Band 3. However, none of them researched sleep as the main variable and its influence on the daily life of the population.

Thus, the main objective of this study was to analyse the influence of sleep and its changes concerning the health status and daily activity of older people who lived in a nursing home, by monitoring the participants for a year with Xiaomi Mi Band 2. Specifically, (I) we analysed the sleep and activity performed by older residents and the influence of falls on these parameters; (II) we studied the association between sleep and its related variables (light, deep sleep, and wake after sleep onset (WASO)) with the quality of life, independence in ADLs, cognitive status, risk of falling, and perception of sleep; (III) we analysed whether different environmental factors (temperature, rain, hours of sun, and humidity) influenced the sleep and activity performed by the older adults; lastly, (IV) we researched if there were some changes in the daily functioning and health status of the participants throughout the study, based on the data associated with the assessment tools and the sleep and activity data provided by the Xiaomi Mi Band 2.

2. Methods

2.1. Research design

A longitudinal study was conducted among older people residing as nursing home residents or attending the day centre in Galicia (Spain). The population's characteristics, specifically the daily activity and sleep quality, were registered and monitored for 1 year, beginning in December 2018 and ending in December 2019.

Before starting the study, all participants gave their informed consent to participate. Also, the study protocol was approved by the A Coruña-Ferrol Research Ethics Committee (code:2018/473). and it was registered in the Clinical Trials Protocol Registration and Results System (NCT04592796). In addition, the study was conducted following the Helsinki Statement for human research ethics and European Convention on Human Rights and Biomedicine. The researchers maintained the confidentiality of all data collected and the anonymity of each participant. Thus, the Spanish 2016/679 and European Organic 95/46/E.C. Law on the protection of personal data was respected at all times.[35,36]

2.2. Participants

All residents of the nursing home (n = 44) were considered for participating in the study. The selection was performed through an intentional sample based on inclusion and exclusion criteria. The participants' inclusion criteria were: (a) to be at least 65 years old, (b) to be a user of the residence or day centre where the study was performed, (c) to wear the wristband day and night. Whereas the participants' exclusion criteria were (a) to present a moderate or very severe cognitive impairment, (b) to be in a situation of legal incapacity, (c) to be in a situation of request to be transferred to another centre. Thus, from a total of 44 nursing home residents, only 21 older adults met the inclusion criteria. Characteristics of including participants are shown in Table 3-1.

Table 3-1. Characteristics of participants

Characteristics	N (%)/Mean ± SD
Women	17 (81 %)
Age (years)	86.38 ± 9.26
BMI (Kg/m2)	24.97 ± 4.59
Widowed	19 (90.5 %)
Nursing-home residents	18 (85.7 %)
Cognitive status**	
No cognitive decline	3 (14.30 %)
Very mild cognitive decline	8 (38.1 %)
Mild cognitive impairment	10 (47.6 %)
Health Diagnosis	
Hypertension (I10) *	14 (66.7 %)
Osteoporosis (M80-82) *	14 (66.7 %)
Medication	
Number	6.67 ± 2.35
Corticosteroids	15 (71.4)

*Health conditions were grouped and classified into different types following the International Classification of Diseases and Related Health Problems (ICD-10). /**Cognitive status was obtained by Lobo Mini-Cognitive Examination (Lobo MEC) and classified by Reisberg Global Deterioration Scale (GDS).

2.3. Procedure

Before the data collection phase, the informed consent was signed by the responsible researcher and the person participating in the study.

Following the informed consent process, five assessment tools were administered at baseline and the end of the study (see Appendix 1 [Anexo 7]). During this assessment process, participants completed the EuroQol 5D-5L (EQ 5D-5L)[37] and Pittsburgh Sleep Quality Index (PSQI)[6,38,39] under the assistance and supervision of the researchers. Likewise, the researchers filled out Lobo mini-cognitive examination (MCE),[40,41] Barthel ADL Index[42] and Tinetti scale[43]. In addition, at the project's beginning, some sociodemographic characteristics of each participant were consulted in the nursing home database.

Once the initial assessment was completed and a wristband had been given to each participant, it was explained the use of the Xiaomi Mi Band 2 and the importance of wearing it until the end of the study. Participants did not have the obligation of interacting with the device if they did not want to. Data synchronization and charging of the wristbands were carried out by the research team during the study.

At the end of the research, the researchers want to determine the satisfaction on the project and the wristbands' use. For that, the participants filled out a final questionnaire with the support of the research team. In addition, data associated with the risk of falling, hospital stay, daily living aids, and environmental data from nursing home settings were recorded by the research group throughout the study.

2.4. Measures

Data from all measures were collected in Microsoft Excel and organized according to sociodemographic data, assessment tools, Xiaomi activity and sleep data, environmental data, and fall history. This information on participants was published previously anonymized in a dataset.[44]

Xiaomi Mi Band2

All participants used the Xiaomi Mi Band 2 based on other studies.[12,45] The choice of this wearable was based on its ease of use and cost.[32] Previous studies consider that this wristband reliably measures the number of steps, distance, and duration of sleep, classifying light sleep, deep sleep, and awake time.[25,31] The classification total sleep time (TST) data was based on the National Sleep Foundation's sleep duration recommendations[7–8]: 'hours optimal'[5–6]; 'less optimal sleep duration'; less than 5h 'inadequate sleep duration'; more than 9h 'excessive sleep duration'.[46] The classification of the steps followed the following recommendations: >3000 steps/day 'low level of physical activity'; 3000–8000 steps/days 'moderate physical activity'; <8000 steps/day 'intense level of physical activity'.[47]

MeteoGalicia platform

Some environmental factors were recorded using a meteorological station near the nursing home under study. The meteorological device is from the Meteorological Observation and Prediction Unit of Xunta de Galicia. It aims to predict the weather in Galicia throughout the record of environmental factors such as temperature, rain, sun hours, wind, or atmospheric pressure. Based on scientific evidence on environmental factors and their influence on the quality of life or quality of sleep[48,49], the research group focused on temperature, rainfall, humidity and sun hours data.

Record sheet

A record sheet was made based on scientific evidence.[50] A record was used for the falls, hospital stays, and changes in daily living aids (walker/cane/wheelchair/glasses/hearing aid) that participants experienced throughout the project.

2.5. Statistical analyses

Statistical analysis was conducted in R-project for Statistical Computing (version 4.1.2; GNU project: Auckland) and IBM SPSS Statistics (version 27.0; IBM; Chicago). Descriptive analysis was done using means and standard deviations (± SD) and frequencies or percentages. On the other hand, methodologies and models were proposed because the data set obtained consisted of repeated measures.

Mixed models were carried out in the analysis to determine the association of TST with activity.[51] Taking 'participant' and 'days' as the fixed effects of the model so that the model considers the inherent variability that arises from the differences between participants, and also the different factors that may be due to the season of the year and cannot be easily controlled. For this model, a transformation of the response variable 'steps' was carried out to scale it: $Y = TST + (days/participant)$.

The Granger test was used to check whether any of the variables obtained could predict a time series.[51] Specifically, it was used to find out whether, temporally, the evolution of sleep quality and quantity are good predictors of the progress of the activity. In this case, a $p < 0.05$ indicates that a variable is a good predictor.

The time series were used to know if there was a relationship between days with fewer steps and falls. The time series was divided into three components (trend, seasonality, and residual). It was highlighted that the seasonality was 7 days because the data collection is daily, and the duration of the series is one year. In addition, it was considered that there would be a trend since participants hadn't had the same activity every day of the week.

Spearman's rank correlation coefficients were used for determining the association between sleep and its parameters and the different assessment tools.[51] This methodology was used because the data from scales were ordinal. Moreover, only post-data were taken into because it was measured after recording sleep and activity data. Sleep parameters were coded to know the influence of sleep quality for the analysis:

- Sleep period (light sleep/deep sleep). A value >1 indicates more light sleep hours than deep sleep, <1 indicates less hours of light sleep than deep sleep, and 1 implies the same hours in each stage.
- Total Awake (WASO/(Deep + Light)). The ratio of time awakes to time asleep. A value >1 implies more hours awake than sleeping, and <1 indicates more hours of asleep time than awake time.

The Wilcoxon test for paired data was used to compare the values of the pre-scales and post-scales.[51] In addition, time-series were used to study the temporal evolution of the different variables. These time series were univariate and were obtained by averaging the values of the 21 study participants for each day. Although each time series is divided into three components, we focussed on extracting the trend since we wanted to know whether the variables improved or worsened over time. To find this trend, we fit a local polynomial regression model: $Y = f(x)$. (f indicates the trend).

Finally, we tested the relationship between sleep and activity variables and environmental factor parameters using Spearman correlations.[51]

3. Results

3.1. Statistical description about Xiaomi Mi Band 2 and assessment tools

All participants used the Xiaomi Mi Band 2 for one year, obtaining 61,320 recorded sleep and activity data. The data from this device (Table 3-2) refer that most of the participants slept an average of 321.90 ± 97.61 min, which means less than 7h per day. Specifically, the hours of light sleep were greater than deep sleep. Moreover, participants walked a mean of 1623.29 ± 2080.02 steps, which means less than 3000 steps per day in most cases.

Table 3-2. Descriptive variables

Measure	N (%)/Mean ± SD
Xiaomi Mi Band 2	
Sleep	
TST*	321.90 ± 97.61
TST ≤7-8h. (420-480 min)	19 (90.47 %)
Light sleep	221.21 ± 81.49
Deep sleep	100.65 ± 33.60
WASO	39.87 ± 29.13
Activity	
Steps	1,623.29 ± 2,080.02
Steps≤3000 daily steps	16 (76.21 %)
Assessment tools	
MCE≤23	12 (57.14 %)
VAS EQ 5D-5L≤50	8 (38.09 %)
Barthel≤60	11 (52.38 %)
Tinetti≤24	17 (80.95 %)
PSQI≤5	20 (95.23 %)
Falls	
Average of falls	1 ± 2
Falls≤1	7 (33.3 %)
Mobility aids	
Walker	12 (57.1 %)

TST: total sleep time; WASO: wake after sleep onset; MCE mini-cognitive examination; PSQI: Pittsburgh Sleep Quality Index

Data from assessment tools showed that participants at the end of the study had a higher cognitive impairment (57.14 %), worst perception of their quality of life (38.09 %), greater dependence on ADLs (52.38 %), an increased risk of falling (80.95 %), and the same subjective perception of sleep quality (95.23 %). As for the data associated with fall history, 7 people (33.3 %) suffered any fall during the study.

Regarding assistive products, it is highlighted that 76.2 % of older residents used glasses. The use of mobility aids was changed throughout the study. At the beginning of the study, 33.33 % of participants didn't use mobility aids, and 28.6 % used mobility aid like a walker or cane, respectively. However, at the end of the study, several participants began to use a mobility aid or changed the type of aid. The walker was the most used mobility aid (57.1 %).

3.2. Sleep and activity

We investigated whether there was a relationship between the duration of sleep and the activity (steps) that older people performed during a year. The relationship between both parameters was significant and positive, but the correlation was weak ($r = 0.2643$; $p < 0.001$).

The mixed model (see in Table 3-3) shows that the effect of variable 'days' on activity was not significant, but the influence of TST on activity was significant. This result meant that for each extra hour of TST, the activity of the older person could increase 3.06 times.

Table 3-3. Mixed model on sleep and activity associations

Variable	Value (Y)	St. Error	Df	t-value	p-value
(Intercept)	17.95	4.11	7657	4.36	<0.001
Days	0.00067	0.0022	7657	0.29	0.765
TST	3.06	0.096	7657	31.61	<0.001

In addition, the predictions made with the mixed model were accurate, especially for the low number of steps. The adjusted R2 of the model was 0.8, with the relative share of fixed effects being 0.007, meaning that most of the variability of the data set could be due to random effects on the 'person' variable.

Likewise, we tested whether the quantity and quality of sleep influenced activity using the Granger test (Table 3-4). Results referred that only the quantity of sleep could be a predictor of activity. The quality of sleep, measured with the variable 'Light/Deep Sleep' and 'WASO/TST', were not predictors of activity, having a $p > 0.05$.

Table 3-4. Association between sleep and activity variables using the Granger test

Variables	F-statistics	p-value
Activity-TST	139.21	<0.001
Activity-Light/Deep Sleep	0.0202	0.88
Activity-WASO/TST	2.36	0.12

TST: total sleep time; WASO: wake after sleep onset

During the project, we could observe a total of 25 falls through the analysis of steps. These falls were identified in March, September, October, and November. The results reflect a possible association between the days, when people fell, and the low activity of the participants during the following days. Likewise, the dates with more steps than 'expected' (>2.5 SD in the residuals) were March, April, June, and September. Whereas the dates with fewer steps than 'expected' (<−2.5 SD in the residuals) were February, August, and September. No statistical relationship was found between sleep and falls.

3.3. Sleep parameters and assessment tools

Table 3-5 shows the associations between sleep parameters and assessment tools using Spearman correlations. The results referred to strong and positive associations between TST and light sleep variables with the perception of quality of life, cognitive status, level of independence in ADLs, and risk of falling. However, the perception of sleep quality was moderately negative related to the TST variable and strongly negative related to the light sleep variable.

Table 3-5. Spearman correlations between the quantity of sleep and assessment tools

Variables	Variables			
	TST	Light sleep	Deep sleep	WASO
EQ 5D-5L	0.637***	0.709***	0.177	-0.684***
Lobo MCE	0.753***	0.724***	0.591***	-0.720***
Barthel Index	0.866***	0.874***	0.507*	-0.806***
Tinetti	0.926***	0.935***	0.472*	-0.822***
PSQI	-0.508***	-0.860***	-0.415	0.817***

TST: total sleep time; MCE: mini-cognitive examination; PSQI: Pittsburgh Sleep Quality Index; WASO: wake after sleep onset
***p<0.001; **p<0.01; *p<0.05

Furthermore, we observed negative and high correlations between WASO and the scores of the assessment tools, except with the PSQI scale, which presented a positive association with the WASO variable. Concerning the deep Sleep variable, only weak and positive associations were reported with the tools associated with cognitive status, level of dependence on ADLs, and the risk of falling.

Table 3-6 reports the relationship between sleep quality and different assessment tools. The results showed no statistically significant correlations between the sleep period (light/ deep sleep) and the EQ 5D-5L, MCE, and Barthel index. Although, sleep period was associated weakly and positively with the Tinetti scale and weakly and negatively with the PSQI scale. However, the proportion between WASO and time sleep showed a negative and high association with the assessment tools EQ 5D-5L, Lobo MCE, Barthel Index, and Tinetti. But a positive and high relation with the PSQI scale.

Table 3-6. Spearman correlations between the quality of sleep parameters and assessment tools

Variables	Variables	
	Sleep Period (Light/Deep Sleep)	**WASO/ (Light+Deep Sleep)**
EQ 5D-5L	0.274	-0.759***
Lobo MCE	0.431	-0.759***
Barthel Index	0.409	-0.886***
Tinetti	0.481*	-0.907***
PSQI	-0.491*	0.877***

MCE: mini-cognitive examination; PSQI: Pittsburgh Sleep Quality Index
***p<0.001; **p<0.01; *p<0.05

3.4. Environmental factors and their relationship with sleep and activity

The results showed a statistically significant relationship between TST, and the different environmental factors analysed. We observed weak and positive correlations were found between TST and temperature (rho = 0.3571; $p < 0.001$) and hours of sun (rho = 0.3023, $p < 0.001$). However, low, and negative correlations were identified between TST and humidity (rho = −0.0822, $p < 0.001$) and rain (rho = −0.268, $p < 0.001$).

Moreover, as shown in Table 3-7, positive and strong Spearman correlations were also obtained between TST and light sleep stages and temperature. Likewise, we identified positive but weak associations between deep sleep and WASO with temperature and hours of sun. Nevertheless, we found a negative and low relation between rain and humidity and all sleep variables.

Table 3-7. Spearman correlation between environmental factors and sleep parameters of participants

Variables	Variables			
	TST	**Light sleep**	**Deep sleep**	**WASO**
Temperature	0.601***	0.650***	0.302***	0.274***
Humidity	-0.489***	-0.472***	-0.352***	-0.150***
Rain (l/m^2)	-0.350**	-0.327***	-0.296***	-0.134*
Hours of sun	0.507***	0.489***	0.350***	0.154**

TST: total sleep time; WASO: wake after sleep onset
***p<0.0001; **p<0.01; *p<0.05

Concerning activity, the results reflected that the average of daily steps of the participants were weakly associated with the different environmental factors. Thus, the data showed a positive and weak association between temperature (rho = 0.228, $p < 0.001$) and hours of sun (rho = 0.1645, $p < 0.001$) with the activity of the participants. In contrast, humidity (rho = −0.196, $p < 0.001$)

and rain (rho = −0.201, p < 0.001) had a negative and low correlation with participants' daily steps.

3.5. Influence of the passage of time on the daily life of nursing home residents

Table 3-8 shows the relationship between pre-data and post-data of the assessment tools. Thus, the correlations between the passage of time and all assessment tools were strong and negative, except for PSQI, which presented a positive association.

Table 3-8. Associations between the passage of time and assessment tools

Variable	Pre[a] (Mean ± SD)	Post[b] (Mean ± SD)	IC 95%	V	p-value	r
EQ 5D-5L	68.42±14.84	56.66±15.35	0.66-0.91	5.31	<0.001	0.79
MCE	25.33±3.56	22.66±4.55	0.78-0.90	5.25	<0.001	0.84
Barthel Index	72.85±26.24	62.38±27.36	0.64-0.85	4.79	<0.001	0.75
Tinetti	17.80±8.62	15.66±8.76	0.63-0.84	4.65	<0.001	0.73
PSQI	9.14±2.74	12.04±4.52	-0.90—0.74	-inf.	<0.001	-0.82

MCE: mini-cognitive examination; PSQI: Pittsburgh Sleep Quality Index
[a]Pre scales; [b]Post scales

Moreover, we investigated whether the passage of time influenced the quality and quantity of sleep. Figure 3-1 in plot 'a' showed that the TST of the participants tended to increase in summer season while at the beginning and at the end of the year TST decreases, with a prominent tendency at the end of the year. Also, there was a clear downward trend in the TST quantity, both deep and light sleep. Besides, the time awake remained stable for the study (see plot 'b' in Figure 3-1)

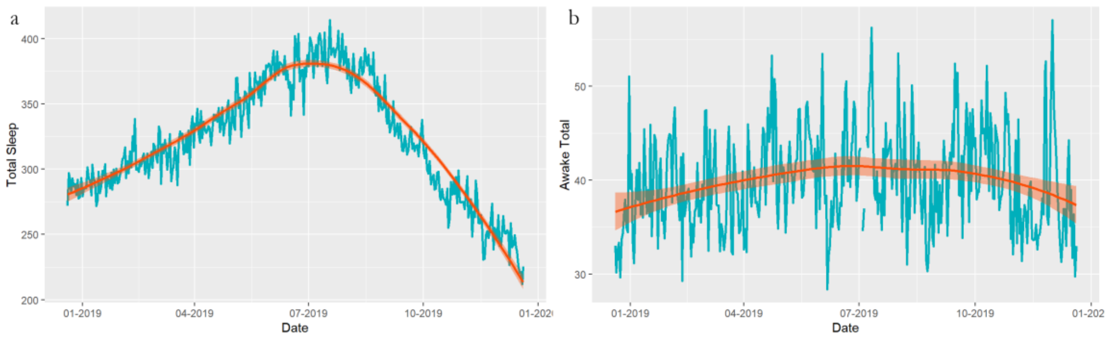

Figure 3-1. Graphical representations of the total sleep time (TST) (a) and the awake time (b) of the participants during the study

In terms of sleep quality, Figure 3-2 in plot 'a' shows an upward trend between the proportion of awake total to TST which was associated with a potential worsened sleep quality over time. Likewise, as shown in Figure 3-2 in plot 'b', the trend was not clear, but we observed a slight decline in sleep quality in the last portions of the graphic. As shown in Figure 3-3, the results report that the daily steps increased during the months of summer. Nevertheless, the trend descended much more in the last months of the study compared to the first months.

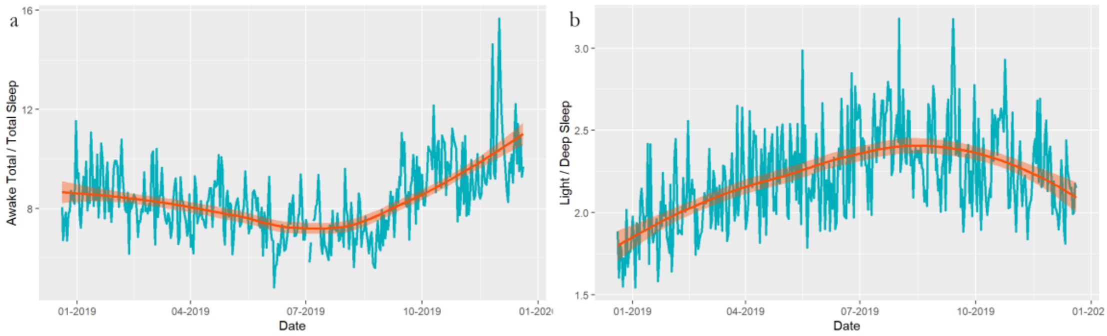

Figure 3-2. Graphical representations of the sleep quality (awake total/total sleep) (a); (light/deep sleep) (b) of the participants during the study

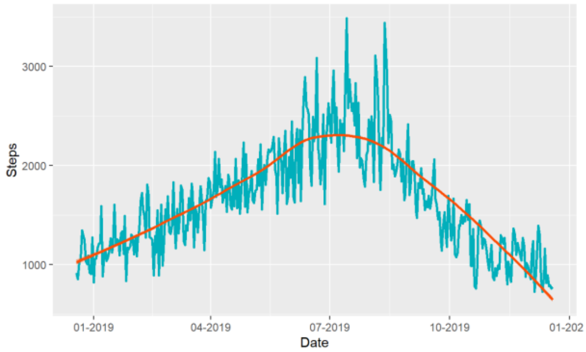

Figure 3-3. Graphical representation of the daily steps of the participants during the study

4. Discussion

This longitudinal study analysed the influence of sleep and its changes concerning the functionality and health status of older people who lived in a nursing home, followed-up with the Xiaomi Mi Band 2 for one year. This study, as opposed to other studies that analysed sleep in an older population living in a nursing home, combined the use of assessment tools (MCE, EQ5D-5L, Barthel Index, Tinetti, and PSQI) and the Xiaomi Mi Band 2 to understand the implications of sleep on the daily lives of nursing home residents.

One of the first objectives of this study was to analyse the relationship between participants' sleep and activity data obtained by the Xiaomi Mi Band 2. The first results focused on participants' sleep duration and the number of steps. These data were similar to those reported in previous studies,[52,53] suggesting that both the TST (5.36 ± 1.62 h), with more light than deep sleep and with WASO of more than 30 min and activity (1623.29 ± 2080.02 steps) were inadequate and below the recommended values for the older population.[46,47]

Our analysis shows a significant but weak association between sleep duration and activity ($r = 0.2643$, $p < 0.001$). Thus, it suggests, as in the work of Kuok *et al.*[53] and Kim *et al.*,[54] that those older residents who had higher sleep duration, could be more active during the day.

The present study calculated through a mixed model how the variable 'days', associated with the days of the year and related daily factors, could influence the sleep and activity of the older participants.[54,55] The result indicated that this variable didn't affect the sleep and activity of older participants. But if, it indicated that the TST could increase 3.06 times the daily steps performed by the participants, as the Granger test values indicated.[54,55]

Regarding falls, seven participants had any falls, a total of 25 falls during the study, so the falls were usual in these participants.[12,14] Scientific evidence reports that the risk of falling influences negatively the quality and duration of sleep and activity in the older population.[12,14] However, our results didn't show significant associations between falls and sleep. But if, they suggest that falls could be a factor of inactivity in the older person, and a low activity could be a possible predictor of falls (>2.5 SD in the residuals). Against these results, we recognize that it is difficult to determine these findings due to the small sample size.

This study also analysed the association between assessment tools and sleep quality and quantity. Some studies refer that sleep problems can be a risk factor to develop cognitive impairment, dependence on ADLs, and risk of falling. In the same way, older people, who have these alterations in their functioning and health status, usually have sleep problems like insomnia, parasomnia, or sleep apnea[2,12,13,56–58] Specifically, our outcomes also reflected a significant relation between sleep parameters with these variables. Moreover, as Martins da Silva *et al.*,[14] our analysis showed that the sleep quality and quantity positively contributed to daily activity and the performance of ADLs of participants.

The evidence indicates that people, who have a positive score in their sleep quality calculated through specific assessment tools such as PSQI, have an adequate quantity of sleep according to the National Sleep Foundation.[15,46] However, our findings suggested that the participants, who had an appropriate period of sleep according to the National Sleep Foundation, referred a lower quantity ($rho = -0.508$, $p < 0.001$) and poor quality ($rho = 0.877$, $p < 0.001$) of sleep by PSQI. Deepening the results, we observed that deep sleep hadn't got a significant association with PSQI, therefore, this controversy could be related to the TST and, specifically, with light sleep. In other words, more light sleep could be associated with poor quality of sleep.

Authors like Wang *et al.*[52] explain that different factors, which can cause alterations in the daily functioning and health status of the person, also can lead to a reduction in their quality of life.[59] In this case, sleep could influence the quality of life since the correlation between EQ5D-5L and WASO was negative ($rho = -0.684$, $p < 0.001$), in contrast with TST ($rho = 0.637$, $p < 0.001$) and light sleep ($rho = 0.709$, $p < 0.001$) that were positives. Moreover, our findings suggested that quality of life also could be indirectly related to cognitive status, dependence on ADLs and risk of falling, taking into account that these variables influenced the quality and quantity of sleep.[59]

We analysed whether different environmental factors influenced the sleep and activity performed by the older adults. The results highlight those environmental factors like temperature, rain, hours of sun and humidity, had a moderate or weak effect on quantity and quality sleep, and activity.

Thus, higher temperature and hours of sun could be positive factors with a weak association in relation to sleep and activity. By contrast, humidity and rain could have a low and negative impact on sleep and activity. In this way, some studies mention the influence of environmental factors on sleep, but they don't deep on the analysis of specific factors.[48,49]

Lastly, we researched the changes on the health and daily functioning status of the participants throughout the study. The evidence refers to some factors as a passage of time can change and affect the sleep architecture.[4,5,60] Epidemiological studies refer that sleep problems increase with age and stabilize around 75 years old.[8,61] Moreover, the National Sleep Foundation identified the following factors naps, WASO, or changes in sleep routines and habits.[46] In this case, we found that the quality and quantity of sleep suffered changes along with the study, emphasizing that sleep seems to improve in summer and get worse at the end of the study. In the same way, like sleep, the scores of assessment tools and activities got worse at the end of the study.

4.1. Limitations

The first limitation of this study is the sample size. Even though there were 44 residents in the nursing home, only 21 met the inclusion criteria. The main exclusion criterion was that part of the study population presented moderate or severe cognitive impairment levels. Moreover, some residents didn't agree to wear the Xiaomi Mi Band 2 device due to discomfort in wearing and sleeping with it. For these reasons, the results of the study cannot be decisive. Therefore, it is considered that further studies should look for other alternatives (i.e., changing the material of the band) to ensure the device's comfort and expand it to other nursing homes.

Another limitation detected was the inclusion of older adults who took medications that could affect their sleep. At the beginning of the study, the authors didn't contemplate this variable. However, it must be included in the exclusion criteria of further research to avoid potential biases.

Furthermore, the research group was conscious that there was data loss because the routines and situations derived of daily living of older adults from a nursing home. In addition, the Xiaomi Mi Band 2 wristband is not a device scientifically validated. Accordingly, although there are already study protocols[49] working on it, the data of this device should be taken with care.

4.2. Clinical implications

The use of Xiaomi Mi Band 2 combined with the assessment tools conforms to an assessment dossier complementary that helps to contrast the subjective data with the objective data. In addition, participants became more aware of their sleep and daily activity through the use of this device. All of this can facilitate the clinical practice of health care professionals.

5. Conclusions

The main conclusion of this study is that sleep and the parameters analysed by the Xiaomi Mi Band 2 can influence the quality of life and occupational performance of older people living in nursing home. The study participants had a TST below the recommended values. In addition, these values could negatively influence the daily activity, which was performed in the nursing home. Sleep and the parameters light and deep sleep had a positive relationship with quality of life, independence in ADLs, cognitive status, risk of falling, and a negative relation with awake time. However, the data from the perception of sleep negatively had an association.

Hours of sun and the high temperature had a positive and weak impact on the quantity and quality of sleep. But rain and humidity had a negative and weak impact. The changes on health and daily functioning status got worse in all the parameters and assessment tools during the study. Lastly, Xiaomi Mi Band 2 could be an objective tool to assess the sleep of older adults.

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Contributorship: Conceptualization, JPL, PCM, and BG; methodology, JPL, PCM, and BG; investigation, FJM-M, PCM, and MCMD; writing–original draft preparation, FJM-M, PCM, and MCMD; writing–review and editing, JPL, BG, LNR, and TP; visualization, FJM-M, PCM, and MCMD; supervision, JPL, BG, LNR, and TP; project administration, JPL, BG, LNR, and TP; funding acquisition, PCM and FJM-M. All authors have read and agreed to the published version of the manuscript.

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4.4. Study for the design of a protocol to assess the impact of stress in the quality of life of workers

4.2.1. Resumen extendido en castellano

Este protocolo está asociado al estudio denominado abreviadamente SQoF-WEAR, sobre la influencia del estrés laboral en la calidad de vida y el funcionamiento ocupacional, la actividad y el sueño de personal trabajador de un entorno universitario. En él se tuvieron en consideración las recomendaciones y las guías de SPIRIT 2013 (véase el Anexo 10). Este protocolo fue publicado en enero de 2021 en la revista internacional IJERPH.

En este estudio, los/as participantes fueron personas trabajadoras de un entorno universitario, específicamente del ámbito de la investigación y la docencia, y de la administración y gestión de tareas asociadas a un centro de investigación. El procedimiento de captación de los/as participantes era llevado a cabo mediante una reunión en los diferentes centros participantes, donde se explicaba el procedimiento de la investigación y las implicaciones de la participación en el estudio. Esta información también se recogió en una hoja que era entregada a los posibles participantes. Finalmente, aquellas personas que quisieran participar en el estudio resolvían las dudas con el investigador principal, y firmaban el CI, si aceptaban participar.

Durante seis meses, los/as participantes tenían que completar un cuestionario diario y otro semanal, mediante la plataforma de *Research Electronic Data Capture Consortium* (REDCap), que es una plataforma que permite crear y administrar cuestionarios. Estos cuestionarios están conformados por preguntas relacionadas con el nivel de estrés en el trabajo, la calidad y la duración del sueño, la actividad diaria y el equilibrio ocupacional.

Al inicio y final del estudio, los/as participantes debían cubrir una serie de herramientas de evaluación, también mediante la plataforma REDCap. Estas escalas están asociadas con la calidad de vida (*EuroQol 5D-5L*), la calidad y cantidad del sueño (PSQI), el nivel de ansiedad (*State-Trait Anxiety Inventory*, STAI) y el nivel de estrés percibido (*Perceived Stress Scale-10*, PSS-10). Además, los/as participantes debían llevar puesto un dispositivo Xiaomi Mi Band 3, tanto de día como de noche, para el registro de la actividad, el sueño y la Frecuencia Cardíaca (FC).

Con relación al proceso de recogida de los datos, los datos del sueño, la actividad y la FC del dispositivo Xiaomi eran obtenidos mediante un sistema de captura que los almacenaba en una base de datos de lenguaje de consulta estructurada (*Structured Query Language*, SQL Server), por lo que podían ser exportados en un archivo .CSV. Los datos de los cuestionarios y escalas de evaluación eran almacenados en la plataforma REDCap. Finalmente, para el análisis de este proyecto, se utilizaron diferentes pruebas estadísticas con el objetivo de determinar el impacto del estrés laboral en el funcionamiento diario, así como también en la actividad diaria y la calidad y cantidad del sueño de la población trabajadora.

4.2.2. Artículo original

Study for the design of a protocol to assess the impact of stress in the quality of life of workers

Abstract: (1) Background: Work stress is one of the most relevant issues in public health. It has a significant impact on health, especially the development of mental disorders, causing occupational imbalance. There is a growing interest in the development of tools with a positive effect on workers. To this end, wearable technology is becoming increasingly popular, as it measures biometric variables like heartbeat, activity, and sleep. This information may be used to assess the stress a person is suffering, which could allow the development of stress coping strategies, both at a professional and personal level. (2) Methods: This paper describes an observational, analytical, and longitudinal study which will be set at a research center in A Coruña, Spain. Various scales and questionnaires will be filled in by the participants throughout the study. For the statistical analysis, specific methods will be used to evaluate the association between numerical and categorical variables. (3) Discussion: This study will lay the foundation for a bigger, more complete study to assess occupational stress in different work environments. This will allow us to begin to understand how occupational stress influences daily life activity and occupational balance, which could directly enhance the quality of life of workers if the necessary measures are taken.

Keywords: work stress; occupational balance; occupational therapy; burnout; wearable technology; participatory health; Xiaomi Mi Smart Band 3.

1. Introduction

Work is one of the most significant areas of occupation in adulthood, and has great relevance at a social and personal level throughout life [1,2]. Work and working conditions have a significant impact on health [3]. Stressful situations occur in the worker when these conditions are altered by different factors (work overload, lack of support, work schedules, or lack of family reconciliation) [4,5,6], giving rise to a specific type of stress called work stress [7,8]. Work stress is defined as "the reaction that the individual may have to work demands and pressures that do not match his knowledge and skills, and that test his ability to cope with the situation" [9].

It is estimated that work stress affects three million workers worldwide [10], and that it represents between 50–60% of the cases of absenteeism and presenteeism [11,12]. In addition, several studies have reported that the health sector suffers the most from this type of problem [13,14,15]. In line with this data, occupational stress has become one of the most relevant problems for public and occupational health [16,17,18].

Work-related stress has important repercussions at the personal and health levels, but also at the social level [19]. Several studies have reported that work-related stress is a trigger for mental disorders (specifically depression [14,20,21], sleep disorders [22,23], heart and/or respiratory diseases, and physical or cognitive fatigue [24,25]. Moreover, if work-related stress is prolonged and worsened over time, it can lead to burnout in the worker [26,27]. Burnout was defined by Maslach, Schaufeli, and Leiter as “a prolonged response to chronic emotional and interpersonal stressors at work, defined by the dimensions of exhaustion and inefficiency” [28].

In addition to the physical or psychological effects that work stress can have, it is also related to alterations in the occupational balance [29], defined as “a balance of engagement in occupation that leads to well-being. The balance may be among physical, mental, and social occupations; between chosen and obligatory occupations; between strenuous and restful occupations; or between doing and being” [30,31]. Several studies refer to the fact that workers experiencing occupational stress are not able to relativize work and everyday occupations, prioritizing paid employment and leaving aside activities related to social interactions, household management, and rest or sleep [29,32,33].

Some studies have associated alterations in occupational balance with perceived stress [17,32]. Both concepts include the demands, needs, and emotions associated with daily life activities, in order to obtain satisfaction and well-being [32]. Studies such as that by Yu Yu *et al.* have emphasized the analysis of perceived stress [34,35], defined as “the individual’s ability to cope with stressful situations” [36]. Its analysis can help us to understand different predictors of stress, and prevent alterations that lead to an occupational imbalance [17].

The effects derived from work stress suppose important direct and indirect consequences for public health [16,37]. They generate an expense to the system due to high demand on health services, and the necessity of treatments that must be maintained in the long term like antidepressants or anxiolytics, which have a minimum duration of several months [38,39]. In addition, there is an economic cost since factors associated with occupational stress, such as low self-esteem, dissatisfaction, and low efficiency in the labor field, affect short-term productivity [40,41]. In the long term, the consequences can be aggravated by the occurrence of workplace accidents or temporary or permanent disabilities, with these representing one of the main causes of early retirement [42,43,44].

Due to the aforementioned, various organizations associated with health and work have the objective of promoting quality of life and well-being, as well as greater productivity, in the worker [11,45]. They consider of interest the creation of strategies and technological solutions for the early detection and control of factors and effects associated with work stress, as well as balance between personal and work life and the promotion of healthy habits [13,46].

Studies related to occupational stress have focused on the measurement of various physiological parameters for the detection of stress [47]. The most common biomarkers and indicators of stress are blood pressure and heart rate, which have been measured in these studies through the use of non-intrusive sensors to determine stress levels in workers [48,49]. However, these devices are generally uncomfortable for the user to carry for a long period of time, as is the case of belt-format pulsometers or portable electrocardiogram (EGC) devices [47,50]. Thus, it is necessary to find new sensors that are comfortable for the user, while providing information of equal quality [51].

In recent years, wearable devices for continuous, real-time monitoring of different parameters have been developed [52]. The measurement of parameters such as sleep and physical activity can be used to identify behavioral patterns of people when they are exposed to stressful situations [52]. Currently, the literature on the use of wearables for the measurement of occupational stress is focused on the development of automatic systems for the accurate assessment of stress, but less on the benefits of the study of stress at the social level [53,54,55]. However, studies such as that of Queirós *et al.* have already used Xiaomi wearable devices for public health purposes [56].

In this study, levels of work stress will be evaluated, along with how it influences the occupational balance and routine of workers. For this purpose, one of the most widely accepted wearables among the population will be used—the Xiaomi Mi Band 3—whose minute-by-minute measurements will be obtained through a data acquisition system developed by the research group. Likewise, specific scales and questionnaires will be used to measure the different aspects that influence quality of life.

Objectives

The main objective of this study is to assess the work stress level and its influence on the quality of life of workers at a research center.

The specific objectives are:

- To itemise the level of some parameters, such as activity, sleep, and heart rate.
- To determine the level and impact of occupational stress in worker's daily life through the information from wristbands and questionnaires.
- To identify patterns of occupational functioning, physical activity, and sleep in these people.
- To study the association between the identified patterns of occupational functioning, activity, and sleep, and the level of occupational stress and quality of life.

2. Materials and Methods

2.1. Study Design

This project will be a pilot study to determine the viability, sample size, cost, and duration of the study. Additionally, this project has been designed in order to "demonstrate that the planned measurements, the data collection instruments, and the data management system are feasible and effective" [57]. If this study proves to be successful, it will be performed with a larger sample from different work settings.

This study will be observational, analytical, and longitudinal. That is, in this study, different variables of the population under study will be observed and recorded without intervention, and with the aim of establishing causal associations between variables. It is considered longitudinal because the variables will be followed for six months, with continuous recording and monitoring of physical activity and the quality of sleep (wristbands). Variables related to work stress, quality of life, and perception of the quality of sleep and the level of physical activity (specific evaluation tools) will also be specifically measured [57]. This study protocol will follow the SPIRIT 2013 guidelines (See File S1) [58].

2.2. Participants and Settings

The study will be conducted in a research center in Galicia; a non-profit organization under private law whose aim is to contribute to the strengthening, empowerment, growth, and improvement of the competitiveness of the Galician information and communication technologies (ICT) sector. Sample selection will be performed through intentional sampling based on inclusion and exclusion criteria.

The participant inclusion criteria is: (a) performing management/administration/research tasks at the research center.

The participant exclusion criteria is: (a) close to retirement (5 years or less); (b) significant health condition complications that prevented active participation in the study; and (c) hypersensitivity in the skin or a recognized allergy to the material of the cases or straps of the wearable wristbands used as one of the measuring instruments of the study.

2.3. Recruitment Process

Entry into the study field will occur at the workplace where the project will be held. The participants will be recruited at the workplace, through an informative meeting that will be conducted at the facilities. In this meeting, the selection criteria for the study and the implications of participating will be presented, highlighting the total duration of participation and the mechanisms that will be followed at an ethical level to guarantee anonymity and the confidentiality of the data.

After the presentation of the main characteristics of the study to the workers attending the meeting, the information sheet will be given to any interested person to consider for as long as they wish, before making a decision regarding participation.

A week later, those workers willing to participate will be visited again to carry out the process of informed consent with the Principal Investigator (PI). In these individual meetings, possible doubts or queries will be resolved, the established selection criteria will be checked for each person, and the informed consent document will be signed if applicable.

2.4. Justification of Sample Size

This pilot study is being suggested in order to determine the feasibility, time, and cost required for a subsequent study, as well as to demonstrate that the selected measurements and instruments are feasible and effective, and to determine, based on the results, the optimal frequency, intensity, and duration of the study.

Likewise, by carrying out this pilot study, we will gain information about the standard deviation and the proportion of participants with the specific characteristics needed for this study, which will allow us to carry out the calculation of the sample size.

2.5. Outcomes

The primary outcome will be to determine the influence of stress and anxiety on the worker. The secondary measures will be: (a) sleep recording and physical activity tracking with the Xiaomi Mi Band 3; (b) quality of life self-perception with the EuroQol 5D-5L (EQ 5D-5L) scale; (c) determination of sleep habits by using the Pittsburgh Sleep Quality Index (PSQI); (d) anxiety self-perception by using the State-Trait Anxiety Inventory (STAI); (e) stress self-perception by using the Perceived Stress Scale-10 (PSS-10); and (f) influence of stress on daily functioning, by using a questionnaire designed by a work stress psychologist professional in consensus with the socio-sanitary professionals of the group.

2.6. Data Collection and Management

Prior to any other data, socio-demographic features of the participants considered as relevant will be collected using a record sheet of our own elaboration. This questionnaire includes questions regarding age, gender, marital status, residential environment, cohabitation unit, educational level, profession, socio-economic level, working hours, overtime working hours, level of perceived stress, other non-work-related stress factors, actions oriented to stress reduction, and medication intake.

Data will be collected from different sources (Figure 4-1). For biometrical data, a Xiaomi Mi Band 3 will be worn by all the participants for six months to measure their physical activity (steps), sleep (hours of sleep and sleep stages), and heart rate (bpm). A self-developed data collection system will be installed in one of the computers of the research center, capturing the data from the wristbands via Bluetooth every time they walk nearby and storing it in a Structured Query Language (SQL) database [59]. When the data is analyzed, it will be retrieved by the SQL database in which it was stored. The data will be exported through CSV in a detailed or accumulated way for analysis in any statistical program.

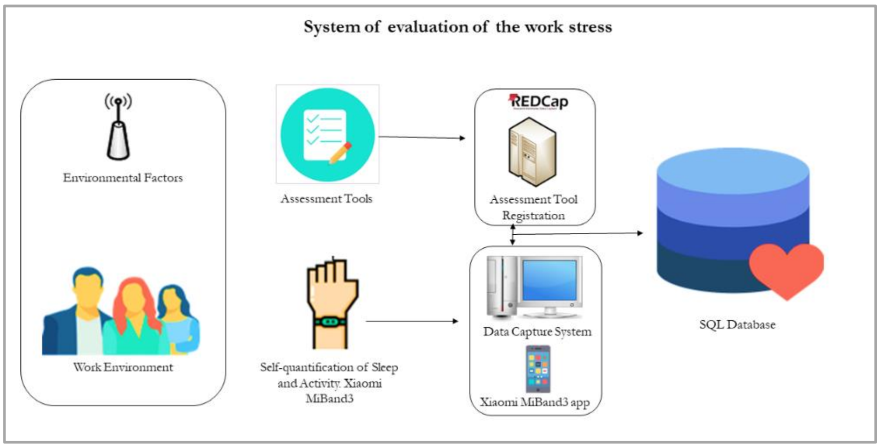

Figure 4-1. Registration and capture of biometric data and the assessment process

The Research Electronic Data Capture Consortium (REDCap), a safe web application to create and manage online surveys and databases [60], will be used to digitally create the questionnaires and tests explained below, which will be sent to the participants to fill out.

In this study, participants will complete a set of assessment tools and a self-made questionnaire associated with work overload, sleep, and physical activity. These assessment tools will be filled in at the beginning and end of the study, while the self-made questionnaire will be answered throughout the study. This information is shown in Figure 4-1.

Table 4-1. Measuring assessment tools

Instrument	Data	Delivery phase
EuroQol-5D-5L (EQ-5D-5L)	Quality of life	Beginning, follow-up, and completion
Pittsburgh Sleep Quality Index (PSQI)	Sleep habits	Beginning, follow-up, and completion
State-Trait Anxiety Inventory (STAI)	Anxiety	Beginning, follow-up, and completion
Perceived Stress Scale-10(PSS-10)	Stress	Beginning, follow-up, and completion
Stress questionnaire	Work stress factors and daily functioning	Daily (3 items) and weekly (4 items)

The scales to be completed are: (1) the EQ 5D-5L, which evaluates mobility, personal care, daily activities, pain/discomfort, anxiety/depression, and global status at the moment of assessment [61], (2) the PSQI, which analyzes the quantity, quality, duration, latency, and efficiency of sleep [62], (3) the STAI, which evaluates the presence of anxiety [63], and (4) the PSS-10, which measures the degree to which, during the last month, people have felt annoyed or worried or, on the contrary, have felt confident in their ability to control their personal problems [64].

Finally, a self-made questionnaire was developed considering the results of a prior poll that assessed different factors potentially related to stress. Those items that were directly related to stress were chosen for the questionnaire. This final questionnaire was agreed on by a stress psychologist professional. It is composed of three daily and four weekly items to answer (Appendix A [see Anexo 9]), related to stress, work commitment and frustration, sleep, physical activity, and occupational balance. All items in the weekly and daily questionnaire are scored from 0 to 5 (0 = Nothing; 1 = Very little; 2 = Little; 3 = Some; 4 = Quite a lot; 5 = A lot).

2.7. Data Analysis

The statistical treatment of the data will be performed with the statistical package IBM SPSS Statistic version 22 (IBM, Chicago, IL, USA). The significance level for hypothesis testing is set at 5%. The numerical variables will be expressed as the mean (M) and standard deviation (SD), including range, minimums, and maximums, while the categorical variables will be shown with their absolute frequency and valid percentage. In addition to the simple description of the data and variables studied, inferential analyses will be conducted in order to determine possible significant relationships between the variables of the study, or to allow the contrast of hypotheses. The Kolmogorov–Smirnov test will be applied to check that the variables behave as a normal distribution [65]. If not, non-parametric tests will be used in the subsequent analysis. The association of numerical variables will be analyzed with the Pearson or Spearman's Rho correlation test, depending on the distribution of the sample. To assess the association of categorical variables, the Chi-square test will be applied, or the likelihood ratio in the case that the frequencies observed are less than 5%. In the case of the association between quantitative and qualitative variables, the comparison of means will be made with Student's t-test and analysis of variance (ANOVA) or Mann–Whitney and Kruskal–Wallis' U test, as appropriate [66]. Finally, and in order to determine whether there are significant and relevant differences between the results of the evaluations performed (initial, intermediate, and final), the Wilcoxon test will be applied [66]. Data analysis includes the cleaning or pre-processing, description, and processing of the stored data. The final objective of these steps is to obtain information for decision making. During pre-processing, erroneous data are removed or corrected to avoid bias in the results. Subsequently, a descriptive statistical study which summarizes certain relationships and distributions in a simple way will allow us to choose which processing strategy to adopt.

2.8. Ethics and Dissemination

This study protocol was approved by the A Coruña-Ferrol Research Ethics Committee under the number 2019/249, with the date of 24 April 2019. In addition, this protocol was registered in

ClinicalTrials under the identifier NCT04584021, on 12 October 2020. It is available at https://clinicaltrials.gov/ct2/show/NCT04584021.

In case any change in the protocol is needed, this will be communicated to the Research Ethics Committee with the assigned reference number. These modifications will be updated in the Clinical Trials register.

The impact that the use of the procedures defined in the project may have on the protection of the personal data of the participants will be evaluated, emphasizing that such data will never leave the information system of the "Tecnología Aplicada a La Investigación en OcupacióN, Igualdad y Salud" (TALIONIS) Group, following the regulations of the Spanish and European Organic Law on the protection of personal data [67,68]. Data confidentiality and anonymity will be maintained through pseudonymization techniques. Once the study is completed, the data will be stored anonymously with the previous authorization of the participants.

The results of the questionnaires and assessment tools will be administered, coded, and managed through the software of REDCap. This platform complies with data protection regulations and stands out for being a widely used tool in clinical trials at an international level. The PI will have access to all the identification data of the participants and all the data collected during the study; the rest of the research team will have access to the data of the participants without identification through the REDCap platform, which allows the capture and consultation of the data anonymously.

The results related to the data of the wearable wristbands will be automatically captured through the wearable wristband data acquisition module. This platform was made following software design standards to guarantee the security and anonymization of the data during capture. It was developed in the Python programming language, along with the necessary libraries for the capture and storage of data in an anonymous way. The data is stored in an SQL server database that, together with the anonymization mechanisms and strategies created by the research team, has data masking mechanisms. In addition, it has limited access to data and security and access control mechanisms. Regarding Bluetooth technology, each bracelet has a unique internal key, generated at random, which is automatically changed. All these software resources are located in a small computer that will be placed in the environment of the center. This computer does not have input and output mechanisms to avoid any person outside the computer trying to access it. The PI will have access to the data related to the identification of the participants, and to the relationship of each participant with the internal number of each wristband. Once the study is finished, this data relationship will be eliminated.

3. Discussion

This pilot study may allow us to design a broader study with more participants in future. Stress is increasingly present in our society, and despite being historically understood as an expected effect derived from the mere activity of working, in recent years it has started to be considered as detrimental, but not unavoidable [69,70]. This kind of study could help with the control and detection of stress, influencing positively its reduction and improving the quality of life of workers [37]. In particular, if this study is successful, it would allow the evaluation of occupational stress by using cheap devices and easy-to-understand questionnaires that can be used by any person without any specific training. It would be possible to establish the influence that working stress has on the daily routines and occupational balance of workers.

In addition to the worldwide increase in stress, the emergence of coronavirus disease 2019 (COVID-19) has meant a significant worsening of the mental health of a large part of the population. Stress, along with anxiety and depression, have spread or become more severe during the pandemic in the general population [71]. Job instability due to unforeseeable lockdowns and restrictive measures leads to increased stress in the population, which along with precarious jobs, generates long-term uncertainty that can further increase general stress levels [72,73].

4. Conclusions

This project contributes to know the influence of occupational stress on the quality of life in a work environment. Therefore, it is intended to observe some parameters (activity, sleep, and heart rate) recorded through Xiaomi Mi Band 3. In addition, it aims to know about the level of work stress in diverse aspects of daily living, using various online self-report questionnaires in different periods of time. This data obtained from the questionnaires and wristbands will allow to determine the level of stress and its influences on quality of life during and after work.

The increasing use of portable devices such as smartphones or wearable devices encourages to obtain real-time biomedical data available for people, without going to health resources. Thus, this project considers as innovative that all measurements are registered online so that the workers can have an insight into their level of stress, the different stressful factors, and other parameters related to their activity, sleep, and heart rate, which influences their quality of life and work activity. It may help them to be more conscientious about their situation, so they can decide to make changes in their daily routines and habits.

Finally, considering the current pandemic situation, the online registration of all measurements will provide a follow-up of the participants without the need for face-to-face meetings.

Supplementary Materials: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (see in Anexo 10).

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Institutional Review Board Statement: This study was approved by the Research Ethics Committee of A Coruña-Ferrol (ref. 2019/249).

Informed Consent Statement: Informed consent was obtained from all participants involved in the study. Written informed consent has been obtained from the participants to publish this paper.

Data Availability Statement: Once the data collection process is finished and these have been coded, structured, and analyzed, these data will be provided, after the Spanish Data Protection Agency's consent, to any researcher that contacts TALIONIS group Principal Investigator, Javier Pereira.

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Conflicts of Interest: The authors declare no conflict of interest.

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4.2.3. Síntesis de los resultados obtenidos de la replicación del proyecto SqoF-WEAR

El protocolo del estudio SQoF-WEAR fue desarrollado en el año 2019 con una muestra de siete trabajadores de un centro de investigación asociado a la UDC. En el año 2021, el equipo investigador volvió a llevarlo a cabo con ciertas variaciones respecto del estudio de protocolo publicado, y con la participación de trabajadores/as tanto de la UDC como de la Universidade do Porto (UP). Para desenvolverlo, se solicitó la ampliación del proyecto a otro país al Comité Ético de Investigación Clínica (CEIC) de A Coruña-Ferrol. También se solicitó el informe favorable para el desarrollo de este estudio al CEIC de la Facultad de Psicología y Ciencias de la Educación de la UP (ref. 2021/06-03).

La investigación contó con la participación de 21 trabajadores/as de A Coruña (15 mujeres con una edad media entre 40-45 años) y de 13 trabajadores de Oporto (7 mujeres con una edad media menor de 30 años). Ambos grupos cubrieron los cuestionarios diarios y semanales durante un mes, además de completar las herramientas de evaluación, tanto al inicio como al final del estudio (véase el Anexo 11). Cabe señalar que en este proyecto los/as participantes no utilizaron el dispositivo Xiaomi Mi Band versión 3, sino la versión 5, durante un mes. De este dispositivo se obtuvieron datos resumidos del sueño (TST, WASO, sueño ligero, sueño profundo y sueño REM), datos minuto a minuto de la actividad (pasos, distancia, y calorías) y de la FC (alta, baja y media). Además, la nueva versión del dispositivo Xiaomi que se empleó permitió visualizar el nivel de estrés de la persona, clasificado como relajado, leve, moderado y alto.

Con respecto a los resultados iniciales, se destaca que el 61,9 % de los/as participantes de la UDC era personal docente e investigador (PDI), con un 46,2 % de personal no permanente. En cambio, el 53,8 % de los/as participantes de la UP era solo personal investigador, con un 87,7 % de personal no permanente. En la Figura 4-2 se puede observar algunos datos relacionados con el estrés percibido por los/as participantes de ambas universidades.

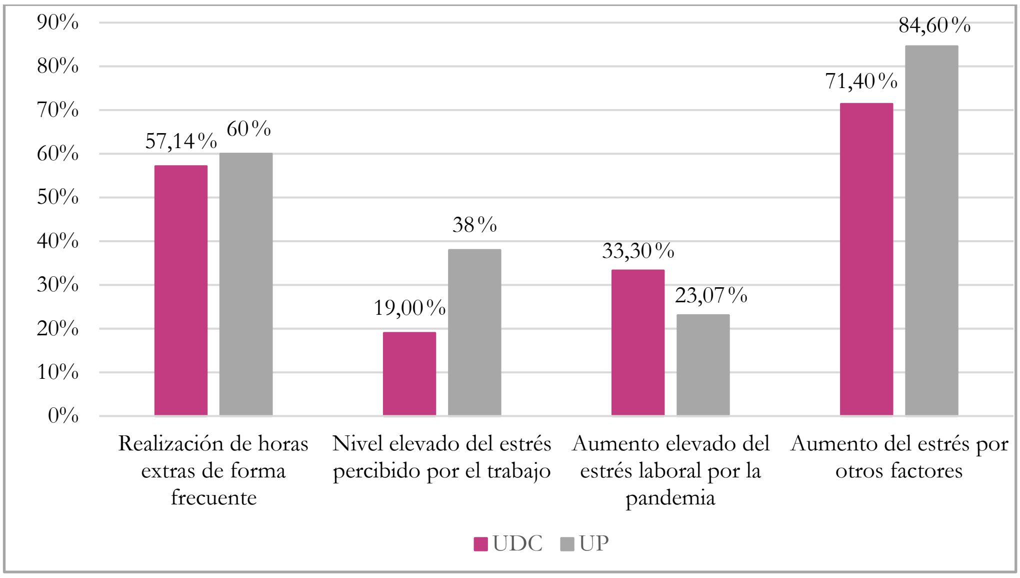

Figura 4-2. Datos sobre la realización de horas extras y el nivel de estrés de los/as participantes de ambas universidades.

En la Figura 4-3 se destaca que la percepción sobre la calidad del sueño y el nivel de frustración en el trabajo fue peor en la población portuguesa. No obstante, el personal de la UDC presentó una peor percepción sobre su equilibrio entre las ocupaciones que realizaba diariamente y también refirió una mayor sobrecarga de tareas en el trabajo.

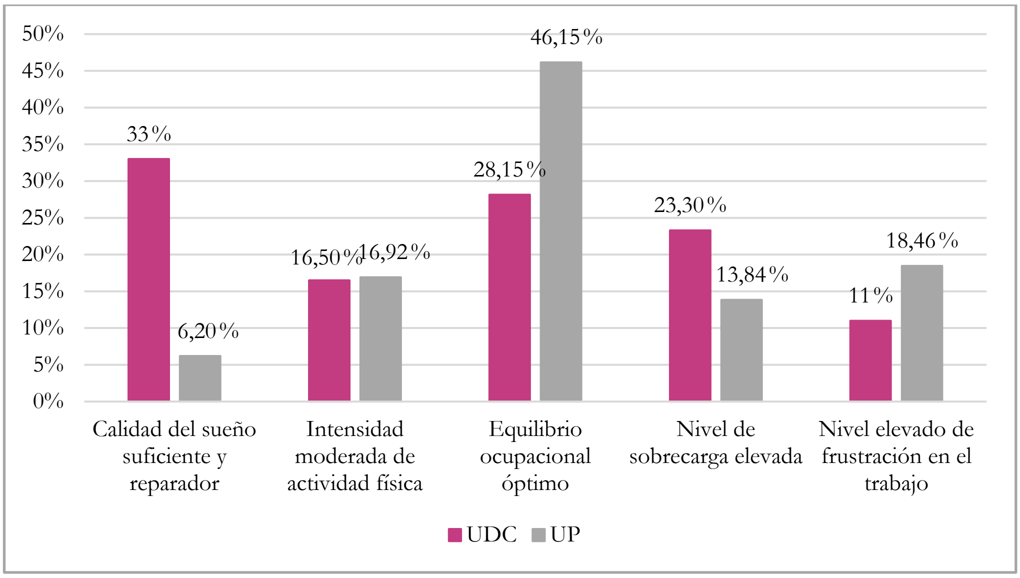

Figura 4-3. Datos relacionados con el sueño, la actividad física, el equilibrio ocupacional y el trabajo correspondientes al personal de ambas universidades.

La Figura 4-4 refleja el número de pasos y el TST de los/as participantes, con medidas similares en ambos grupos, aún que los traballadores de la UP realizaron de media un número mayor de pasos y durmieron más que los/as participantes de la UDC.

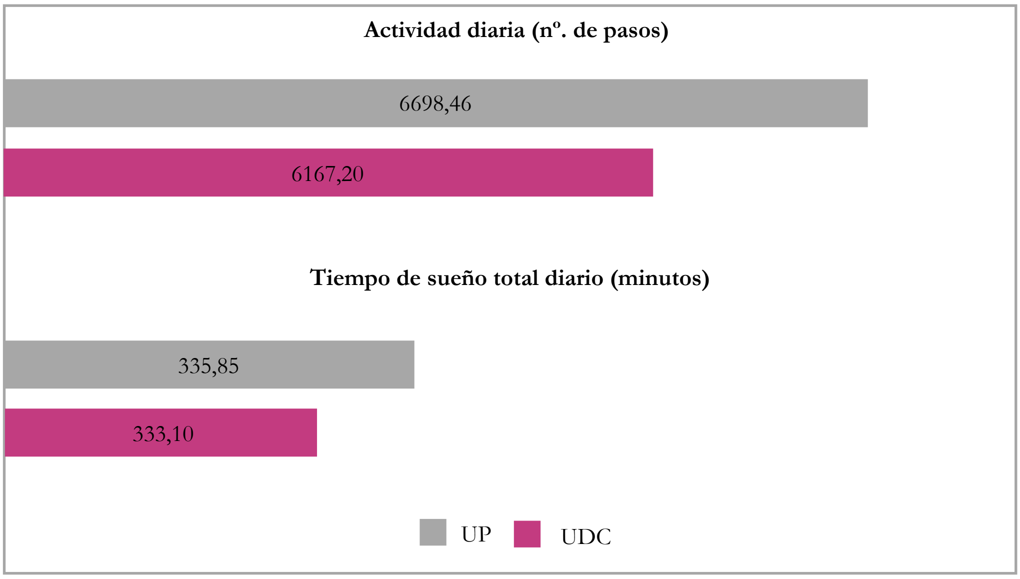

Figura 4-4. Media diaria de los datos relacionados con la actividad y el sueño de los/as participantes de la UDC y de la UP.

Capítulo 5. Discusión

En este capítulo se recoge una reflexión crítica sobre los resultados obtenidos en los diferentes estudios que constituyen esta tesis doctoral. Asimismo, se realizó una comparativa de los resultados de la tesis con la literatura científica sobre la temática de estudio. El eje central de todas las reflexiones se concentró en el estudio del rendimiento y uso de un dispositivo ponible (*wearable*) para conocer las implicaciones del sueño en la vida diaria de las diferentes poblaciones de estudio. Finalmente, como resultado de estas investigaciones, en este capítulo se presentan las futuras líneas de investigación y las implicaciones clínicas relacionadas con el uso de los dispositivos *wearables* para la monitorización de parámetros biomédicos como el sueño.

5.1. Síntesis de los antecedentes y objetivo principal

El sueño es una función biológica necesaria para la supervivencia en el ser humano y también una ocupación significativa en la vida diaria, con relevantes implicaciones en el desempeño del resto de actividades de la vida diaria (AVD(s)) (Green & Brown, 2015; Solet, 2016). Diversos factores relacionados con el estado de salud, el entorno, el estado socioeconómico o los cambios sociales pueden alterar el sueño e incidir en el desarrollo de problemas en él (Grandner, 2017). En los últimos años, los problemas del sueño aumentaron, destacando que alrededor del 30-50 % de la población manifiesta quejas asociadas con la baja calidad y cantidad del sueño (Pavlova & Latreille, 2019). Al respecto, la evidencia muestra que los problemas del sueño son reconocidos como un reto para la salud pública, debido a su prevalencia y a su impacto en la calidad de vida de la sociedad, tanto en el ámbito sanitario como en el económico y social (Magnusson *et al.*, 2021).

Por otro lado, la literatura reciente refleja los avances y el impacto de los dispositivos ponibles (*wearables*), en concreto de las pulseras de actividad, en la población (Shelgikar *et al.*, 2016; Xu *et al.*, 2022). Estos dispositivos tienen la capacidad de registrar diferentes parámetros biomédicos, como el sueño, en tiempo real (De Zambotti *et al.*, 2019). En el ámbito clínico y científico, se requiere conocer la precisión y fiabilidad de estos dispositivos en la monitorización del sueño en diferentes poblaciones (De Zambotti *et al.*, 2019).

Por eso, el objetivo principal de esta tesis doctoral es estudiar como una posible solución tecnológica, el uso de los dispositivos *wearables* para la monitorización y la medición del sueño y sus parámetros, y las implicaciones de estos, en diferentes poblaciones, junto con otras herramientas de evaluación.

5.2. Resumen de los resultados principales de la tesis

La primera publicación científica y el manuscrito presentados en esta tesis doctoral reflejan tanto el diseño y procedimiento, como los resultados de validación del dispositivo Xiaomi Mi Band 5. Específicamente, en el manuscrito se destaca que el dispositivo Xiaomi presentó una precisión del 77 % en la detección de las fases del ciclo sueño-vigilia.

La segunda publicación científica, por su parte, refirió que existía una relación entre la duración del sueño de las personas mayores y su actividad diaria. De igual manera, los resultados muestran que la duración del sueño y sus parámetros influyen en la calidad de vida, el estado cognitivo, el nivel de dependencia de las AVD(s) y el riesgo de caídas de los/as residentes mayores.

Por último, en la tercera publicación científica se describe el protocolo de una investigación relacionada con la influencia del estrés laboral en el desempeño ocupacional, el sueño y la actividad en un entorno laboral. Asimismo, se muestra una síntesis de los resultados previos obtenidos en la aplicación de este protocolo, en el que se resaltan las diferencias entre las variables investigadas en función de las características de la población de estudio.

5.3. Discusión general

La validación y aplicación del dispositivo Xiaomi Mi Band como una posible solución tecnológica para la monitorización del sueño permitió desenvolver una serie de reflexiones. Estas reflexiones, junto a la literatura reciente, dieron lugar a una discusión generalizada sobre los hallazgos, limitaciones e implicaciones de esta tesis en el ámbito científico y en futuras investigaciones sobre el sueño.

5.3.1. El sueño en el dispositivo Xiaomi Mi Band 5

Tal y como recoge la evidencia, las pulseras Xiaomi Mi Band son uno de los dispositivos más populares del mercado mundial (Statista, 2022). Así, su aceptación en la población, junto a la falta de estudios sobre su rendimiento en el seguimiento del sueño, motivaron el desarrollo de su validación, recogida en las dos primeras publicaciones científicas de esta tesis doctoral.

Las investigaciones sobre la validación de los dispositivos de seguimiento del sueño son uno de los retos de la comunidad científica. Este tipo de estudios pueden promover que el uso de esta tecnología sea más fiable y objetiva, mediante el conocimiento de las limitaciones (De Zambotti *et al.*, 2019). Su diseño debe cumplir una serie de procedimientos para obtener resultados lo más precisos posibles (Consumer Technology Association, 2019). Así, la publicación de protocolos de validación de tales dispositivos que detallen estos procedimientos y los resultados obtenidos tras su aplicación, promueven la actualización de los datos de rendimiento de nuevos modelos disponibles en el mercado (Menghini *et al.*, 2021), así como la comparación de los resultados obtenidos por los diferentes dispositivos y la continuidad de las investigaciones relacionadas con ellos, lo que fomenta la evidencia científica sobre esta temática (Depner *et al.*, 2020; Menghini *et al.*, 2021).

En este sentido, la primera publicación científica pretendió explicar todos los pasos que se siguieron en el proceso de validación del dispositivo Xiaomi Mi Band 5, aplicando las recomendaciones y guías referenciadas por otros/as investigadores/as y entidades, relacionadas con el sueño y este tipo de tecnología (Depner *et al.*, 2020). Del mismo modo, el manuscrito detalló el procedimiento utilizado para el tratamiento y obtención de los datos de ambos dispositivos antes de proceder a su análisis.

Por otro lado, los estudios de validación se pueden enfrentar a algunos retos, que complican el proceso de análisis de los datos (Menghini *et al.*, 2021). La literatura reciente refiere que para conocer de forma precisa las estimaciones de las fases del sueño-vigilia por parte de un dispositivo *wearable* es necesario que la estructuración de sus datos sea igual o similar a los del estándar de oro, la polisomnografía (PSG) (Menghini *et al.*, 2021).

Durante la elaboración de esta tesis doctoral se encontró la dificultad de la obtención de los datos en bruto del dispositivo Xiaomi Mi Band 5. Como se observó en otros estudios de validación, la obtención de los datos en épocas de 30 segundos, como los registra la PSG, no suele estar al alcance del/a usuario/a (De Zambotti *et al.*, 2019; Liang e Chapa Martell, 2018), aunque algunos autores relatan que las marcas de esos dispositivos facilitaron el acceso a los datos en bruto (Menghini *et al.*, 2021), en otros casos los/as investigadores /as no tuvieron esa posibilidad.

La evidencia también hace referencia a otros desafíos que confrontan este tipo de tecnología y que pueden influir en la detección de las diferentes fases del ciclo sueño-vigilia (De Zambotti *et al.*, 2019). Uno de estos factores es la clasificación de las etapas del sueño, ya que en general, estos dispositivos suelen clasificar los datos del sueño en cuatro etapas, mientras que la PSG los clasifica en cinco (Liang & Chapa-Martell, 2021).

Otro factor que puede influir en el rendimiento de estos dispositivos es el inicio del registro del sueño, ya que a diferencia de la PSG, comienzan su registro al detectar una de las etapas del sueño, lo que dificulta la obtención de mediciones como las latencias del inicio del sueño (*sleep onset latency*, SOL) (Liang & Chapa Martell, 2018; Pesonen & Kuula, 2018). Por esta razón, en esta tesis se tomó como referencia el inicio del sueño, junto con el apagado y encendido de luces de la PSG, para la comparativa de ambos instrumentos.

Los resultados de esta validación concuerdan con algunos estudios previos (De Zambotti *et al.*, 2018; Kahawage *et al.*, 2020). En términos generales, y como se recoge en el manuscrito, el dispositivo Xiaomi Mi Band 5 presentó ciertas limitaciones en la detección y la clasificación de algunas etapas y algunos parámetros del sueño. La detección de las etapas de sueño y de despierto por el dispositivo Xiaomi fue precisa en un 89 % y en un 35 % de las veces, respectivamente. Sin embargo, el nivel de concordancia debido al azar entre ambos instrumentos, marcado por el índice de Kappa, fue de 0,22; considerado como razonable. Por otra parte, el dispositivo Xiaomi sobreestimó entre 5-30 minutos las variables del sueño de PSG como el tiempo de sueño total (*total sleep time*, TST), la eficiencia del sueño (*sleep efficiency,* SE), el sueño ligero y el sueño profundo; también, subestimó entre 19-31 minutos los parámetros del sueño de la PSG como los tiempos de vigilia posterior al inicio del sueño (*wake time after sleep onset*, WASO), el sueño de movimiento ocular rápido (*rapid eyes movements*, REM) y el tiempo despierto.

En relación con lo anterior, algunos/as investigadores/as indican que las clasificaciones de las etapas del ciclo sueño-vigilia suelen ser más precisas en los dispositivos actuales, porque combinan datos sobre la FC y la actividad de la persona para determinarlas (Roberts *et al.*, 2020; Svetnik *et al.*, 2021). A pesar de esto, la existencia de largos períodos de inmovilidad del/a usuario/a durante el período del sueño puede incidir negativamente en las clasificaciones de algunas de sus etapas (De Zambotti *et al.*, 2019; Kubala *et al.*, 2020). En esta línea y de acuerdo con estudios previos (De Zambotti *et al.*, 2018; de Zambotti *et al.*, 2019; Menghini, Yuksel, *et al.*, 2021), el dispositivo Xiaomi Mi Band 5 identificó incorrectamente algunas etapas del sueño, concretamente, clasificó etapas de sueño profundo y REM como sueño ligero.

Por otro lado, actualmente está emergiendo la digitalización de los sistemas de salud, promoviendo así la medicina participativa en la sociedad (Almalki *et al.*, 2015; Nieto-Riveiro *et al.*, 2018). En este sentido, la validación de los dispositivos empleados para la monitorización de aspectos de salud, entre los que se encuentra el sueño, es fundamental para que esos datos puedan ser útiles en el ámbito clínico (de Zambotti *et al.*, 2019). Esto es apoyado por la comunidad científica, que resalta la importancia de validar estos dispositivos en poblaciones con alguna condición de salud como pueden ser los trastornos del sueño (De Zambotti *et al.*, 2019; Shelgikar *et al.*, 2016).

No obstante, los/as investigadores/as son conscientes de que el rendimiento de estos dispositivos puede verse alterado por las interrupciones del sueño derivadas de sus propios trastornos (Shelgikar *et al.*, 2016). Concretamente en la investigación que dio lugar a esta tesis, la muestra está conformada por 25 personas con algún trastorno del sueño, siendo las apneas obstructivas del sueño (AOS) el trastorno mayoritario. Los resultados de este grupo de participantes muestra un rendimiento del dispositivo Xiaomi menor (Moreno-Pino *et al.*, 2019).

Por el contrario, en el grupo de participantes sin trastornos del sueño, el dispositivo Xiaomi presentó resultados más positivos que concuerdan con otras investigaciones similares (Chinoy *et al.*, 2021; De Zambotti *et al.*, 2018). En este grupo, la pulsera Xiaomi fue más precisa en la detección de algunas etapas del sueño, especialmente en la estimación del sueño PSG TST y PSG sueño profundo (Kubala *et al.*, 2020).

5.3.2. El sueño: una ocupación relevante en la población mayor

Los/as investigadores/as del sueño refieren que los dispositivos *wearables* permiten un seguimiento continuo del sueño y sus parámetros, además de la posibilidad de conocer su relación con diversos factores asociados con la salud y el funcionamiento diario (De Zambotti *et al.*, 2019). Así, en esta tesis doctoral se realizó un seguimiento a 21 personas mayores residentes de un centro gerontológico mediante el uso del dispositivo Xiaomi y varias herramientas de evaluación. Este estudio también les permitió a estos/as participantes conocer y explorar el uso de un dispositivo tecnológico como es la pulsera Xiaomi Mi Band 2.

En el Capítulo 1. Introducción, se refleja que la mala calidad y cantidad del sueño, junto con los trastornos asociados, se relacionan con el fenómeno del envejecimiento (Miner & Kryger, 2017). Los resultados de esta tesis doctoral muestran que los/as participantes tuvieron una duración del sueño por debajo de las recomendaciones establecidas, ya que durmieron de media 5,36 horas durante un año (Hirshkowitz *et al.*, 2015). En este sentido, el 95,23 % de los/as participantes refirieron una mala percepción de su calidad y cantidad de sueño. Los datos obtenidos en este estudio de la tesis también reflejan una relación del sueño con la actividad; específicamente, la duración del sueño puede ser un factor de predicción de la actividad diaria de las personas mayores (Lorenz *et al.*, 2014).

En este estudio, también se utilizaron diferentes herramientas de evaluación relacionadas con la percepción sobre el estado de salud y la calidad de vida de las personas. Así, se analizó la relación de las herramientas subjetivas, que recogen la percepción del/a participante, con una herramienta objetiva, como es la Xiaomi Mi Band 2. Los resultados señalan una relación estadística entre los datos de sueño y las puntuaciones de las escalas. De acuerdo con la literatura científica, los/as participantes con una mayor duración y calidad del sueño, presentaban un mejor estado cognitivo, mayor independencia en las AVD(s) y menor riesgo a caer (Martins da Silva *et al.*, 2020; Okuyan, 2017). En consecuencia, presentaban una buena percepción de su calidad de vida (Okuyan, 2017).

No obstante, los resultados destacan la relación estadísticamente negativa entre los datos del sueño del dispositivo Xiaomi y los datos obtenidos de la *Pittsburgh Sleep Quality Index* (PSQI). Así, la percepción que tienen los/as usuarios/as sobre su sueño, difiere de los datos objetivos de la pulsera Xiaomi. Con relación a este resultado, la evidencia señala la falta de relaciones significativas o la relación negativa entre algunos instrumentos del sueño, como la PSG, y la percepción de los/as participantes mediante la PSQI (Lorenz *et al.*, 2014; O'Donnell *et al.*, 2009). En este sentido, en el estudio de validación del dispositivo Xiaomi, que forma parte de esta tesis, se puede observar que los/as participantes con un trastorno del sueño, diagnosticado mediante la prueba PSG, y los/as participantes sin trastorno del sueño presentaron una percepción de su calidad y cantidad de sueño similar mediante la PSQI (9,8 y 10,30; respectivamente).

Por último, este estudio longitudinal también permitió realizar diversas observaciones sobre diferentes parámetros durante un largo período de tiempo, concretamente un año. Por tanto, se observó como las fluctuaciones en el tiempo y el ambiente podrían incidir en el estado de salud y el funcionamiento diario de la población estudiada. De acuerdo con la literatura, ciertos factores ambientales analizados se relacionaron con una mayor inactividad de los/as residentes y con un peor estado de su sueño (Schehl & Leukel, 2020). Asimismo, los resultados evidencian que la percepción sobre el estado de los/as participantes, el sueño y su actividad diaria disminuyeron en los últimos meses del año, con un empeoramiento que podría tener relación con el paso del tiempo o los factores ambientales (Grandner, 2017).

5.3.3. El estrés laboral y sus implicaciones sobre el sueño

En esta tesis también se presenta un trabajo asociado al estrés laboral y su influencia en el desempeño ocupacional, el sueño y la actividad física. Dicho estudio de protocolo se puede considerar innovador debido a su formato en línea, que evita la necesidad de reuniones e intervenciones presenciales con las personas participantes. De igual manera, este estudio pretendía que los/as participantes fuesen más conscientes de su estado de estrés, sueño, actividad y equilibrio en el resto de las ocupaciones, mediante la combinación de un dispositivo *wearable* y el uso de cuestionarios diarios y semanales.

El protocolo finalmente fue aplicado en una universidad en España y otra en Portugal. La participación de ambas instituciones le permitió al equipo investigador tener una perspectiva más amplia sobre el estrés en la actividad laboral y los aspectos relacionados con el sueño y la actividad diaria, debido a las diferencias culturales relacionadas con los hábitos y rutinas de cada país (Glaskin & Chenhall, 2013; Leive & Morrison, 2020).

La evidencia refleja que factores como la exigencia de horas extra, la inestabilidad laboral o las condiciones del puesto de trabajo pueden provocar estrés laboral y afectar al estado de salud del/a trabajador/a (Galant-Miecznikowska *et al.*, 2016). Estos factores se observan en los resultados de esta tesis, ya que la realización de horas extra fue un aspecto común en ambas universidades. No obstante, los resultados muestran un mayor nivel de estrés en los/as trabajadores/as de la Universidade do Porto (UP), que además presentaron una mayor situación de inestabilidad laboral.

Por otra parte, los cambios en las rutinas y los hábitos laborales generados por la pandemia de la COVID-19, también tuvieron una influencia significativa en los/as trabajadores/as (Zhuo *et al.*, 2020). De hecho, cuando este estudio se llevó a cabo la situación y normas sobre la pandemia diferían en ambos países, lo que pudo influir en los resultados obtenidos (Massar *et al.*, 2022). En concreto, el personal de la Universidade da Coruña (UDC), que combinó más horas de teletrabajo con la presencialidad, presentó más estrés debido a la pandemia. Asimismo, fue el que más estrés percibió por otros factores como el cuidado de otros (Stendardo *et al.*, 2021).

La evidencia también relaciona el estrés laboral con los problemas del sueño, que pueden provocar falta de motivación, frustración y bajo rendimiento laboral (Grandner, 2017). Los resultados revelan que los/as trabajadores/as de la UP presentaron una peor percepción de su estado del sueño, pero tuvieron, de media, una mayor duración del sueño de acuerdo con el dispositivo Xiaomi Mi Band 5.

Finalmente, la literatura refiere que la combinación del estrés laboral junto al agotamiento y a los problemas del sueño pueden provocar alteraciones en el tiempo de dedicación a las diferentes ocupaciones diarias, es decir, en su equilibrio ocupacional (Håkansson & Ahlborg, 2017). Según los hallazgos de esta tesis, los/as trabajadores/as de la UDC presentaron una mayor sobrecarga de tareas y un peor equilibrio ocupacional.

5.4. Limitaciones

Los resultados de las investigaciones que conforman esta tesis doctoral plantean una serie de limitaciones, que comienzan en la muestra. Así, en el segundo artículo científico se destaca que la muestra fue reducida debido a que solo 21 de los 44 residentes del centro participaron en la investigación debido a los criterios de inclusión definidos.

Con relación a los datos del dispositivo Xiaomi, en el manuscrito, se refleja que hubo varios factores que pudieron limitar el nivel de precisión de los resultados, en particular en relación con la falta de acceso a los datos en bruto y a los algoritmos del dispositivo Xiaomi. Además, en el segundo artículo se resalta que las alteraciones en las rutinas de algunos/as de los/as participantes mayores, con el uso continuo del dispositivo Xiaomi, pudieron provocar una pérdida de datos.

5.5. Futuras líneas de investigación

La presente tesis doctoral pretendió mostrar la relevancia de un dispositivo *wearable* como una solución tecnológica de bajo coste en la monitorización del sueño y sus parámetros en diferentes poblaciones.

En primer lugar, es necesario continuar realizando futuras investigaciones enfocadas en los dispositivos *wearables*. Por una parte, estos estudios podrían complementarse con investigaciones de metodología cualitativa para profundizar sobre el empleo de los dispositivos *wearables*, en el nivel de aceptación en función de diferentes grupos de edad e incluso, distinguiendo entre población con o sin trastornos del sueño. Por otra parte, es necesario conocer a través de estudios comparativos las incongruencias que puedan existir entre las medidas objetivas, en este caso los dispositivos *wearables*, en comparación con las medidas subjetivas, como las herramientas de medición de la calidad y cantidad del sueño.

En segundo lugar, con el propósito de obtener conclusiones más exhaustivas acerca del fenómeno de estudio podrían formularse estudios de casos y controles u otro tipo de diseños, en los que se evidencien las diferencias existentes en los datos obtenidos en población con o sin trastornos del sueño, con un tamaño de la muestra adecuado, e incluso diferenciando por grupos de edad (personas estudiantes, en etapa laboral o jubilados) y por género.

5.6. Implicaciones clínicas

Los hallazgos de esta tesis doctoral muestran la relevancia del uso de la tecnología *wearable* para la monitorización del sueño, contribuyendo a que las personas sean más conscientes de su sueño con un dispositivo no-invasivo, en tiempo real y de forma objetiva.

Concretamente, los resultados de la validación muestran que el dispositivo Xiaomi podría ser una herramienta de rastreo (*screening*) para la detección de posibles cambios o alteraciones en el estado del sueño de una persona, tanto en el ámbito clínico como científico. Así, estos dispositivos promueven una mayor involucración de la persona en los estudios, al poder ser más consciente de su estado de salud y de los posibles cambios que se producen en él. Todo esto puede contribuir a la promoción de hábitos saludables en la sociedad. En este sentido, se pueden crear guías con recomendaciones dirigidas a profesionales sociosanitarios que quieran integrar los dispositivos *wearables* en los procesos de salud de una forma participativa, promoviendo así la medicina participativa en la población y contribuyendo a la transformación digital de los sistemas de salud.

Finalmente, tal y como se propone en el proyecto SqoF-WEAR, el uso de este tipo de dispositivos contribuye a que la población general conozca la influencia de diferentes parámetros biomédicos, como son el sueño y el estrés, sobre la calidad de vida y el funcionamiento diario, siendo conscientes de sus hábitos y rutinas, en diferentes entornos como el laboral.

Chapter 6. Conclusions

Based on the reflections obtained after comparing the results of the studies with the scientific evidence on the topic, a series of conclusions are obtained that respond to both the general objective and the specific ones set out in this doctoral thesis. Thus, these conclusions highlight the use of wearable devices as an assessment tool for the analysis of sleep and its implications in people's daily lives.

Based on the findings obtained in the different studies that make up this doctoral thesis, conclusions were obtained. The overall conclusion is that wearable devices, such as the Xiaomi Mi Band 5 wristband, can be a possible technological solution to promote awareness of the relevance and implications of sleep and healthy lifestyle habits in the daily life of the population. Likewise, this device could be a tool to detect possible changes in long-term sleep. Specifically, it is concluded that :

- Validation studies are relevant to know the accuracy of the data from these devices depending on the population characteristics. In this way, people will be safer about the truthfulness of the data, and they can have an objective measure of their state of health.

- Sleep has relevant implications in different populations, such as the older population, where the presence of sleep disorders is significant. For this reason, research on sleep monitoring can allow us to analyze the implications of sleep on people's daily lives. Thus, it facilitates decision-making by health professionals to improve the sleep quality of the older with whom they work and even to provide feedback on possible changes or alterations in their sleep status.

- In the work environment, wearable devices can facilitate the detection of possible changes in different biomedical parameters, such as sleep, associated with work stress. Such detection can promote worker awareness and facilitate decision-making to mitigate problems arising from work-related stress.

- Technology as wearable devices can help improve and understand people's state of health, both physically and psychosocially. It can also lead to the development of personalized health plans, favoring the advancement of new models for person-centered health and social services and promoting participatory medicine.

Capítulo 6. Conclusiones

En base a las reflexiones obtenidas tras la comparación de los resultados de los estudios con la evidencia científica sobre la temática, se obtuvieron una serie de conclusiones que responden tanto al objetivo general como a los específicos expuestos en esta tesis doctoral. Así, estas conclusiones tratan de destacar el uso de los dispositivos ponibles (*wearables*) como una herramienta para el análisis del sueño y sus implicaciones en la vida diaria de las personas.

En base a los hallazgos obtenidos en los diferentes estudios que conforman esta tesis doctoral, la conclusión general es que los dispositivos ponibles (*wearables*), como la pulsera Xiaomi Mi Band, pueden ser una posible solución tecnológica que promueva una mayor concienciación sobre la relevancia e implicación del sueño y los hábitos de vida saludable en la vida diaria de la población. Asimismo, este dispositivo podría ser una herramienta para detectar posibles cambios en el sueño a largo plazo. Específicamente, se concluye que:

– Los estudios de validación son relevantes para conocer la precisión de los dispositivos en cuanto a los datos almacenados, en función de las características de la población. De esta manera, las personas tendrán mayor seguridad sobre la veracidad de estos y, así tener una medida objetiva sobre su estado de salud.

– El sueño tiene importantes implicaciones en diferentes poblaciones, como la población mayor, donde la presencia de los trastornos del sueño es significativa. Por esto, las investigaciones sobre el seguimiento del sueño pueden permitir analizar las implicaciones del sueño en la vida diaria de las personas. Así, se facilita la toma de decisión de los/as profesionales sociosanitarios/as para mejorar la calidad del sueño de las personas mayores con las que trabajan, e incluso, realizar una retroalimentación (*screening*) sobre los posibles cambios o alteraciones de su estado del sueño.

– En el ámbito laboral, los dispositivos *wearables* pueden facilitar la detección de posibles cambios en diferentes parámetros biomédicos, como puede ser el sueño, asociados al estrés laboral. Esta detección puede fomentar la conciencia del/a trabajador/a y facilitar la toma de decisiones para mitigar los problemas derivados del estrés laboral.

– La tecnología y por consiguiente los dispositivos *wearables* pueden ayudar a conocer mejor el estado de salud de las personas, tanto a nivel físico como psicosocial. Esto puede también dar lugar al desarrollo de planes de salud personalizados, favoreciendo el avance cara nuevos modelos de prestación de servicios sociosanitarios centrados en la persona y potenciando la medicina/salud participativa.

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Anexos

Anexo 1. Producción científica relacionada con la tesis doctoral

En este apartado, se recogen diferentes artículos científicos y presentaciones en congresos, nacionales e internacionales, que fueron publicados por la doctoranda y su grupo de investigación, y que se asocian con la temática de la tesis doctoral.

Artículos relacionados

1. Miranda-Duro MdC, Nieto-Riveiro L, **Concheiro-Moscoso P**, Groba B, Pousada T, Canosa N, Pereira J. Occupational Therapy and the Use of Technology on Older Adult Fall Prevention: A Scoping Review. International Journal of Environmental Research and Public Health. 2021; 18(2):702. https://doi.org/10.3390/ijerph18020702
2. Miranda-Duro MdC, Nieto-Riveiro L, **Concheiro-Moscoso P**, Groba B, Pousada T, Canosa N, Pereira J. Analysis of Older Adults in Spanish Care Facilities, Risk of Falling and Daily Activity Using Xiaomi Mi Band 2. Sensors. 2021; 21(10):3341. https://doi.org/10.3390/s21103341
3. Nieto-Riveiro L, Groba B, Miranda M. Carmen, **Concheiro P**, Pazos A, Pousada T, Pereira J. Technologies for participatory medicine and health promotion in the elderly population. Medicine. 2018; 97(20): e10791. 10.1097/MD.0000000000010791

Presentaciones en congresos nacionales e internacionales derivadas de la tesis

1. **Concheiro-Moscoso P**, Groba B, Monteiro-Fonseca S, Canosa N, Queirós C. SQoF-WEAR Project. The Use of Wearable Devices to Identify the Impact of Stress on Workers' Quality of Life. Engineering Proceedings. 2021; 7(1):25. https://doi.org/10.3390/engproc2021007025
2. Martínez-Martínez FJ, **Concheiro-Moscoso P**, Miranda-Duro MDC, Boedo FD, Muiño FJM, Groba B. Validation of Self-Quantification Xiaomi Band in a Clinical Sleep Unit. Proceedings. 2020; 54(1):29. https://doi.org/10.3390/proceedings2020054029
3. **Concheiro-Moscoso P**, del Carmen Miranda-Duro M, Fraga C, Queirós C, Marques AJPdS, Groba B. Design of a System to Implement Occupational Stress Studies Trough Wearables Devices and Assessment Tests. Proceedings. 2020; 54(1):19. https://doi.org/10.3390/proceedings2020054019
4. **Concheiro-Moscoso P**, Groba B, Canosa N. Sleep Disturbances in Nursing Home Residents: Links to Quality of Life and Daily Functioning. Proceedings. 2019; 21(1):12. https://doi.org/10.3390/proceedings2019021012
5. **Concheiro-Moscoso P**, Groba B, Pereira J, Miranda-Duro M.d.C, Nieto-Riveiro L, Pousada T. Sleep Disturbances in Nursing Home Residents in Spain: Links to Quality of Life and Daily Functioning. 19th IPA/SEPG Joint International Congress. 2019.

6. **Concheiro-Moscoso P**, Groba B, Pereira J, Miranda-Duro M.d.C, Nieto-Riveiro L, Pousada T. Las alteraciones del sueño en la vida diaria de las personas mayores mediante el uso de dispositivos wearables. 31º Congreso Internacional de Xeriatría e Xerontoloxía. 2019.
7. **Concheiro-Moscoso P**, Groba B, Pereira J. Estudio observacional de los trastornos del sueño en la calidad de vida y el funcionamiento diario de las personas mayores institucionalizadas. Ageing Congress 2018.

Anexo 2. Artículo "Study Protocol on the Validation of the Quality of Sleep Data from Xiaomi Domestic Wristbands" (primera y última página)

International Journal of
Environmental Research and Public Health

MDPI

Protocol

Study Protocol on the Validation of the Quality of Sleep Data from Xiaomi Domestic Wristbands

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Abstract: (1) *Background*: Sleep disorders are a common problem for public health since they are considered potential triggers and predictors of some mental and physical diseases. Evaluating the sleep quality of a person may be a first step to prevent further health issues that diminish their independence and quality of life. Polysomnography (PSG) is the "gold standard" for sleep studies, but this technique presents some drawbacks. Thus, this study intends to assess the capability of the new Xiaomi Mi Smart Band 5 to be used as a tool for sleep self-assessment. (2) *Methods*: This study will be an observational and prospective study set at the sleep unit of a hospital in A Coruña, Spain. Forty-three participants who meet the inclusion criteria will be asked to participate. Specific statistical methods will be used to analyze the data collected using the Xiaomi Mi Smart Band 5 and PSG. (3) *Discussion*: This study offers a promising approach to assess whether the Xiaomi Mi Smart Band 5 correctly records our sleep. Even though these devices are not expected to replace PSG, they may be used as an initial evaluation tool for users to manage their own sleep quality and, if necessary, consult a health professional. Further, the device may help users make simple changes to their habits to improve other health issues as well. Trial registration: NCT04568408 (Registered 23 September 2020).

Keywords: sleep; health promotion; daily life activities; occupation; polysomnography; Xiaomi Mi Smart Band 5; wearable technology; participatory health; internet of things

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1. Introduction

Sleep is an occupational area that has considerable implications on our daily life [1,2]. Thus, sleep disorders have become one of the most important common problems in public health [3]. The prevalence of sleep disorders increases with age [4], even though they can appear at any life stage. Bad quality and quantity of sleep, sleep arousals, and a strong will to take diurnal naps are the main complaints among the general population [5,6]. Epidemiological studies indicate that between 20% and 48% of adults between 34 and 60 years old have difficulties initiating and maintaining sleep [7]. In fact, insomnia, which is the most common sleep disorder, is present in 30–45% of the population [8].

Several studies state that sleep disorders are related to health status and quality of life in the general population [9], leading to difficulties in the performance of daily life activities, which in turn causes physical exhaustion, low productivity, a greater risk of falling, mood problems, and diurnal sleep, among many others [10–14].

These factors related to sleep disorders cause a direct and indirect economic burden, causing public health costs to rise [15,16]. Different studies have shown a direct relation

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Anexo 3. Material suplementario del artículo “Study Protocol on the Validation of the Quality of Sleep Data from Xiaomi Domestic Wristbands”

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number on which item is reported
		Administrative information	
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	The title is on the page 1.
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	It is in the “Abstract: Trial Registration” section, on the page 1.
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	This item is in the “Abstract: Trial Registration” section, on the page 1.
Funding	4	Sources and types of financial, material, and other support	It is in the “Funding” section on the page 6.
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	The names are indicated below the title. The affiliations and the "Authors' contributions" section are on the page 1 and 6, respectively.

Continued

	5b	Name and contact information for the trial sponsor	The information of the principal investigator is specified in the "Availability of data and material" section (page 6).
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	It is in the "Author's contributions" and "Funding" sections (page 6).
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	It is in the "Author's contributions" section (page 6).
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	It is in the "Background" section (page 1-3).
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	It is in the "Objective" section, on the page 3.
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	It is specified in the "Methods-study design" section, on the page 3.
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	It is in the "Methods-study settings" section, on the page 3.
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	It's in the "Methods-eligibility criteria" section, on the page 3.

Continued

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	It is in the "Methods-Recruitment process" section (page 3-4).
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	It is in the "Methods-Eligibility criteria" section (page 3).
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	It is in the "Methods-Outcomes" section, on the page 4.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	It is in the "Methods-Recruitment process" section, on the page 3-4.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	It is in the "Methods-Justification of sample size" section, on the page 4.
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	It is in the "Methods-Recruitment process" section, on the page 3-4.

Continued

Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementati on	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	It is in the "Methods-Data collection and management" section (page4-5).
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	It is in the "Methods-Data collection and management" section, on the page 4-5.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	It is in the "Methods-Data analysis" section, on the page 5.

Continued

	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	It is in the "Ethics and dissemination" section (page 5-6).
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	It is in the "Ethics and dissemination" section (page 5-6).
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	It is in the "Ethics and dissemination" section (page 5-6).
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	It is in the "Ethics and dissemination" section (page 5-6).
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	It is in the "Conflicts of Interest" section (page 7).

Continued

Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	It is in the "Ethics and dissemination" section, on the pages 5-6.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	It is in the "Ethics and dissemination" section, on the pages 5-6.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	It is in the "Ethics and dissemination" and "Discussion" sections, on the pages 5-6.
	31b	Authorship eligibility guidelines and any intended use of professional writers	It is in the "Author's contributions" section (page 6).
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	It is in the "Availability of data and materials" section (page 6).
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	It is in the "Availability of data and materials" section (page 6).
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Anexo 4. Manuscrito "Quality of sleep data validation from the Xiaomi Mi Band 5 compared with Polysomnography" (primera y última página)

Original Paper

Quality of Sleep Data Validation from the Xiaomi Mi Band 5 Compared With Polysomnography

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Abstract

Background: Polysomnography is the gold standard for measuring and detecting sleep patterns. In recent years, activity wristbands have become popular because they record continuous data in real time. Thereby, comprehensive validation studies are needed to analyze the performance and reliability of these devices in the recording of sleep parameters. **Objective:** This study compared the performance of one of the best-selling activity wristbands, the Xiaomi Mi Band 5, against polysomnography in measuring the sleep stages. **Methods:** This study was carried out in a hospital in A Coruña, Spain. People who attended to perform a polysomnography study in a sleep unit were recruited to wear a Xiaomi Mi Band 5 simultaneously for one night. The total sample was 45 adults with and without sleep disorders. **Results:** Overall, the Xiaomi Mi Band 5 had 78% accuracy, 89% sensitivity, 35% specificity, and 0.22 Cohen's kappa. It significantly overestimated polysomnography total sleep time, "light sleep" (N1+N2), and "deep sleep" (N3). In addition, it underestimated polysomnography wake after sleep onset and rapid eye movement sleep. Moreover, the Xiaomi Mi Band 5 performed better in people without sleep problems than people with sleep problems, specifically in detecting total sleep time and "deep sleep". **Conclusions:** The Xiaomi Mi Band 5 can be a potential device to monitor sleep and to detect changes in sleep patterns, especially for people without sleep problems. Moreover, additional studies are necessary with this device in people with different types of sleep disorders.

Trial Registration: NCT04568408. Available: https://clinicaltrials.gov/ct2/show/NCT04568408 (Registered September 23, 2020).

Keywords: sleep; health promotion; occupation; polysomnography; Xiaomi Mi Band 5; internet of things

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Anexo 5. Material suplementario del manuscrito "Quality of sleep data validation from the Xiaomi Mi Band 5 compared with Polysomnography"

Table S1. Summary of main findings of Xiaomi and other devices.

	Xiaomi			Fitbit			
	Mi Band 5	**Mi Band 3** [9]	**Mi Band 2** [30]	**Alta HR** [34,36]	**Charge HR** [35]	**Charge 2** [37]	**Jabwone UP3** [38]
TST (minutes)	-29.54 (72.54)	61 (-)	69.64 (67.43)	53.33 (-) / -59.78 (99.62)	-8 (21)	-9(24)	59.1 (-)
WASO (minutes)	31.44 (61.92)	-	-33.57 (42.84)	-48.37 (-) / 36.14 (48.60)	5.6 (14.3)	5 (19)	-
SOL (minutes)	-8.62 (53.76)	-	-	-1.99 (-) / 23.22 (24.47)	2.5 (11.4)	4 (9)	-
SE (%)	-5.82 (17.67)	-	13.25 (-)	11.78 (-) / -	-1.8 (4.5)	-	14.9 (-)
Time in N1+N2 ("light sleep") (minutes)	-29.81 (67.98)	-	-	138.30 (-) / -68.82 (76.77)	-	-34 (34)	-
Time in N3 ("deep sleep") (minutes)	-14.64 (59.97)	-	-	-59.40 (-) / 74.24 (46)	-	24 (28)	-
Time in REM (minutes)	19.49 (36.40)	-	-	18.50 (-) / -2.78 (33.32)	-	1 (27)	-
Awake (minutes)	28.36 (72.69)	-	-	-96.97 (-) / 41.93 (55.92)	-	-	-

Outcomes Epoch by Epoch analysis					
	Mi Band 5	**Alta HR** [36]	**Charge 2** [37]	**Õura Ring** [39]	**Actigraphy** [60]
Accuracy	0.78 (0.13)	-	-	-	-
Sensitivity	0.89 (0.16)	0.87 (-)	0.96 (-)	0.95 (4.5)	0.96 (-)
Specificity	0.35 (0.11)	0.44 (-)	0.61 (-)	0.48 (19.1)	0.37 (-)
Cohen's kappa	0.22 (0.23)	-	0.52 (0.14)	-	0.79 (-)

Supplementary file 2. Analysis of data according to the type of sleep disorder

The group with sleep disorders was divided according to the type of disorder to determine the performance of the Xiaomi Mi Band 5. The authors decided to divide the group between people with obstructive sleep apnea (OSA, n = 18) and people with other types of sleep disorders ("Other SDis", n = 7) such as insomnia, narcoleptic syndrome, a combination of hypersomnia and narcoleptic syndrome, and a combination of sleep apnea syndrome and hypoventilation syndrome. The authors chose this division because the number of people with the other sleep problems is small.

Results

Comparison of PSG and Xiaomi Mi Band 5 Sleep Measures

Table S2 shows the results for PSG and the Xiaomi Mi Band 5 in OSA and “Other SDis” group There were no significant differences in sleep measures such as "initial sleep onset," TSPD, SE, and “light sleep” in the OSA group. However, the Xiaomi Mi Band 5 significantly overestimated PSG TST, PSG SOL, and PSG "deep sleep", and it underestimated PSG WASO, PSG awakenings, PSG REM, and PSG awake time. In the “Other SDis” group, there were no significant differences in WASO, "light sleep", and REM sleep variables. Nevertheless, the Xiaomi Mi Band 5 significantly overestimated PSG TSPD, PSG TST, PSG "deep sleep", and the percentage in PSG SE. This device underestimated PSG "initial sleep onset ", PSG awakenings and PSG awake time.

Table S2. Comparison of polysomnography (PSG) and Xiaomi Mi Band 5 sleep measures in the OSA and “Other SDis” groups.

		PSG		**Xiaomi Mi Band 5**		t	z	*P*	d
		Mean (SD)	±95% CI	Mean (SD)	±95% CI				
Lights-on (hh:mm)	*OSA*	07:02 (00:19)	07:12-06:52	-	-	-	-	-	-
	Other SDis	23:49 (00:33)	07:24-06:34	-	-	-	-	-	-
Lights-off (hh:mm)	*OSA*	23:39 (00:32)	23:55-23:23	-	-	-	-	-	-
	Other SDis	06:59 (00:27)	00:20-23:18	-	-	-	-	-	-
Initial sleep onset (hh:mm)	*OSA*	00:07 (00:45)	00:29-23:44	00:16 (01:16)	00:54-23:38	-0.54	-	**0.595**	-0.228*
	Other SDis	01:02 (01:25)	02:21-023:43	00:02 (01:09)	01:06-22:59	2.32	-	0.059	0.878***
TIB (minutes)	*OSA*	445.90 (38.87)	465.24-426.57	-	-	-	-	-	-
	Other SDis	428.80 (47.09)	472.36-385.25	-	-	-	-	-	-
TSPD (minutes)	*OSA*	412.96 (45.83)	435.75-390.16	403.46 (49.79)	428.23-378.70	0.91	-	**0.378**	0.213*
	Other SDis	353.32 (89.53)	436.12-270.52	400.53 (63.25)	459.02-342.04	-2.03	-	0.089	-0.767**
TST (minutes)	*OSA*	353.67 (59.46)	383.24-324.10	379.14 (56.93)	407.45-350.82	-	-1.87	0.031	-0.440*
	Other SDis	267.30 (115.24)	373.88-160.72	349.70 (111.77)	453.07-246.32	-	-2.98	0.024	-1.13***
WASO (minutes)	*OSA*	59.29 (48.77)	83.54-35	24.32 (30.45)	39.47-9.18	-	2.36	0.031	0.556**
	Other SDis	86.03 (81.54)	161.44-10.61	50.83 (83.63)	128.18--26.52-	-	1.03	**0.341**	0.391*
Awakenings (> 5 minutes) (number per night)	*OSA*	3.17 (1.73)	4.02-2.30	0.77 (0.88)	1.21-0.34	-	4.84	<0.001	1***
	Other SDis	4.14 (3.24)	7.13-1.15	0.57 (1.13)	1.62--0.47	-	2.69	0.036	1***
SOL (minutes)	*OSA*	22.87 (19.69)	32.66-13.07	49.14 (55.50)	76.74-21.55	-	-1.81	0.087	-0.427*
	Other SDis	68.98 (68.45)	132.29-5.67	21.77 (24.38)	44.32--0.78	-	2.03	0.089	0.767**

Table S2. Comparison of polysomnography (PSG) and Xiaomi Mi Band 5 sleep measures in the OSA and "Other SDis" groups. (Continued)

		PSG		Xiaomi Mi Band 5		t	z	*P*	d
		Mean (SD)	±95% CI	Mean (SD)	±95% CI				
SE (%)	*OSA*	81.12 (11.28)	86.73-75.51	84.40 (13.53)	91.13-77.67	-	-0.80	**0.433**	-0.289*
	Other SDis	63.44 (27.47)	88.85-38.03	82.17(23.41)	103.83-60.51	-	-3.10	0.021	-1.17***
Time in N1 (minutes)	*OSA*	10.86 (8.50)	15.08-6.63	-	-	-	-	-	-
	Other SDis	13.86(9)	22.18-5.53	-	-	-	-	-	-
Time in N2 (minutes)	*OSA*	219.63 (47.63)	243.32-195.95	-	-	-	-	-	-
	Other SDis	166.86 (81.17)	241.94-91.80	-	-	-	-	-	-
Time in N1+N2 ("light sleep") (minutes)	*OSA*	230.49 (44.66)	252.70-208.29	237.22 (48.73)	261.45-212.99	-0.39	-	**0.699**	-0.193*
	Other SDis	180.73 (84.83)	259.18-102.27	234.99 (85.62)	314.18-155.80	-1.93	-	**0.101**	-0.731**
Time in N3 ("deep sleep") (minutes)	*OSA*	51.19 (29.98)	66.10-36.28	81.56 (34)	98.46-64.65	-3.51	-	0.003	-0.828***
	Other SDis	38.57 (26.61)	63.18-13.95	63.69 (29.54)	91.01-36.37	-1.74	-	**0.131**	-0.661**
Time in REM (minutes)	*OSA*	71.98 (28.14)	85.97-57.99	48.81(36.21)	66.82-30.80	2.87	-	0.010	0.678**
	Other SDis	48 (34.05)	79.49-16.50	51.01 (37.85)	86.01-16	-0.35	-	**0.749**	-0.227*
Awake (minutes)	*OSA*	81.64 (50.46)	106.73-56.54	56.17(48.22)	80.15-32.19	-	1.86	0.079	0.440**
	Other SDis	155 (114.71)	261.11-48.89	72.60 (93.56)	159.14-13.93	-	2.98	0.024	1***

REM, rapid-eye-movement; SDis, sleep disorder; SE, sleep efficiency; SOL, sleep onset latency; TIB, time in bed; TSPD, total sleep period duration; TST, total sleep time; WASO, wake after sleep onset.
t values correspond to t-tests. z values correspond to the Mann-Whitney-Wilcoxon test. d values correspond to Cohen's d: small effect (*), moderate effect (**), or large effect (***).

Bland-Altman Plots

Table S3 presents Bland Altman biases, SD ±95% CI, and the lower and upper agreement limits. In the OSA group, the Xiaomi Mi Band 5 significantly overestimated PSG TST by 25.47 minutes, PSG SOL by 26.27 minutes, and PSG "deep sleep" by 30.36 minutes. It underestimated PSG WASO by 34.96 minutes, PSG awakenings by 2.39 epochs, PSG REM sleep by 23.17 minutes, and PSG awake by 25.46 minutes. Furthermore, this device significantly overestimated PSG TST by 82.40 minutes, PSG TSPD by 47.21 minutes, PSG SE by 18.73 points, PSG "light sleep" by 54.27 minutes, and PSG "deep sleep" by 25.12 minutes in the "Other SDis". It underestimated PSG "initial sleep onset" by 59 minutes, PSG awakenings by 3.57 epochs, and PSG awake by 82.40 minutes.

Table S3. Bland-Altman parameters for the comparison between polysomnography (PSG) and the Xiaomi Mi Band 5 in the OSA and "Other SDis" groups.

		Bias (SD)	**±95% CI of the bias**	**Lower agreement limit**	**Upper agreement limit**	**Number of participants exceeding the agreement limits**
Initial sleep onset (hh:mm)	*OSA*	-00:09 (01:13)	00:26-00:45	-02:12	02:30	1
	Other SDis	00:59 (01:07)	02:02-00:03	-01:12	03:10	3
TST (minutes)	*OSA*	-25.47 (57.87)	3.30-54.25	-138.89	87.96	0
	Other SDis	-82.40 (72.95)	-14.93-149.87	-225.39	60.58	1
TSPD (minutes)	*OSA*	9.49 (44.47)	31.61-12.62	-77.68	96.66	0
	Other SDis	-47.21 (61.52)	9.69-104.10	-167.78	73.36	1
WASO (minutes)	*OSA*	34.96 (62.90)	66.24-3.68	-88.32	158.25	0
	Other SDis	35.19 (89.99)	118.42-48.03	-141.19	211.57	1
Awakenings (> 5 minutes) (number per night)	*OSA*	2.39 (2.09)	3.43-1.35	-1.7	6.48	2
	Other SDis	3.57 (3.50)	6.81-0.33	-3.18	10.32	1
SOL (minutes)	*OSA*	-26.27 (61.47)	4.29-56.84	-146.76	94.21	1
	Other SDis	47.21 (61.52)	104.10-9.68	-73.36	167.78	1
SE (%)	*OSA*	-3.28 (17.31)	5.33-11.88	-37.21	30.66	1
	Other SDis	-18.73 (15.97)	-3.95-33.50	-50.03	12.58	1
Time in N1+N2 ("light sleep") (minutes)	*OSA*	-6.72 (72.55)	29.36-42.80	-148.93	135.48	1
	Other SDis	-54.27 (74.28)	28.07-122.97	-199.87	91.33	1
Time in N3 ("deep sleep") (minutes)	*OSA*	-30.36 (36.66)	-12.13-48.59	-102.21	41.48	0
	Other SDis	-25.12 (38.02)	10.05-60.29	-99.65	49.41	0
Time in REM (minutes)	*OSA*	23.17 (34.16)	40.16-6.18	-43.79	90.13	0
	Other SDis	-3.01 (23.77)	18.97-24.99	-49.60	43.57	0
Awake (minutes)	*OSA*	25.46 (57.87)	54.25-3.31	-87.96	138.90	
	Other SDis	82.40(72.95)	149.87-14.93	-60.59	225.39	

CI, confidence interval; REM, rapid-eye-movement; SDis, sleep disorders; SE, sleep efficiency; SOL, sleep onset latency; TSPD, total sleep period duration; TST, total sleep time; WASO, wake after sleep onset.

Epoch by Epoch analysis

Table S4 shows the accuracy and Kappa levels for the sleep/wake and sleep stages classifications by Xiaomi Mi Band 5. In the sleep/wake epochs identification, the accuracy level was 0.77 and 0.74 for OSA and "Other SDis" groups. The accuracy in the detection of sleep stages was low, with values between 0.42 and 0.48 for both groups. Concerning Kappa, the values were slight in the OSA group, and they were between fair and slight in the "Other SDis" group.

Table S4. Overall accuracy and kappa statistics for 2-way and 4-way epoch by epoch classification for OSA and "Other SDis" groups.

	2-way		**4-way**	
	Accuracy	**Kappa**	**Accuracy**	**Kappa**
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
OSA	0.77 (0.10)	0.16 (0.23)	0.42 (0.10)	0.10 (0.14)
Other SDis	0.74 (0.15)	0.22 (0.33)	0.48 (0.07)	0.13 (0.15)

Cohen's Kappa (k): 0-0.2 (slight); 0.21-0.40 (fair); 0.41-0.60 (moderate); 0.61-0.80 (substantial); > 0.80 (almost perfect)

Conclusion

In general, Xiaomi significantly overestimated and underestimated most of the sleep measures in both groups. However, the Xiaomi device was less accurate in the estimates of sleep variables in the "Other SDis" group. Concerning the performance of Xiaomi in the detection of sleep/wake stages and sleep stages, the results were similar in both groups. However, the Kappa coefficients were slightly higher in the "Other SDis" group.

Anexo 6. Artículo "Use of the Xiaomi Mi Band for sleep monitoring and its influence on the daily life of older people living in a nursing home" (primera y última página)

Original Research

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SAGE

Use of the Xiaomi Mi Band for sleep monitoring and its influence on the daily life of older people living in a nursing home

Patricia Concheiro-Moscoso[1,2], Betania Groba[1,2], Francisco José Martínez-Martínez[1,3], María del Carmen Miranda-Duro[1,2], Laura Nieto-Riveiro[1,2], Thais Pousada[1,2] and Javier Pereira[1,2]

Abstract

Background: Lower quantity and poorer sleep quality are common in most older adults, especially for those who live in a nursing home. The use of wearable devices, which measure some parameters such as the sleep stages, could help to determine the influence of sleep quality in daily activity among nursing home residents. Therefore, this study aims to analyse the influence of sleep and its changes concerning the health status and daily activity of older people who lived in a nursing home, by monitoring the participants for a year with Xiaomi Mi Band 2. **Methods:** This is a longitudinal study set in a nursing home in [Details omitted for double-anonymized peer reviewed]. The Xiaomi Mi Band 2 will be used to measure biomedical parameters and different assessment tools will be administered to participants for evaluating their quality of life, sleep quality, cognitive state, and daily functioning. **Results:** A total of 21 nursing home residents participated in the study, with a mean age of 86.38 ± 9.26. The main outcomes were that sleep may influence daily activity, cognitive state, quality of life, and level of dependence in activities of daily life. Moreover, environmental factors and the passage of time could also impact sleep. **Conclusions:** Xiaomi Mi Band 2 could be an objective tool to assess the sleep of older adults and know its impact on some factors related to health status and quality of life of older nursing homes residents. **Trial Registration:** NCT04592796 (Registered 16 October 2020) Available on: https://clinicaltrials.gov/ct2/show/NCT04592796.

Keywords

Sleep, aging, participatory health, quality of life, activities of daily life, occupational therapy, wearable technology, xiaomi mi smart band 2

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Introduction

Sleep is considered an occupation that performs a vital role in people's health and well-being.[1] As people age, the duration and quality of sleep are negatively influenced by alterations in its sleep-wake cycle, with less restful deep sleep and sleep stages fragmented by increased nocturnal awakenings.[2,3] Likewise, changes associated with the passage of time, such as changes in roles, environment, or healthy lifestyle habits, affect sleep status.[4,5] In the aging stage, sleep problems are often underdiagnosed, and their prevalence depends on social and environmental factors and daily habits and routines.[2,6] Globally, it is estimated that 40%–60% of the older population has poor sleep quality and sleep difficulties.[7] Therefore, sleep problems have become a problem associated with the growing aging phenomenon,[8,9] and a relevant public health problem, mainly affecting older people's quality of life.[7,8]

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Table 9. Continued.

Assessment tool	Description	Score
		<19 points mean a high risk of falling, 19–24 represents a moderate risk of falling, and <24 reflects low fall risk[43].
Pittsburgh Sleep Quality Index	The PSQI assesses sleep quality. Specifically, it has 19 items associated with quantity, quality, duration, latency, and sleep efficiency[38].	The total score of the PSQI scale is the result of adding seven components, rated from 0 to 3. The resulting score ranges from 0 to 21, a total score of 0 indicates no sleep difficulties, and a score of 21 means severe difficulties in all sleep areas, so the higher score, the worse sleep quality[38]. However, previous studies referred to more appropriate cut-off scores to indicate 'poor sleep quality' in groups as susceptible to sleep problems as the older population[6,39]. Thus, following the indications of these authors, it was considered: that a PSQI total score of <5 indicated 'good sleep quality'; 5–9 points indicated 'modest sleep quality'; and >10 points indicated 'poor sleep quality'[6,39].

MCE: mini-cognitive examination; PSQI: Pittsburgh Sleep Quality Index; VAS: Visual Analogue Scale; GDS: Global Deterioration Scale; ADL: activities of daily living.

Anexo 7. Apéndice del artículo "Use of the Xiaomi Mi Band for sleep monitoring and its influence on the daily life of older people living in a nursing home"

Table 9. Assessment tools

Assessment tool	Description	Score
Lobo Mini-Cognitive Examination	The participants' cognitive status was evaluated using the Lobo MCE, a brief test used to detect the existence of cognitive impairment[1].	A total score between 0-23 indicates the presence of cognitive impairment, while a total score between 23-35 suggests mild cognitive impairment or absence[1]. Also, the Reisberg Global Deterioration Scale (GDS) classified the cognitive function of the participants in the following stages based on the score obtained on the Lobo MCE: "No cognitive decline" (30-35 points), "Very mild cognitive decline" (25-30 points); "Mild cognitive impairment" (20-24 points), "Mild dementia" (15-19 points), and "Moderate dementia" (0-14 points)[2]. It is highlighted that of Lobo MCE was used as a screening tool to detect the presence of cognitive impairment and to determine the association between the cognitive status and the rest of the variables. So, the GDS was only used to ascertain the baseline cognitive status of the study population at the beginning of the study.
EuroQol 5D-5L	The participants' perception of the quality of life and health status was analyzed using the EQ 5D-5L scale[3]. It has made up of two components[3]. The descriptive system includes five dimensions (mobility, personal care, daily activities, pain/discomfort, and anxiety/depression)[3].	Its score is based on five points assigned to each of the dimensions according to the severity level (1=Absence of problems, 5=Presence of severe problems) that provide a profile (i.e.,12332) on health status[3]. The Visual Analogue Scale (VAS) extends from 0 (the worst imaginable state of health) to 100 (the best imaginable state of health)[3].
Barthel Activities of Daily Living Index	This hetero-administrated tool allows measuring the performance in ADLs(Novak *et al.*, 1996).	It values the level of independence in some daily activities and has a range of total scores between 0-100, with 0 the maximum dependence and 100 the maximum independence. The total scores are interpreted as follows: <20 (total dependence), 21-60 (severe dependence), 61-90 (moderate dependence), 91-99 (mild dependence), 100 (independence/90 if the person is wheelchair)[4].
Tinetti scale	This tool assesses the person's gait and balance. It is used to detect the risk of falling.	A higher score indicates a higher functionality, and a lower score reflects the possibility of fall risk[5]. The balance scale has a maximum score of 16 points, and the gait scale has a score of 12 points. The total score range is 0-28, with 0 as the maximum level of risk of falling and 28 as the minimum level of risk of falling[5]. The different scores can be interpreted as follows: <19 points mean a high risk of falling, 19-24 represents a moderate risk of falling, and <24 reflects low fall risk[5].

Continued

Assessment tool	Description	Score
Pittsburgh Sleep Quality Index	The Pittsburgh Sleep Quality Index (PSQI) assesses sleep quality. Specifically, it has 19 items associated with quantity, quality, duration, latency, and sleep efficiency(Buysse *et al.*, 1989).	The total score of the PSQI scale is the result of adding seven components, rated from 0-3. The resulting score ranges from 0-21, a total score of 0 indicates no sleep difficulties, and a score of 21 means severe difficulties in all sleep areas, so the higher score, the worse sleep quality[6]. However, previous studies referred to more appropriate cut-off scores to indicate "poor sleep quality" in groups as susceptible to sleep problems as the older population[7,8]. Thus, following the indications of these authors, it was considered: that a PSQI total score of <5 indicated "good sleep quality"; 5-9 points indicated "modest sleep quality"; and >10 points indicated "poor sleep quality"[7,8].

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Anexo 8. Artículo "Study for the design of a protocol to assess the impact of stress in the quality of life of workers" (primera y última página)

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MDPI

Study Protocol

Study for the Design of a Protocol to Assess the Impact of Stress in the Quality of Life of Workers

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Abstract: (1) Background: Work stress is one of the most relevant issues in public health. It has a significant impact on health, especially the development of mental disorders, causing occupational imbalance. There is a growing interest in the development of tools with a positive effect on workers. To this end, wearable technology is becoming increasingly popular, as it measures biometric variables like heartbeat, activity, and sleep. This information may be used to assess the stress a person is suffering, which could allow the development of stress coping strategies, both at a professional and personal level. (2) Methods: This paper describes an observational, analytical, and longitudinal study which will be set at a research center in A Coruña, Spain. Various scales and questionnaires will be filled in by the participants throughout the study. For the statistical analysis, specific methods will be used to evaluate the association between numerical and categorical variables. (3) Discussion: This study will lay the foundation for a bigger, more complete study to assess occupational stress in different work environments. This will allow us to begin to understand how occupational stress influences daily life activity and occupational balance, which could directly enhance the quality of life of workers if the necessary measures are taken.

Keywords: work stress; occupational balance; occupational therapy; burnout; wearable technology; participatory health; Xiaomi Mi Smart Band 3

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1. Introduction

Work is one of the most significant areas of occupation in adulthood, and has great relevance at a social and personal level throughout life [1,2]. Work and working conditions have a significant impact on health [3]. Stressful situations occur in the worker when these conditions are altered by different factors (work overload, lack of support, work schedules, or lack of family reconciliation) [4–6], giving rise to a specific type of stress called work stress [7,8]. Work stress is defined as "the reaction that the individual may have to work demands and pressures that do not match his knowledge and skills, and that test his ability to cope with the situation" [9].

It is estimated that work stress affects three million workers worldwide [10], and that it represents between 50–60% of the cases of absenteeism and presenteeism [11,12]. In addition, several studies have reported that the health sector suffers the most from this type of problem [13–15]. In line with this data, occupational stress has become one of the most relevant problems for public and occupational health [16–18].

Work-related stress has important repercussions at the personal and health levels, but also at the social level [19]. Several studies have reported that work-related stress is

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Anexo 9. Material suplementario del artículo "Study for the design of a protocol to assess the impact of stress in the quality of life of workers"

Appendix A. Weekly and daily questionnaire items.

Daily Questionnaire	
The three following questions, which reflect stress, work commitment, and frustration, will be sent to participants on a daily basis.	
Item 1	How exhausted did you feel today for reasons related to your work?
Item 2	How motivated were you at work today?
Item 3	How irritated or frustrated were you today for reasons related to your work?
Weekly Questionnaire	
The questions that will be sent on a weekly basis are the following:	
Item 1	During this week you have been stressed out as a result of facing: • Meetings you consider pointless • Communication problems • Task overload
Item 2	During this week, have you felt that your sleep has been sufficient and repairing
Item 3	During this week, how do you evaluate the intensity of your physical activity?
Item 4	During this week, how would you rate your occupational balance? Occupational balance is understood as equal and optimal participation in your activities of daily life (work, sleep and rest, self-care activities, home, and care activities, and leisure/free time).

Anexo 10. Material suplementario del artículo “Study for the design of a protocol to assess the impact of stress in the quality of life of workers”

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number on which item is reported
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	The title is on the page 1.
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	It is in the “Ethics and dissemination” section, on the page 6.
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	This item is in the “Ethics and dissemination” section, on the page 6.
Funding	4	Sources and types of financial, material, and other support	It is in the “Funding” section on the page 7.
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	The names are indicated below the title. The affiliations and the "Authors' contributions" section are on the page 1 and 7, respectively.
	5b	Name and contact information for the trial sponsor	The information of the principal investigator is specified in the "Availability of data and material" section (page 7).
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	It is in the “Author’s contributions” and “Funding” sections (page 7).

Continued

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	It is in the "Author's contributions" section (page 7).
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	It is in the "Background" section (page 1-3).
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	It is in the "Objective" section, on the page 3.
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	It is specified in the "Methods-study design" section, on the page 3.
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	It is in the "Methods-participants and settings" section, on the page 3.
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	It's in the "Methods-participants and settings" section, on the page 3.
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	It is in the "Methods-Recruitment process" section (page 3).
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	It is in the "Methods-Eligibility criteria" section (page 3-4).
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	It is in the "Methods-Outcomes" section, on the page 4.

Continued

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	It is in the "Methods-Recruitment process" section, on the page 3-4.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	It is in the "Methods-Justification of sample size" section, on the page 4.
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	It is in the "Methods-Recruitment process" section, on the page 3-4.
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA

Continued

Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	It is in the "Methods-Data collection and management" section (page4-5).
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	It is in the "Methods-Data collection and management" section, on the page 4-5.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	It is in the "Methods-Data analysis" section, on the page 6.
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA

Continued

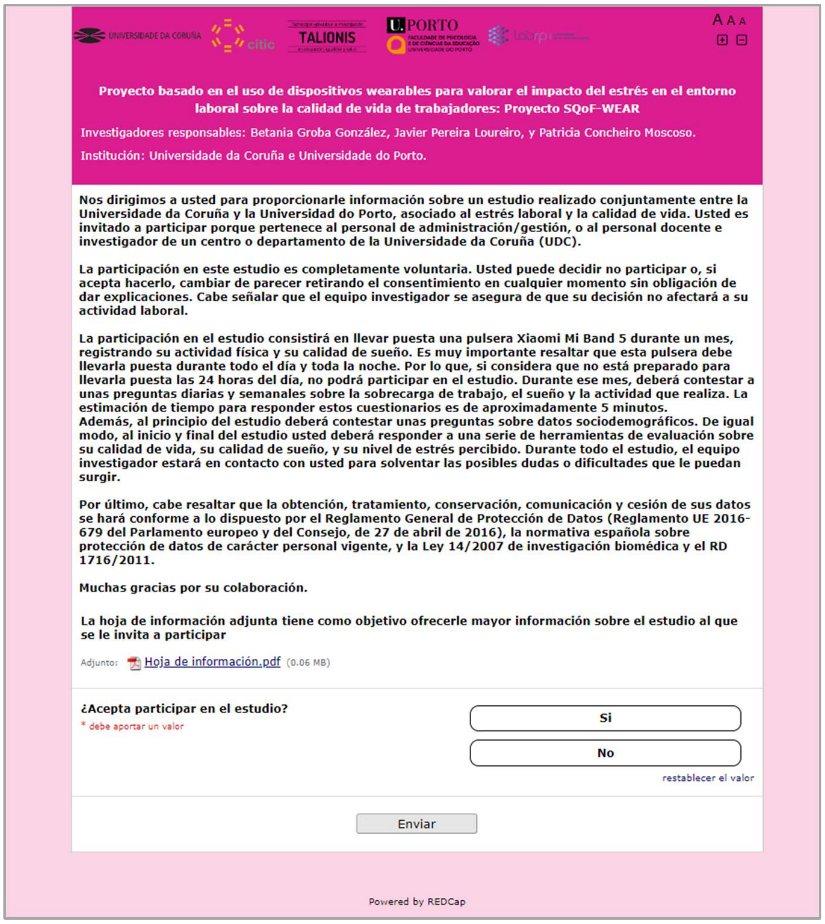
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	It is in the "Ethics and dissemination" section (page 6-7).
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	It is in the "Ethics and dissemination" section (page 6-7).
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	It is in the "Ethics and dissemination" section (page 6-7).
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	It is in the "Ethics and dissemination" section (page 6-7).
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	It is in the "Conflicts of Interest" section (page 7).
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	It is in the "Ethics and dissemination" section, on the pages 6-7.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	It is in the "Ethics and dissemination" section, on the pages 6-7.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	It is in the "Ethics and dissemination" and "Discussion" sections, on the pages 7.

Continued

	31b	Authorship eligibility guidelines and any intended use of professional writers	It is in the “Author’s contributions” section (page 7).
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	It is in the “Availability of data and materials” section (page 7).
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	It is in the “Availability of data and materials” section (page 7).
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.

Anexo 11. Capturas del Consentimiento Informado, el cuestionario sociodemográfico, las herramientas de evaluación y los cuestionarios diarios y semanales implementados en la plataforma REDCap



AAA

Proyecto basado en el uso de dispositivos wearables para valorar el impacto del estrés en el entorno laboral sobre la calidad de vida de trabajadores: Proyecto SQoF-WEAR

Investigadores responsables: Betania Groba González, Javier Pereira Loureiro, y Patricia Concheiro Moscoso.

Institución: Universidade da Coruña e Universidade do Porto.

Nos dirigimos a usted para proporcionarle información sobre un estudio realizado conjuntamente entre la Universidade da Coruña y la Universidad do Porto, asociado al estrés laboral y la calidad de vida. Usted es invitado a participar porque pertenece al personal de administración/gestión, o al personal docente e investigador de un centro o departamento de la Universidade da Coruña (UDC).

La participación en este estudio es completamente voluntaria. Usted puede decidir no participar o, si acepta hacerlo, cambiar de parecer retirando el consentimiento en cualquier momento sin obligación de dar explicaciones. Cabe señalar que el equipo investigador se asegura de que su decisión no afectará a su actividad laboral.

La participación en el estudio consistirá en llevar puesta una pulsera Xiaomi Mi Band 5 durante un mes, registrando su actividad física y su calidad de sueño. Es muy importante resaltar que esta pulsera debe llevarla puesta durante todo el día y toda la noche. Por lo que, si considera que no está preparado para llevarla puesta las 24 horas del día, no podrá participar en el estudio. Durante ese mes, deberá contestar a unas preguntas diarias y semanales sobre la sobrecarga de trabajo, el sueño y la actividad que realiza. La estimación de tiempo para responder estos cuestionarios es de aproximadamente 5 minutos.
Además, al principio del estudio deberá contestar unas preguntas sobre datos sociodemográficos. De igual modo, al inicio y final del estudio usted deberá responder a una serie de herramientas de evaluación sobre su calidad de vida, su calidad de sueño, y su nivel de estrés percibido. Durante todo el estudio, el equipo investigador estará en contacto con usted para solventar las posibles dudas o dificultades que le puedan surgir.

Por último, cabe resaltar que la obtención, tratamiento, conservación, comunicación y cesión de sus datos se hará conforme a lo dispuesto por el Reglamento General de Protección de Datos (Reglamento UE 2016-679 del Parlamento europeo y del Consejo, de 27 de abril de 2016), la normativa española sobre protección de datos de carácter personal vigente, y la Ley 14/2007 de investigación biomédica y el RD 1716/2011.

Muchas gracias por su colaboración.

La hoja de información adjunta tiene como objetivo ofrecerle mayor información sobre el estudio al que se le invita a participar

Adjunto: Hoja de información.pdf (0.06 MB)

¿Acepta participar en el estudio?
* debe aportar un valor

Si

No

restablecer el valor

Enviar

Powered by REDCap

Figura 4. Captura de ejemplo del CI del proyecto SQoF-WEAR en la plataforma REDCap

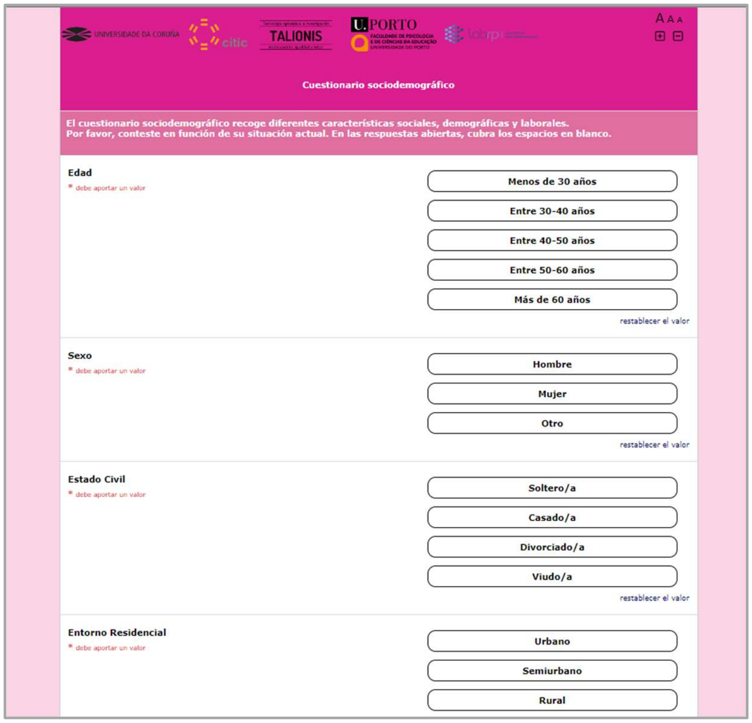


Figura 5. Captura de ejemplo del cuestionario sociodemográfico del proyecto SQoF-WEAR en la plataforma REDCap

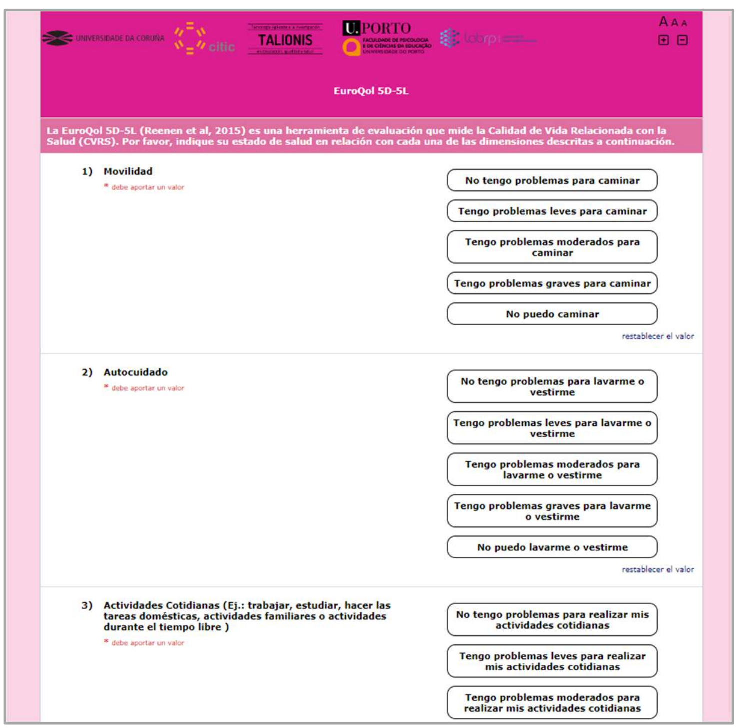
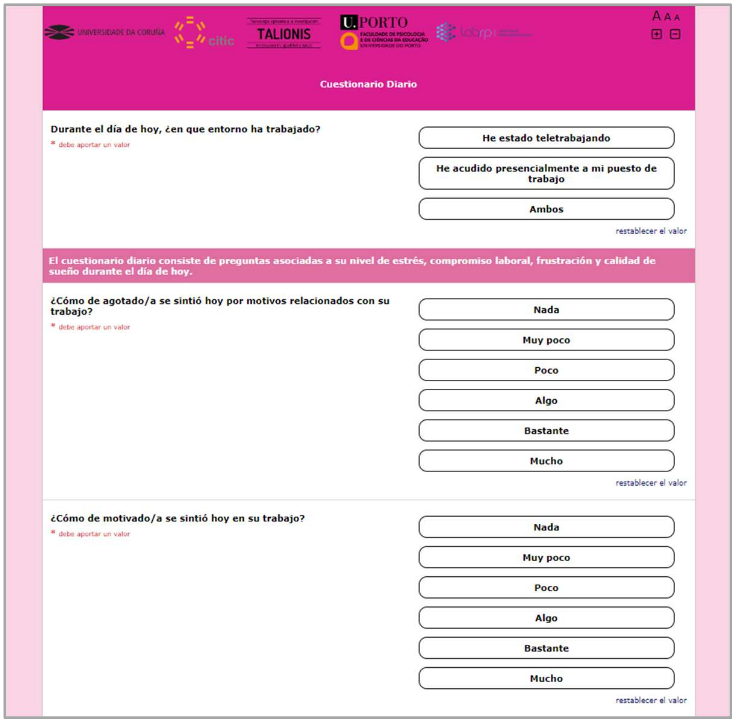


Figura 6. Captura de ejemplo de la escala *EuroQol 5D-5L* del proyecto SQoF-WEAR en la plataforma REDCap


Cuestionario Diario

Durante el día de hoy, ¿en que entorno ha trabajado?
* debe aportar un valor
- He estado teletrabajando
- He acudido presencialmente a mi puesto de trabajo
- Ambos

restablecer el valor

El cuestionario diario consiste de preguntas asociadas a su nivel de estrés, compromiso laboral, frustración y calidad de sueño durante el día de hoy.

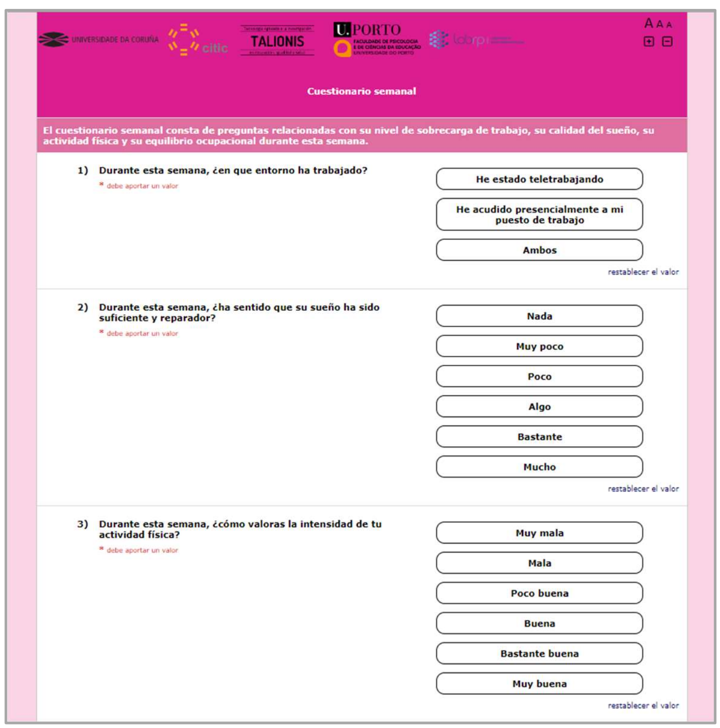
¿Cómo de agotado/a se sintió hoy por motivos relacionados con su trabajo?
* debe aportar un valor
- Nada
- Muy poco
- Poco
- Algo
- Bastante
- Mucho

restablecer el valor

¿Cómo de motivado/a se sintió hoy en su trabajo?
* debe aportar un valor
- Nada
- Muy poco
- Poco
- Algo
- Bastante
- Mucho

restablecer el valor

Figura 7. Captura de ejemplo del cuestionario diario del proyecto SQoF-WEAR en la plataforma REDCap


Cuestionario semanal

El cuestionario semanal consta de preguntas relacionadas con su nivel de sobrecarga de trabajo, su calidad del sueño, su actividad física y su equilibrio ocupacional durante esta semana.

1) Durante esta semana, ¿en que entorno ha trabajado?
* debe aportar un valor
- He estado teletrabajando
- He acudido presencialmente a mi puesto de trabajo
- Ambos

restablecer el valor

2) Durante esta semana, ¿ha sentido que su sueño ha sido suficiente y reparador?
* debe aportar un valor
- Nada
- Muy poco
- Poco
- Algo
- Bastante
- Mucho

restablecer el valor

3) Durante esta semana, ¿cómo valoras la intensidad de tu actividad física?
* debe aportar un valor
- Muy mala
- Mala
- Poco buena
- Buena
- Bastante buena
- Muy buena

restablecer el valor

Figura 8. Captura de ejemplo del cuestionario semanal del proyecto SQoF-WEAR en la plataforma REDCap